

**AN INTEGRATED APPROACH  
TO FOOD SAFETY**

食物安全的整體策略

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## **LegCo Panel on Food Safety and Environmental Hygiene**

立法會食物安全及環境衛生事務委員會

### **Reorganisation Plan for the Food Safety**

#### **Regulatory Framework**

食物安全監管架構的重組計劃

## **PURPOSE**

### 主旨

This paper serves to provide members with background information concerning the importance of integration of all food safety activities into a food safety regulatory framework and draws parallels in this approach with other Governmental bodies overseas.

本文旨在向各委員，就關於採取整體策略來設計食物安全監管架構的重要性，提供背景資料，並引証其他國家政府在這方面的做法供各位參考。

## **BACKGROUND**

### 背景資料

2. On the 28<sup>th</sup> November, the Administration briefed the Legislative Council Panel on Food Safety and Environmental Hygiene on the broad outline of a proposal to create a new Department, namely the Department of Food Safety, Inspection and Quarantine (DFSIQ) in order to improve food safety. This proposal also included the formation of another new Department, the Department of Agriculture and Environmental Hygiene (DAEH). 2005年11月28日，政府向立法會食物安全及環境衛生事務委員會報告了為加強食物安全工作而新成立「食物檢驗檢疫署」的建議，建議還包括重組成立另一新的部門，即「漁農環境衛生署」（漁農環衛署）。

3. Unfortunately the DAEH included staff of the Agriculture, Fisheries and Conservation Department (AFCD) that are involved in the promotion, facilitation, marketing and development of agricultural and fisheries products. It is with regards to this structure that this paper will aim to show, that the exclusion of these staff

from a food safety department will lead to a complete failure of the primary objective of the creation of the DFSIQ; that is, **improving food safety and public health for the people of Hong Kong**.

不幸的是，漁農環衛署卻安置著原漁農自然護理署負責漁農產品推廣、技術支援、市場管理和漁農業發展的同事。就這個安排，我們藉本文向大家指出，把這部分同事排除在負責食物安全工作的部門編制之外是非常錯誤的，**這樣做將無法達致政府本來透過成立新的食檢署以加強食物安全，保障市民健康的目標。**

## AN INTEGRATED APPROACH TO FOOD SAFETY

### 食物安全工作的整體策略

4. In the United Nations' Food and Agricultural Organisation (FAO)'s paper *Strategy for a Food Chain Approach to Food Safety and Quality: A framework document for the development of future strategic direction* it states that "more efforts are necessary to share information, communicate **more effectively and ensure that all components and actors in the food chain fully participate in food safety**". It identifies the lack of such synergy to be a major shortcoming in the food safety systems of developed countries.

聯合國糧農組織在「**食物安全和質量控制的食物鏈策略：未來策略發展方向的架構文件**」一文指出：「**(各國) 必須花更大的努力做好(食物鏈上)各環節的信息分享和溝通工作，並保證鏈上的所有環節及其有關人員全力參與到食物安全的工作中。**」文件指出了缺乏環節間的協同效應是目前許多發達國家食安管理體制中的主要缺陷。

5. This "farm to fork" integrated approach is not a new idea and developed countries have long recognised the interlinked nature of food production. This type of strategy requires the assessment and monitoring of the risks to consumer health beginning with raw materials. From this initial focus, farming practices and food marketing or processing activities are then a logical progression; **it requires regulatory action** to manage this risk; and **it requires the development** and operation of adaptable control systems to monitor and enforce the regulations designed to encompass these processes. Each element constitutes an equally

important part of a complex web; thus changes or advancements in food processing might lead to updating of existing safeguards, whilst feedback from the frontline primary producers can help to earlier identify and manage both existing and emerging risks. Each part of this chain must gel seamlessly if Hong Kong's objectives of the highest possible food safety standards are to be achieved.

這一「從農場到餐桌」的整體策略並不是一個嶄新的概念，發達國家很早已意識到食物生產過程環環相扣的特性。這種策略要求人們從生產食物的原材料開始，就消費者健康的影響，對相關的風險進行評估和監測。基於此，從農場的生產和加工活動開始，逐步開展有關的工作是必然的選擇，它需要監管行動去管理這些過程出現的風險，同時亦需要建立起一個可行的管理系統，把這些過程納入監測和強行管制的範圍之內。整個過程的每一環節對食安工作來說都是同等重要的，因此，食品加工技術的變化或提昇可能會導致現行監管措施的改變；而前線源頭生產者的反饋意見亦能幫助監管機構及早發現和管理已出現的和可能出現的風險。食物鏈上每一環節必須完美地連接起來，才能達到使香港市民享有高水平的食物安全服務的目標。

6. These sectors therefore demand a comprehensive and fully integrated approach to food safety. The roles of all stakeholders in the food chain are plainly obvious. **Animal feed, fertiliser and agricultural chemical manufacturers, farmers, food distributors, food processors and food operators** have an intimate responsibility for the safety of our food. Government authorities are then tasked with collaborating with and monitoring these primary producers to ensure that Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) guidelines are adhered to in order to prevent problems from appearing further down the food chain.

基於上述的分析，要搞好食安工作，所有這些環節必須高度地整合成一個有機的整體，而各環節上的持份者所扮演的角色是不言而喻的。在保證食物安全的問題上，**動物飼料生產商、肥料及農藥製造商、農民、食品加工商及所有負責處理食物的人員**都肩負著義不容辭的責任，政府的監管部門應該積極與這些源頭食物生產者合作並督促他們採取「良好農耕操作」或「良好製造業操作」的指引，以免把食安問題推到食物鏈的下游環節。

7. The separation of these various functions of the authorities is illogical and will lead to less coherent, more ineffective and a less dynamic food policy meaning that we are less able to

deal with new and emerging threats.

把政府在這些不同環節的相關職能分開是不合常理的，這樣做只會使整個監管系統變得鬆散、低效率和失去活力，削弱我們對新舊威脅的應對能力。

8. **The administration mistakenly believes that there exists a conflict of interest between the regulatory and advisory functions of Government. The proposed structure aims to put in place this artificial demarcation between the various functions of Government.** Without the expertise involved in primary production and distribution, the 'eyes and ears' of the food chain will be **separated from the 'hands and feet'**. The consequence is easy to predict. A lack of communication from those on the frontline will lead to problems surfacing further down the food chain, most likely involving the general public directly and threatening the integrity of our public health system and creating social disharmony.

政府管理層錯誤地認為把「監管」和「支援」兩個職能置於同一個部門之下存在著利益衝突的問題。現時政府建議的重組架構，目的正是人為地把政府那些相關的各項職能分拆開來。很明顯，沒有專家參與到源頭生產及運送等過程之監測，就等於把保證食物安全的「眼睛耳朵」和「手腳」割裂開來，而其後果是不難預見到的。缺乏與源頭生產環節的溝通將導致食物鏈下游不斷出現問題，很可能直接影響到廣大市民，威脅到市民對整個公眾健康系統的信心和破壞社會的和諧氣氛。

9. Public resources in the new food safety department should be viewed with a best value-for-money approach. The use of strategic testing on chemicals and residues that are not only of public health significance but are actually being used in the field is consistent with this approach. **It is futile to continue testing for chemicals which are no longer used but it is far more dangerous to exclude testing for chemicals which may be harmful to us.** And yet the very people with the knowledge, with the daily exposure to farmers, with close communication with those users are being excluded. Concluding that this is a step backward in food safety policy requires no leap of faith.

在如何運用負責食安工作的新部門的公眾資源這個問題上，政府必須以物有所值的原則來進行。要做到這一點，就要對那些對公眾健康有重大影響，而同時又確實在農場生產過程中使用過的化學物質及其殘留物，進行有針對性的測試。**如果我們不斷地檢測那些對公眾健康有重大危害，但卻在生產過程中已不再使用的化**

學物質，那只會白費力氣，浪費資源。然而，我們現在的做法正正是把那些具有這方面專業知識同時又和農場生產有日常接觸的人員排除於整體食安監管系統之外，這樣的安排顯而易見是整體食安政策的大倒退。

## **Local examples of food safety issues demonstrating the importance of complete integration of all food safety sectors**

本港搞好食安工作的成功例子 - 採取整體策略的重要性 -

### ***Accredited Farm Scheme (Agriculture)- details at appendix 3***

*信譽農場計劃（農業）詳請見附件 3*

10. During the late 1980s and the beginning of the 1990s, there were a series of food poisoning incidents caused by the consumption of vegetables tainted with high levels of poisonous residues. **Eating of vegetables was described as 'playing Russian roulette'** in the news (source: SCMP, 19 March 1994).

上個世紀八十年代末及九十年代初，本港發生了一系列的農藥毒菜事件，**進食蔬菜被報紙比喻為在賭場「玩俄羅斯轉盤」**（南華早報 1994 年 3 月 19 日）。

11. From 1990-1994, 926 Hong Kong people were hospitalised after consumption of vegetables alleged to be contaminated with methamidophos, an unregistered pesticide commonly used in mainland China on fruit trees and fibre crops. In those days, tons of vegetables in the vegetable wholesale market were dumped every time a food poisoning case occurred. **Drivers delivering vegetables and street hawkers were detained for investigation for selling 'poisonous food'.**

從 1990 至 1994 年，926 位香港市民因進食蔬菜之後入院，據聞的原因是甲胺磷中毒，那是一種內地常用於果樹及纖維作物蟲害防治的高毒農藥。在那段日子，每次出現毒菜事件的時候，批發市場就倒棄數以噸計的新鮮蔬菜，**運菜的司機和賣菜的小販甚至曾被以「售賣有毒食品」的罪名扣查。**

12. Local farmers, as well as the public, were seriously affected by this food scare. The Agriculture and Fisheries Department (AFD), as it was then known, **started to formulate a system to curb the problem as early as 1990.** The department researched the pesticides commonly used by both local and

mainland farmers. Agricultural officers would then classify the pesticides into different categories according to their modes of action and toxicity. Simultaneously, entomologists (insect specialists) and plant pathologists studied the common pests and diseases encountered by farmers so that proper control methods could be derived.

當時本地的農友和市民都受到「毒菜驚魂」很大的影響。當年的漁農處早在 1990 年就開始研究解決這個問題的方法，部門花了 3-4 年的時間調查和研究本地及內地農民使用農藥的情況，根據毒性大小和作用機理對不同的農藥的進行分類，同時，昆蟲學家和植物病理學專家則對常見的病蟲害問題開展研究並提出解決方法。

13. AFD then developed a quick residue screening method that would require only 30 minutes completing.

漁農處然後再研發了農藥殘留的快速測定方法，使測試能在 30 分鐘內完成。

14. AFD then proceeded to launch the Accredited Farm Scheme in November 1994. In short, the scheme used a full multi-factorial approach. The first and most important thing was to **establish a relationship with the producer**. AFD's message was simple; that we would help them overcome technical problems to produce a good and safe crop. In return they had to follow our advice. Any illegal irregularities, if deliberate, would be reported and regulatory action taken.

當準備工作完成之後，漁農處於 1994 年正式推出「信譽農場計劃」。簡而言之，該計劃採取的是「多環節整合」策略，第一步，同時亦是最重要的一步，就是**和生產者建立良好的互信關係**。漁農處的信息簡單而明確，那就是我們幫助農民解決技術難題，使他們能夠生產出質優安全的蔬菜。農民歡迎我們從而遵循我們的建議，在這個前題下，任何蓄意違規的做法就會報告給監管執法的同事，並對之施予相應的懲處。

15. Working with the industry and assisting them to engage in good production practices so as to minimise food safety problems was and still is the priority of the Accredited Farm Scheme and it demonstrates very well how food safety in vegetables crops can be achieved with the strategy outlined above.

與業界緊密合作，協助他們採用良好的耕作方法，從而把食安風險減至最低，這一直是該計劃的最高原則，而這一做法成功地証明了蔬菜的食安問題可以透過上述的策略來解決。

16. The Scheme is currently jointly run by AFCD, the Federation of Vegetable Marketing Co-operative Societies (FVMCS) and the Vegetable Marketing Organization (VMO). It is a co-operation with the industry and does not only include local farms but also extends to vegetable farms in the Mainland. It aims at promoting the adoption of good agricultural practices and environmental friendly production to reduce microbial contamination and the unnecessary use of chemical pesticides. Technical support and guidance emphasising integrated pest management and the proper use of pesticides are provided to farmers.

信譽農場計劃現時由漁護署、新界蔬菜產銷合作社有限責任聯合總社（菜聯社）和蔬菜統營處（菜統處）共同參與實施。與業界的合作不限於本地，還有內地，無論那裏的農民，我們的目的都是推廣良好的農耕方法，減少微生物污染和避免不當地使用農藥，並把病蟲害綜合防治的策略和方法傳授給農友。

17. The operation of the farms is closely monitored with on-farm inspection involving the whole production process from seedling production, irrigation, fertilisation, harvesting to post-harvest handling and storage. Samples of vegetables, soil, irrigation water and pesticide products are also taken from the farm for analysis of pesticide/heavy metal residues. Any malpractices or anomalies can be identified and rectified right on the farm before the vegetables are produced and distributed. The vegetables are then marketed through VMO where they will be further sampled for pesticide residue analysis to ensure that they are safe for consumption.

我們密切監測農場的運作，親身到場進行檢查，從種苗的生產、灌溉、施肥、收割及採收後處理和存放都不放過，蔬菜樣本、土壤樣本和灌溉水和農藥樣本都從農場取回實驗室進行農藥殘留及重金屬的分析化驗。任何不當的生產方法和不正常現象，在蔬菜收割及批銷之前已在農場就地糾正。蔬菜經菜統處的批發市場批銷前，再次抽樣檢定農藥殘留水平，進一步保證產品安全及適宜食用。

18. Since the implementation of the scheme, the incidents of pesticide poisoning resulting from vegetable consumption have dropped drastically. When the scheme was first launched, about 3.5 to 4% of vegetables passing through the VMO Vegetable

Wholesale Market at Cheung Sha Wan were found to be tainted with pesticide residues. **In recent years, the level has been reduced to negligible levels which have been maintained.**

自計劃實施之後，毒菜事件數目急劇下降。在計劃剛剛推行的初期，菜統處檢測到含農藥殘留的蔬菜佔 3.4 - 4%，而近年該比例長期維持在微不足道的水平。

### **Avian Influenza** 禽流感

19. Since 1997, Hong Kong has been at the forefront in terms of our ability to tackle and control outbreaks of avian influenza. We are recognized worldwide as leaders in this field and many countries have attempted to learn from and adapt some of our control measures in an effort to prevent a worldwide pandemic. A crucial control point in our preventive measures has been the Cheung Sha Wan Temporary Wholesale Poultry Market (CSWTWPM). Since all live birds, whether they are locally produced or imported from the Mainland are funnelled into this system the market is an essential link in the line of defence against bird flu. Over the past few years, **AFCD has developed an elaborate system involving the close collaboration of the wholesale market and the local chicken farms working together to ensure food safety, as well as reducing the risk of avian flu outbreaks;**

1997 年以來，香港在對付和控制禽流感方面一直處於世界領先的地位。許多國家都試圖仿效我們的做法，以防止全球性的流感大爆發。我們的多項措施中，其中關鍵的一項是圍繞長沙灣臨時家禽批發市場進行的。由於該市場是所有來自本地和外地的活家禽的集散地，所以，它成為防範禽流感的重要關口。在過去的幾年，漁護署圍繞該市場設計了一套嚴密的控制措施，具體內容如下：

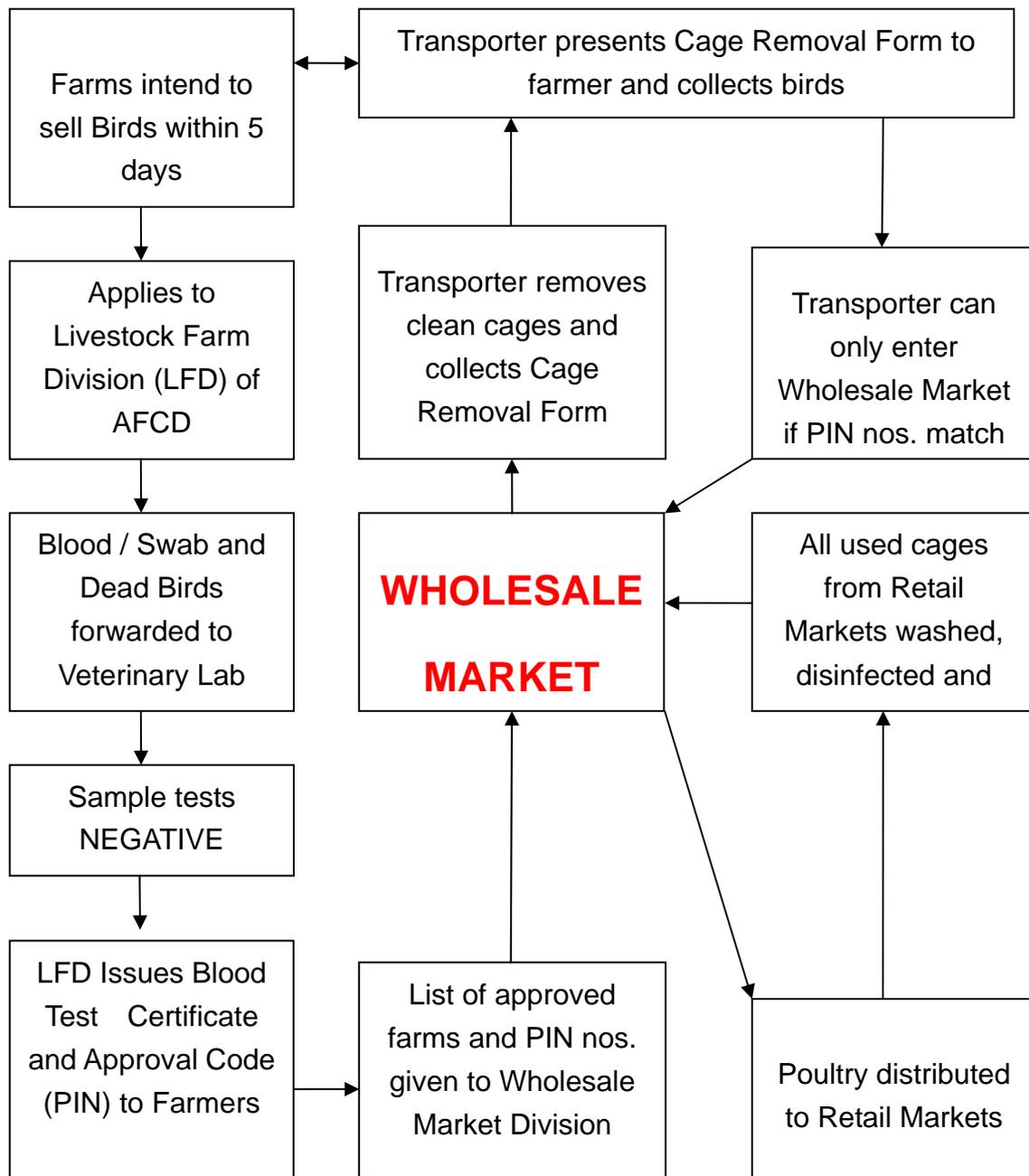
- Any batches of local chickens which a farmer wishes to market must first undergo blood testing by AFCD officers. 所有本地雞入市前必須先由漁護署人員抽血檢查。
- Upon receipt of a satisfactory blood test result, the farmer is issued with a blood test certificate and a approval code(PIN) which is only known to the farmer and the wholesale market through communication with the Livestock Farm Division (LFD) of AFCD.

驗血測試通過之後，該雞農會獲漁護署禽畜農場科簽發一張驗血證明書和一個只有農友自己和批發市場知道的核准編號(密碼)。

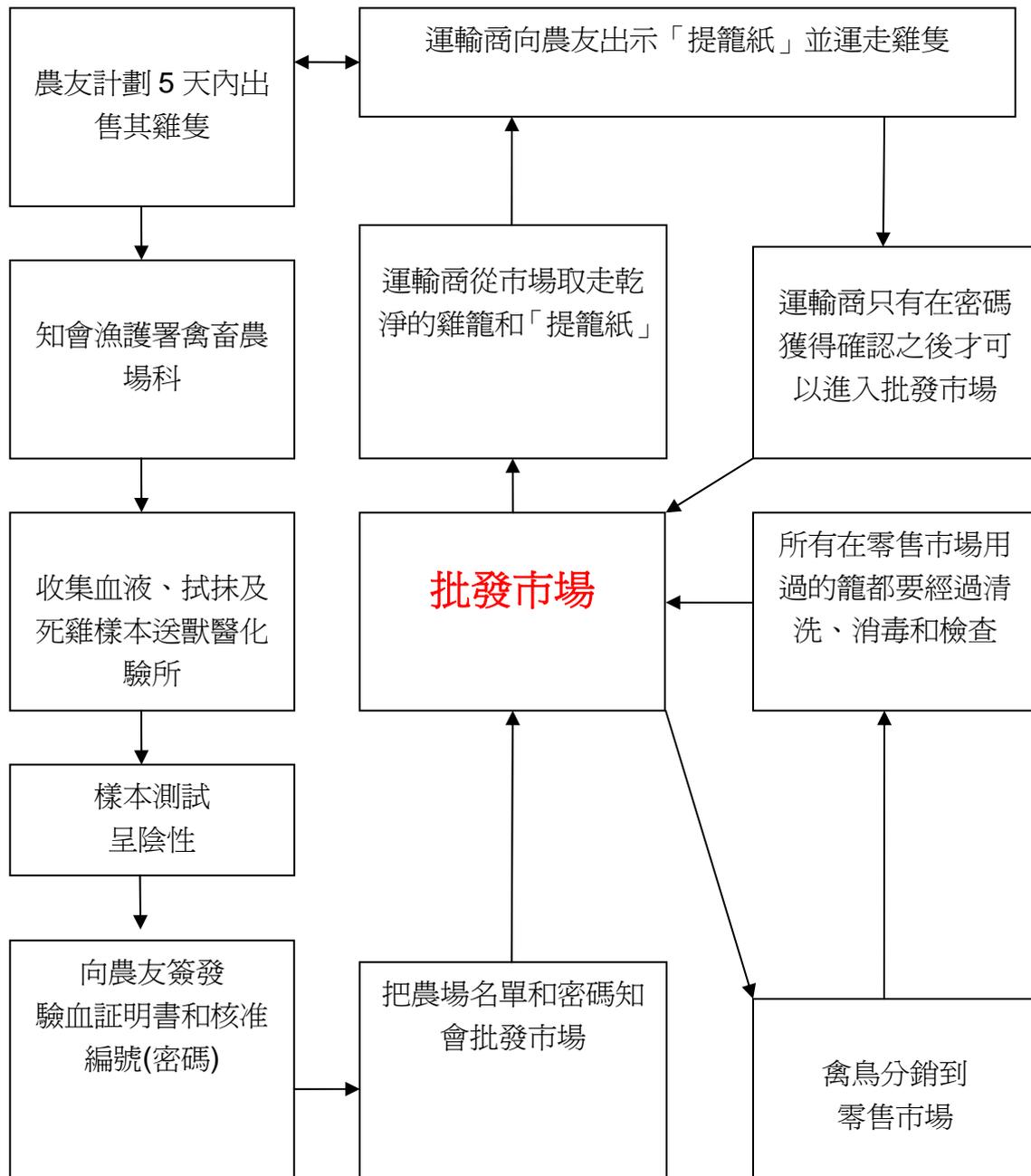
- Cages used to collect the chickens from the farm must be accessed from CSWTWPM and all of these cages must go through the cage cleaning machines at the wholesale market.  
所有運載雞隻上市用的雞籠必須經批發市場的洗籠機統一處理。
- When removing these clean cages from the wholesale market, an AFCD officer inspects the hygiene status of the cages and issues a cage removal form.  
當任何人從市場取走乾淨雞籠時，漁護署職員要先檢查籠的衛生情況，合格後才簽發「提籠紙」。
- This form must be presented to the farmer before he will allow the entry of these cages into his farm.  
農友要看到「提籠紙」之後，才可允許雞籠進入自己的農場。
- Upon arrival at the wholesale market, the PIN number written on the blood test certificate is matched with the list provided by the LFD. A mismatch will lead to the birds being detained.  
當雞隻運載到批發市場時，市場的管理人員將核對驗血證明書上的密碼，如果密碼不對，該批雞隻就會被扣留。
- The wholesale market AFCD staff will then check the number of birds sent from the farm to the LFD and if any irregularities are found, then veterinary officers of LFD will investigate the reasons.  
漁護署在批發市場的同事還會把進入市場的雞隻數目通知禽畜農場科，如果某批雞隻之數目與驗血證明書上所標明的數目不同，禽畜農場科的獸醫師會調查並跟進有關原因。

This complex system was implemented within 24 hours during the February 2002 outbreak as a means to allow chickens to be sold during the Lunar New Year and yet ensure that only healthy birds reached the consumer. **The whole system therefore relies on extremely close collaboration between several parties and the speed of implementation would not have been possible without all sectors being represented under one organisation.**

這一複雜的程序在 2002 年 2 月禽流感爆發期間，於 24 小時之內實施，保證了市民在農曆新年能夠買到健康鮮活的雞隻。**整個系統的成功實施和運作全賴幾個環節的人員緊密合作，如果他們不是在同一個部門下統一指揮，如此高效率地實施這些措施是不可能的。**



**Diagrammatic Representation of the Integration of Local Chicken Farms and the Wholesale Market**



圖示從本地雞場到批發市場的禽流感監控措施

## **Accredited Fish Farms**

### *優質漁場計劃*

20. The Accredited Fish Farm Scheme (AFFS), rolled out in June 2005, is an example on how fisheries facilitation activities would ensure safe fisheries produce for the public. **The AFFS was developed to produce safe, high quality, and sustainable fisheries produce through a process of farm registration, fry registration, and proper quality assurance.** The process will involve experts in the field to provide advice to fish farmers on culture techniques and husbandry practices, regular farm inspection, and monitoring of produce. The first batch of accredited fish produce was marketed on 6 December 2005 with fish tags under a brand name to allow easy recognition and was well received by the public with confidence that such produce is safe and of premium quality.

今年 12 月 6 日，漁護署推出了「優質漁場計劃」，它是另一個說明源頭支援如何保證食物安全的例子。**計劃透過實行漁場註冊、魚苗登記和適當的質量管理等措施，使漁場可持續地出產安全高質的鮮魚產品。**在該計劃下，本署的專家常到漁場向漁民提供關於養殖技術和漁場管理操作的建議，定期巡查各漁場和監測活魚產品的品質。而這些優質漁場出產的每條鮮魚都會帶有特定的標記，防止假冒，方便消費者辨別出這些質優安全的產品。這個計劃推出之後，大受業界的好評和歡迎，十分成功。

**Other examples of integrated work can be seen at Appendix 2.**

其他應用整體策略的例子見附件 2。

## Comparisons with other countries

### 與其他地方的比較

#### **Singapore**

##### 新加坡

21. The Agri-Food and Veterinary Authority (AVA) of Singapore shows what can be achieved with the right approach to food safety. Singapore is, very much like Hong Kong, a major food-importing country. Our populations, social and economic structures are not dissimilar.

新加坡的農產食品和獸醫局(AVA)給我們看到正確的食物安全處理方法可達致的成效。新加坡與香港非常相似，大家都是主要依賴入口食品的地方。我們的人口、社會及經濟結構都很相近。

22. From the 1980's Singapore already had what it called "*an integrated food safety programme to ensure the safety of an ever-increasing volume and variety of imported primary food*". On 1 April 2000, a statutory body (AVA) was established which encompassed food, agriculture and fisheries activities. On 1 July 2002, the AVA took over the Food Control Division, formerly of the Ministry of the Environment and thus took over regulation of both fresh produce and processed foods, from production right up to just before retail.

自八十年代新加坡已提倡“推行整體性食物安全計劃以確保品種與數量日益增加的主要食物的安全”。在二零零零年四月一日新加坡成立農產食品和獸醫局(AVA)管理食品、農業及漁業活動。在二零零二年七月一日該局接替新加坡環境部食物管制科的工作，從而負責所有新鮮食品及加工產品的監管工作，監管範圍由生產至批銷。

23. However, the AVA is also tasked with the promotion and development of agriculture and fisheries industries (e.g. the development of Agrotechnology Parks; their world-renowned floriculture industry (e.g. orchids); a stated goal to provide 40% of fish consumed locally by 2010 from the 4% currently; the world's largest exporter of ornamental fish, and production of table eggs from 2 million laying hens producing 30% of local consumption.

在監查食物安全的同時，該農產食品和獸醫局(AVA)亦從事漁農業的推動及發展工作，例如，發展農業科技園、推動世界馳名的花卉養殖工業(蘭花)、立志在 2010 年把當地水產在市場的佔有率由現時的 4%提高到 40%、把成爲世界上最大的觀賞魚出口地作爲奮鬥目標、以及協助當地家禽行業保持二百萬蛋雞的生產規模以提供當地 30%茶蛋食用量。

**24.** In contrast, Hong Kong actually produces more food locally than Singapore. Hong Kong produces about 20% of live pigs and 50 % of live poultry, 5 % of fresh vegetables and almost 50 % of marine fish. This means that the integration of sectors and expertise is even more crucial. And yet, **Hong Kong is proposing exactly the opposite and segregating these crucial links leading to a disjointed structure.**

與新加坡相比，香港其實比新加坡生產更多的本地產品，市場上約 20%的活豬、50%的活雞、5%的新鮮蔬菜及近 50%的海魚均爲本地產品。這意味著各生產行業及有關專家的整體合作更加重要。但是政府現時卻推出與之背道而馳的建議，計劃分拆這些環節之間不可分割的連繫，這樣做只能堆砌出一個支離破碎的監管架構。

An organization chart for the AVA is at Appendix 10.

新加坡農產食品和獸醫局(AVA)的組織架構見附件 10

## **California**

美國加州

**25.** The California Department of Food and Agriculture's (CDFA) goals include ensuring that only safe and quality food reaches the consumer, protecting against invasion of exotic pests and diseases, promoting California agriculture and food products both at home and abroad and building coalitions supporting the state's agricultural infrastructure to meet evolving industry needs. In other words, **it plays both a regulatory and advisory role** to producers and processors of meat, eggs, dairy products and produce. This, in a state that is the largest agricultural producer in the United States accounting for 13.2% of the national production.

美國加州食品及農業部的工作目標包括確保消費者所選購的食物均爲安全及優質的食物、保護農業免受外來病蟲害的入侵、向本土及海外推介加

州的農業和食品、建立產銷聯盟以支援加州農業的基礎建設以滿足持續演變的行業需求。換言之，該部門同時對肉類、蛋類、奶類產品及其他農作物的生產者和加工者**扮演著監管及諮詢的角色**。加州是美國最大的農產品生產地，佔全國農業生產總量的 13.2% 。

26. **The CDFA also participates in and supports food safety research necessary to address on-farm intervention strategies that will affect the viability of California's agricultural industries.** The CDFA's Animal and Plant Production Food Safety Programmes work directly with the State's agricultural trade groups and associations as well as individual producers, processors, and shippers of fresh produce and animal products to promote development and implementation of voluntary on-farm quality assurance programs. Program efforts focus on outreach and education programs as well as partnerships with other agencies and producers to develop effective on-farm prevention and control strategies.

加州食品及農業部亦參與及支持那些關於農場源頭干預策略的食物安全研究，而這些研究對加州農業生存和發展至關重要。該部門的動植物生產食品安全計劃直接與加州農業貿易團體及協會、個人生產者、加工者和新鮮食品及動物產品運銷商一起推動、發展及執行自願性的農場品質保證計劃。該計劃主力推行外展和教育工作，以及與其他代理商和生產者建立夥伴關係，發展有效的源頭預防及控制策略。

27. The Marketing Branch of CDFA oversees the State's 51 marketing programs, which provide an organizational structure, with governmental oversight, for agricultural producers and handlers that allows them to collectively solve production and marketing problems that they could not effectively address individually. This role is currently carried out by AFCD in association with the Vegetable Marketing Organisation (VMO) and Fish Marketing Organisation (FMO). The Director of Agriculture, Fisheries and Conservation is also the Director of Marketing and Registrar of Cooperative Societies.

加州食品及農業部的市場分署監督州內 51 個市場推廣計劃，該分署是一個由政府監察的組織，為生產者及處理者提供一個橋樑，以助他們共同解決個別人士無法有效解決的生產及銷售問題。本港漁農自然護理署協同蔬菜統營處及漁類統營處正是扮演著同類角色。漁農自然護理署署長同時也

是統營處處長及合作社註冊官。

28. In terms of enforcement activities, CDFA is responsible for meat and poultry inspection programmes, animal health and zoonotic diseases through surveillance and monitoring programmes. CDFA also licences and inspects dairy establishments and regulates the production of dairy products. Their Inspection Service Programmes and Center for Analytical Chemistry also ensures that fruit, vegetables, animal feed, fertilizers, veterinary drugs are safe through a process of licensing, registration, inspection, sampling and laboratory testing.

在執法行動方面，加州食品及農業部負責肉類及家禽的檢驗工作，調查及監察動物健康及人畜互通的傳染病。該部門亦巡查奶牛場設施，向奶牛場發牌，及監管奶類產品的生產過程。部門下的檢驗服務計劃及化學分析中心亦透過發牌、註冊、巡查及抽樣檢驗等手段確保水果、蔬菜、動物飼料、肥料和獸醫用藥的安全性。

## **Australia**

### **澳州**

29. The Department of Agriculture, Fisheries and Forestry (DAFF) has under its ambit the responsibility for Australia's agriculture, fisheries, forestry and food industry.

澳洲漁農林業部負責管理澳洲的農業、漁業、林務及食品工業。

30. The Product Safety and Integrity (PSI) area of DAFF contributes to the department's involvement in the development and implementation of policies and programs on food safety issues of national and international significance, with particular emphasis on on-farm food safety risk management. PSI also provides policy advice and manages issues relating to agricultural and veterinary chemicals, fertilisers and animal feedstuffs.

澳洲漁農林業部屬下的產品安全及誠信部(PSI)負責制定和執行與國內外食品安全相關的政策和計劃，尤其著重在農場源頭的食品安全風險管理。該部門還會提供政策性的意見及管理農業及獸醫化學品、肥料及動物飼料的有關事宜。

Important food safety related areas include:

與食品安全相關的重要範圍包括:

31. Providing strategic and influential contributions to the development of domestic policy for veterinary chemicals as well as overseeing Australian Government responsibilities for the National Registration Scheme for Agricultural & Veterinary Chemicals (National Registration Scheme) the regulatory framework for veterinary chemicals;

為當地獸醫化學品政策的制定提供策略性及具影響性的建議，及管理澳洲政府所執行的農用和獸醫用化學品國家註冊計劃。

32. Facilitating a national approach to developing and implementing policy for risk management of veterinary chemical use and 'on-farm' food safety issues (zoonotic animal diseases, environmental contaminants and antimicrobial resistance);

促進制定與落實有關獸醫化學品風險管理及農場源頭食物安全管理（例如人畜傳染病、環境污染物和藥品抗藥性）的全國性政策。

33. Running industry and government committees that are responsible for developing national approaches to on-farm food safety issues such as SAFEMEAT;

管理由業界與政府聯合組成的有關委員會，這些委員會專門負責就農場源頭食物安全問題制定全國性的管理辦法，例如「安全靚肉」計劃；

34. Coordinating the department's contribution, in consultation with industry, in **managing national food safety emergencies** and providing strategic and influential contributions to the development of international policy for veterinary chemicals through forums such as the Organisation for Economic Co-operation and Development, the Food and Agriculture Organization and United Nations Environment Program; and

就**處理好全國性食物安全突發事故事宜**，徵詢業界意見並統籌部門的做法，並透過經濟發展合作組織(OECD)、聯合國糧農組織(FAO)和聯合國環境計劃(UNEP)等平台，就國際獸醫化學品政策的制定提供策略性及影響性意見；及

35. Coordinating Australia's involvement with the setting of international food standards through the Codex Alimentarius Commission and contributing to international food safety and standards policy development through such forums as the Food Safety Quadrilaterals (a group consisting of Australia, New Zealand, Canada and the United States).

代表澳洲參與食品法典委員會制訂國際食物標準，並透過『食物安全四邊會談』(小組包括澳洲、紐西蘭、加拿大和美國)，為國際食物安全標準的政策發展提供建議。

36. DAFF is also tasked with the promotion of agricultural produce both at home and overseas. It's role is to increase the competitiveness, profitability and sustainability of these industries through;

漁農林業部還致力向國內外推廣當地農產品。其角色是透過下列措施以提升業界的競爭力、產品利潤、及可持續發展能力：

- The sustainable use and management of the natural resources
- Protecting the health and safety of plant and animal industries
- A responsive and efficient industry
- Improved market access and performance
- Benefiting from new technology and practices
- Skilled, financially self-reliant producers.
  - 可持續地運用及管理自然資源
  - 保護行業內動植物的健康及安全
  - 建立起一個積極進取及高效率的相關行業
  - 優化營商環境及市場表現
  - 應用高新科技及經營策略
  - 培養技巧純熟而經濟自立的生產者。

37. The Australian Quarantine and Inspection Service (AQIS) is also part of the Australian Government Department of Agriculture, Fisheries and Forestry.

澳洲漁農林業部轄下還設有澳洲檢疫及檢驗處 (AQIS)。

38. AQIS and other areas of the Department work with industry and trading partners to facilitate, gain, improve and maintain market access for agricultural commodities, and AQIS participates in international forums to develop policies and standards for trade in food products.

澳洲檢疫及檢驗處及部門的其他單位與相關行業及貿易伙伴一道，共同攜手促進、增強、改良及維護農產品的營商環境，該處亦藉國際會議參與發展和制定食品貿易的政策及標準。

39. **AQIS and Food Standards Australia New Zealand (FSANZ) jointly run the Imported Food Inspection Scheme developing food risk assessment policy and have handling operational responsibility for inspection and sampling.**

澳洲檢疫及檢驗處和澳紐食物標準組織 (FSANZ) 共同推行入口食物檢驗計劃，以發展食物風險評估政策，以及負責檢驗及採樣的工作。

40. **In addition AQIS's import and export inspection and certification is essential to maintaining Australia's highly favourable animal, plant and human health status and access to export markets. Quarantine controls at Australia's borders also minimise the risk of exotic pests and diseases to protect Australia's agriculture industries and environment.**

澳洲檢疫及檢驗處的進出口檢查和簽證服務對澳洲能夠維持動植物及人類健康和拓展海外市場非常重要。在澳洲邊境實施檢疫監控，亦使外來害蟲和疾病對澳洲農業和環境帶來的風險大幅降低。

An organisational chart showing Australia's integration of enforcement and facilitation groups can be found at appendix 11.

有關澳州政府執法與推廣拓展職能整合的組織圖見附錄 11。

## **France**

法國

41. The Ministry of Agriculture and Fisheries of the Republic of France has amongst its responsibilities, purview over the following sectors;

法國農業及漁業部的權責包括以下範疇

- Food quality and food safety
- The Natural environment
- The development of agriculture and agro-technological sectors
- The development of aquaculture
- 食品質素及食物安全
- 自然環境
- 農業及農業科技的發展
- 水產養殖業的發展

## Conclusions 總結

42. The above examples and comparisons with other countries demonstrate the necessity of a farm to fork approach. **The proposed structure, which will do without this methodology and integration of multi-disciplinary sectors in food safety policy in Hong Kong, will undermine public confidence in our ability to protect public health.**

上述種種例證以及各國經驗的比較，足以說明採取「由農場至餐桌」這種整體策略的必要性。由於捨棄整體策略的思想方法，加上在食物安全政策上沒有週詳考慮如何進行跨專業陣營的整全配合，現行建議的重組計劃勢必削弱普羅大眾對我們能否保障公眾健康的信心。

43. It is very important to recognize the fact that both the government and industry have a mutual objective of supplying safe and quality food to consumers and it should also be a shared responsibility. Working with the industry and assisting them to engage in good production practices so as to minimise food safety problems should be the priority of all administrations.

政府和業界都擁有一個共同的目標，那就是為消費者提供安全而具質素的食物，雙方因而肩負著與此相關的責任，認清這一事實是非常重要的。與業界共同合作，協助他們採取優良的生產營運措施，務求將食物安全的問題減至最少，實為全體行政當局首要關注的事宜。

44. Relying on a reactive approach that only serves to penalise those who fail to meet regulatory requirements without working towards the goal of strengthening food safety at the source is not the way forward for protecting the well-being of the people of Hong Kong.

僅僅依賴一種只懂得懲罰未符合法例要求的違規者，卻不致力於增強食物安全源頭管理的被動性監管模式，決不是一條邁向保障香港市民福祉的道路。

45. There has never been a better time, with the establishment of a new food safety organisation, to grasp the opportunity and prevent problems in food safety from arising in the first place. The separation of 'facilitation' and 'enforcement' will inevitably lead to a bias in enforcement as more and more food items are discovered which do not meet safety standards. Ironically as more resources are put into enforcement and testing activities, there will be no concomitant improvement in food safety. In fact, quite the opposite will occur. **By ignoring the preventive approach and embracing the narrow perspective of end-stage control, the current proposal is destined to fail.**

我們現在面臨一個不容錯失的大好時機，那就是藉設立一個全新食物安全機構的良機，從起始點就去根治食物安全問題。將「支援」與「監管」分家，勢必導致側重監管執法現象的出現，因為我們只會發現越來越多不符合安全標準的食品。倍受諷刺的是，當我們投放更多的資源在執法和檢測工作時，並不會因此而改善了食物安全。事實上，更可能導致相反的效果。**捨棄「預防勝於治療」的策略，而擁抱「下游監管」這種狹窄的反智思維，這樣設計出來的現行方案是註定會失敗的。**

**Staff of the Agriculture, Fisheries and Conservation  
Department and the Food and Environmental Hygiene  
Department**

漁農自然護理署及食物環境衛生署的員工

**Appendix 1**  
**Excerpts from International  
Food Safety Organisations**  
國際食物安全機構的警句摘錄

**Excerpts from International Food Safety Organisations**

**國際食品安全機構的警句摘錄**

**Food and Agriculture Organisation – Appendices 5 & 8**

The Food and Agriculture Organisation (FAO) defines the food chain approach as “*recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain – by all involved with the production, processing, trade and consumption of food*”.

**聯合國糧食及農業組織 附件 5 & 6**

聯合國糧食及農業組織界定「食物鏈策略」為「在食物的生產、處理、銷售直至進食整個過程中，所有涉及其中的人員，一同認知到大家必須共同承擔為消費者提供安全、健康和營養豐富食品的責任。」

**World Health Organisation – Appendix 4**

The World Health Organisation (WHO) says that “*Food safety must be addressed along the entire food chain by measures based on sound scientific information at both national and international levels*”. The WHO further adds that “*Food safety programmes are increasingly focusing on a farm-to-table approach as an effective means of reducing food-borne hazards. This holistic approach to the control of food-related risks involves consideration of every step in the chain, from raw materials to food consumption. Hazards can enter the food chain on the farm and can continue to be introduced or exacerbated at any point in the chain until the food reaches the consumer*”.

**世界衛生組織 附件 4**

世界衛生組織指出，「要保障食物安全，必須在整條食物鏈的每一環節上，採取各項根據國內外科學成果而制定出來的措施。」該組織還補充強調，「各類食物安全計劃正越來越重視「從農場到餐桌」的整體策略，並視之為減少食源風險的有效途徑。這一全盤考慮的源頭風險控制方法，要求充分顧及到從原材料起至食物被進食為止這個食物鏈全過程中的各個環節，那是因為風險的確可以從農場生產的層面進入食物鏈，並且繼續會從鏈中任何一個環節滲入甚至變本加厲，直至食物到達消費者手中為止。」

## European Union – Appendices 6 & 7

The European Union states “*Food safety needs to be organised in a more co-ordinated and integrated way. The guiding principle is that food safety policy must be based on a comprehensive, integrated approach. This means throughout the food chain (farm to table) across all food sectors. This farm to table policy covers all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.*”

### 歐盟 附件 6 & 7

歐盟指出：「須用更為協同和整合的方式來構建食物安全體系。我們的指導原則就是，食物安全政策必須建基於一個週詳而整合的模式上，即顧及到整條食物鏈(由農場到餐桌)上的所有環節。這一「農場到餐桌」政策涵蓋食物鏈中的全部領域，包括飼料生產、前期生產、食品加工處理、貯存、運輸和零售。」

## World Organisation for Animal Health

The World Organisation for Animal Health (OIE) states that “*The need to develop preventive measures, enabling the sanitary quality of all the foodstuffs produced to be controlled, has gradually been recognised, as is the case in other fields of activity. The systems have evolved towards a global procedure for controlling food safety hazards at each stage of production*”.

### 世界動物衛生組織

世界動物衛生組織提出：「研發各種預防措施，從而使所有食品的衛生質素得到監控，這一需要就如其他領域的活動一樣，已經逐步受到大眾的重視。這些監控體系已經朝全球一統化的方向的演變，強調在每個生產階段控制影響食物安全的各樣不利因素。」

**Appendix 2**  
**Examples of Integrated Food**  
**Safety Activities**

食物安全整體策略的實例

# 1. Farm Auditing 農場審查



Crops - Checking composting procedure and kinds of fertilizer used 作物農場 - 檢查堆肥程序和被使用的各種肥料



Crops - Checking fertilizers & pesticides used 作物農場 - 檢查被使用的肥料和殺蟲劑



Crops - Checking greenhouse pests 作物農場 - 檢查溫室病蟲害



Crops - Checking irrigation system and water quality 作物農場 - 檢查灌溉系統和水質



Crops - Checking postharvest treatment 作物農場 - 檢查收割後的處理



Crops - Checking the kind of crops grown in order to predict the choice of pesticides 作物農場 - 檢查作物品種以預測殺蟲劑的使用



Crops - Checking vegetable collection depot 作物農場 - 檢查農作物的收集站

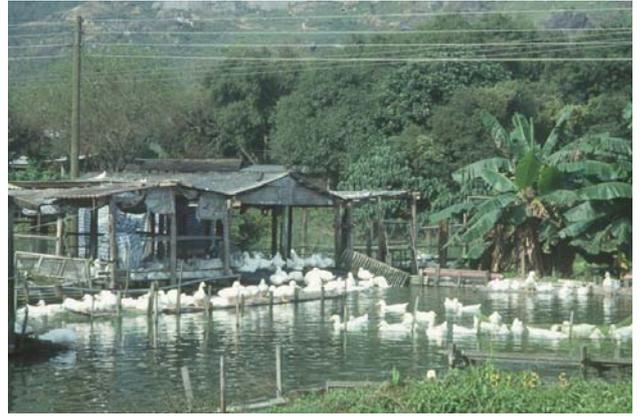


Crops - Taking seedling crops for residue testing 作物農場 - 採集苗期作物以進行殘留農藥測試

# 1. Farm Auditing 農場審查



Dairy - Checking animal health status & examining dairy product quality 奶製品農場 - 檢查動物的健康狀況及奶製品質素



Ducks - Checking health status of ducks 鴨場 - 檢查鴨子的健康狀況



Fish - Checking of fish feed 養魚場 - 檢查飼料



Fish - Checking of water quality 養魚場 - 水質的檢查



Pigeons - Checking egg hygiene 鴿場 - 檢查鴿蛋的衛生



Pigeons - Checking of animal health status 鴿場 - 檢查健康狀況



Pigs - Biosecurity checking - disinfection tank at gate 豬場 - 生物安全檢查 - 大門的消毒水池



Pigs - Checking waste treatment facility 豬場 - 檢查糞便處理設施

# 1. Farm Auditing 農場審查



Poultry - Biosecurity checking - disinfection tank at gate 雞場 - 生物安全檢查 - 大門的消毒水池



Poultry - Biosecurity checking - bird proof net 雞場 - 生物安全檢查 - 防鳥網



Poultry - Checking growth condition of the chicken 雞場 - 檢查雞隻生長狀況



Poultry - Checking health status of chicken 雞場 - 檢查雞隻健康狀況

## 2. Building up Partnership with Stakeholders 與俱共同目標的人仕建立伙伴關係



A symbol linking up all stakeholders 連接有共同目標人仕的標誌



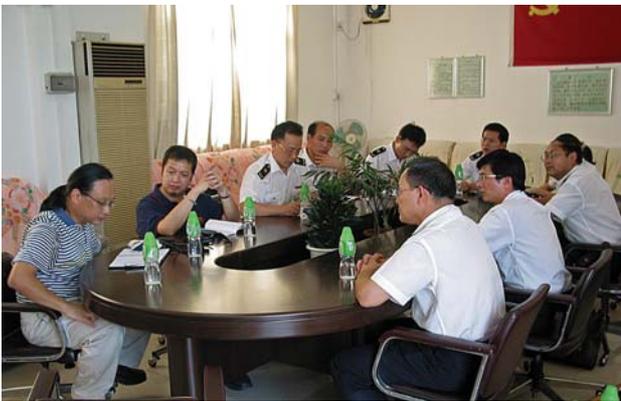
Accredited farm in mainland 內地信譽農場



Communicating with consumers 聯絡本地消費人仕



Communication between farmer and loan administrator selected from the public 農民與選自公眾的基金管理人之間的交流



Communication between HK and mainland officials 香港和大陸官員之間的交流



Communication between producers and government 生產者和政府之間的交流



Communication between stakeholders about wholesale market affairs 有共同關注點人仕對批發市場事務的交流



Communication with cooperative society leader 與合作社領袖的交流

## 2. Building up Partnership with Stakeholders 與俱共同目標的人仕建立伙伴關係



Communication with organic farmer 與有機農民的交流



Communication with rural leaders 與鄉村領袖的交流



Communication with the media 與媒體的交流



Farmer taking pride of the accreditation 以信譽農場為榮的農民



Producing a happy farmer rather than a trouble maker 以一個高興的農民取代一個麻煩製造者

# 3. Education 教育



Delivery of research results to public 向公眾遞送研究成果



Information for the public about local produce 有關本地農作物生產地點的資料



Leaflet about safe use of pesticide 關於殺蟲劑安全使用的小冊子



Providing consultation on horticultural technique to farmer 提供園藝技術諮詢給農民



Providing consultation on aquacultural technique to farmer 提供水產養殖諮詢給農民



Training course about residue testing for mainland officials 為大陸官員而設的殘留測檢訓練課程



Training on fish farm management 養魚場管理的訓練課程



Training on pest control 病蟲害的訓練課程

## 4. Provision of Aid and Infrastructure 提供援助及基礎建設



Administration of agricultural loan 農業貸款基金的管理



Assessing animal health condition to determine loan risk 評估動物的健康狀況決定貸款風險



Assessing crop damage caused by silting in relief exercise 在緊急援助中對農作物損失的評估



Assessing farm management in loan application 在貸款申請中評估農場管理



Building irrigation channel for farmers 為農民建造灌溉渠



Carrying out soil improvement program 推行土壤改良計劃



Diagnosing soil quality 診斷土壤質量



Emergency relief - Assessing crop damage after flooding 緊急救援 - 在洪水淹沒後進行損毀評估

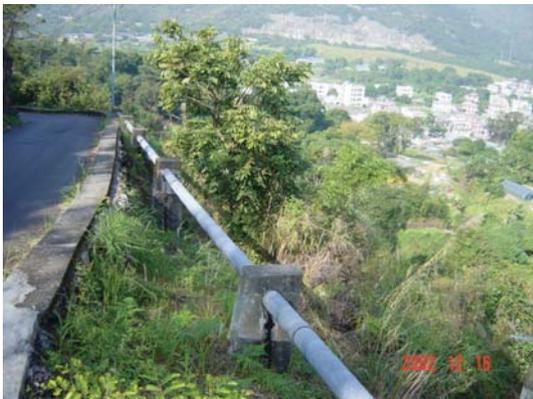
# 4. Provision of Aid and Infrastructure 提供援助及基礎建設



Emergency relief - Provide to farmers and fishermen after natural disaster 緊急救援 - 在自然災害之後提供幫助給農民和漁民



Lending out hatchery loan to ensure local chick availability 借孵卵機貸款來確保本地雞花供應



Long distance delivery of irrigation water 長途遞送灌溉水



Maintenance of control valve from an irrigation reservoir 保養灌溉水庫的控制閥門



Provision of irrigation water and related infrastructure 提供灌溉水和相關的基礎設施



Solving farmers' problems to ensure loan repayment ability 解決農夫的問題以確保貸款償還能力

## 5. International Cooperation 國際合作



APEC experts on food pest risk assessment APEC 在食物有害物風險估價方面的專家



FAO experts on plant quarantine 聯合國糧農組織之植檢專家



Mainland expert on crop pests 內地作物病蟲害專家



UK expert on Sternorrhyncha insect 英國同翅目昆蟲學家

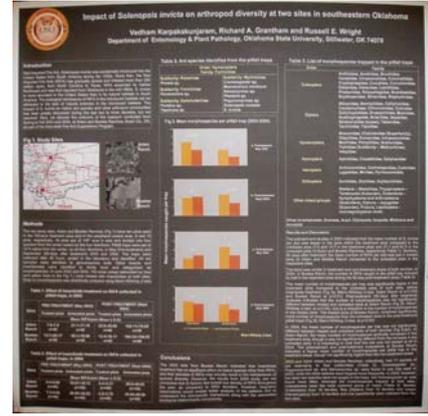


US experts on the red imported fire ant 美國紅火蟻專家

# 6 Research and Development 研究與發展



Building up literature collection 搜集文獻



Carry out adaptive research based on overseas information 以海外資料進行本地化應用研究



Develop mulching to reduce herbicide use 利用覆蓋物減少除草劑的使用



Develop unique local produce e.g. Kei Mei Chicken 發展獨特的本地農產品, 例如嘉美雞 1



Develop unique local produce e.g. Kei Mei Chicken 發展獨特的本地農產品, 例如嘉美雞 2



Development of net house against fruit fly 發展網屋以對付果實蠅



Development of soil cover against ground pests 發展地膜以對付地下害蟲蠅



Home designed rain shelter 自家設計的遮雨棚

# 6 Research and Development 研究與發展



Install artificial reef to enhance fish number and variety 設置人工魚礁以  
增加魚類數目和品種



Introducing new fishes for cultivation 引進新的魚種作飼養



Monitoring of pest - fruit fly trap on left, gypsy moth trap on right 有害  
物的監視 - 左-果實蠅陷阱，右-吉普賽蛾陷阱



Preserving unique local crops e.g. Hok Tau White Cabbage from Dan  
Chuk Hang 保存獨特本地作物，例如丹竹坑的鶴壁白



Protective structure for pest control 防病蟲害之網屋



Selection of exotic crop 挑選外來特別的農作物



Selection of good seeds 挑選優良的種子



Study on animal feed 研究動物的飼料

# 6 Research and Development 研究與發展



Study on chicken manure composting 研究雞糞堆肥



Study on environmental control greenhouse 研究環控溫室 1



Study on environmental control greenhouse 研究環控溫室 2



Study on fertilizers 對肥料的研究



Study on production economy 關於生產經濟的研究

# 7. Enforcement Tools and Enforcement 強制執行之工具與強制執行



Against use of fresh chicken manure on crops 對使用未發烤的雞糞作肥料的調查



Against use of illegal pesticides 對非法殺蟲劑的使用進行查究



Against use of polluted water for irrigation 對使用受污染的水於灌溉進行調查



Screening pathogens on fishes from local farm and wholesale market 為來自本地農場和批發市場的魚進行病原檢測



Self-developed method for mass screening vegetable for residue in wholesale market 自我開發的農藥殘留測檢法應用於批發市場大量蔬菜監察上 1



Self-developed method for mass screening vegetable for residue in wholesale market 自我開發的農藥殘留測檢法應用於批發市場大量蔬菜監察上 2



Self-developed method for mass screening vegetable for residue in wholesale market 自我開發的農藥殘留測檢法應用於批發市場大量蔬菜監察上 3



Sending court bailiff to recover defaulted loan 派法庭監守員追討拖欠的貸款

## 8. At Wholesale Market 在批發市場



Cage labelling for inward live poultry 為進入批發市場之活家禽掛上標籤以茲識別



Checking hygiene of cages before delivery to local farms 檢查運往本地農場的禽籠以確保清潔



Disposal of cholera contaminated seafood 處理受霍亂污染的海鮮



Helping traders with sea water disinfection 為批發商消毒海水



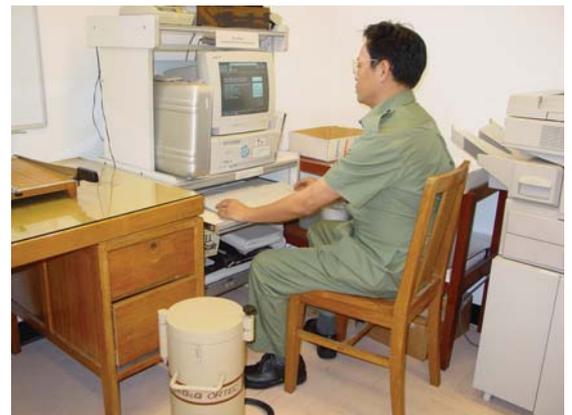
Inspecting fruit crops 檢查果類蔬菜



Inspecting package materials 檢查蔬果包裝



Inspecting vegetable crop 檢查蔬果



Measure radioactivity level of vegetables for food safety 為食物安全量度蔬菜輻射量

## 8. At Wholesale Market 在批發市場



Monitor crate washing to enhance biosecurity 為加強生物安全監察雞籠清洗



Taking samples for lab testing while produce still unloading 在蔬果下貨期間已抽取樣本到實驗室進行殘留測檢



Tracking produce transaction 追蹤農產品的交易

# 9. Pests & Diseases Surveillance 病蟲害監察



Aphid (*Rhopalosiphum maidis*) on sweet corn 粟米上的蚜蟲 (*Rhopalosiphum maidis*)



Blister beetle (*Mylabris phalerata*) on okra 黃秋葵上的斑芫 (*Mylabris phalerata*)



Checking of substandard crop 檢查未達標準的農作物 1



Checking of substandard crop 檢查未達標準的農作物 2



Citrus longhorn (*Anoplophora chinensis*) on Citrus 柑桔上的柑桔天牛 (*Anoplophora chinensis*)



Green soft scale (*Coccus viridis*) on greenhouse crops 溫室作物上的蚧殼蟲 (*Coccus viridis*)



Leaf spot disease (*Cercospora ipomoeae*) on water spinach 蕹菜葉斑病 (*Cercospora ipomoeae*)



Moth bug (*Ricania guttata*) on wampei 黃皮上的蛾蟬 (*Ricania guttata*)

## 9. Pests & Diseases Surveillance 病蟲害監察



New serious pest - a pea leafminer 新重要害蟲的發現 - 豆潛葉蠅



Red palm weevil (*Rhynchophorus ferrugineus*) on Canary date palm 在金絲棕櫚上的紅棕櫚象鼻蟲 (*Rhynchophorus ferrugineus*)



Wolly aphid (*Astegopteryx* sp.) on sugarcane 在甘蔗上的粉蚜蟲 (*Astegopteryx* sp.)



Yellow cottony cushion scale (*Icerya seychellarum*) on fruit tree 在水果樹上的黃棉蚧殼蟲 (*Icerya seychellarum*)

# 10. Multi-Disciplinary Cooperation 跨學科之合作



Assess crop compensation value for Lands Department 為地政處評估農作物的賠償值



Assist eradication of fire ant for quarantine service 協助檢疫人員消滅紅火蟻



Assist eradication of reed pest for conservation service 協助自然護理人員消滅蘆葦害蟲



Auditing work of country park service 審查郊野公園人員的工作



Determination of crop rates for land resumption departments 為收地部門制定作物賠償單位價



Diagnosis of fire ant (*Solenopsis invicta*) for Plant Quarantine service 為檢疫人員鑑定紅火蟻 (*Solenopsis invicta*)



Diagnosis of avian malaria vector (*Pseudolynchia canariensis*) for veterinary lab 為獸疫實驗人員鑑定禽鳥瘧疾的媒介 (*Pseudolynchia canariensis*)



Diagnosis of fruit fly (*Bactrocera dorsalis*) for public health service 為公眾衛生人員鑑定果實蠅 (*Bactrocera dorsalis*)

# 10. Multi-Disciplinary Cooperation 跨學科之合作



Diagnosis of intercepted beetle (*Medon* sp.) on coconut husk for Quarantine service 為檢疫人員鑑定截獲的甲蟲 (*Medon* sp.)



Diagnosis of lygaeid pest (*Dimorphopterus spinolae*) on reed for conservation service 為自然護理人員鑑定蘆葦害蟲 (*Dimorphopterus spinolae*)



Diagnosis of old world screw worm (*Chrysomya bezziana*) for medical service 為醫護人員鑑定侵擾人類的麗蠅 (*Chrysomya bezziana*)



Diagnosis of termite (*Cryptotermes declivis*) on wishing tree for LCSD 為康文署人員鑑定許願樹內的白蟻 (*Cryptotermes declivis*)



Diagnosis of weevil in wood packing material for Plant Quarantine service 為檢疫人員鑑定包裝木材內的象甲



Diagnosis of wood packing material pest (*Trypodendron lineatum*) for Plant Quarantine service 為檢疫人員鑑定包裝木材內的害蟲 (*Trypodendron lineatum*)



Requesting service from Herbarium on identification of fruit fly host 請求植物標本室協助鑑定果實蠅的寄主植物



Requesting service from Herbarium on identification of soft scale host 請求標本植物室協助鑑定蚧殼蟲的寄主植物

# 10. Multi-Disciplinary Cooperation 跨學科之合作



Serving as convener between farmers and Lands Dept regarding agricultural structures 在申請建造農用建築物上作為地政處與農民的橋樑



Sharing pest survey technique with conservation service 與自然護理人員分享害蟲調查的技術



Training conservation enforcement staff on recognition of endangered butterflies 訓練自然保育人員認識頻危物種的蝴蝶

# 11. Promotion of Food Produces 推銷糧農產品



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (1)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (2)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (3)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (4)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (5)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (6)

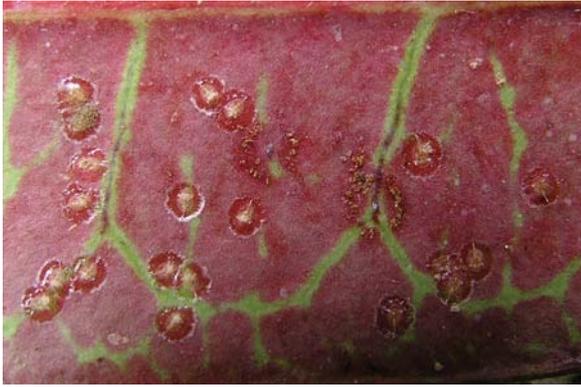


Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (7)



Promotion of local and accredited farm produce 推銷本地和信譽農場的農產品 (8)

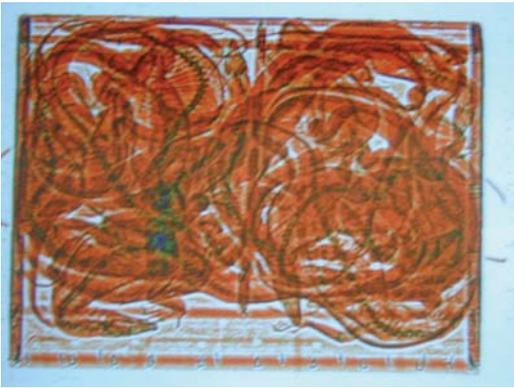
## 12. Animal & Plant Quarantine 動植物檢疫



Eradication of croton whitefly (*Orchamoplatus mammaeferus*) originated from Indonesia 滅除源自印尼的灑金榕白粉虱 (*Orchamoplatus mammaeferus*)



Interception of illegal food turtle import 截獲違法進口的食用水魚



Interception of illegal import of lizard 截獲違法進口的蜥蜴



Interception of illegal import of snake 截獲違法進口的蛇



Interception of a jewel beetle (*Belionota* sp.) from pine imported from Canada 截獲在加拿大入口松樹上的吉丁 (*Belionota* sp.)



Longhorn larvae (*Cerambycidae*) inside wood packaging materials from USA 從來自美國的木包裝材料中找到的天牛幼蟲 (*Cerambycidae*)



Powdery beetle (*Dienerella beloni*) carried along in construction materials from Europe 從來自歐洲建築材料中找到的粉蠹 (*Dienerella beloni*)

**Appendix 3**  
**Excerpts of Materials Related**  
**to Accredited Farm Scheme**  
**與信譽農場計劃相關文件的摘錄**

# Agriculture and Fisheries Department Accredited Farm Scheme Farmer's Reference Manual

November, 1994 Version

## Content

- I. Definition
- II. Objective
- III. Merits of the Scheme
- IV. Obligation and Requirements of Accreditation
- V. Accreditation Procedure
- VI. Prestige and Entitlement
- VII. Principles of Good Agricultural Practices
  - 1. Horticulture Aspects
  - 2. Pest Management
- VIII. Marketing Situation

Appendix I: How to obtain further information

Appendix II: Crop Advisory Leaflets Available from AFD

Appendix III: Reference for Further Consultation

Appendix IV: Chemical Guides for Controlling Common Pests and Diseases  
on Vegetables

## I. Definition

An accredited vegetable farm is a farm endorsed by the Agriculture and Fisheries Department as producing safe vegetables of good quality.

## II. Objective

- Produce high quality vegetables, i.e.
  - fresh,
  - with appealing appearance and
  - pest free.
- Produce healthy vegetables safe to consumers
- Promote environmental friendly crop production methods to reduce use of pesticides

## III. Merits of the Scheme

- Producing premium quality produce to meet the demand of the public.
- Safeguard public health and benefits of farmers by easy identification of safe vegetables.
- Conserve the environment by proper use of pesticides.
- Through the scheme, AFD strengthens the advisory service on production techniques, use of farm equipment, pest control methods and farm management etc.
- Encouraging Chinese counterparts to participate resulting in upgrading of vegetables imported into Hong Kong.
- A safe working environment is provided to all farm personnel.

#### **IV. Obligation and Requirements of Accreditation**

1. The responsible person of the farm is obliged to follow the principles of good agricultural practice as laid out in the latter part of this reference manual. He should also attend continuous vocational training as arranged by the Agriculture and Fisheries Department.
2. The farmer must be co-operative in allowing officers of the Agriculture and Fisheries Department to inspect the farm on a regular basis.
3. The farmer must allow pesticide, soil and water samples to be taken by the officers of the Agriculture and Fisheries Department for analysis without any obligation. The kind and quantity of pesticide/soil/water samples are to be determined by the Agriculture and Fisheries Department.
4. The farmer must allow vegetable samples to be taken at any point (be it in the farm, in the wholesale market or elsewhere) by officers of the Agriculture and Fisheries Department for analysis without any obligation. The kind and quantity of vegetable samples are to be determined by the Agriculture and Fisheries Department.
5. The farmer must follow the advice from the Agriculture and Fisheries Department to withdraw or temporarily suspend the sale of produce immediately upon notification.
6. Accreditation status will be withdrawn if the farmer is found in breach of any of our requirements.

#### **V. Accreditation Procedures**

Upon application, the farm will be monitored for a minimum period of 3 months or full production of a crop. If the farm management is found to conform to the good agricultural practices and no harmful pesticide residue is found on the produce, accreditation can be made.

Once accredited, the farm will be subject to continuous monitoring and technical instruction.

#### **VI. Prestige and Entitlement**

Accredited farm will display an indicative logo on their produce and in their farm premises.

#### **VII. Principles of good Agricultural Practice**

##### **1. Horticultural Practices**

###### Essential

- Select suitable variety
- Use suitable amount of fertilizers (use organic fertilizers whenever possible)
- Manage the field tenderly
- Contact Horticultural Section of AFD if in doubt.

###### Vegetable Variety Selection

- Select suitable varieties adaptable to local climatic conditions
- Select pest and disease resistant varieties
- Select heat resistant/tolerant varieties

#### Choose and Using Organic Fertilizers

- Select organic sources: e.g. Pig-on-litter compost, peanut cake, horse manure
- Apply proper methodology

#### Mass Seedling Production

- Use proper compost media
- Select suitable container or plug tray
- Produce uniform and healthy seedlings
- Hardening the transplants

#### Protected Cultivation - Hydroponics

- Almost pesticide free cultivation
- Low labour input culture

#### Growing Technique for Special Vegetables

- Spinach (Appendix II: RM 8)
- Chinese White Cabbage (Appendix II: RM 9)
- Lettuce (Appendix II: RM 10)
- Kale (Appendix II: RM 11)
- Leaf Mustard (Appendix II: RM 12)
- Chinese Flowering Cabbage (Appendix II: RM 13)
- Tomato (Appendix II: RM 14)
- Yard Long Bean (Appendix II: RM 15)
- Cucumber (Appendix II: RM 16)
- Hairy Gourd (Appendix II: RM 17)
- Angle Gourd (Appendix II: RM 18)

#### Good Horticultural Practice

- Proper use of fertilizers
- Using good quality irrigation water
- Proper soil management

#### Field Sanitation

- Frequently weeding
- Removal of pest infested plants
- Removal of crop residue

## **2. Pest management**

### Steps to Follow

1. Regular inspect the fields and look for signs of pest/disease damage.
2. Apply integrated pest management as list below whenever possible.
3. Contact Plant Protection Section of AFD if in doubt.

### Integrated Pest Management Technique

#### a. Cultural Control

- Field sanitation
- Use resistant variety
- Crop rotation
- Raise healthy seedling before transplanting
- Apply optimal rate of fertilizer to strengthen the natural immunity or defence mechanism of the crop
- Adjust planting and harvesting date to escape attack of pest
- Intercropping
- Mulching for pest and weed control

#### b. Chemical Control: Safe and Proper Use of Pesticide

- Choosing the most suitable pesticides
- Choosing the appropriate spraying equipment
- Precautions before application
- Precautions after application
- Proper storage
- Accurate harvesting time
- First aid (Appendix II: CL13)

#### c. Biological Control

- Use of biological pesticides e.g. *Bacillus thuringiensis* (2P12)
- Use of biological control agents
- Use of pheromones

#### d. Physical Control

- Greenhouse/ Protective tunnel
- Colour / Sticky traps
- Bait traps
- Reflective materials

## **VIII. Marketing Situation**

Produce of accredited farmers will be sent through labelled baskets to the Vegetable Marketing Organisation for guided marketing to the accredited retailers.

# Good Agricultural Practice

## Common Horticultural Practice for Pest Control

1. Observe field sanitation
2. Use resistant variety
3. Adopt field and/or crop rotation
4. Employ proper production sequences such as massing seedling production prior to field cultivation.
5. Apply optimal rate of fertilizer to strengthen the natural immunity or defense mechanism of the crops.
6. Adjust planting and harvesting date to escape attack peak of pest
7. Use biological controls whenever possible
8. Use trap crop as a control technique when applicable

## Safe & Proper Use of Pesticides

1. Choosing
  - buy only properly packed, labeled and registered pesticides.
  - do not purchase pesticide from hawkers or unregistered retailers.
2. Spraying Equipment
  - Choose proper spraying equipment with particular reference to nozzle size and design.
  - Check the equipment carefully for leakage and dripping.
3. Applying
  - read and follow the label instructions
  - observe the minimum harvesting interval stipulated in the label
  - wear appropriate protective clothing
  - keep foodstuffs, pets and children away
  - do not eat, drink or smoke during application
  - apply during calm weather
  - avoid strong sunlight which may denature the pesticide
  - spray area must be free of livestock
4. Aftercare
  - Any spray solution remaining should be used up by spraying round perimeter of the crops and not retained for future use, or disposed of in a way that will contaminate the environment.
  - Clean the spraying equipment immediately after use.
  - Cleanse the exposed parts of the body, especially hand and face, before food.
  - Remove clothing and wash skin immediately in case of contamination.
  - The protective clothing should be laundered.
  - Do not reuse pesticide containers and dispose them in proper place.
5. Storage
  - keep pesticides in the original container
  - do not remove the label
  - keep pesticides safely away from food and children

## 6. Harvesting

- Pre-harvesting safety period stipulated on the pesticide label must be observed.

## 7. First Aid

- Seek medical help without delay,
- Take the pesticide container or label to the hospital to facilitate treatment.

## Training

- Farm personnel should be encouraged to attending vocational training course organized by the government or other institutes to upgrade their skill and knowledge.

## Record Keeping

- Pesticide in stock: What is found? When purchased? What quantity? Information of the supplier / manufacturer.
- Pesticide application record: crop age, pesticide identity, formulation, dilution rate, volume applied
- Crop information: when sowed, transplanted, sprayed, horticultural practice applied, harvested
- Weather records: Diurnal temperature, rainfall, humidity

## Penalty

- Minor Offenses\*\*
  - Written warning
  - Three written warnings in 2 years would result in cancellation of the accreditation for at least 1 year.
- Major Offense (i.e. causing citizen food poisoning, uncooperative attitude towards awarding authority)
  - Immediate cancellation of the accreditation for at least 1 year.

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\*\*

### Minor Offenses:

- improper farm recording
- improper installation or use of farm safety equipment
- improper use of pesticide
- improper farming practice

**PESTICIDE MONITORING PROGRAM**  
**IMPLEMENTED BY EXTENSION OFFICERS**

- Visit to accredited farms should be made on a regular basis.  
(Say bi-weekly depending on staff strength and practicability)
- Information about farming practice and usage of pesticides should be gathered as far as possible. (Below is an example of a filled questionnaire.)

Farmer:	Chan Tai Fok		Tel:	453 3943
Address:	18 Ding Wu Village		District:	Yuen Long
Crop Cultivated:	Area	Growth Stage (e.g. Seedling, young crop, mature crop)	Major Problem	Pesticide / Remedy
Lettuce	2 dc	young crop	nil	zineb sprayed
spinach	2 dc	seedling	serious springtail infestation	abandoned the crop, then liming
Matrimony vine	4 dc	mature crop, harvested continuously	nil	2P156 (brand unknown) sprayed
fallow land	3 dc	-	-	-
Pesticides in farmer's possession:	Registration Number	Brand	Common Name	Remark
	2P44	-	Cartap	
	2P48	Submarine	Chlorpyrifos	
	2P52	Canon	-	
	-	Sunrise	methyl benzimidazol-2-ylcarbamate	sample taken
	2P54	-	Copper oxychloride	
	2P12	Centari, Dipel	Bt	
Remark:	<ol style="list-style-type: none"> <li>1. Sample of matrimony vine taken to test for 2P156 or other residue,</li> <li>2. Sample of unknown pesticide labeled Sunrise taken for analysis.</li> </ol>			
Reporting Officer: (Name, not signature)	Ding Yat Sha FOII(YL)		Contact Tel:	733 0000

- In case of doubts (as exemplified above), samples of crops and/or pesticides should be taken for further study. Pesticide sample should be sent to PPRU (HQs, 8/F) for further processing. Vegetable samples must be taken to VMO Residue Lab for residue extracting within the same date of sampling.

# Accredited Farm Scheme Residue Monitoring Procedure

## Creation of Farmer Register

- A register of farmers participating in the accredited farm scheme (hereafter will be addressed as farmer(s) for simplicity) is maintained by the responsible district extension office.
- Individual farmer will have his own file recording his particulars, farm size, cropping pattern, pesticide usage and yield expectancy.

## Field Visit and Creditability Validation

- During the planting period, staff from technical sections of Tai Lung Experimental Station will conduct regular field visits jointly with crop extension staff to provide technical assistance to farmers, to assess the growth conditions of the crops and to record the types of pesticide used. The results are recorded in a survey form as given in Appendix I.
- Farmers are requested to provide information on pesticide application timing and kinds of pesticides used. At least one vegetable sample will be taken by Crop Division during growing season to the VMO Residue Laboratory to verify the pesticide information provided by the farmer.
- Analytical results from VMO will be sent to AO(PP) who will collate and feed back any discrepancy to the appropriate district extension office and recorded in the farmer register. Should residue of unregistered pesticide detected, the farmer will be deprived of the right of being accredited and may be prosecuted if sufficient evidence is gathered.
- 
- At least one full crop must be found satisfying the requirements of accredited farm produces (i.e. vegetables of high quality and residue within recommended limits (see below for details)) before the accreditation is given out to the appropriate farmers.

## Quality Assurance Before Harvesting

- About three days before the expected harvesting date, extension officer will visit the farm and take vegetable samples to VMO for residue checking.
- Should the residue level found exceeding the MRL figures provided by AFD, TO(VMO) will pass the result to AO(PP) who will give appropriate advice such as to postpone the harvest or wash the crop to the farmers through the extension officer. In case of residue of unregistered pesticide being detected, the farmer will be deprived of the right of being accredited and may be prosecuted if evidence is sufficient.

## Final Checking During Wholesaling

- Every batch of accredited farm produces selling through VMO will be sampled for residue checking during wholesaling.
- Produce will be rejected and sell suspended if the produce is found to contain unregistered pesticide residue. Sample will be sent to the Department of Health for follow up action. Produce found to contain registered pesticide residue exceeding the MRL figures recommended by AFD will not be allowed to market as accredited produce. A decision making flow chart summarizing all three aforesaid levels of residue checking is given as Appendix II.

### **Revocation of Accreditation**

- If a farmer is found uncooperative in allowing appropriate sample or information to be taken during the assessment period, AO(PP) and district AO should discuss and recommend whether accreditation is appropriate.
- Should a farmer's produce is detected to contain excessive level of residue during wholesaling or unregistered pesticide residue at any stage of sampling, his accreditation status will be immediately terminated. Status can only be revived after stringent reassessment.

Ref.: AF VMO 06/17 October 24, 1994 (Rejected Version)

# **Accredited Farm Scheme**

## **Residue Testing Procedures**

### 1. Levels and Objectives

1.1 Pesticide residue testing are conducted both at farm level and wholesale market level with specific objectives:

#### A. Farm Level Testing

1.2 Vegetable samples are collected both during crop growing stage and pre-harvest stage with the purposes of validating farmer's credibility and compliance to good agricultural practice respectively.

#### B. Wholesale Market Level Testing

1.3 Produces are also subject to pesticide screening and subsequent residue analysis during wholesaling at VMO for quality assurance.

### 2. Procedures for Residue Testing At Farm Level

#### A. Crop Growing Stage

2.1 During crop growing period, technical staff of Crop Division will conduct regular field visits to provide technical assistance/advice to farmers, to assess the growing conditions of the crops and to record farmer's pesticide usage. The results are recorded in a survey form as given in Appendix I.

2.2 The officer shall request farmers to provide information on pesticide application timing and kinds of pesticides used. He will also make an assessment of his observations. During these farm visits he should collect at least one vegetable sample randomly from the field preferably at a stage where pesticides have been used recently. He should send the sample (500 g) together with the pesticide information via AO(PP)2/3 to the VMO Residue Laboratory for residue analysis.

2.3 TO(VMO) should conduct multi-residue analysis taking into consideration of the information provided. The analytical report should be sent within 24 hours after receiving of the sample to AO(PP)2/3 who will cross check the laboratory results with the survey information to see if the farmer is providing true and full information to AFD staff during field visit.

2.4 Should residue of unregistered pesticide be detected, AOPP2/3 will inform District AO who would recommend to SADO the deletion of the farmer from the accredited list. The case will also be pass on to the Plant and Pesticide Regulatory Unit for following-up. Prosecution action may be taken if sufficient evidence is gathered.

2.5 Any other discrepancy pertaining to the use of pesticides will be examined by AO(PP)2/3 and appropriate advice will be given to the farmer on safe and effective use of pesticides.

### B. Pre-Harvesting Stage

2.6 Three days before the expected harvesting date, extension officer of the Agricultural Development Division will visit the farm and take 0.5 Kg random vegetable samples to VMO for residue checking. Pesticide usage information should be provided if available.

2.7 TO(VMO) should conduct multi-residue analysis taking into consideration of the information provided and previous growing season testing results. The analytical report should be sent within 24 hours after receiving of the sample to AO(PP)2/3 for interpretation. Copy of the report should be duplicate for AO(W)/AO(SE) 僣 reference.

2.8 Should residue of unregistered pesticide detected, AO(PP)2/3 will inform AO(SE)/AO(W) and the farmer will be deprived of the right of being accredited. The case will be pass on to the Plant and Pesticide Regulatory Unit for follow-up action. Prosecution action may be taken if sufficient evidence is gathered.

2.9 Should residue of registered pesticide detected with the level far exceeding the maximum residue level set by AFD, AO(PP)2/3 will inform AO(W)/AO(SW) to advise farmer to postpone the harvest. Steps 2.6 & 2.7 will be repeated.

### 3. Procedures for Residue Testing At Wholesale Market Level

3.1 During wholesaling in VMO, staff under supervision of TO(VMO) will take one kilogram of random vegetable sample from every batch of produces marketing through the channel of accredited farm scheme and deliver the sample immediately to the lab for quick residue screening.

3.2 In the unlikely event that the screening test reveals the presence of pesticide residue, the sample will be subject to detail residue analysis by gas chromatography.

#### Residue of Unregistered Pesticide Detected

3.3 Should residue of unregistered pesticide detected, TO(VMO) will immediately refer the case to the Department of Health for follow-up action.

3.4 TO(VMO) will also inform SM of the case who will take necessary action to suspend the marketing of any unsold produce through the accredited farm produce channel.

3.5 SM will also inform the appropriate accredited retailers who have purchased the problematic vegetable.

3.6 TO(VMO) will inform AO(W)/AO(SE) who will recommend to SADO the deletion of the farmer from the accredited list.

3.7 TO(VMO) will inform AO(PP)2/3 about the case. AO(PP)2/3 will then refer the incidence to the Plant and Pesticide Regulatory Unit for follow-up under the Pesticide Ordinance, Cap. 133. Prosecution action may be taken if sufficient evidence is gathered.

#### High Level Residue Of Registered Pesticide Detected

3.8 Should residue of registered pesticide detected with the concentration exceeding the maximum residue level set by AFD, TO(VMO) will inform SM who will take necessary action to suspend the marketing of any unsold produce through the accredited farm produce channel.

3.9 SM will also inform the appropriate accredited retailers who have purchased the problematic vegetable.

4.0 Finally TO(VMO) will inform AO(W)/AO(SE)/AO(PP)2/3 about the incidence. AO(W)/AO(SE) will recommend to SADO the deletion of the farmer in concern from the accredited list.

Ref.: AF VMO 06/17 November 1, 1994 (Final Version)

Pesticide Maximum Residue Limits (MRLs)  
And Acceptable Daily Intake (ADI)  
Figures Relevant To The Agriculture & Diet Of Hong Kong

## 1. Introduction

The World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) have, since 1966, been establishing acceptable daily intake (ADI) levels of pesticides for man and maximum residue limits (MRL) for pesticides on crops. FAO study pesticide composition, chemistry, analysis, use patterns to calculate the MRLs that result following good agricultural practice. WHO reviews toxicological and related data and, where possible, estimates an ADI for humans. ADIs and MRLs have not been evaluated for every pesticide/crop combination but enough data has been accumulated to propose realistic figures where none are at present available.

The ADI of any particular chemical is based on a no-adverse-effect level (NOAEL) established through evaluation of, ideally, toxicological data generated from long term feeding studies. All factors (e.g. acute effects, carcinogenic effect, potential delayed neurotoxicity) are considered in deriving the NOAEL. A safety factor is then incorporated - generally a hundred fold decrease in dose - to arrive at the theoretical ADI. Such figures are illustrated in Appendix A.

As the Accredited Farm Scheme aims to promote and supervise good agricultural practice, it can be taken that the quoted MRLs will not be exceeded. However, it has still to be established whether, given the typical diet of the Hong Kong population, the international MRL values would still result in a pesticide intake within the recommended ADI. Such an evaluation is given below.

## 2. Evaluation of MRLs

The present work evaluated FAO MRLs and WHO ADIs to ensure that they were applicable to a southern Chinese diet. Where there are no suitable figures, MRL values have been calculated for such a diet. In these calculations the theoretical diet has taken vegetable consumption as follows:

Vegetable type	Maximum daily consumption (g)
Cruciferous vegetables	250
Cucurbits	130
Leguminous vegetables	100
Solanaceous fruit vegetables	200
Bulb vegetables	200
Compositae vegetables	200
Sweet corn	100

Spinach (at 100g) and such vegetables as leeks, celery and carrots (at 100g) were also included in the evaluation.

Using equation 1, guideline MRLs were calculated from international ADI values for all crop/pesticide combinations in Table 1 and 2. These guideline values were then compared with the international MRL figures to ensure that adoption of the latter would not result in a pesticide intake over and above the acceptable ADI.

$$\text{Maximum MRL} = \frac{\text{ADI(Mg/kg)} \times \text{Body Wt (Kg)}}{\text{Dietary intake (Kg)}} \quad \text{Equation 1}$$

This exercise confirmed that where FAO MRL values were available, almost all were applicable to crops in Hong Kong. Four insecticide/crop and seven fungicide/crop combinations were, however, highlighted where consumption of vegetables with residues at FAO MRL values would result in a higher than recommended intake of pesticides. The combinations were:

- carbaryl on cruciferous crops and solanaceous fruit vegetables;
- malathion on cruciferous and compositae vegetables;
- benomyl on solanaceous fruit and compositae vegetables; and
- chlorothalonil on cucurbits, cruciferous, solanaceous fruit, bulb and compositae vegetables

For these cases, acceptable MRLs for the southern Chinese diet were calculated (using equation 1) and have been inserted in both tables.

Equation 1 was also used to calculate guideline MRL values for pesticide/crop combinations for which no values have yet been ratified by FAO. When making this calculation, the resultant value was divided by a further safety factor to allow for variation in diet and to equate guideline figures with already established FAO values. For eight of the fourteen insecticides this factor was 2. The safety factor for the remaining 6 was established at 10 to give guideline MRL values similar to FAO MRL values already supplied. In calculating guideline MRLs for fungicides, a conversion factor of 10 was used for all but two. These two (bitertanol and chlorothalonil) used a factor of 2.

For three insecticides where no WHO ADI figures or FAO MRL values were available, guideline MRL values were calculated using No Effect Level data and taking a hundred fold conversion factor from NOEL to ADI as follows:

	LD50 (Mg/Kg)	NOEL 2 years (Mg/Kg diet)	ADI mg/kg (Conversion factor of 100)	ADI for 50Kg person (mg)	Proposed MRL (Mg/Kg)
Prothiophos	1,500	5.0 (rats)	0.050	2.5	1.0
Quinalphos	62 - 137	3.0 (rats)	0.030	1.5	1.0
Teflubenzuron	--	4.75 (dogs)	0.047	2.35	5.0

Similarly, no FAO MRL values, WHO ADI values or NOEL figures have been determined for the two copper based fungicides. The values quoted (Table 2) are taken from German MRL requirements which state a general plant limit of 10mg/kg for copper oxychloride. This level has been halved for Hong Kong recommendations.

### **3. Conclusion**

The proposed maximum levels of insecticide (Table 1) and fungicide (Table 2) residues on crops grown in Hong Kong are considered adequate to ensure that there will be no acute or chronic threat to consumers. It should be easy to maintain residue levels below those quoted if crops are grown according to good agricultural practice. The levels have been selected so that even if residues reach the MRL values listed, consumption of the vegetables will, according to the international data available at present, not adversely affect the consumer.

Ian G. Hunter  
AO(PP)1  
September 1994

File: L/M 668/94(AF CRP 04/39)

*Annex A to Appendix IV.*

CODEX ALIMENTARIUS MAXIMUM RESIDUE LIMITS  
AND WHO ACCEPTABLE DAILY INTAKE LEVELS  
FOR INSECTICIDES AND FUNGICIDES  
USED ON VEGETABLE CROPS

## b) FUNGICIDES

**Cucurbits**

Hong Kong Crop	Pesticide	Pesticide Group	WHO Hazard Classification	Nearest Codex Crop	Codex MRL (mg/kg)	WHO ADI (mg/Kg body wt)
Cucurbits e.g. cucumbers & gourds	benomyl	Benzimidazole	Un	Cucumber	0.5	0.02
	bitertanol	Conazole	Un	Cucumber	0.5	0.01
	chlorothalonil	Chlorophenyl	Un	Cucumber	5.0	0.003
	copper hydroxide	Copper	-	-	-	-
	copper oxychloride	Copper	-	-	-	-
	mancozeb	Ethylenebis(di)	Un	-	-	0.05
	metalaxyl	Acylalanine	III	Cucumber/squash	0.5/0.2	0.03
	triforine	Trichloromethyl	Un	-	-	0.02
	vinclozolin	Dichloroanilide	Un	Cucumber	1.0	0.07
	zineb	Ethylenebis(di)	Un	-	-	0.05

**Cruciferous Vegetables**

Hong Kong Crop	Pesticide	Pesticide Group	WHO Hazard Classification	Nearest Codex Crop	Codex MRL (mg/kg)	WHO ADI (mg/Kg body wt)
Cruciferous Vegetables e.g. brassicas, Chinese radish & water cress	benomyl	Benzimidazole	Un	Brussel sprouts	0.5	0.02
	bitertanol	Conazole	Un	-	-	0.01
	chlorothalonil	Chlorophenyl	Un	cab/broc/cauli	5/5/5	0.003
	copper hydroxide	Copper	-	-	-	-
	copper oxychloride	Copper	-	-	-	-
	mancozeb	Ethylenebis(di)	Un	-	-	0.05
	metalaxyl	Acylalanine	III	cab/cauli	0.5/0.5	0.03
	triforine	Trichloromethyl	Un	brussel sprouts	0.2	0.02
	vinclozolin	Dichloroanilide	Un	cab/cauli	1/1	0.07
	zineb	Ethylenebis(di)	Un	-	-	0.05

**Leguminous Vegetables**

Hong Kong Crop	Pesticide	Pesticide Group	WHO Hazard Classification	Nearest Codex Crop	Codex MRL (mg/kg)	WHO ADI (mg/Kg body wt)
Leguminous Vegetables e.g. peas & beans	benomyl	Benzimidazole	Un	beans (D)	2.0/0.2	0.02
	bitertanol	Conazole	Un	Beans (PI)	0.5	0.01
	chlorothalonil	Chlorophenyl	Un	Beans (PI)	5.0	0.003
	copper hydroxide	Copper	-	-	-	-
	copper oxychloride	Copper	-	-	-	-
	mancozeb	Ethylenebis(di)	Un	-	-	0.05
	metalaxyl	Acylalanine	III	peas/soya beans	0.05/0.05	0.03
	triforine	Trichloromethyl	Un	Beans (PI)	1.0	0.02
	vinclozolin	Dichloroanilide	Un	Beans (PI)/peas	2.0/1.0	0.07
	zineb	Ethylenebis(di)	Un	-	-	0.05

## b) FUNGICIDES

**Solanaceous Fruit Vegetables**

Hong Kong Crop	Pesticide	Pesticide Group	WHO Hazard Classification	Nearest Codex Crop	Codex MRL (mg/kg)	WHO ADI (mg/Kg body wt)
Solanaceous fruit vegetables e.g. egg plant, peppers and tomatoes	benomyl	Benzimidazole	Un	tomato/eggplant/pepper	5/0.5/5	0.02
	bitertanol	Conazole	Un	-	-	0.01
	chlorothalonil	Chlorophenyl	Un	tomato/peppers	5/10	0.003
	copper hydroxide	Copper	-	-	-	-
	copper oxychloride	Copper	-	-	-	-
	mancozeb	Ethylenebis(di)	Un	-	-	0.05
	metalaxyl	Acylalanine	III	toamto/peppers	0.5/1.0	0.03
	triforine	Trichloromethyl	Un	tomato	0.5	0.02
	vinclozolin	Dichloroanilide	Un	tomato/peppers	3/3	0.07
	zineb	Ethylenebis(di)	Un	-	-	0.05

**Bulb Vegetables**

Hong Kong Crop	Pesticide	Pesticide Group	WHO Hazard Classification	Nearest Codex Crop	Codex MRL (mg/kg)	WHO ADI (mg/Kg body wt)
Bulb Vegetables	benomyl	Benzimidazole	Un	onion	2.0	0.02

## 瓜類白粉病

### 寄主作物：

白粉病為瓜類最主要的病害之一。主要為害青瓜（黃瓜）、南瓜、苦瓜、佛掌瓜。其次為冬瓜、節瓜和絲瓜。除瓜類外，還可侵染豆類和其他花卉、雜草。

### 病徵：

主要為害葉片，葉柄和莖蔓上也可以發生，一般不為害果實。發病初期，葉面或背面產生點點白色近圓形的小粉斑，以葉面為多。嚴重時，許多粉斑擴大相連佈滿全葉，整片葉如覆蓋了一層白粉，受害葉片多枯黃死亡，使植株早衰。

### 病原：

白粉病菌在香港有兩種：*Sphaerotheca fuliginea* (Schlecht) Poll. 稱單絲殼白粉菌，異名《對症用藥手冊》*Sphaerotheca cucurbitae* (Jacz.) Z.Y. Zhao。另一種為 *Erysiphe cichoracearum* DC. 稱二孢白粉菌。此二菌皆屬子囊菌亞門真菌，為專性寄生菌，只在活體寄主上存活，無性世代為半知菌亞門粉孢屬。分生孢子無色、單孢，橢圓形、串生。有性世代產生子囊殼及子囊孢子。

### 發生期：

在香港病菌多以菌絲或分生孢子在寄主上越冬，成為翌年初侵染源。分生孢子藉氣流或雨水傳播。影響本病發生最重要的因素是濕度，其次是溫度。一般濕度大有利此病流行。所以，雨後乾燥，田間濕度大，白粉病流行的速度加快，尤其當高溫乾燥和高溫高濕交替出現，此病很易流行。白粉病對幼葉及老葉較少引起發病，而以中段的中成葉為多。種植過密，通風不良，植株生長弱時，有利此病發生，溫室或塑膠棚發生較露地嚴重。

### 防治方法：

1. 加強栽培管理，增加植物生長勢，提高抗病能力。
2. 栽種抗病品種或耐病品種。
3. 藥劑防治，可選擇噴施下列其中一種殺菌劑，發病初期開始施用，每十天噴施一次，按照病情發展而決定是否繼續噴藥。農藥要在中午前噴，噴灑均勻。盡量避免長期連續使用同一種農藥。

香港農藥登記號碼	中文商用名稱及形態 (英文註冊名稱)	稀釋倍數	施用分量(毫升或克) (以八公升噴霧器為準)
2P047	殺菌靈；百菌清 (Chlorothalonil) 75% 水溶性粉劑	1:600	13克
2P031	百科 (Bitertanol) 25% 可濕性粉劑	1:1000	8克
2P017	億力、免賴得 (Benomyl) 50% 可濕性粉劑	1:2000	4克
2P206	(Propiconazole) 25% 乳化劑	1:2000	4毫升
2P188	(Tridemorph) 80% 乳化劑	1:2000	4毫升
2P185	(Triadimefon) 25% 可濕性粉劑	1:3000	3克

## 毒斯本5%粒劑之使用方法

**中文名稱:** 毒斯本5%粒劑

**英文名稱:** Chlorpyrifos 5% Granule (w/w)

**註冊編號:** 2P48 (GR)

**包裝:** 淨重3公斤庄  
**售價:** 約港幣\$100  
**供應商:** 茶聯社 或  
蔡興利種子行

### **使用方法:**

作物	適用害蟲	每次用藥量	摘要
玉米	亞洲玉米螟	每株施藥量 1-1.5克	1.生育初期如發生玉米螟,將藥粒施於心葉一次 2.雄花抽穗前10-15天,再將粒劑施於心葉一次 3.收割前五至七天停止用藥

### **舉例:**

- 假設以一斗種地計算,每株玉米種植之行距為40cm,株距為30cm,共可栽種約2250株玉米
- 若每株施藥量為1.2克,總施藥量為  
 $2250 \text{株} \times 1.2 \text{克}$   
 $= 2700 \text{克}$
- 以每包3公斤庄之毒斯本粒劑售價為HK\$100來計算,每斗種地每次施藥所需費用:  
 $\frac{2700 \text{克}}{3000 \text{克}} \times \$100$   
 $= \$90$
- 若每造玉米施藥兩次,所需費用合共:  
 $\$90 \times 2 = \$180$

## 甜菜夜蛾 (*Spodoptera exigua* (Hübner))

**別名:** 貪夜蛾, Beet armyworm

**寄主:** 椰菜, 椰菜花、白菜、蘿卜、生菜、番茄、青椒、矮瓜、馬鈴薯、青瓜、西葫蘆、豇豆、茴香、白蘿卜、芹菜、菠菜、韭菜與甜粟等農作物。

### 為害狀:

初孵幼蟲群集葉背,吐絲結網.在其內取食葉肉,留下表皮,成透明的小孔. 3齡(經三次脫皮後的幼蟲) 後可將葉片吃成孔洞或缺刻,嚴重時僅餘葉脈和葉柄,致使菜苗死亡,造成缺苗斷壟,甚至毀種.3齡以上的幼蟲甚至可鑽蛀青椒、番茄及粟米果實,造成落果、爛果。

在超甜玉米上,甜菜夜蛾常與斜紋夜蛾(*Spodoptera litura* (Fabricius)) 及棉鈴蟲(*Helicoverpa armigera* (Hübner)) 共同在臨收成前數星期內為害果實,通常情況下,是在粟米果實中部鑽孔而入,間中從穗進入者也有.由於為害通常發生在收成前不久,所以實際破壞情度並不大,但由於賣相受到影響,以至不能出售,經濟損失頗為嚴重.從過往經驗所得,甜菜夜蛾、斜紋夜蛾和棉鈴蟲合共起來的破壞,在超甜玉米上大約是10-40%不等,故作物的後期觀察與防治是絕對不應疏忽的。

### 生活習性:

在香港及廣洲一帶,由於同屬於亞熱帶地區,甜菜夜蛾能全年生長繁殖,且無明顯越冬現象.成蟲夜間活動,最適宜的溫度為20-23°C、相對濕度為50-75%.成蟲有趨光性.成蟲產卵期3-5天,每雌可產100-600粒.卵期2-6日.幼蟲共5齡(少數6齡).3齡前群集為害,但食量小,4齡後,食量大增,晝伏夜出,有假死性,蟲口過大時,幼蟲會自相殘殺.幼蟲發育歷期11-39天.老熟幼蟲會離開植物,而進入泥土化蛹,蛹發育歷期7-11天。

### 防治:

由於成蟲有趨光性.故可以利用黑光燈作測報及誘殺.又由於此害蟲寄主很廣,因此必須勤除染草,以絕蟲源,在化學防治方面,基於3齡前幼蟲群集為害,晝伏夜出,施藥時應盡可能在黃昏或天明前進行,而噴灑部位,應集中於粟米株的下半部,特別是粟米果實的外面及穗部,農藥方面,可考慮使用20% 毒磷靈乳油(2P48)1000倍稀釋噴霧。

### 參考文獻:

呂佩珂等 1992 中國蔬菜病蟲原色圖譜 農業出版社

Ref.: RM21 / 漁農處植物保護組 / 1Z94

## 瓜類炭疽病

### 寄主作物：

炭疽病是瓜類的主要病害之一。各種瓜類包括青瓜、冬瓜、節瓜、絲瓜、苦瓜、白瓜、葫蘆瓜等均會被侵害。

### 病徵：

幼苗期,子葉邊緣發生褐色半圓形或圓形病斑,基部縊縮變色和倒伏。成株葉上斑點初呈水浸狀,後擴大為圓形或近圓形病斑。青瓜病斑為黃褐色,外圍有一圈黃暈。病葉自下向上發展。嚴重時,葉片枯死。葉柄和莖上病斑橢圓形或紡錘形,稍向內陷,後期縱裂。果實上病斑初呈水漬狀,淡綠色。擴大後呈圓形或橢圓形,稍凹陷。在潮濕環境下,在病斑上常產生粉紅色黏質物。

### 病原：

*Colletotrichum orbiculare* (Berk. & Mont.) Arx. 葫蘆科刺盤孢,屬半知菌亞門真菌。分生孢子盤聚生,初為埋生,紅褐色。後突破表皮呈黑褐色,剛毛散生于分生孢子盤中。分生孢子梗無色,圓筒狀,分生孢子長圓形、單胞、無色。分生孢子萌發產生 1~2 根芽管,頂端生附著胞。附著胞暗色,近圓形,壁厚。

### 發生期：

以菌絲體和擬菌核隨病殘體留在地面越冬,後形成分生孢子盤並產生大量分生孢子成為初侵染源。分生孢子借雨水和地面流水傳播。10℃~30℃均可發病,濕度是誘發本病重要因素。空氣濕度大,易發病。此外,通風不良,氮肥過多,連作,植株衰弱發病重。

### 防治方法：

1. 採用無病種子。選用抗病品種。輪作。
2. 加強田間管理,低窪和排水不良地不宜種瓜。
3. 溫室內栽培,應加強濕度管理,改善通風,保持濕度70%以下。
4. 發病初期,開始噴藥。可選取下列任何一種藥劑,隔7-10天噴一次,連續防治2~3次。

香港農藥 登記編號	中文商用名稱及形態 (英文註冊名稱)	稀釋倍數	施用濃度(毫升/克)(以八 公升肩掛式噴霧器為準)
2P047	殺菌靈、百菌清 Chlorothalonil) 75% 水溶性粉劑	1:500	16克
2P183	多福淨、甲基多保淨(Thiophanate- methyl) 70% 可濕性粉劑	1:1000	8克
2P194	好生靈、阿斯巴(Zineb) 65% 可 濕性粉劑	1:500	16克

Ref.: RM27 / 漁農處植物保護組 / 94年11月

Sun Fung Accredited Farm (新豐信譽農場) & Sun Wai Farm (新圍農場)  
Puluo, Guangdong

Auditing Report (18.v.95)

**INTRODUCTION**

1. Both Sun Fung Farm and Sun Wai Farm (SWF) belong to Mr. Yeung Yuk Man. However to the farm managers Mr. Lee Siu Jin (of Sun Wai) and Mr Cheong Chow Wong (of Sun Fung), only Sun Fung Farm's production are sold to Hong Kong as accredited produces. Thus to differentiate the two, Sun Fung is hereby called the Sun Fung Accredited Farm SFAF while the other is just referred to as SWF. Unless otherwise reported below, other findings were already detailed in AO(PP)2's report of 24.莧菜.95 (Encl. 5).

**FARM MANAGEMENT**

Farm Managers

2.

SWF	李兆金先生	Lee Siu Jin
SFAF	莊周汪先生	Cheong Chau Wong

Man-Power Distribution

3. Each farm has 250 workers taking care of 750 acres of land.

**HORTICULTURAL PRACTICE**

Crop Under Cultivation

4.

SWF	SFAF
上海白	青海白
江門白	白菜
芥菜	菜心
芥蘭	芥菜
唐生	唐生
通菜	莧菜

Fertilizers

5. Both farms use the same protocol of fertilizer application detailed as follows:-

Fertilizer / mu	Cost
3 packs of chicken manure	\$18 x 3
1 pack of bone meal	\$50
5 catty of compound fertilizer	\$1 x 5
200 catty of peanut cake	\$1 x 200
2 packs of plant ash	--
Total	\$309 / mu

Packaging

6. Mr. Cheong claimed that the number of designated baskets for holding the accredited produces provided by VMO was only one-fifth of what had been asking for and thus making

the packaging arrangement very inconvenient. Mr. Jorbic Wong of FVMCS has promised to follow-up on the issue.

### Seed Saving

7. Under the administration of SWF, 70-80 mu land in the nearby mountain area was reserved for saving seed of *Brassica campestris* L. ssp. *chinensis* var. *utilis* Tsen & Lee cv. '四九' whose seed is not (?or not always) available in the local and Hong Kong market. The variety produce stout stalk accompanied by small leaves - an ideal flowering cabbage crop.

### Cultivation Difficulty

8. Manager of SFAF said that he had technically difficulty in cultivation sweet pea. Technical advice from use will be appreciated.

## PESTS AND DISEASES CONTROL

### Pesticides

9. Both farms shared the same range of pesticides, viz.:

Class	Pesticide	農場用名	Reg. No.	Remarks
Insecticide	<i>Bacillus thuringiensis</i>	大寶水	2P12	--
	Chlorpyrifos	樂斯本	2P48	--
	Cypermethrin	氰氰	2P62	--
	Dimehypo	刹蟲雙	--	unregistered, LD <sub>50</sub> (rat)=451 mg/Kg, used in non-crop situation
	Isoprocarb	葉蟬散	--	unregistered, LD <sub>50</sub> (rat)=403-485 mg/Kg, contact insecticide
	Rotenone	魚藤	2P175	--
Fungicide	Gingjiangmycin	井崗霉素	--	unregistered; however 74 of the 76 isomers gingjiangmycin is registered as validamycin A (2P190)
	Metalaxyl	瑞毒霉(甲霜靈)	--	unregistered; however mancozeb/metalaxyl is registered as 2P128
	Zineb	藍粉	2P194	--
Herbicide	Paraquat dichloride	草水	2P147	--
Plant Growth Regulator	Chlorfluazuron (Atabron)	抑太保	--	unregistered, LD <sub>50</sub> >8500 mg/Kg

### Unusual Pests

10. The pests listed below normally do not attack Cruciferae crops. However since SWF and SFAF were numerous paddy fields in between their land, it provided breeding ground for these pests which then migrated to the Brassica crop. Yet the pest status of them were only moderate.

PEST	SYMPTOM	HOST	COMMON
<i>Nezara viridula</i>	Green stink bug	<i>Brassica campestris</i> L. ssp. <i>chinensis</i> var. <i>utilis</i> Tsen & Lee	Chinese flowering cabbage
<i>Nezara viridula</i>	Green stink bug	<i>Brassica juncea</i> var. <i>multiceps</i>	Leaf mustard, hsu-li-

		Tsen & Lee	hung
<i>Leptocorisa acuta</i>	Paddy stink bug	<i>Brassica campestris</i> L. ssp. <i>chinensis</i> var. <i>utilis</i> Tsen & Lee	Chinese flowering cabbage

### Residue Testing

11. The results of residue testing of 12 samples were attached in the Annex. No excessive residue was detected.

### **SPECIAL RECOMMENDATIONS**

12. Due to language barrier and technical complexity of the following recommendations, some of the points are not conveyed to the farm managers during the visit. Thus it is recommended a separate written recommendation incorporating the following points should be issued to Mr. Yeung Yuk Man, owner of the two farms.

Item	SFAF	SWF
Pesticide Storage	Storage room is too small. All pesticides should be probably labeled and preferably put on shelves.	All pesticides should be probably labeled and preferably put on shelves.
Pesticide Record	Usage and stock record should be probably done.	Ditto
Storage of Paraquat	need special warning sign e.g. displaying crossbones and with the word '毒藥'	Ditto
Remain of Spray	Never left any remain of spray or pesticide concentrate in unlabelled bucket, even in locked store	--
Spraying tanks and nozzles	Need better cleaning	Ditto
Unregistered Pesticides	刹蟲雙 & 葉蟬散 should never be used on crop near to the harvesting date (stop using at least 3 weeks before harvest)	Ditto
Beneficial Weed	A purple flower Compositae weed (pending herbarium identification) was found providing nutrient to numerous beneficial parasitic wasps. Such weed should be encouraged to flourish.	Ditto
Weed & Herbicides	--	Two broad-leaf-weeds (pending for herbarium identification) were found competing with the kale in the field. If hand weeding is impossible or not desired, napropamide [奈丙酰胺 (大惠利、草奈胺)] can be used.
Crop Deployment	Intercropping (間種) instead of continuous cropping (連種) should be encourage; this can help to alleviate the cabbage flea beetle problem.	Ditto
Crop Rotation	Should be encouraged especially when the lower price season for brassica crops can be anticipated.	Ditto

Removal of Crop Residue	Should be done immediately; Alternatively the crop residue can be used as trap crop.	Ditto
-------------------------	---	-------

Conclusion

13. The overall management of the two farms are found satisfactory.

Clive Lau  
AO(PP)3  
May 22, 1995

c.c.  
AO(Hort)  
AO(PP)2  
SFO(Hort)  
FOI(Ento)

Ref.: (13) in GD/AF/001

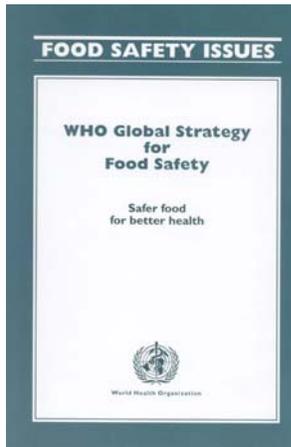
**PANYU, CHINA (24~25 MAY, 1995)**  
**PLANT PROTECTION ASSESSMENT REPORT**

		黃閣	漁窩頭	靈山 下泥	靈山 新沙	番禺農科所	橫瀝	萬頃沙
Plant Growth	General Comment	Very uneven (varied between 30 cm to flowering stage) , 50 out of 85 mu might have harvest	Batch 1-3: Very uniform; Batch 4: non-uniform	Transplanted: V. Weak with slender stem; Direct Sowed: Normal	Uniform healthy Crop	Uniform healthy Crop	Improper thinning resulting in many points bearing twin plants; otherwise crop is strong and healthy	Batch 1: lost to tornado; Batch 2: 15 Mu, normal Batch 3: 90 mu normal
	Single cone per plant (-- = poorly done to ++ = most plants bear only one cone)	+	+	-	+	--	++	--
	Planting Density (✓✓= optimum to ✕✕ too dense)	✓	✕	✓	✓✓ (>1 foot apart between plant)	✓	✓✓	✓
Pest & Disease	Asian Corn Borer (✓=detected or ✕ not detected)	✕	✕	✕	✕	✓ (moderate, 1~2 per 20 plants)	✕	✕
	Corn Ear Worms (CEW)** (-- = not found to ++ = high infestation)	—	--	++	--	++	++	-
	Natural Enemies of Corn Pests	Spiders	Ants	Ants (found preying on CEW), <i>Paederus fuscipes</i>	Not detected	Ants	Ants, Ladybird	Not detected
	Other Insects	<i>Henosepilachna vigintioctopunctata</i> , <i>Popillia ?newmann</i> , ? <i>Tabanidae</i> sp.	<i>Dappula tertia</i> , Tipulidae sp., <i>Tabanus</i> sp., <i>Euproctis ?taiwana</i> , Muscidae sp., <i>Cletus trigonus</i> , <i>Henosepilachna vigintioctopunctata</i>	? <i>Tephritidae</i> sp., <i>Phyllophaga coccinchina</i> , obvious damaged by Scarabaeidae	Black ? <i>alticinae</i>	<i>Euproctis</i> sp., <i>Nezara viridula</i> , <i>Popillia ? newmann</i>	<i>Eysarcoris montivagus</i> , Nitidulidae sp.	Nil
	Diseases	Nil	Whole crop suffered from leaf blight caused by <i>Cochliobolus carbonum</i> [Imp.:	Moderate mixed infection of leaf blight (C. <i>carbonum</i> ) and large leaf spot (C.	Nil	Nil	Very mild infection of leaf blight (C. <i>carbonum</i> ) and symptom was restricted to the	Nil

**Appendix 4**  
**World Health Organisation's**  
**Global Strategy**  
**for Food Safety**

世界衛生組織

關於全球食物安全策略的文件



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## Summary

The Fifty-third World Health Assembly, in resolution WHA53.15, requested the Director-General to put in place a global strategy for surveillance of foodborne diseases and to initiate a range of other activities on food safety and health. Since then WHO has organized a strategy planning meeting on food safety (Geneva, 20-22 February 2001). Following further consultation with Member States, WHO has drawn up a global food safety strategy, including surveillance, as outlined in this document.

### Global food safety concerns

**Microbiological hazards** and the foodborne diseases they cause are an increasingly important public health problem. In many countries significant increases have been reported over the past few decades in the incidence of diseases caused by microorganisms transmitted mainly by food, such as *Salmonella* spp. and *Campylobacter* spp. New, serious hazards have emerged in the food chain, such as enterohaemorrhagic *Escherichia coli* and bovine spongiform encephalopathy.

**Chemical hazards** remain a significant source of foodborne illness. Chemical contaminants in food include natural toxicants, such as mycotoxins and marine toxins, environmental contaminants, such as mercury and lead, and naturally occurring substances in plants. Food additives, micronutrients, pesticides and veterinary drugs are deliberately used in the food chain; however, assurance must first be obtained that all such uses are safe.

Although traditional approaches have proved largely successful, risk assessment now needs also to take account of susceptible populations, combined low-level exposure to several chemicals, endocrine effects, and effects on development of the fetal neural system. More data on food intake and on the concentrations of contaminants in food are needed, in particular in developing countries, in order to permit assessment and management of these risks, including setting of national and international standards.

**New technologies**, such as genetic engineering, irradiation of food, and modified-atmosphere packaging, can improve food production and food safety. However, the potential risks associated with application should be objectively and rigorously assessed well before these technologies are widely introduced. The basis for risk assessment should be communicated effectively, so that the public can be involved at the early stages of the process. Assessment should be based on internationally agreed principles and should be integrated with consideration of other factors, such as health benefits, socioeconomic factors, ethical issues and environmental considerations.

**Building capacity** in food safety is essential in most countries, especially developing ones. Both positive and negative experiences from countries with well-developed food safety systems could be used as a means to improve systems globally. Foodborne disease has a significant impact not only on health but also on development. Moreover, globalization of the food trade and development of international food standards have raised awareness of the interaction between food safety and export potential for developing countries.

Putting food safety on the political agenda is the first step in reducing foodborne illness; however, even with this step in place, many developing countries lack the technical expertise and financial resources to implement food safety policies. Support from donors for capacity building in order both to protect health and to improve food trade, would help to build up a framework for sustainable development.

## WHO Global Strategy for Food Safety

### Goal

To reduce the health and social burden of foodborne disease.

## Methods

The goal will be achieved through three principal lines of action:

- advocating and supporting the development of risk-based, sustainable, integrated food safety systems;
- devising science-based measures along the entire food production chain that will prevent exposure to unacceptable levels of microbiological agents and chemicals in food;
- assessing and managing foodborne risks and communicating information, in cooperation with other sectors and partners.

## Approaches

**Surveillance of foodborne diseases.** Surveillance is the basis for the formulation of national strategies to reduce food-related risks. Detailed and accurate knowledge about the nature and level of foodborne diseases is a prerequisite for action to lower these levels. Therefore, the present paucity of reliable data on foodborne diseases in most countries is a major impediment for evidence-based interventions. A surveillance system employing sentinel sites and regional and international laboratory networks would be a major improvement in most regions. In addition, internationally agreed methods are needed for surveying foodborne diseases and linking them to food contamination on the basis of risk. This requires an interdisciplinary approach that includes all sectors dealing with foodborne diseases and food safety in both the health and agriculture sectors.

It is essential for Member States to be committed to strengthening systems for surveillance of foodborne diseases. WHO will facilitate the strengthening of systems based on laboratory and epidemiological findings and of their linkages to programmes for monitoring food contamination. WHO and its collaborating centres will promote key sentinel sites both in developing countries and globally for surveillance of foodborne diseases.

**Better risk assessment.** WHO, in collaboration with FAO, will develop tools for appropriate risk assessment. With the help of these tools, joint WHO/FAO expert groups will compile information on chemicals and microorganisms in food and their link to foodborne disease. Such assessments can serve as the basis for setting international standards and guidelines, and for national food regulations or other initiatives. The provision of tools and information will permit the effective transfer of risk-assessment technology and data between countries, including developing countries.

The developing discipline of microbiological risk assessment provides a tool to set priorities for future interventions. Effective management of microbiological hazards is enhanced through the use of preventive approaches, such as the Hazard Analysis and Critical Control Point (HACCP) system, which is a tool for process control of points critical for preventing hazards in food. Use of these new tools, suitably adapted for developing countries, should be advocated in order to improve public health through the reduction of microbiological hazards in food and their associated diseases.

**Safety of new technologies.** WHO will promote a holistic approach to the production and safe use of foods derived from new methods of production, including genetic engineering. This approach is supported by a framework for evaluation that includes safety considerations, health benefits, environmental effects, and socioeconomic consequences. The framework provides a basis for internationally agreed methods and guidelines for evaluating the safety of new technologies and guidance for Member States in framing policies on the use of foods and food ingredients derived by new technologies.

**Public health in the Codex Alimentarius.** WHO will work to ensure that consumer health concerns are reflected in the priorities of the Codex Alimentarius Commission. In this regard, WHO is promoting a thorough review and optimization of the work of the Commission. In general, WHO seeks greater involvement of the health sector in the development of Codex standards, guidelines and recommendations. WHO will support the effective participation of developing countries in the work of the Commission.

**Risk communication.** The results of risk analyses should be communicated in a readily understandable form. WHO will support the development of methods for fostering dialogue among, and participation of, stakeholders, including consumers, in the communication process. Methods for assessing the effects of risk communication should be evaluated. In line with the methodology so developed, WHO will produce food safety publications and other products for targeted audiences.

**International cooperation.** WHO will work for the establishment of an international coordination group on food safety to ensure a consistent, effective approach to food safety. This group should be geared to coordinating at country level activities on food safety undertaken by international bodies. WHO will support Member States in introducing health concerns into considerations on the globalization of food trade.

**Capacity building.** WHO will formulate regional food safety strategies on the basis of the WHO global food safety strategy and of specific regional needs such as technical support, educational tools and training. Donor support will be needed to prioritize food safety in public health in developing countries. A network of WHO collaborating centres will be established in order to further capacity building.

## **Foreword**

### ***Food safety: a public health priority***

Foodborne disease takes a major toll on health. Thousands of millions of people fall ill and many die as a result of eating unsafe food. Deeply concerned by this, the Fifty-third World Health Assembly (May, 2000) adopted a resolution calling upon the World Health Organization (WHO) and its Member States to recognize food safety as an essential public health function. The resolution also called on WHO to develop a Global Strategy for reducing the burden of foodborne disease.

The availability of safe food improves the health of people and is a basic human right. Safe food contributes to health and productivity and provides an effective platform for development and poverty alleviation. People are becoming increasingly concerned about the health risks posed by microbial pathogens and potentially hazardous chemicals in food. Up to one-third of the populations of developed countries are affected by foodborne illness each year, and the problem is likely to be even more widespread in developing countries. The poor are the most susceptible to ill-health. Food and waterborne diarrhoeal diseases, for example, are leading causes of illness and death in less developed countries, killing an estimated 2.2 million people annually, most of whom are children. Diarrhoea is the most common symptom of foodborne illness, but other serious consequences include kidney and liver failure, brain and neural disorders, and death. The debilitating long-term complications of foodborne disease include reactive arthritis and paralysis.

Trends in global food production, processing, distribution and preparation present new challenges to food safety. Food grown in one country can now be transported and consumed halfway across the world. People demand a wider variety of foods than in the past; they want foods that are not in season and often eat away from home. Institutionalizing children in schools and childcare facilities and a growing number of elderly persons in hospitals and nursing homes means that food for many is prepared by a few and can therefore be the source of major foodborne disease outbreaks. Greater life expectancy and increasing numbers of immunocompromised people mean a larger vulnerable population for whom unsafe food is often an even more serious threat.

WHO and its Member States have responded to these new challenges by recognizing that protecting food safety is an essential public health function. Food safety must be addressed along the entire food chain by measures based on sound scientific information at both national and international levels. WHO's capacity to assess the risks posed by chemical and microbiological hazards and by new food-related technologies must be enhanced. New methods are needed for evaluating and reducing the burden of foodborne disease. Food safety strategies can be implemented only by countries that have an adequate capacity to do so, and WHO will continue to assist Member States in establishing and updating that capacity.

WHO is committed to achieving better health for all people and recognizes food safety as a global public health priority. The strategy outlined in this document defines a strengthened role for WHO in food safety, suggests the approaches to be taken to reduce the risks posed by microbial and chemical hazards in food, and provides a roadmap for making the world's food safer. As food safety affects the entire community, all stakeholders must be involved. Thus, effective implementation of this strategy will require strengthened partnerships between international organizations involved in food safety as well as between agencies at the national level.

### ***Why is food safety an essential public health issue?***

Serious outbreaks of foodborne disease have been documented on every continent in the past decade, illustrating both the public health and social significance of these diseases. Consumers everywhere view foodborne disease outbreaks with ever-increasing concern. Outbreaks are likely, however, to be only the most visible aspect of a much broader, more persistent problem. Foodborne diseases most seriously affect children, pregnant women, the elderly and people already affected by

other diseases. Foodborne diseases not only significantly affect people's health and well-being, but they also have economic consequences for individuals, families, communities, businesses and countries. These diseases impose a substantial burden on health-care systems and markedly reduce economic productivity. Poor people tend to live from day to day, and loss of income due to foodborne illness perpetuates the cycle of poverty.

### **New challenges to food safety**

The integration and consolidation of agricultural and food industries and the globalization of the food trade are changing the patterns of food production and distribution. These conditions are creating an environment in which both known and new foodborne diseases can become prevalent. Food and feed are distributed over far greater distances than before, creating the conditions necessary for widespread outbreaks of foodborne illness. In a recent crisis, more than 1500 farms in Europe received dioxin-contaminated feed from a single source over a two-week period. Food produced from animals given this contaminated fodder found its way onto every continent within weeks. The effects of exposure to dioxin from this source on public health may become known only after years of investigation. The international spread of meat and bonemeal prepared from cattle affected by bovine spongiform encephalitis (BSE) needs no further description. The full economic consequences of such incidents and the anxiety raised among consumers are still being assessed.

Other factors account for the emergence of food safety as a public health issue. Increasing urbanization leads to greater requirements for transport, storage and preparation of food. Increasing wealth, an urban lifestyle and sometimes a lack of facilities mean that people eat much of their food away from home. In developing countries, food is often prepared by street vendors. In developed countries, up to 50% of the food budget may be spent on food prepared outside the home. All these changes lead to situations in which a single source of contamination can have widespread, even global consequences. Developing countries in particular are experiencing rapid changes in their health and social environments, and the strains on their limited resources are compounded by expanding urbanization, increasing dependence on stored foods and insufficient access to safe water and facilities for safe food preparation.

The globalization of the food trade offers many benefits to consumers, as it results in a wider variety of high-quality foods that are accessible, affordable and safe, meeting consumer demand. A diversity of foods in a balanced diet improves nutritional status and health. The global food trade provides opportunities for food-exporting countries to earn foreign exchange, which is indispensable for the economic development of many countries and for improving the standard of living of many people. However, these changes also present new challenges to safe food production and distribution and have been shown to have widespread repercussions on health.

Food safety programmes are increasingly focusing on a farm-to-table approach as an effective means of reducing foodborne hazards. This holistic approach to the control of food-related risks involves consideration of every step in the chain, from raw material to food consumption. Hazards can enter the food chain on the farm and can continue to be introduced or exacerbated at any point in the chain until the food reaches the consumer.

Although significant progress has been made in many countries in making food safer, thousands of millions of people become ill each year from eating contaminated food. The emergence of increased antimicrobial resistance in bacteria causing disease is aggravating this picture. The public is increasingly aware of the risks posed by pathogenic microorganisms and chemical substances in the food supply. The introduction of new technologies, including genetic engineering and irradiation, in this climate of concern about food safety is posing a special challenge. Some new technologies will increase agricultural production and make food safer, but their usefulness and safety must be demonstrated if they are to be accepted by consumers. Furthermore, the evaluation must be participatory, transparent and conducted using internationally agreed methods.

Until recently, most systems for regulating food safety were based on legal definitions of unsafe food, enforcement programmes for the removal of unsafe food from the market and sanctions for the responsible parties after the fact. These traditional systems cannot respond to existing and emerging

challenges to food safety because they do not provide or stimulate a *preventive* approach. During the past decade, there was a transition to risk analysis based on better scientific knowledge of foodborne illness and its causes. This provides a preventive basis for regulatory measures for food safety at both national and international levels. The risk-based approach must be backed by information on the most appropriate and effective means to control foodborne hazards.

### **International food standards based on health considerations**

In resolution WHA 16.42 (May 1963), the Sixteenth World Health Assembly approved the establishment of the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Food Standards Programme, with the Joint FAO/WHO Codex Alimentarius Commission (Codex) as its principal organ. The objective of Codex is to develop standards for food, protecting the health of the consumers and ensuring fair practices in the food trade.

Codex has elaborated many international standards on food safety, and often Member States have used these in national legislation. Recent international agreements managed by the World Trade Organization (WTO) have put even further emphasis on the importance of Codex standards. Under WTO, health and safety requirements must be justifiable on the grounds of protecting public health and must be based on a sound, scientific risk assessment. When available, standards from Codex for food safety issues, International Office of Epizootics (OIE) for issues of animal health, and International Plant Protection Convention (IPPC) for plant health should be used as references.

The elaboration of health-based international standards and their adoption by Member States will improve the safety of food in both the domestic market and at a global level. It can also facilitate safe trade in food and contribute economically to development and to improving living standards in food-exporting countries. Effective participation in the development of international standards to ensure that they meet the needs of all Member States is vital to this process.

## ***Major issues in food safety***

Foodborne illness can be caused by microbiological, chemical or physical hazards. The nature and extent of these risks are being elucidated by an increasing body of scientific data, although several areas of information gathering, such as the surveillance of foodborne illness, need to be strengthened. There is also mounting concern about new technologies and especially the introduction of genetically modified organisms into the food supply.

### **Microbiological hazards**

Foodborne illness caused by microorganisms is a large and growing public health problem. Most countries with systems for reporting cases of foodborne illness have documented significant increases over the past few decades in the incidence of diseases caused by microorganisms in food, including pathogens such as *Salmonella*, *Campylobacter jejuni* and enterohaemorrhagic *Escherichia coli*, and parasites such as *cryptosporidium*, *cryptospora*, trematodes.

Approximately 1.8 million children in developing countries (excluding China) died from diarrhoeal disease in 1998, caused by microbiological agents, mostly originating from food and water. One person in three in industrialized countries may be affected by foodborne illness each year. In the USA, some 76 million cases of foodborne illness, resulting in 325 000 hospitalizations and 5000 deaths, are estimated to occur each year. There are only limited data on the economic consequences of food contamination and foodborne disease. In studies in the USA in 1995, it was estimated that the annual cost of the 3.3–12 million cases of foodborne illness caused by seven pathogens was US \$6.5–35 billion. The medical costs and the value of the lives lost during just five foodborne outbreaks in England and Wales in 1996 were estimated at UK£ 300–700 million. The cost of the estimated 11 500 daily cases of food poisoning in Australia was calculated at AU\$ 2.6 billion annually. The increased incidence of foodborne disease due to microbiological hazards is the result of a multiplicity of factors, all associated with our fast-changing world. Demographic profiles are being altered, with increasing proportions of people who are more susceptible to microorganisms in food.

Changes in farm practices, more extensive food distribution systems and the increasing preference for meat and poultry in developing countries all have the potential to increase the incidence of foodborne illness. Extensive food distribution systems raise the potential for rapid, widespread distribution of contaminated food products. Changes in food production result in new types of food that may harbour less common pathogens. Intensive animal husbandry technologies, introduced to minimize production costs, have led to the emergence of new zoonotic diseases, which affect humans. Safe disposal of manure from large-scale animal and poultry production facilities is a growing food safety problem in much of the world, as manure frequently contains pathogens.

Changes in eating patterns, such as a preference for fresh and minimally processed foods, the increasingly longer interval between processing and consumption of foods and the increasing prevalence of eating food prepared outside the home all contribute to the increased incidences of foodborne illness ascribed to microbiological organisms. The emergence of new pathogens and pathogens not previously associated with food is a major public health concern. *E. coli* O157:H7 was identified for the first time in 1979 and has subsequently caused illness and deaths (especially among children) owing to its presence in ground beef, unpasteurized apple cider, milk, lettuce, alfalfa and other sprouts, and drinking-water in several countries. *Salmonella typhimurium* DT104 has developed resistance to five commonly prescribed antibiotics and is a major concern in many countries because of its rapid spread during the 1990s.

These changes in microbiological hazards in foods have been recognized by the World Health Assembly and by Codex. The 22<sup>nd</sup> session of the Codex Alimentarius Commission and the 45<sup>th</sup> Codex Executive Committee requested FAO and WHO to convene an international expert advisory body similar to the Joint Expert Committee on Food Additives (JECFA) and the Joint Meeting on Pesticide Residues (JMPR) on the microbiological aspects of food safety to address in particular microbiological risk assessment. The results of these risk assessments will provide the scientific basis for measures to reduce illness from microbiological hazards in foods.

Effective management of microbiological hazards is enhanced through the use of tools such as Microbiological Risk Assessment (MRA) and Hazard Analysis and Critical Control Point (HACCP) systems. Sound microbiological risk assessment provides an understanding of the nature of the hazard, and is a tool to set priorities for interventions. HACCP is a tool for process control through the identification of critical control points. The ultimate goal is improvement of public health, and both MRA and HACCP are means to that end.

## **Chemical hazards**

Chemicals are a significant source of foodborne illness, although effects are often difficult to link with a particular food. Chemical contaminants in food include natural toxicants such as mycotoxins and marine toxins, environmental contaminants such as mercury, lead, radionuclides and dioxins, and naturally occurring chemicals in plants, such as glycoalkaloids in potatoes. Food additives and nutrients such as vitamins and essential minerals, pesticide and veterinary drug residues are deliberately used to increase or improve the food supply, but assurance must first be obtained that all such uses are safe.

Chemical contamination of food can affect health after a single exposure or, more often, after long-term exposure; however, the health consequences of exposure to chemicals in food are often inadequately understood. While assessments of the risks associated with exposure to pesticides, veterinary drugs and food additives are usually supported by extensive information, fewer data are available on the toxicology of contaminants in food. New understanding of the potential for chemicals to affect the immune, endocrine and developing nervous systems should continue to be incorporated into hazard characterizations of chemicals in food.

Risk assessments must take into account the potential risks of sensitive population groups such as children, pregnant women and the elderly. They must also address concern about cumulative, low-level exposure to multiple chemicals. Testing procedures and other methods of assessment for adequate evaluation of these potential risks are being developed and validated. Estimates of the exposure of specific subpopulations are often hampered by inadequate data on dietary intake and on

levels of contamination of food. This lack of information is exacerbated in developing countries, where little reliable information is available on the exposure of their populations to chemicals in food.

Public awareness about chemicals in food is relatively high, and consumers continue to express concern about the risks to health due to the deliberate addition of chemicals to food. Increasing concern is also being expressed about the introduction of contaminants into the food chain from industrial pollution of the environment. Recognition that some pesticide residues and other chemicals may affect the hormonal system has further heightened public concern about persistent organic pollutants (POPs).

The challenges for risk assessment of chemicals include consideration of susceptible populations such as children, pregnant women and the elderly, cumulative low-level exposure to multiple chemicals and effects on fetal neural development. Work is needed to develop and validate methods to evaluate these potential risks adequately. The Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food) database should be expanded to include more countries and more comprehensive data on the food intake of subpopulations and on the concentrations of contaminants in food commodities. Improved risk assessments with minimized uncertainty will provide a better, more acceptable basis for international and national standard setting and reduce concern about the safety of food.

### **Surveillance of foodborne disease**

Outbreaks of foodborne disease attract media attention and raise consumer concern. However, cases of foodborne illness occur daily in all countries, from the most to the least developed. As most of these cases are not reported, the true dimension of the problem is unknown, and efforts to secure the resources and support necessary for the identification and implementation of effective solutions often fail.

Effective control of foodborne disease must be based on evaluated information about foodborne hazards and the incidence of foodborne disease. Development of a strategy to reduce food-related risks requires knowledge about the current levels of foodborne disease in Member States. It must also be based on an appreciation of the targets and time-frame for improving food safety. This should be an on-going process, in which new targets are set when old ones are achieved, and progress should be monitored continuously in targeted surveys.

The absence of reliable data on the burden of foodborne disease impedes understanding about its public health importance and prevents the development of risk-based solutions to its management. Innovative strategies and methods are needed for surveying foodborne disease and food contamination. A laboratory-based surveillance system should be based on sentinel sites and regional and/or international laboratory networks. A necessary prerequisite for risk-based strategies based on optimized surveys is an interdisciplinary approach involving strong collaboration among all sectors dealing with foodborne disease surveillance and food safety in the health sector.

### **New technologies**

New technologies, such as genetic engineering, irradiation of food, ohmic heating and modified-atmosphere packaging, can be used to increase agricultural production, extend shelf life or make food safer. Their potential benefit for public health is great: for example, genetic engineering of plants has the potential to increase the nutrient content of foods, decrease their allergenicity and improve the efficiency of food production. However, the potential public health effects of these technologies have raised concern globally during the past decade.

Some new technologies benefit the health and economy of communities and contribute to sustainable development. However, countries should be provided with the results of objective, rigorous assessments of the potential risks associated with these technologies before being asked to accept them. Moreover, countries should be assisted in developing capacities to evaluate such results. The basis for the safety assessments should be easy to understand and well communicated, so that the public can be involved at the early stages of this process. The evaluation should be based on

internationally agreed principles that include factors other than considerations of safety and risk, such as (health) benefits, socioeconomic factors, ethical issues and environmental assessments. These considerations should be developed with other WHO partners such as FAO, the United Nations Environment Programme (UNEP), the Organisation for Economic Co-operation and Development (OECD) and the World Bank.

## **Capacity building**

Most developed countries continue to expand the capacity to protect their populations from exposure to unacceptable levels of microorganisms and chemicals in food. Public awareness of the risks involved is relatively high in these countries, and many governments have made clear commitments to improve food safety.

Developing countries have many competing priorities in their health agendas, and food safety has not, in the past, been recognized as a vital public health issue. However, it is becoming clear that foodborne disease has a significant impact on health. The globalization of the food trade and the development of international food standards have also raised awareness of food safety in developing countries. Placing food safety on the political agenda is the first vital step in reducing foodborne illness.

The consumption of locally produced food is more common in developing countries. Fewer processed and packaged foods are available, large volumes of fresh food are traded in traditional markets, and food eaten outside the home is typically prepared by street vendors. Most of the concern for food safety is related to inappropriate use of agricultural chemicals, poor storage of food, an absence of food inspection, lack of infrastructure such as potable water and adequate refrigeration and lack of awareness about food safety and hygiene.

Many developing countries are poorly equipped to respond to existing and emerging food safety problems. They lack technical and financial resources, an effective institutional framework, trained manpower and sufficient information about the hazards and risks involved. The risks are especially great in countries where low national income coincides with rapid industrial and agricultural development.

A WHO survey in 1989 of national capacities for effective protection against adverse environmental factors, including a clean water supply, basic sanitation and food safety, showed that less than 10% of the 136 developing countries had adequate capacities. Few of these countries had adequate legislation, standards or regulations or the capacity to enforce and assess them. Most lacked adequately skilled staff, effective mechanisms for intersectoral action and adequate financing and strategies to overcome these limitations. Therefore, while the identification of hazards and risks in food is vital in strategic planning, the capacity to assess and manage those risks is fundamentally lacking in many developing countries. Future work will focus on identifying gaps in the infrastructure and capacity of Member States to address food safety, and tailored programmes will be designed to close those gaps. WHO will advocate food safety as a public health issue at the national level and as a priority for funding from donors. WHO will also provide appropriate technical assistance and education tools for food safety initiatives.

## ***The role of WHO in food safety***

### **WHO's mandate**

WHO has a specific mandate for the protection of public health. Its mission is '*the attainment by all people of the highest possible level of health*'. WHO's role in food safety is to reduce the burden of foodborne illness by advising and assisting Member States to reduce exposure to unacceptable levels of chemicals or microorganisms in food.

The 1948 WHO Constitution includes specific charges relating to food safety:

- assist governments in strengthening health services relating to food safety;
- promote improved nutrition, sanitation and other aspects of environmental hygiene;
- develop international standards for food; and,
- assist in developing informed public opinion among all peoples on matters of food safety.

WHO's approach to achieving these changes is to cooperate with countries on technical issues and to stimulate cooperation so that people everywhere may achieve health for all, while maintaining a healthy environment and charting a course for sustainable development. A food supply that is adequate in quantity, quality, accessibility and safety is a prerequisite for achieving and maintaining the health of the world's population.

### **WHO food safety initiatives**

WHO has been involved in food safety for over five decades. Many WHO activities in this area are carried out in close collaboration with FAO. In May 1963, the Sixteenth World Health Assembly approved the establishment of the Joint FAO/WHO Food Standards Programme, with the Codex Alimentarius Commission as its principal organ. The main objective of the Commission is to protect the health of consumers and to ensure fair practice in food trade through the elaboration of food standards contained in a food code (Codex Alimentarius). The participation of WHO was required because of its mandate for public health and food safety.

In 1978, the Health Assembly requested the Director-General to develop a food safety programme and address the control of foodborne diseases and food hygiene.

WHO's central role is a normative one and includes international standard setting and the facilitation of risk assessments. WHO has promoted the concept of risk analysis as a framework for the management of food safety. The main focus is the development of methods for quantitative microbiological and chemical risk assessment, foodborne disease surveillance and assessment of the safety of the products of genetic engineering.

WHO also provides technical assistance to governments, through its regional offices, to ensure a safe food supply for their populations. As a part of its mandate to support capacity building in Member States, WHO provides training in food sanitation in community-based programmes and the Healthy Market Initiatives. In collaboration with international, regional and national agencies, it provides training in risk analysis and other aspects of food safety. WHO assists national governments in developing and implementing food safety programmes and food legislation and provides support for setting up information systems for monitoring food contamination and surveying foodborne disease.

### **World Health Assembly resolution**

The Fifty-third World Health Assembly in May 2000 gave unanimous support for resolution WHA53.15 on food safety. This resolution confirmed food safety as an essential public health priority and committed WHO and its Member States to a range of multisectoral and multidisciplinary actions to promote the safety of food at local, national and international levels. Specifically, it resolved to expand WHO's responsibilities in food safety, and to use limited resources efficiently to promote food safety as an essential public health function, and suggested appropriate interventions to improve global food safety.

### **Development of the Global Strategy**

The WHO Global Strategy for Food Safety has been developed with the assistance of experts from Member States, regional advisers in food safety, international partners and related programmes at WHO. Its aim is to identify global needs in food safety and to provide a global approach to reducing the burden of foodborne illness. The Strategy was endorsed by the WHO Executive Board in January 2002.

The WHO Global Strategy for Food Safety outlines the broad lines of action needed to reduce foodborne illness. WHO is now elaborating a more detailed long-term workplan outlining specific activities and initiatives to ensure the Strategy's success. The Strategy is predicated on a long-term commitment to food safety as a means of improving public health, which will be reflected in medium- and long-term workplans.

The proposed Global Strategy takes into account strategies and resolutions on food safety that have been adopted by regional committees. Countries are urged to take guidance from the Strategy in improving food safety.

# ***The WHO Global Strategy for Food Safety***

## **Defining the challenge**

Traditional food safety measures have not been efficient in preventing foodborne disease over the last decades. WHO's goal of reducing the public health burden of foodborne disease can best be achieved through systematic application of risk analysis. Structures and systems must therefore be developed at national, regional and international levels to survey foodborne disease, conduct risk assessments and implement risk management strategies. Capacity building and coordination of scientific effort are essential roles of WHO and are important elements of its Food Safety Strategy, but these must be combined with strong commitment and resources in order to ensure food safety through targeted, risk-based prevention initiatives.

WHO will take a prominent role in promoting food safety and act as the international broker and coordinator of food safety initiatives, primarily in cooperation with FAO. Effective participation of Member States, especially developing countries, is needed in setting international standards as well as guides for food safety initiatives.

While the existing activities in food safety have focused primarily on hazards in food, the proposed strategy will address the broader concept of risk along the entire food production chain. It will take into consideration the need for sustainable agricultural production systems in all regions of the world and will redirect some of the existing approaches to ensure that they meet the emerging challenges of global food safety.

## **Principal goal**

*To reduce the health and social burden of foodborne disease.*

It will be achieved by :

- advocating and assisting in the development of risk-based, sustainable, integrated food safety systems ;
- developing science-based measures along the entire food production chain that will prevent exposure to unacceptable levels of microbiological agents and chemicals in food; and
- assessing, communicating and managing foodborne risks, in cooperation with other sectors and partners.

## **Approaches**

The Strategy includes the following approaches:

- I. Strengthening surveillance systems of foodborne diseases;
- II. Improving risk assessments;
- III. Developing methods for assessing the safety of the products of new technologies;
- IV. Enhancing the scientific and public health role of WHO in Codex;
- V. Enhancing risk communication and advocacy;
- VI. Improving international and national cooperation;
- VII. Strengthening capacity building in developing countries.

It should be recognized that important interlinkages exist between these approaches. General approaches, such as communication and capacity building, will therefore have to be considered not only in their own right but also as important, integrated parts of other, specific approaches.

## Approach I

### Strengthening surveillance systems of foodborne diseases

Surveillance of foodborne diseases is becoming an increasingly high priority in the public health agenda in many countries. It is instrumental for estimating the burden of foodborne diseases, assessing its relative impact on health and economics and evaluating disease prevention and control programmes. It allows rapid detection and response to outbreaks. In addition, it is a major source of information for conducting risk assessment, and more broadly for risk management and communication. Foodborne disease surveillance should be integrated with food monitoring data along the entire feed-food chain. Integrating such data would result in robust surveillance information and allow appropriate priority setting and public health interventions. Intersectoral and inter-institutional collaboration are of paramount importance.

The WHO strategy recognizes that surveillance of foodborne diseases should be given a high priority in the development of food safety infrastructure. Building capacity for public health laboratories to conduct laboratory-based surveillance and for conducting epidemiologically-based surveillance are important global public health objectives. The needs of developing countries should be particularly considered. WHO should be proactive in establishing one or more sentinel sites for foodborne disease in developing countries. There is a need to develop and coordinate a global approach to strengthen surveillance at national, regional and international levels. Foodborne disease reporting should be integrated into the revision of the International Health Regulations.

WHO will initiate a Global Strategy for the surveillance of foodborne diseases by urging Member States to set up laboratory-based systems covering both outbreaks, sporadic cases and for monitoring contamination of food by chemicals and microorganisms. When requested by Member States, WHO will support capacity building for data collection and surveillance systems. WHO will also establish common, internationally agreed formats for harmonized data collection and determine the minimal data requirements for future food safety initiatives in the regions. WHO will seek to develop a web-based system to collect, report and communicate data from surveys conducted in Member States. A surveillance system for *Salmonella* and antimicrobial resistance already exists.

#### Activities

- Encourage Member State's commitment to foodborne disease surveillance.
- Facilitate the strengthening of foodborne disease surveillance systems (laboratory- and epidemiologically-based systems) and food monitoring programmes.
- Promote sentinel sites in developing countries.
- Develop and coordinate global approaches for foodborne disease surveillance.

## Approach II

### Improving risk assessments

The development by Codex of an internationally agreed framework for risk analysis that serves as a basis for setting food standards at national and international levels has focused attention on the adequacy of risk assessments. WHO has a long history of providing assessments of especially chemical risk in food to Codex and to Member States. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are recognized as being at the forefront of scientific knowledge in assessing the risks of chemicals in food. The pressure on these advisory bodies to meet the needs of the Commission is increasing. In addition to the more traditional tasks, JECFA and JMPR must also deal with issues such as cumulative exposure to low concentrations of chemicals, fetal neurotoxicity and the special risks of vulnerable subpopulations. To meet the needs in this area, the work of WHO in risk assessment will be strengthened, and the reports of the assessments will be more detailed and be made available to

Member States more promptly. WHO will also review the procedures used by the expert bodies to ensure consistency and transparency, and to avoid conflict of interests.

Through the GEMS/Food programme, WHO plays a leading role in promoting the collection, collation and evaluation of data on chemicals in foods and the total diet at regional and international levels. The programme databases must be strengthened to meet the demand for information on differences in exposure to chemicals in different regions and for different subgroups within populations, such as children. These challenges are being taken up by WHO and are being incorporated into the work of JECFA and JMPR. It is recognized that one of the major problems of the current international risk assessment is the lack of exposure data from developing countries.

WHO and FAO have been in the forefront of the development of risk-based approaches for the management of public health hazards in food. Risk analysis is well established for chemical hazards. Now WHO and FAO are extending the experience and expertise developed in risk analysis for chemical hazards to microbiological hazards. WHO and FAO have embarked on a new programme of activities with the objective of conducting risk assessments that can serve as a basis for the reduction of microbiological risk along the entire food chain, from the primary producer to the consumer.

The risk assessments are developed through the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA). The results of these risk assessments will be published in a new series of documents on microbiological risk assessment. The methodology used in these assessments should be made available to Member States in readily accessible format, and capacity building efforts should be made in this area, especially in developing countries.

#### **Activities**

- Development of internationally agreed tools for national and international standard setting and for setting national priorities and food safety initiatives.
- Development of timely, appropriate risk assessments to serve as a basis for international standards and guidelines and national food regulations.
- Development of accurate, comprehensive information on the global status of foodborne disease and on chemicals and microorganisms in food.
- Development of timely, readily available risk assessments from JECFA, JMPR and JEMRA to Member States.
- Effective transfer of technologies and data for microbiological risk assessments between countries.

### **Approach III**

#### **Developing methods for assessing the safety of the products of new technologies**

The application of biotechnology to food production presents consumers with new challenges and questions. Resolution WHA 53.15 recognized genetic engineering of food as an important public health issue and resolved that WHO should strengthen its capacity to provide a scientific basis for decisions on the effects on human health of genetically modified foods.

WHO and FAO have worked since 1990 to achieve consistent standards and criteria for assessing the safety of foods and food ingredients derived from genetic engineering. The Joint FAO/WHO Expert Consultation on Foods derived from Biotechnology, held in June 2000, established the substantial equivalence approach as an initiating step in assessing safety and risks associated with genetically modified food. The safety assessment itself requires an integrated, consistent, case-by-case approach to the evaluation of such foods. A subsequent Expert Consultation focused mainly on the allergenic potential of genetically modified foods, which remains the most widely discussed issue in this area. Reliable methods are needed for assessing the allergenic potential of foods produced by

recombinant DNA technologies. These consultations represent the initiation of a series of expert meetings looking into biotechnology assessment, most recently including an expert consultation on foods derived from genetically modified microorganisms. The outcome of these consultations are used by Member States and by the Codex Alimentarius Commission, which has established a time-limited Task Force on Foods derived from Biotechnology.

WHO continues to take part in discussions on this subject by providing expert advice on the health risks of these new technologies and by contributing to a better understanding of new developments in order to address the concerns of consumers. Future work will be coordinated with the activities of other international organizations. WHO will continue to provide a scientific framework for the safety and nutritional assessment of foods derived from biotechnology, as well as for the inclusion of other scientific aspects of the introduction of such foods. WHO will support broadening the scope of evaluation, so that environmental, cost-benefit, socioeconomic and other considerations can be integrated in a more coherent system.

#### **Activities**

- Promotion of a holistic approach to the production and safe use of foods and food ingredients derived by both traditional and new methods of production, including genetic engineering.
- Development of improved, internationally agreed methods and guidelines for evaluating the safety of new technologies.
- Formulation of policy and guidance on the use of foods and food ingredients derived from genetic engineering.
- Development of a framework for evaluation that includes not only considerations of safety but also factors such as health benefits, environmental effects and socioeconomic consequences.

#### **Approach IV**

##### **Enhancing the scientific and public health role of WHO in Codex**

The global distribution of food increases the possibility that contaminated food produced in one country could pose a risk in other or all parts of the world. The establishment of global food safety standards will help to protect people everywhere from the risks of foodborne disease. While considerable resources are allocated to food safety in most developed countries, the greatest challenges remain in building systems and infrastructures for reducing foodborne illness in developing countries.

Resolution WHA53.15 recognized the importance of standards, guidelines and other recommendations of Codex in protecting the health of consumers and ensuring fair practices in food trade. WHO plays a major role in the scientific and public health work of Codex, by providing scientifically based risk assessments of short-term and long-term risks to health related to food. It also plays a significant role by advocating that the standards set by the Commission are based on considerations of public health and safety.

WHO will improve the methods for risk assessment for chemicals and microbiological hazards in food in order to provide accurate, globally representative bases for standard setting by Codex. The risk assessments will also provide adequate information to risk managers on issues such as the risks associated with exposure of children, pregnant women, the elderly and malnourished populations to foodborne hazards.

The adoption and enforcement of national standards consistent with Codex standards will help to ensure a safe food supply and will also facilitate entry into the global marketplace. It is essential that developing countries and regions participate effectively in the development of Codex standards. To do so, they must develop and/or improve their surveillance and monitoring methods for food contamination and intake and use these data to establish achievable international limits and

recommendations for hazards in food. WHO will assist countries with local technical and scientific training and, when possible, assist them in obtaining the necessary data for risk assessments.

WHO will work to ensure that the priorities of consumer health concerns will be reflected in the priorities of the Codex Alimentarius Commission. As part of this work WHO is promoting a thorough review and optimization of the work of the Codex system.

#### **Activities**

- Encourage and support greater involvement of the health sector in the development of Codex standards, guidelines and recommendations.
- Work to ensure that the decisions of Codex are based on the premise that the health of consumers must be protected.
- Encourage and assist in the effective participation of developing countries in the work of Codex.
- Promote a thorough review and optimization of the work of Codex.

### **Approach V**

#### **Enhancing risk communication and advocacy**

WHO recognizes the importance of open, intelligible risk communication between all parties subject to foodborne risks and will take a prominent role in both global and regional initiatives. Good communication will result in useful dialogue between the stakeholders (consumers, industry, producers) in risk analysis and will enable their participation in the process. It will also increase information sharing and consumer education aimed at improving food safety practices at home.

The high level of trust that Member States have in WHO places it in a responsible position with regard to risk communication on matters of food safety. Risk communication must address the specific needs of the target audience — Member States, consumers, producers, the food industry and regulators — by gauging which mechanisms and technologies are best for delivering the messages. Countries may need special assistance in risk communication strategies. Special consideration should be given to WHO communication efforts in the case of international crisis situations.

The WHO risk communication strategy must encompass information derived from risk assessments, crisis response and rapid alert systems and perceptions of risk. Communication of uncertainties and greater transparency in risk assessment and risk management are both important and WHO should explore ways to improve effective interaction between risk assessors and risk managers. WHO risk assessments must thus be clear and concise and be made available promptly.

One of the major impediments to improving food safety at a global level is the relatively low priority given to this issue in the public health agendas of many developing countries. WHO will advocate food safety as a priority. It will sensitize policy-makers in Member States by emphasizing the many public health and economic gains to be achieved by increased activity in this area. Examples of such gains are the alleviation of human suffering and prevention of loss of life, the reduction of poverty, reduction of the costs of medical treatment and those associated with sick leave, and improvement of the marketability of food with all the attendant benefits for economic development, including promotion of tourism.

WHO will continue to exercise a leadership role in food safety by developing a risk communication strategy and a range of products designed to promote food safety in Member States.

### **Activities**

- Advocacy to ensure that food safety is considered a public health priority.
- Advocacy to ensure that the results of risk assessments and analyses are communicated in a readily understandable form to permit dialogue between stakeholders, including consumers.
- Development and delivery of food safety products and publications for and to targeted audiences.
- Development of dialogues and methods for fostering participation, including focusing and evaluating the effects of risk communication.

## **Approach VI**

### **Improving international and national cooperation**

Wide-ranging cooperative activity is needed to ensure safe food at both national and international levels. WHO must work in collaboration with other international organizations to include food safety as an essential public health function. The goal of such collaboration is sustainable, integrated food safety systems to ensure a reduction in health risks along the entire food chain, from primary production to the consumer. WHO has established a network of collaborating centres for various aspects of food safety which have contributed significantly to the work of the Organization.

WHO's scientific and public health role in the work of Codex, undertaken jointly with FAO within the Joint FAO/WHO Food Standards Programme, will expand to meet the challenges of food safety and to ensure that standards are set on the basis of the protection of public health. WHO will also continue its work with WTO to ensure that Member States take health considerations into account in the globalization of trade. WHO collaborates on food safety with the United Nations Environment Programme (UNEP), the United Nations Development Programme (UNDP), the International Labour Office (ILO), the Organization for Economic Cooperation and Development (OECD), and many other nongovernmental organizations, including Consumers International (CI), International Association of Consumer Food Organizations, the Industry Council for Development (ICD), the International Life Sciences Institute (ILSI), development banks and academia. This collaboration should be based upon the comparative expertise of each organization.

At the country level, WHO will improve the coordination of food safety activities in order to raise awareness about the public health issues and to reduce duplications of effort and confusion about the roles of the various sectors involved in food safety. The *Guidelines for strengthening food control Systems* drafted by WHO and FAO and the preparation of guidelines for national food legislation are examples of the type of assistance provided to Member States.

### **Activities**

- Support Member States in taking health considerations into account in the globalization of food trade, in cooperation with WTO.
- Establish an international coordination group on food safety to ensure a consistent, effective approach to food safety.
- Coordinate and support activities on food safety undertaken by international bodies at the country level.
- Develop effective links and coordination among agencies involved in food safety in Member States.

## Approach VII

### Strengthening capacity building in developing countries

WHO attempts to improve food safety in Member States predominantly through its regional and country offices. While much progress has been made by the provision of technical cooperation for the development of national food safety programmes and capacity building, much remains to be done.

Resolution WHA53.15 requested the Director-General to support capacity building in Member States, and especially in less developed countries, and to facilitate their full participation in the work of Codex and its various committees, including risk analysis.

Inadequate capacities in developing countries continue to be a major obstacle in achieving WHO's food safety objectives. Underdevelopment poses difficulties for producing safe food, for domestic consumption and export. Countries that gain these capacities can improve health at both national and international levels. Improved capacity for surveying and monitoring is essential in enabling individual countries to assess the risks associated with food hazards and to set priorities and manage those risks more effectively.

Many developing Member States are considering the adoption of new food laws and food regulatory systems. In establishing systems for delivering safer food, they can draw lessons from the experience of more developed Member States and build food safety programmes that are based on the public health principle of prevention, rather than on the concept of sanctions. Their programmes should include laws that give them a clear mandate and the authority to include prevention and to take a holistic view in reducing foodborne disease.

Capacity building activities range from advocacy to technical collaboration with ministries of health (and other partners) in Member States and include human resource development. The building of national capacity for food safety involves many players, such as the health, agriculture, trade and commerce sectors as well as provincial and municipal governments, and NGOs. It is essential that capacity building be based on collaboration and coordination among these actors. The health portfolio is often, but not always, the most appropriate lead agency at the national level.

Capacity building must start with an assessment of gaps and needs to ensure that the activities are appropriate and will address deficiencies, including the absence of national food safety plans, outdated laws and regulations, the absence of surveys for foodborne disease, poorly resourced and structured food inspectorates and a lack of educational and training materials for food safety. The key steps include strengthening local technical and scientific capacity and developing effective educational tools and programmes.

The WHO regional offices have developed or are in the process of developing regional strategies for food safety. The Global Strategy has taken these draft regional strategies into consideration. Success in capacity building depends on strong involvement of the regional offices in identifying food safety capacity needs and priorities. Training remains an important component of capacity building. WHO collaborating centres should be better used for training staff in fields such as surveillance of foodborne disease and laboratory techniques. These centres could also be used in coordinating regional food safety activities and to achieve food safety goals through innovative solutions.

#### Activities

- Encourage donor support for food safety as a priority in public health in developing countries.
- Development of regional food safety strategies based on both the common elements outlined in the WHO food safety strategy and specific regional needs.
- Establishment of a network of WHO collaborating centres engaged in capacity building.
- Provision of technical assistance and educational tools for food safety initiatives.

## Annex

### **Resolution WHA53.15 on food safety adopted by the Fifty-third World Health Assembly (May 2000)**

*The Fifty-third World Health Assembly,*

*Deeply concerned that foodborne illnesses associated with microbial pathogens, biotoxins and chemical contaminants in food represent a serious threat to the health of millions of people in the world;*

*Recognizing that foodborne diseases significantly affect people's health and well-being and have economic consequences for individuals, families, communities, businesses, and countries;*

*Acknowledging the importance of all services – including public health services – responsible for food safety, in ensuring the safety of food and in harmonizing the efforts of all stakeholders throughout the food chain;*

*Aware of the increased concern of consumers about the safety of food, particularly after recent foodborne-disease outbreaks of international and global scope and the emergence of new food products derived from biotechnology;*

*Recognizing the importance of the standards, guidelines and other recommendations of the Codex Alimentarius Commission for protecting the health of consumers and assuring fair trading practices;*

*Noting the need for surveillance systems for assessment of the burden of foodborne disease and development of evidence-based national and international control strategies;*

*Mindful that food-safety systems must take account of the trend towards integration of agriculture and the food industry and of ensuing changes in farming, production and marketing practices and consumer habits in both developed and developing countries;*

*Mindful of the growing importance of microbiological agents in foodborne-disease outbreaks at international level and of the increasing resistance of some foodborne bacteria to common therapies, particularly because of the widespread use of antimicrobials in agriculture and in clinical practice;*

*Aware of the improvements in public health protection and in development of sustainable food and agricultural sectors that could result from enhancement of WHO's food-safety activities;*

*Recognizing that developing countries rely for their food supply primarily on traditional agriculture and small- and medium-sized food industry, and that in most developing countries, the food-safety systems remain weak,*

1. *URGES Member States:*

(1) *to integrate food safety as one of their essential public health and public nutrition functions, and to provide adequate resources to establish and strengthen their food safety programmes in close collaboration with their applied nutrition and epidemiological surveillance programmes;*

(2) *to design and implement systematic and sustainable preventive measures aimed at reducing significantly the occurrence of foodborne illnesses;*

- (3) *to develop and maintain national and, where appropriate, regional, means for surveillance of foodborne diseases and for monitoring and control of relevant microorganisms and chemicals in food; to reinforce the principal responsibility of producers, manufacturers and traders for food safety; and to increase the capacity of laboratories, especially in developing countries;*
- (4) *to integrate measures into their food safety policies aimed at preventing development of microbial agents that are resistant to antibiotics;*
- (5) *to support the development of science in the assessment of risks related to food, including analysis of risk factors relevant to foodborne disease;*
- (6) *to integrate food safety matters into health and nutrition education and information programmes for consumers, particularly within primary and secondary school curricula, and to initiate culture-specific health and nutrition education programmes for food handlers, consumers, farmers, producers and agro-food industry personnel;*
- (7) *to develop outreach programmes for the private sector that can improve food safety at consumer level, with emphasis on hazard prevention and orientation for good manufacturing practices, especially in urban food markets, taking into account the specific needs and characteristics of micro- and small-food industries, and to explore opportunities for cooperation with the food industry and consumer associations in order to raise awareness of the use of good and ecologically safe farming practices and of good hygienic and manufacturing practices;*
- (8) *to coordinate the food safety activities of all relevant national sectors concerned with food safety matters, particularly those related to risk assessment of foodborne hazards, including the influence of packaging, storage and handling;*
- (9) *to participate actively in the work of the Codex Alimentarius Commission and its committees, including activities in the emerging area of food-safety risk analysis;*
- (10) *to ensure appropriate, full and accurate disclosure in labelling of food products, including warnings and “best before” dates where relevant;*
- (11) *to legislate for control of the reuse of containers for food products and for the prohibition of false claims;*

2. *REQUESTS the Director-General:*

- (1) *to give greater emphasis to food safety, in view of WHO’s global leadership in public health and in collaboration and coordination with other international organizations, notably the Food and Agriculture Organization of the United Nations (FAO), and within the Codex Alimentarius Commission, and to work towards integrating food safety as one of WHO’s essential public health functions, with the goal of developing sustainable, integrated food-safety systems for the reduction of health risk along the entire food chain, from the primary producer to the consumer;*
- (2) *to provide support to Member States in identification of food-related diseases, assessment of foodborne hazards, and storage, packaging and handling issues;*
- (3) *to provide support to developing countries for the training of their staff, taking into account the technological context of production in these countries;*

- (4) *to focus on emerging problems related to development of antimicrobial-resistant microorganisms stemming from the use of antimicrobials in food production and clinical practice;*
- (5) *to put in place a global strategy for surveillance of foodborne diseases and for efficient gathering and exchange of information in and between countries and regions, taking into account the current revision of the International Health Regulations;*
- (6) *to convene, as soon as practicable, an initial strategic-planning meeting of food safety experts from Member States, international organizations, and nongovernmental organizations with an interest in food safety issues;*
- (7) *to provide, in close collaboration with other international organizations active in this area, particularly FAO and the International Office of Epizootics (OIE), technical support to developing countries in assessing the burden on health of foodborne diseases, in prioritizing disease-control strategies through the development of laboratory-based surveillance systems for major foodborne pathogens including antimicrobial-resistant bacteria, and in monitoring contaminants in food;*
- (8) *in collaboration with FAO and other bodies as appropriate, to strengthen the application of science in assessment of acute and long-term health risks related to food and, specifically, to support the establishment of an expert advisory body on microbiological risk assessment, to strengthen the expert advisory bodies that provide scientific guidance on food safety issues related to chemicals, and to maintain an updated databank of this scientific evidence to support Member States in making health-related decisions in these matters;*
- (9) *to ensure that the procedures for designating experts and preparing scientific opinions are such that they guarantee the transparency, excellence and independence of the opinions delivered;*
- (10) *to encourage research to support evidence-based strategies for the control of foodborne diseases, particularly research on risk factors related to the emergence and increase of foodborne diseases and on simple methods for management and control of health risks related to food;*
- (11) *to examine the current working relationship between WHO and FAO, with a view to increasing the involvement and support of WHO in work of the Codex Alimentarius Commission and its committees;*
- (12) *to provide support to Member States by assuring the scientific basis for health-related decisions on genetically modified foods;*
- (13) *to support the inclusion of health considerations in international trade in food and food donations;*
- (14) *to make the largest possible use of information from developing countries in risk assessment for international standard-setting, and to strengthen technical training in developing countries by providing them with a comprehensive document in WHO working languages, to the extent possible;*
- (15) *proactively to pursue action on behalf of developing countries, so that the level of technological development in developing countries is taken into account in the adoption and application of international standards for food safety;*

*(16) to respond immediately to international and national food-safety emergencies and to cooperate with countries in crisis management;*

*(17) to call upon all stakeholders – especially the private sector – to take their responsibility for the quality and safety of food production, including awareness of environmental protection throughout the food chain;*

*(18) to provide support for capacity building in Member States, especially those from the developing world, and to facilitate their full participation in the work of the Codex Alimentarius Commission and its different committees, including activities in food-safety risk-analysis processes.*

(Eighth plenary meeting, 20 May 2000 –  
Committee A, second report)

**Appendix 5**  
**Food and Agriculture**  
**Organisation's**  
**Strategy for**  
**a Food Chain Approach to**  
**Food Safety and Quality**

聯合國糧農組織

關於以食物鏈策略

控制食物安全和品質的文件



**COMMITTEE ON AGRICULTURE**

**Seventeenth Session**

**Rome, 31 March-4 April 2003**

**FAO's Strategy for a Food Chain Approach to Food  
Safety and Quality: *A framework document for the  
development of future strategic direction***

**Item 5 of the Provisional Agenda**

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# I. Introduction

1. The 28th Session of the Committee on World Food Security (CFS) discussed, *inter alia*, the issue of food safety and quality. The CFS recommended that FAO submit a draft framework document to COAG, COFI and CFS in 2003 which would function as a point of reference for the future strategic development of a food chain approach to food safety and those aspects of food safety related to quality<sup>1</sup>.

2. FAO defines the food chain approach as recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing, trade and consumption of food. This approach encompasses the whole food chain from primary production to final consumption. Stakeholders include farmers, fishermen, slaughterhouse operators, food processors, transport operators, distributors (wholesale and retail) and consumers, as well as governments obliged to protect public health. The holistic approach to food safety along the food chain differs from previous models in which responsibility for safe food tended to concentrate on the food processing sector. Its implementation requires both an enabling policy and regulatory environment at national and international level with clearly defined rules, and the establishment of food control systems and programmes at national and local levels throughout the food chain.

3. Adopting a food chain framework goes beyond ensuring the safety of food. It facilitates more generally a consumer-driven approach to agriculture and food safety systems, implying potential future shifts in the agricultural sectors in many countries. For example, production systems may be challenged by opportunities to integrate nutritional considerations in food at-source. Farmers may also need to make new farming and technology choices to meet demands for a safe and healthy diet in response to new regulations and standards, changing global consumption patterns, improved market access and value-added opportunities<sup>2</sup>, as well as respond to increasing concerns over the sustainability of existing agricultural systems.

4. Shifts in food production and processing systems within a food chain approach will increasingly respond to consumer demand and become more environmentally, economically and nutritionally viable - the foundation of a more integrated, preventive food chain strategy to food safety. The framework document broadly outlines the most important issues in the development of a food chain approach to food safety, while the broader implications of a food chain approach on production and post-production systems, biosecurity and nutrition are addressed in other COAG

documents<sup>3</sup>. FAO recognises the need to more fully incorporate a food chain approach in its food safety strategy and acknowledges that this revised strategic direction will require an integrated and preventive approach to the management of food safety throughout the entire food chain, meeting sustainability concerns and building on aspects of the implementation of international commitments such as Agenda 21.

5. FAO has a large food safety programme. The Food and Nutrition Division (ESN) hosts the Joint Secretariat of the Codex Alimentarius Commission (CAC), which has implemented the Joint FAO/World Health Organization (WHO) Food Standards Programme for more than forty years. This programme has two primary objectives: to protect food consumer health, and to ensure fair practices in food trade. As part of this food safety programme, FAO provides scientific advice for standard setting through joint FAO/WHO expert committees or meetings, such as the Joint Expert Committee on Food Additives and Contaminants (JECFA), the Joint Expert Meeting on Pesticide Residues (JMPR) and the Joint Expert Meetings on Microbiological Risk Assessment (JEMRA). There are other examples of ad-hoc joint expert consultations on new or emerging problems, such as the Joint FAO/WHO Expert Consultation on Acrylamide or the ad-hoc Committee on Foods derived from Biotechnology. In addition, many of the normative and field programmes of FAO's technical departments, including its Economic and Social, Agriculture and Fisheries Departments, directly or indirectly contribute to improving the capacity of food safety and safety-related quality control systems.

6. Food safety has traditionally focused on enforcement mechanisms to remove unsafe food from the market after the fact, instead of a more pronounced mandate for the prevention of food safety problems. Generally, the orientation of many food safety systems tends to be reactive and defined by enforcement criteria instead of preventive and holistic in the approach to risk assessment and reduction<sup>4</sup>. Integrated strategies for reducing the most significant risks throughout the entire food chain should be incorporated into any revised strategic direction in food safety systems. Such systems in both developed and developing countries are under unprecedented challenges, arising from demographic change, shifts in food consumption patterns, increased urbanisation, more intensified food production techniques and the need to adapt new technologies. The globalisation of international trade in food, as well as food safety standards, is an additional and overriding challenge to these systems.

7. FAO, in response to the CFS request, must first redefine its own food chain approach in regard to food safety and quality issues related to safety in order to effectively assist its Members to respond to the challenges outlined above. A revised

strategic direction that incorporates a food chain approach would assist Members to establish or improve comprehensive food systems, from primary producer to consumer – *from farm or sea to the plate* - as the food chain approach is sometimes described. Responsibility for providing safe food is shared by all players in a system adopting a food chain approach and this responsibility is placed unambiguously within the agricultural and food sector, broadly defined to include production of food of plant and animal origin (including seafood), post-harvest treatment, processing and handling of food at wholesale, retail and household levels.

8. A food chain approach will build on FAO's on-going work to support standards-settings on food safety as part of the FAO/WHO Codex Alimentarius Commission<sup>5</sup> – together with the related provision of scientific advice (risk assessment, capacity-building and technical assistance). However, integrating FAO's existing programmes within a more comprehensive and integrated food safety framework may require some additional resources in terms of the Medium-Term Plan 2004-2009 (MTP).<sup>6</sup>

9. The first section of this document will discuss food safety and safety-related quality issues and challenges within a dynamic and evolving global context. The second part of the document proposes a strategic direction to build on FAO's existing normative work related to food standards and the related provision of scientific and technical advice. The evolving views of key FAO partners in this field, such as WHO, as well as those that are increasingly articulated by national and international authorities are incorporated. The mechanisms to develop and implement a revised strategic food chain approach within the framework of the MTP are discussed. The document concludes by identifying those issues suggested for review and endorsement by COAG and FAO governing bodies. For this framework document, discussions in regard to quality of food are limited to those quality aspects related to safety.

## **II. Evolving Global Context for Food Safety**

10. The strategic development of a food chain approach to food safety must be considered within a global context that is constantly evolving and dynamic. Globalisation of food trade requires the development of a more integrated and preventive approach within food safety systems. As international trade in food and farm products increases, it will become increasingly difficult to resolve food safety problems of any one country without collaborative international efforts to develop integrated, preventive strategies. Increased trade also implies potentially increased

costs, as food scares become increasingly global. The economic consequences of contaminated food and farm products can be potentially devastating, with the estimated US\$6 billion in costs incurred by the United Kingdom in response to the Bovine Spongiform Encephalopathy (BSE) crisis but one recent example<sup>7</sup>. Failure to attain international food safety standards can result in significant financial losses for food exporting countries (for example, exporters of groundnuts with aflatoxin problems – a food quality issue related to safety).

11. The close relationship between health and economic development must also be considered in terms of more globalised food safety systems. Food (and the water used for its production, processing and preparation) is a likely vector of many microbiological, chemical and physical hazards (*see Annex I*). Food-borne disease or illness caused by these hazards pose major and growing public health and economic problems in both developed and developing countries. Recent examples include the emergence of BSE in Europe as a disease transmittable through food, and the dioxin contamination of animal feed in 1999 (from a single source) that was identified on every continent within weeks. Food and waterborne diarrhoeal diseases are estimated to kill more than 2 million people a year, most of whom are children, in developing countries - comparable to the number of deaths attributable to malaria every year.

12. The discussion above demonstrates just how important the integrative and preventive aspects of a food chain approach are for the evolving needs of food safety systems. Within these systems, governments are obliged to set, impose and control food safety standards while other food quality standards (such as taste, appearance) may be privately established. Public interventions are also necessary to protect consumers from fraud. Furthermore, the Rome Declaration on World Food Security (1996) clearly stated that all people have the right to safe food whatever the level of their effective demand for it. Public authorities of low income countries in which poor people are the majority often do not have the capacity to establish and/or control food safety standards. Governments of these countries may recognise the right to safe food but cannot fulfil this right, particularly as the reduction of food-borne hazards incurs costs in terms of financial and institutional resources that developing countries often cannot provide. However, it is also important to note that very significant and costly food-borne illnesses and diseases have occurred and will continue to occur in developed countries – despite food and farm systems generally recognised as safe.

13. Food safety must be considered within a global context that is dynamic and evolving as part of the *globalisation* process. Globalisation is generally characterised by increased international trade, more integrated markets, more rapid adoption of new

technologies, increased market concentration and information transfer. All of these aspects have important implications, both positive and negative, for food safety and the development of a food chain approach to food safety strategy. Increasingly open trade in food and farm products can potentially benefit both consumers and producers through greater variety of foods/products or new export income earning opportunities. However, the potentially negative impacts of this trend include the possibility that food-borne diseases are more easily transmitted among countries even more rapidly - posing health risks to consumers and financial risks to food producers/processors who fail to attain rigorous and increasingly *globalised* food safety standards.

14. Globalisation is also changing how food and farm products are processed and traded. Fresh produce and processed products are increasingly marketed globally, with greater concentration of market power in a few dominant food multinationals. These companies generally have the financial and technological capacity to ensure that their fresh produce and food products are safe and that any sources of food contamination may be more easily traced. However, given the more integrated and global nature of these firms, once unsafe and/or contaminated food enters the food chain, it is very likely to be more rapidly distributed and thus expose a greater number of people to increased risk.

15. The increasing role of new and more innovative technology in food production, post-harvest treatment, processing, packaging and sanitary treatment is also significant in the context of food safety and more globalised food trade. The use of recombinant DNA in plant and animal production, and food irradiation, are important examples of new technologies that - while potentially of great benefit - may pose risks to food safety due to their recent introduction or the relative lack of experience in their application to a wide variety of environments. New technologies may not always be correctly applied, and they may have unsuspected and harmful side effects over the longer term.

16. Increasing public awareness of food safety hazards, concern over threats to health attributable to food hazards and reduced confidence in the ability of current food supply systems to manage food safety risks are additional factors to be considered in the development of a food chain strategy. Information is rapidly disseminated and the media quickly spreads news of food safety emergencies. Consumer organizations concerned with food safety issues continue to increase their political influence and this trend is of great benefit to the consumer. However, food-safety concerns and food scares that are not scientifically substantiated may create unnecessary obstacles and potentially hinder development of potentially useful new technology. Consumers are

now equally concerned about the quality of their diet with relation to health and risk of chronic diseases. The need to address their concerns with regard to the nutritional quality of the diet can be easily and closely interwoven with food safety during the development of the food chain strategy.

17. There are other widespread changes in the global food economy that impact on a food chain approach to food safety, ranging from the farm through to the consumer. For example, the increased intensification of food production (plant, livestock and fishery) practices may increase the risk of chemical contamination through pesticide and veterinary residues or microbiological pathogens, such as Salmonella. An increasing tendency to eat away from home in commercial settings, coupled with increased consumption of convenience and semi-cooked foods that require refrigeration (short shelf life), as well as the consumption of larger quantities of raw fruits and vegetables, may also directly increase the health risk from microbiological pathogens to consumers, particularly the emergence of new ones such as *E. coli* 0157.H7.

18. Intensified farm practices, integrated and increased trade through globalisation and changes in consumer eating patterns have implications for how FAO can strategically react to the challenges posed by food safety and food safety-related quality issues. The development of a food chain approach in a future food safety strategy for FAO must incorporate not only the generalised elements of a more globalised, dynamic environment but also those broad characteristics of the differing food safety situations in developed and developing countries, noting that the countries in transition share certain elements from both country groups.

### **III. Food Safety Systems in Developed and Developing Countries**

19. The food systems of **developed countries** have evolved over time, having incorporated many diverse scientific, technological, legal and societal advances. The food safety systems in these countries usually involve inter-related activities of various groups, guided by national food laws and regulations that include food control systems and activities that mostly address enforcement criteria such as monitoring, surveillance, inspection, hazard containment, outbreak management, education and information – essentially the primary attributes of comprehensive and effective food safety systems. However, there are still serious shortcomings. WHO reports indicate

that one person in three in developed countries may be affected by food-borne illness each year. There is high consumer awareness of the potential threats to health posed by food-borne hazards and recent food safety emergencies have undermined consumer confidence in the effectiveness and integrity of food safety systems.

20. Three main shortcomings can be identified in the food safety systems of developed countries. Firstly, the source systems of primary production (including concentrate feed used for animal production) are vulnerable to hazards such as the recent BSE and dioxin crises. This situation is mainly due to an overemphasis on intense, lower cost production practices and is to the detriment of environmental and food safety concerns. Secondly, food safety and food control systems are under enormous and increasing pressure to rapidly identify, analyse and respond to emerging hazards - as well as monitor and control the increasing volume and diversity of food produced, consumed in the fresh state, processed and traded. Finally, despite recent efforts to expand the use of risk analysis, more efforts are necessary to share information, communicate more effectively and ensure that all components and actors in the food chain fully participate in food safety. Overall, the traditional approach to food safety in addressing all the issues of a food chain may be defective, and this has contributed to a lowered sense of consumer confidence in these systems. There are recent examples of efforts to develop a preventive and integrated food chain approach to address the shortcomings mentioned above, notably with the creation of the Canadian Food Inspection Agency (CFIA) and the European Food Authority (EFA).

21. Food systems in **developing countries** are extremely diverse and tend to be less organised, comprehensive and effective than those of developed countries. The food safety systems in these countries are challenged by problems of rapidly growing populations, urbanisation and natural environments that expose consumers to a wide range of potential food safety risks. The informal sector is often a significant producer and distributor of fresh and processed food products (including seafood and '*street*' foods) for direct consumption. Self-provisioning occurs in rural and urban areas and is correspondingly important in terms of food supply. All of these factors make effective food safety regulation and control much more difficult to achieve.

22. Food safety standards in developing countries may actually attain those of international standards, but the lack of technical and institutional capacity to control and ensure compliance essentially makes the standards less effective. Inadequate technical infrastructure - in terms of food laboratories, human and financial resources, national legislative and regulatory frameworks, enforcement capacity, management and coordination - weakens the ability to confront these challenges. Such systemic

weaknesses may not only threaten public health but may also result in reduced trade access to global food markets. Consumers in developing countries, who are generally more preoccupied with the access side of food security, are generally ill informed and unaware of food safety matters, partially due to the few, if any, organized consumer groups. Thus, public sector intervention must commit resources to ensure adequate but low cost consumer protection against food safety hazards: food markets alone will not provide the necessary incentive – and this is also true for developed countries.

23. The perceived weaknesses in the food safety situations of developing countries can be summarised as follows. Production systems tend to be extremely diverse, and often have many small-scale, unorganized producers and informal markets. The food sector is rapidly evolving in these countries, with little technical support for the introduction of new, more intensive production technologies by small and medium-scale enterprises. The food processing industrial sector is often under-financed and fragmented and there is often too little purchasing power in terms of consumer demand for food considered *safe*. Rapid rates of urbanisation, changing food production systems and consumption habits have all contributed to increased environmental risks. Furthermore, the regulatory frameworks for food safety are often either incomplete or outdated and the systems tend to suffer from inadequate technical, institutional and managerial food control capacity. Despite these weaknesses, it is important to note that over the past 10 years, many of the major food scares in developed countries (particularly in the European Union) have originated in those countries.

## **IV. Framework for the Development of a Food Chain**

### **Approach to Food Safety**

24. FAO defines the food chain approach as recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing and trade of food. As such, the implications of a food chain approach are much broader than those aspects limited to food safety systems. The broader implications of a food chain approach for production and post-production systems, biosecurity and nutrition are addressed in other COAG documents<sup>9</sup>. This framework document, however, specifically outlines the most important issues in the development of a food chain approach to food safety.

25. Widespread changes in the global food economy and the dynamic environment in which food safety issues must be considered have led to a more profound appreciation of just how inter-related the needs of both developing and developed countries are in terms of the strategic development of a food chain approach to food safety. There are five broadly defined inter-related needs on which to base future strategic direction in support of a food chain approach to food safety:

- Food safety from a food chain perspective should incorporate the three fundamental components of **risk analysis** - *assessment, management and communication* – and, within this analysis process, there should be an **institutional separation** of science-based risk assessment from risk management – which is the regulation and control of risk. A **prudent approach** to risk assessment and management should also be adopted.
- **Tracing techniques** (*traceability*) from the primary producer (including food products and animal feed used in the production of animal products), through post-harvest treatment, food processing and distribution to the consumer must be improved.
- **Harmonisation of food safety standards**, implying increased development and wider use of internationally agreed, scientifically-based standards is necessary.
- **Equivalence in food safety systems** – achieving similar levels of protection against food-borne hazards whatever means of control are used – must be further developed, particularly as required by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the WTO.
- Increased emphasis on **ex-ante risk avoidance or prevention at source** within the whole food chain – *from farm or sea to plate* – is necessary to complement the conventional ex-post approach to food safety management based on regulation and control.

26. The development of a framework for a food chain approach to food safety should be based on a strategic response to the complex set of challenges and needs areas described previously in this document. As such, a framework for the future development of a food chain approach to food safety should be broadly based on three key elements:

- Universally adopting a risk-based approach to food safety.
- Complementing the current, traditional emphasis on regulation and control of end products in food safety systems with a **more pronounced and comparable emphasis on prevention of food contamination at source** -

including development and dissemination of good practices/safety assurance systems (i.e. Hazard Analysis and Critical Control Point/HACCP).

- Adopting a **holistic approach to food safety that encompasses the whole food chain** – *from farm or sea to plate* – and adheres to the FAO definition of a food chain approach in which responsibility for the production of safe food is shared along the entire food chain.

27. The key elements described above are based on ideas that have received increasingly widespread support among national and international institutions concerned with food safety. These concepts are timely, relevant and critically important to the successful future development of food safety strategy within FAO. The inter-related nature of these key action areas implies that enhanced collaboration with international and national partners in food safety matters (potentially beyond the remit of FAO) would be necessary.

28. FAO's work in support of these broad strategic elements (and within the framework of developing a new food safety strategy) would involve the appropriate balance of normative and field activities based on risk assessment, scientific advice, technology transfer, consumer education and capacity-building. Most importantly, FAO would continue to provide a valuable and significant forum for further discussion and information exchange in the area of food chain analysis and food safety systems. A more detailed discussion of the key elements outlined above provides further support for the inclusion of these concepts in a food chain approach to food safety.

29. **Universal adoption of a risk-based approach to food safety** is a relatively recent innovation that received additional impetus from the WTO SPS Agreement. A risk-based approach to the management of food safety hazards by definition implies risk analysis. Food control resources are thus directed to those hazards posing the greatest threat to public health and where the potential gains from risk reduction are large relative to resource use. Establishing risk-based priorities requires sound scientific knowledge and effective systems for reporting the incidence of food-borne diseases. Risk strategies also demand rigorous follow-up and improved international cooperation through information exchange and risk communication. However, while independent scientific research and knowledge are the foundation of sound risk assessment, it is important to note that risk management very often involves a political process. The political nature of governmental regulation and control of food safety (risk management), may partially explain why consumers are increasingly insistent that risk assessment and management are separate functions, despite the need for the

responsible government authorities to interact to manage risk effectively. Food safety systems utilising a food chain approach would also benefit from cross-sectoral analyses that incorporate other risk domains and assessments related to plant and animal life and health and related topics, such as biosecurity.

30. Complementing the current emphasis on regulation and control of food safety systems with **preventive measures to control the introduction of food contamination at-source** is a critically important element in the development of a revised strategy. This necessitates the adoption of practices in food production, post-harvest treatment, processing and handling that reduce the risk of microbiological, chemical and physical hazards from entering the food chain (or controlling at source, if feasible). There are some cases in which the hazard simply cannot be removed from foodstuffs, for example, those hazards involving chemical contaminants. The adoption of sound practices along the food chain – based on the principles defined in Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) – are the keys to discharging this responsibility along the food chain. In-plant controls of food processing operations should also be based on HACCP analysis - to the extent that capacity, experience and resources permit. The core components of food safety systems, however, will remain the application (and compliance) of food product regulations developed through internationally agreed, science-based food standards.

31. **Adopting a holistic, food chain approach to food safety** recognises that primary responsibility for supplying safe and palatable food lies with all those involved in food production, post-harvest treatment, processing and trade. This *'at-source'* responsibility encompasses all stakeholders throughout the food chain. Stakeholders may include farmers and the suppliers of farm inputs (especially animal feed and veterinary supplies), fisherfolk, slaughterhouse and packing-house operators, fish processing plants, food manufacturers, transport operators, wholesale and retail traders, caterers, food service establishment operators, street food vendors and others. This responsibility also extends to the end consumer who must be educated to ensure that food is properly stored, hygienically prepared and food shelf lives are respected. A holistic, integrated food chain approach should further engender the need for close contact and collaboration between, for example, food control authorities and those responsible for environmental protection and water quality. Furthermore, this approach should permit greater *traceability* of food products and facilitate - not only the withdrawal from markets of hazardous or contaminated foods - but also the identification of weak hazard-promoting links in the chain.

32. The three **strategic elements** discussed in this section recognise that the responsibility for ensuring food safety (as well as adequate quality related to safety) is shared by the food, agriculture and fishery sectors and all involved with the production, post-harvest treatment, processing and trade of food. Diverse government ministries, such as public health, industry, consumer affairs, environment, agriculture and fisheries, are often jointly responsible for the development of official standards, technical regulations and enforcement of food safety. However, often it is the private sector that must make daily, practical decisions on investment, management and costs to ensure that food production, post-harvest treatment, processing and distribution comply with food safety standards. Food safety systems that incorporate the key elements described above will ensure a food chain approach and the continued and improved collaboration between public and private sector bodies throughout the entire food chain.

## **V. Developing and Implementing the Proposed Strategy**

33. A revised food safety strategy incorporating a food chain approach would broaden the traditional focus to include relevant components of Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) particularly related to food safety<sup>9</sup> and the food chain – *the farm or sea to plate* approach. A revised strategy would involve additional work for prevention at-source, such as the development and dissemination of practices to prevent food-borne hazards from entering the food chain. This may be very useful in animal production (feeding and processing) as these products are particularly prone to food-borne hazards. Additional work on preventive pre- and post-harvest practices for crops could prevent safety problems and loss due to contamination and deterioration in storage and processing.

34. Generally, a revised food chain approach to food safety within FAO would enhance the capacity of Member Nations, particularly those in developing countries, to analyse food safety risk, apply and ensure compliance with international standards and participate fully in standard-setting. The development and application of good farming and manufacturing practices appropriate to the unique ecological, economic and societal conditions of developing countries is also necessary. Implementing a revised food safety strategy would require enhanced collaboration with international partners, particularly WHO<sup>10</sup> and the United Nations Industrial Development Organization (UNIDO) and continued focus on information exchange.

35. FAO's normative work in food safety and quality-related to safety is focused on food standards, related capacity-building linked to the Codex Alimentarius, and developed in close collaboration with WHO. Codex Alimentarius includes standards for all principle foods (whether processed, semi-processed or raw) for distribution to the consumer, with provisions related to food hygiene, food additives, pesticide residues, contaminants, labelling, presentation, methods of analysis and sampling. The Codex Secretariat is housed in the FAO Food and Nutrition Division (ESN), which has primary responsibility for normative work in food safety (activities include technical advisory services, capacity-building, training and institutional development).

36. FAO, in collaboration with WHO, provides expert scientific advice for standards setting through Codex expert committees and/or meetings (*JECFA*, *JMPR* and *JEMRA*). Contributions are interdisciplinary and involve programmes related to veterinary drug residues with the Animal Production and Health Division (AGA) and pesticide residues with the Plant Production and Protection Division (AGP). Food safety programmes related to agricultural processing and post-harvest management are managed by the Agricultural Support Systems Division (AGS). The FAO Fisheries Department is directly involved in fish product safety, including risk analysis and safety control methods (HACCP) for fish processing plants.

37. A brief review of the FAO Medium Term Plan (MTP) for 2004-2009 provides an indication of resource allocation (by amount and programme area) to those food safety issues relevant to a food chain approach<sup>14</sup>. Four strategic objectives particularly relevant to a future development of food safety strategy are listed below (followed by the percent resource allocation for 2002-2007).

- **A2 - Access of vulnerable and disadvantaged groups to sufficient, safe and nutritionally adequate food** (3.0%).
- **B1 - International instruments** concerning food, agriculture, fisheries and forestry, and the production, **safe use and fair exchange** of agricultural, fishery and forestry goods (7.9%).
- **B2 - National policies, legal instruments, supporting mechanisms that respond to domestic requirements and are consistent with international policy/regulatory framework** (7.9%).
- **C1 - Policy options and institutional measures** to improve efficiency and adaptability in production, processing and marketing systems and meet the changing needs of producers and consumers (13.6%).

38. These strategic objectives account for approximately 30% of FAO's planned programme resources in the MTP 2002-2007. However, only a relatively small fraction of the resources will actually address food safety and quality aspects related to safety issues despite the potential adoption of a food chain approach to food safety strategy. A more detailed listing of those FAO programmes that may significantly contribute to the four objectives discussed above is attached in *Annex II*.

39. The current MTP programme areas related to food safety continue to focus on Codex normative work, although several work areas incorporate a broader food chain approach with technical, food hazard-preventive measures based on good agricultural practices. There are also instances in which work areas are usefully inter-related - such as Programmes 214A9 '*Enhancing food quality and safety by strengthening handling, processing and marketing in the food chain*' and 221P8 '*Food quality and safety throughout the food chain*'. If the proposed framework to develop a broadened strategy based on a food chain approach is supported by COAG, identification of similar linkages in the MTP would be necessary, as well as additional resources particularly for the regional or sub-regional offices.

40. Food safety work in FAO is also interdisciplinary. The **Priority Areas for Interdisciplinary Action** address two important sub-topics related to food safety issues: Biosecurity for Agriculture and Food Production; and WTO Multi-lateral Trade Negotiations (MTNs) on Agriculture, Fisheries and Forestry<sup>12</sup>. The Biosecurity PAIA priorities are *inter alia* to monitor, assess and evaluate international policies and instruments relevant to food safety, including guidelines to support risk analysis related to biosecurity and develop and strengthen national biosecurity strategies and infrastructure. The Interdepartmental Working Group of this PAIA could also provide a useful forum for discussion and an additional mechanism to ensure the alignment of FAO's normative (and field) work in food safety and quality related to safety with a food chain '*farm or sea to plate*' approach. This PAIA is also expected to provide the institutional location for developing the proposed International Portal for Food Safety, Animal and Plant Health, a new global platform for the exchange of sanitary and phytosanitary information.<sup>13</sup>

## VI. Views and Recommendations from COAG

41. COAG is invited to consider this document as a framework for the future development and reinforcement of a food chain approach to food safety in FAO. This draft framework embraces a holistic, preventive approach to address the complex

challenges of improving food safety systems in Member Nations. It builds on the important existing food standards work of FAO, Codex Alimentarius Commission and WHO and associated risk assessment, scientific advice and capacity-building activities and considers how the adoption of a food chain approach is important for future strategic direction. Fundamentally, a regulatory framework (including standardised international methodology) should be in place to form *at-source* evaluations – in addition to *ad hoc* monitoring and enforcement after food products have entered the food chain.

42. **Recommendations are welcome** on the proposal to develop a revised food safety strategy, particularly how a revised strategy should best account for the varying needs of FAO Members, the work and responsibilities of other interested organizations and institutions, as well as the overall mandate of FAO. COAG may wish to recommend further action to Council and inform the CFS of discussions related to this document. *(This document also will be shared with COFI, the next session of which precedes that of COAG, as an information document).*

43. COAG may also wish to provide guidance as to the broader implications and opportunities of a food chain approach for FAO's programmes beyond food safety, in particular on issues such as production and post-production systems (including finance and marketing), biosecurity and nutrition<sup>14</sup>.

## **Annex I:**

### ***Examples of food-borne hazards***

#### ***Biological hazards***

- Zoonotic agents that may enter the food chain (e.g. *Brucella*, *Salmonella sp.*, prions),
- Pathogens predominantly foodborne (e.g. *Listeria monocytogenes*, *Trichinella*, *Toxoplasma*, *Campylobacter jejuni*, *Yersinia enterocolitica*),
- Established pathogens emerging in new vehicles or new situations (e.g. *Salmonella enteritidis* in eggs, hepatitis A viruses in vegetables, Norwalk/Norwalk-like viruses in seafoods),

- Pathogens newly associated with food-borne transmission (e.g. *E. coli* O157:H7, *Vibrio vulnificus*),
- Antimicrobial resistant pathogens (e.g. *Salmonella typhimurium* DT 104).

### ***Chemical hazards***

- Naturally occurring toxicants (e.g. marine biotoxins, mycotoxins),
- Environmental or industrial contaminants (e.g. mercury, lead, PCBs, dioxin, radionuclides),
- Residues of agricultural chemicals such as pesticides, of veterinary drugs and of surface sanitizers,
- Toxic substances migrant from packaging or other materials in contact with food,
- New issues in toxicology (e.g. allergenicity, endocrine disruption from pesticide residues).

### ***Physical hazards***

- Foreign matter (e.g. pieces of glass or wood),
- Inedible parts of the food (e.g. pieces of bone, fruit stones).

Source: Adapted from FAO, Safe Food and Nutritious Diet for the Consumer, Box 1, p.4.

## **Annex II:**

### ***List of FAO Programme Entities relating to food safety and quality: MTP 2004-09***

The programme entities have been grouped on the basis of their objectives or major output(s) as to their contribution to FAO's work on food safety and safety-related quality in either food standards (Codex) and related technical advice and capacity-building or good agricultural practices (GAP) and comprehensive food chain approaches.<sup>15</sup> A third group comprises borderline cases relating mainly to GAP that do not refer directly to food safety issues but which could do so in practice. The lead implementing divisions are identified. As these programmes are generally quite broad,

it is not possible to estimate the allocation of resources within them to food safety and quality.

Group 1: Work relating mainly to Codex and food standards

221P2 Joint FAO/WHO Food standards programme (Codex Alimentarius) - ESN

221P5 Food quality control and consumer protection - ESN

221P6 Food safety assessment and rapid alert system - ESN

221P7 Public information about nutrition, food quality and safety - ESN

212P2 Pesticide management - AGP

233A4 Consumption, safety and quality of fish - FII

215P1 Capacity building and risk analysis methodologies for compliance with food safety standards and pesticide control and strengthened sanitary and phytosanitary measures through irradiation of food and agricultural commodities - AGE.

213A6 Veterinary public health management and food and feed safety - AGA.

Group 2: Work relating mainly to good agricultural practices (GAP)/ food chain approach

221P8 Food quality and safety throughout the food chain – ESN

214A9 Enhancing food quality and safety by strengthening handling, processing and marketing in the food chain - AGS.

213A8 Technologies and systems for efficient natural resource use in livestock production - AGA

Group 3 Work related to GAP which does not specifically address food safety but could do so

210A1 Sustainable intensification of integrated production systems – AGD

214A4 Agribusiness development targeted to small and medium post-production enterprises - AGS

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<sup>1</sup>Report of the 28<sup>th</sup> session of the Committee on Food Security, 6-9 June 2002, Rome, CL 123/10.

<sup>2</sup>This issue and its practical applications are further discussed in the related COAG paper COAG/2003/6 'Framework for Good Agricultural Practices'.

<sup>3</sup>Please refer to COAG/2003/6 - Good Agricultural Practices; COAG/2003/9 – Biosecurity in Food and Agriculture; and information paper COAG/2003/Inf.3 – Summary Report of the FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases.

<sup>4</sup>Food Chain 2001 – “Food Safety – a Worldwide Challenge” Dr. Gro Harlem Brundtland, Director-General, WHO, Uppsala, Sweden, March 2001.

<sup>5</sup>These activities will need to take into account the evaluation of the Codex Alimentarius and other FAO and WHO food standards work under the leadership of Professor Bruce Traill, which reported in September 2002.

<sup>6</sup>CL 123/7

<sup>7</sup>Food Chain 2001 – “Food Safety – a Worldwide Challenge” Dr. Gro Harlem Brundtland, Director-General, WHO, Uppsala, Sweden, March 2001.

<sup>8</sup>Please refer to COAG/2003/6 - Good Agricultural Practices; COAG/2003/9 – Biosecurity in Food and Agriculture; and information paper COAG/2003/Inf.3 – Summary Report of the FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases.

<sup>9</sup>Please refer to COAG/2003/6 Good Agricultural Practices, which discusses those aspects of good agricultural practices not explored in this document.

<sup>10</sup>WHO also is currently (late 2002) developing a strengthened food safety strategy.

<sup>11</sup>CL 123/7

<sup>12</sup>Note the following definition: “Biosecurity is composed of three sectors, namely food safety, plant life and health, and animal life and health. These sectors include food production in relation to food safety, the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction of genetically modified organisms (GMOs) and their products, and the introduction and safe management of invasive alien species and genotypes.” Source COAG/01/8.

<sup>13</sup>A document entitled ‘Concept paper for the Development of the International Portal for Food Safety, Animal and Plant Health (IPFSAPH)’ is available.

<sup>14</sup>Some of these issues are discussed in COAG/2003/6 - Good Agricultural Practices; COAG/2003/9 – Biosecurity in Food and Agriculture; and information paper COAG/2003/Inf.3 – Summary Report of the FAO/WHO Expert Consultation on Diet, Nutrition and the Prevention of Chronic Diseases.

<sup>15</sup>For further details, see the Medium Term Plan, 2004-2009, CL123/7



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**WHITE PAPER ON FOOD SAFETY**

**Appendix 6**  
**European Union**  
**White Paper on Food Safety**  
歐盟關於食物安全的白皮書

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## **EXECUTIVE SUMMARY**

Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission. This White Paper reflects this priority. A radical new approach is proposed. This process is driven by the need to guarantee a high level of food safety.

### ***European Food Authority***

The establishment of an independent European Food Authority is considered by the Commission to be the most appropriate response to the need to guarantee a high level of food safety. This Authority would be entrusted with a number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national agencies and scientific bodies. The European Food Authority will provide the Commission with the necessary analysis. It will be the responsibility of the Commission to decide on the appropriate response to that analysis. A European Food Authority could be in place by 2002 once the necessary legislation is in place. Before finalising our proposals we are inviting all interested parties to let us have their views by end April. A definitive legislative proposal would then be brought forward by the Commission.

### ***Food Safety Legislation***

The setting up of the independent Authority is to be accompanied by a wide range of other measures to improve and bring coherence to the corpus of legislation covering all aspects of food products from “farm to table”.

Already the Commission has identified a wide range of measures that are necessary to improve food safety standards. The White Paper sets out over 80 separate actions that are envisaged over the next few years.

There have been enormous developments in the past decades, both in the methods of food production and processing, and the controls required to ensure that acceptable safety standards are being met. It is clear that, in a number of areas, existing European legislation has to be brought up to date.

Following the Commission’s Green Paper on food law (COM(97)176 final), and subsequent consultations, a new legal framework will be proposed. This will cover the whole of the food chain, including animal feed production, establish a high level of consumer health protection and clearly attribute primary responsibility for safe food production to industry, producers and suppliers. Appropriate official controls at both national and European level will be established. The ability to trace products through the whole food chain will be a key issue. The use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate. The ability to take rapid, effective, safeguard measures in response to health emergencies throughout the food chain will be an important element.

Proposals for the animal feed sector will ensure that only suitable materials are used in its manufacture, and that the use of additives is more effectively controlled. Certain food quality issues, including food additives and flavourings and health claims, will be addressed, whilst controls over novel foods will be improved.

The risks associated with the contamination of foods have been brought into sharp focus by the recent dioxin crisis. Steps will be taken to address those areas where the existing legislation in this sector needs to be improved to provide adequate protection.

### ***Food Safety Controls***

The experience of the Commission's own inspection service, which visits Member States on a regular basis, has shown that there are wide variations in the manner in which Community legislation is being implemented and enforced. This means that consumers cannot be sure of receiving the same level of protection across the Community, and makes it difficult for the effectiveness of national authority measures to be evaluated. It is proposed that, in co-operation with the Member States, a Community framework for the development and operation of national control systems will be developed. This would take account of existing best practices, and the experience of the Commission's inspection services. It will be based on agreed criteria for the performance of these systems, and lead to clear guidelines on their operation.

In support of Community-level controls, more rapid, easier-to-use, enforcement procedures in addition to existing infringement actions will be developed.

Controls on imports at the borders of the Community will be extended to cover all feed and foodstuffs, and action taken to improve co-ordination between inspection posts.

### ***Consumer Information***

If consumers are to be satisfied that the action proposed in White Paper is leading to a genuine improvement in Food Safety standards, they must be kept well informed. The Commission, together with the new European Food Authority, will promote a dialogue with consumers to encourage their involvement in the new Food Safety policy. At the same time, consumers need to be kept better informed of emerging Food Safety concerns, and of risks to certain groups from particular foods.

Consumers have the right to expect information on food quality and constituents that is helpful and clearly presented, so that informed choices can be made. Proposals on the labelling of foods, building on existing rules, will be brought forward. The importance of a balanced diet, and its impact on health, will be presented to consumers.

### ***International dimension***

The Community is the world's largest importer/exporter of food products. The actions proposed in the White Paper will need to be effectively presented and explained to our trading partners. An active role for the Community in international bodies will be an important element in explaining European developments in Food Safety.

## *Conclusions*

The implementation of all the measures proposed in the White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection.

Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

The Commission believes that the establishment of a new Authority, which will become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore and maintain consumer confidence.

The success of the measures proposed in this White Paper is intrinsically linked to the support of the European Parliament and the Council. Their implementation will depend on the commitment of the Member States. This White Paper also calls for strong involvement of the operators, who bear the prime responsibility for the daily application of the requirements for Food Safety.

Greater transparency at all levels of Food Safety policy is the thread running through the whole White Paper and will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

## CHAPTER 1: INTRODUCTION

1. The European Union's food policy must be built around high food safety standards, which serve to protect, and promote, the health of the consumer. The production and consumption of food is central to any society, and has economic, social and, in many cases, environmental consequences. Although health protection must always take priority, these issues must also be taken into account in the development of food policy. In addition, the state and quality of the environment, in particular the eco-systems, may affect different stages of the food chain. Environment policy therefore plays an important role in ensuring safe food for the consumer.
2. The agro-food sector is of major importance for the European economy as a whole. The food and drink industry is a leading industrial sector in the EU, with an annual production worth almost 600 billion €, or about 15% of total manufacturing output. An international comparison shows the EU as the world's largest producer of food and drink products. The food and drink industry is the third-largest industrial employer of the EU with over 2.6 million employees, of which 30% are in small and medium enterprises. On the other hand, the agricultural sector has an annual production of about 220 billion € and provides the equivalent of 7.5 million full-time jobs. Exports of agricultural and food and drink products are worth about 50 billion € a year. The economic importance and the ubiquity of food in our life suggest that there must be a prime interest in food safety in society as a whole, and in particular by public authorities and producers.
3. Consumers should be offered a wide range of safe and high quality products coming from all Member States. This is the essential role of the Internal Market. The food production chain is becoming increasingly complex. Every link in this chain must be as strong as the others if the health of consumers is to be adequately protected. This principle must apply whether the food is produced within the European Community or imported from third countries. An effective food safety policy must recognise the inter-linked nature of food production. It requires assessment and monitoring of the risks to consumer health associated with raw materials, farming practices and food processing activities; it requires effective regulatory action to manage this risk; and it requires the establishment and operation of control systems to monitor and enforce the operation of these regulations. Each element forms part of a cycle: thus, developments in food processing can require changes to existing regulations, whilst feedback from the control systems can help to identify and manage both existing and emerging risks. Each part of the cycle must work if the highest possible food safety standards are to be enforced.
4. These facts therefore demand a comprehensive and integrated approach to food safety. This does not mean that the EU should be exclusively responsible for all aspects of food safety. However, it demands that all aspects of food safety are addressed at EU level. For example, EU legislation has to be enforceable in an efficient way in the Member States in line with the principle of subsidiarity. Responsibility for enforcement above all should remain primarily a national, regional and local responsibility. However, the Internal Market means that these are not exclusively national responsibilities: each Member State has a duty towards not only to its own citizens but to all citizens of the EU and third countries for the food produced on their territory.

5. It is necessary to underline that the European food chain is one of the safest in the world and that the present system has generally functioned well. Food safety measures have formed part of the body of European legislation since the early days of the Community. Historically, these measures have mainly been developed on a sectoral basis. However, the increasing integration of national economies within the Single Market, developments in farming and food processing, and new handling and distribution patterns require the new approach outlined in this White Paper.

Community and Member State food safety systems have been under unprecedented pressure during recent feed and food emergencies. These emergencies have exposed weaknesses which call for action by the responsible authorities (Commission, Member States and the Parliament), to re-enforce, improve and further develop existing systems.

6. Food safety needs to be organised in a more co-ordinated and integrated way. This will allow existing weaknesses to be addressed, whilst at the same time creating a genuinely world-leading food safety framework, which can deliver a high level of public health and consumer protection in accordance with the requirements of the EC Treaty. However, the most comprehensive system cannot function without the full collaboration of all parties involved. The proper functioning of any system depends decisively on the commitment of the Member States and operators, as well as third countries.

7. The European Union needs to re-establish public confidence in its food supply, its food science, its food law and its food controls. This White Paper on Food Safety outlines a comprehensive range of actions needed to complement and modernise existing EU food legislation, to make it more coherent, understandable and flexible, to promote better enforcement of that legislation, and to provide greater transparency to consumers. This will provide the response to the conclusions of the Helsinki European Council in December 1999.

The Commission is determined to implement the actions outlined in this White Paper as a matter of priority. A detailed Action Plan on food safety with a precise timetable for action over the next three years is provided in the Annex. Under this timetable, the most important proposals should be put forward by the Commission before the end of 2000, allowing for a coherent and up-to-date body of food law supported by a new European Food Authority to be in place by the end of 2002. The Commission looks forward to the full co-operation of the Parliament and Council in the implementation of this ambitious programme.

There has already been extensive consultation and discussion concerning improvements to the EU's food legislation arising from the Green Paper on the general principles of food law (COM (97) 176 final). This White Paper presents the changes the Commission proposes in this area. However, in addition, the Commission envisages the creation of a European Food Authority as a further measure. In respect of this proposal, the Commission wishes to elicit public debate, informed comment and broad consultation. Interested parties are therefore invited to submit comments on Chapter 4 of this White Paper by the end of April 2000.

## CHAPTER 2: PRINCIPLES OF FOOD SAFETY

This White Paper makes proposals that will transform EU food policy into a proactive, dynamic, coherent and comprehensive instrument to ensure a **high level of human health and consumer protection**.

8. The guiding principle throughout this White Paper is that food safety policy must be based on a **comprehensive, integrated approach**. This means throughout the food chain <sup>1</sup> ('farm to table'); across all food sectors; between the Member States; at the EU external frontier and within the EU; in international and EU decision-making fora, and at all stages of the policy-making cycle. The pillars of food safety contained in this White Paper (scientific advice, data collection and analysis, regulatory and control aspects as well as consumer information) must form a seamless whole to achieve this integrated approach.
9. The roles of all stakeholders in the food chain (feed manufacturers, farmers and food manufacturers/operators; the competent authorities in Member States and third countries; the Commission; consumers) must be clearly defined: feed manufacturers, farmers and food operators have the primary **responsibility** for food safety; competent authorities monitor and enforce this responsibility through the operation of national surveillance and control systems; and the Commission concentrates on evaluating the ability of competent authorities to deliver these systems through audits and inspections at the national level. Consumers must also recognise that they are responsible for the proper storage, handling and cooking of food. In this way, the **farm to table policy** covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale, will be implemented systematically and in a consistent manner.
10. A successful food policy demands the **traceability** of feed and food and their ingredients. Adequate procedures to facilitate such traceability must be introduced. These include the obligation for feed and food businesses to ensure that adequate procedures are in place to withdraw feed and food from the market where a risk to the health of the consumer is posed. Operators should also keep adequate records of suppliers of raw materials and ingredients so that the source of a problem can be identified. It must be emphasised however that unambiguous tracing of feed and food and their ingredients is a complex issue and must take into account the specificity of different sectors and commodities.
11. This comprehensive, integrated, approach will lead to a more **coherent, effective and dynamic** food policy. It needs to address the shortcomings which flow from the current sectoral, rigid approach, which has limited its ability to deal rapidly and flexibly with risks to human health. The policy needs to be kept under constant review and, where necessary, be adapted to respond to shortcomings, to deal with emerging risks, and to recognise new developments in the production chain. At the same time, the development of this approach needs to be **transparent**, involving all the stakeholders and allowing them to make effective contributions to new developments. The level of transparency already achieved by making public

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<sup>1</sup> Throughout this White Paper, the term 'food chain' covers the whole of the feed and food chain

scientific opinions and inspection reports should be extended to other food safety related areas.

12. **Risk analysis** must form the foundation on which food safety policy is based. The EU must base its food policy on the application of the three components of risk analysis: risk assessment (scientific advice and information analysis) risk management (regulation and control) and risk communication.
13. The Commission will continue to use the best available science in developing its food safety measures. The organisation of the independent scientific advice, and the role of a new European Food Authority in providing this advice, will be dealt with in Chapter 4. The Commission recognises that consumers and the food industry need to be confident that this advice is being produced to the highest standards of independence, excellence and transparency.
14. Where appropriate, the **precautionary principle** will be applied in risk management decisions. The Commission intends to present a Communication on this issue.
15. In the decision making process in the EU, **other legitimate factors** relevant for the health protection of consumers and for the promotion of fair practices in food trade can also be taken into account. The definition of the scope of such legitimate factors is presently being studied at international level particularly in Codex Alimentarius. Examples of such other legitimate factors are environmental considerations, animal welfare, sustainable agriculture, consumers' expectation regarding product quality, fair information and definition of the essential characteristics of products and their process and production methods.

## CHAPTER 3: ESSENTIAL ELEMENTS OF FOOD SAFETY POLICY: INFORMATION GATHERING AND ANALYSIS – SCIENTIFIC ADVICE

Information gathering and analysis are essential elements of food safety policy, and are particularly important for the identification of potential feed and food hazards.

16. Methods and indicators to identify problems are manifold. They may include data derived from controls carried out along the feed and food chain, disease surveillance networks, epidemiological investigations and laboratory analysis. Correct analysis of data would facilitate study of the evolution of known food hazards and the identification of new ones; it would thus become possible to better define and adapt food safety policy as necessary. The role of Member States in information gathering is crucial, and needs to be well defined.

### *Monitoring and surveillance*

17. The Commission collects a large amount of information on issues relating to food safety. The major sources of information are networks for public health monitoring and surveillance (in particular communicable disease reporting systems under Decision 2119/98), surveillance plans of zoonoses and residues, rapid alert systems, information systems in the agricultural sector, environmental radioactivity monitoring and research activities and associated research networks. However, the existing systems have been developed independently from each other and therefore co-ordination of the different sources of information is not always done. Moreover, a large amount of the available information is not fully exploited. Integration of data collection systems and analysis of data should be the two guiding principles in this area in order to draw maximum benefits from the current systems for data gathering. The Community needs a comprehensive and effective food safety monitoring and surveillance system integrating all the above sources of information. The expertise of the Commission Joint Research Centre could provide a useful support in this matter.

The first objective should be an on-going and day to day management of the information to allow a real time response to potential hazards. Secondly, such a system would enable the Commission to develop a more pro-active and forward-looking role. It should aim at the early identification of potential hazards to prevent crises arising rather than reacting to them. It would also facilitate long-term policy planning and priority setting.

### *Alert systems*

18. In general, the Rapid Alert System for Food functions well for foodstuffs intended for the final consumer. Various other types of notification systems exist in different areas, such as transmissible diseases in human and animals, animal products stopped at the external borders of the EU, movements of live animals and the ECURIE system in case of radiological emergency. But once again, integrated use of the information is difficult, because of the difference in objectives and scope of these systems. In addition, certain areas are not covered at all, for example, animal feed.

The creation of a comprehensive and harmonised legal framework enlarging the scope to all food and feed of the current Rapid Alert System is necessary. It should extend obligations of economic operators to notify food safety emergencies and ensure appropriate information of consumers and trade organisations. Furthermore, an appropriate link with other rapid information systems must be made. This system should also be extended to third countries for incoming and outgoing information.

### ***Research***

19. Scientific excellence requires investment in R&D to expand the scientific knowledge base with regard to food safety. Under the Fifth Framework Programme for Research, Community R&D projects on food safety are carried out on the basis of multi-annual work programmes. These programmes include indirect action (shared cost actions) and direct action executed by the Commission Joint Research Centre. Their objectives are mostly geared towards improving scientific knowledge and contributing towards a sound scientific basis for policy and regulation. The Fifth Framework Programme has been oriented towards a problem solving approach with citizens and their needs at its centre. Research actions will be carried out in particular on advanced food technologies, safer methods of food production and distribution, new methods for assessing contamination and chemical risks and exposures, the role of food in promoting health, harmonised systems of food analyses.

However, in specific cases where a potential human health problem has been identified, the initiation of ad hoc and immediate research is often necessary. At present, these needs could be partially covered by the Commission Joint Research Centre, but the present system must be endowed with overall flexibility and adequate financial resources to be able to finance R&D projects in direct response to food emergencies. Therefore, budgetary and administrative procedures, including a regular revision of the research work programme and dedicated and targeted calls for proposals, must be created in order to respond to urgent challenges.

### ***Scientific co-operation***

20. Scientific information is compiled by national institutions and organisations throughout the Community on a wide range of issues relating to food safety under the Scientific Co-operation or SCOOP system. Only in a limited number of areas has co-ordination of scientific information been undertaken to build a European picture, when in many cases it is precisely this EU dimension which is lacking to provide the information necessary for an EU risk assessment. Priority setting for the collation of scientific information must be enhanced and co-ordinated with the work programme of the Scientific Committee(s). Scientific co-operation should also be initiated in third countries as appropriate.

### ***Analytical support***

21. A system of Community Reference Laboratories has been established for products of animal origin to give specialised analytical support to the Commission and to laboratories in the Member States. They develop detection methods and assist laboratories in the Member States to apply these methods. Effective central management needs to be provided in order to ensure that these laboratories become a real network of Community laboratories at the service of the EU policy. Given its scientific capabilities and infrastructures, the Joint Research Centre could perform

this task. In addition, the establishment of Community Reference Laboratories for new areas should be examined.

Scientific information underpins Food Safety policy. It is clear that scientific advice on food safety must be of the highest quality. It must be provided in a timely and reliable manner to those responsible for taking decisions to protect consumer health.

### *The current system for scientific advice*

22. The system for the provision of scientific advice to the Commission was completely reorganised in 1997 with emphasis on the fundamental principles of excellence, transparency and independence. Scientific opinions are currently provided by eight sectoral Scientific Committees<sup>2</sup>, of which five cover, directly or indirectly, the feed and food areas. In addition, a Scientific Steering Committee has been set up which provides advice on multidisciplinary matters, BSE, harmonised risk assessment procedures, and co-ordination of questions which cut across the mandates of more than one of the sectoral Committees (e.g. anti-microbial resistance). This co-ordination task is particularly important because food safety questions are increasingly addressed as a continuum from the farm to the table. The Committee Secretariats are provided by the Commission services.

Members of these Committees are chosen following rigorous assessment of their scientific excellence in their field of competence. Their independence is guaranteed through the strict application of declarations of interests.

In the field of radioactive contamination of feed and food, specific groups of scientific experts have been established under Article 31 of the Euratom Treaty.

### *The nature of the questions put to the Committees*

23. Many of the questions concern the evaluation of dossiers submitted by the industry for Community authorisation (pesticides, novel foods, food and feed additives). Others questions concern specific health problems e.g. contaminants or microbiological risk. A third category concerns broader assessments of risk as typified by anti-microbial resistance.

### *Obligatory consultation of the Committees*

24. Some food safety legislation requires the Commission to consult a scientific committee prior to making proposals which may affect public health. This situation is not systematically reflected in other legislation in the food safety sector and will have to be reviewed in order to ensure that all food safety legislation is adequately based on independent scientific advice.

### *Limitations of the current system*

25. Since the reform, the Committees have provided some 256 opinions, many of which include evaluations of a large number of individual substances. It has become evident

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<sup>2</sup> Food, Animal Nutrition, Veterinary-Public Health, Plants, Animal Health and Animal Welfare, Cosmetic products & non-food products, Medicinal products and medical devices, Toxicity, Ecotoxicity and Environment

that the existing system is handicapped by a lack of capacity and has struggled to cope with the increase in the demands placed upon it. Furthermore, the recent dioxin crisis could only be managed by delaying work in other areas and has shown the need to have a system which is able to respond rapidly and flexibly. This lack of capacity has led to delays which have consequences both for the Commission's legislative programmes, and hence its ability to respond to consumer health problems, and for industry where commercial dossiers are involved. This situation will be exacerbated by the increased demands that will be placed on the scientific committees resulting, for example, from the proposed programme for reform of food legislation as set out later in this White Paper.

#### ***The need for systematic provision of risk assessment data***

26. Risk assessment depends upon the availability of accurate, up-to-date, scientific data. These may include, for example, epidemiological information, prevalence figures and exposure data. Support mechanisms for the provision of such information barely exist and need to be established. As the European Union enlarges, data covering the new Member States will also need to be taken into consideration. The need to develop effective information gathering systems at European and world level requires a new approach, which will make the best use of available resources.

#### ***The need for scientific networks***

27. In many areas, the lack of capacity identified above could be addressed by reducing the amount of time-consuming preparatory work required of Committee members and external experts.

Community risk assessments for pesticides, biocides and chemicals are already underpinned by networks of Member State institutes, which are established under sectoral legislation. This has greatly enhanced the work and efficiency of the relevant scientific committees. It allows an effective peer review system, and thereby provides a means of making maximum use of Member States' expertise without being prejudicial to the independence of the Committees. Networks also have great potential for the collection of data. This approach needs to be extended and consideration must be given to the better exploitation of existing networks.

#### ***Concluding remarks***

28. In the light of the shortcomings outlined in this Chapter, it is clear that reinforced systems are required to respond to the overall objective of improving consumer health protection and restoring confidence in the EU's Food Safety policy. Improvements will therefore be made in the areas of monitoring and surveillance, the rapid alert system, food safety research, scientific co-operation, analytical support and the provision of scientific advice. The setting up of a European Food Authority responsible for, inter alia, these areas is considered in the next Chapter. The report 'The future of scientific advice in the EU' by Professors Pascal, James and Kemper will be taken into account for the establishment of the Authority, as well as for the improvement of the present system in the transitional phase.

## CHAPTER 4: TOWARDS ESTABLISHING A EUROPEAN FOOD AUTHORITY

The Commission envisages the establishment of an independent European Food Authority, with particular responsibilities for both risk assessment and communication on food safety issues.

29. A key priority for the Commission is to take effective measures to ensure a high level of consumer protection through which consumer confidence can be restored and maintained. This task has many facets. First there is the confidence question itself – how is that to be achieved? Secondly, we must ensure that not only is confidence restored but, even more importantly, that it is retained. In other words, the system that is implemented to restore confidence must be sufficiently durable and flexible to ensure that consumer confidence is maintained on an ongoing basis.

In addition to the range of measures proposed in this White Paper, the Commission also envisages the establishment of a European Food Authority. The key criteria for establishing such an authority are considered in this Chapter. The Commission believes that major structural changes are necessary in the way food safety issues are handled, having regard to the experience over the last few years and the generally accepted need functionally to separate risk assessment and risk management. The establishment of a new Authority will provide the most effective instrument in achieving the changes required to protect public health and to restore consumer confidence. It is clear therefore that the primary focus of such an Authority will be the public interest.

This Chapter is designed to elicit public debate and informed comment. The Commission wishes to have a broad consultation on establishing a European Food Authority. Interested parties are therefore invited to submit comments by the end of April 2000.

### *Potential scope of the Authority*

30. The role of an Authority must be defined in the context of the process of risk analysis, which comprises risk assessment, risk management and risk communication.
31. The objective of **risk assessment** is the provision of scientific advice. Extensive information gathering and analysis is a pre-requisite for sound and up-to-date scientific advice. Networks for monitoring and surveillance in the area of public health and animal health, information systems in the agricultural sector and rapid alert systems, as well as R&D programmes, play an important role in the generation of scientific knowledge.
32. Legislation and control are the two components of **risk management**.

Legislation comprises primary legislation adopted by Council alone or in co-decision with the European Parliament and implementing legislation adopted by the Commission under conferred powers. Legislation implies a political decision and involves judgements not only based on science but on a wider appreciation of the

wishes and needs of society. There must be a clear separation between risk management and risk assessment.

The Commission, in its role of guardian of the Treaty, is responsible for ensuring that Community legislation is properly transposed into national law and properly implemented and enforced by national authorities in the Member States. The control function is carried by the Commission's Food and Veterinary Office (FVO), which reports on its findings and makes recommendations. FVO reports are key elements for the Commission in deciding whether to take safeguard measures within the Community or for imports from third countries, or to take infringement proceedings against Member States. Furthermore, the Commission, in establishing agreements with third countries that recognise the equivalency of food safety controls under the WTO/SPS agreement, calls on the FVO for an evaluation of the health situation in the third countries concerned.

33. The inclusion of risk management in the mandate of the Authority would raise three very serious issues.

Firstly, there is a serious concern that a transfer of regulatory powers to an independent Authority could lead to an unwarranted dilution of democratic accountability. The current decision-making process provides a high degree of accountability and transparency, which could be difficult to replicate in a decentralised structure.

Secondly, the control function must be at the heart of the Commission's risk management process if it is to act effectively on behalf of the consumer, notably in ensuring that recommendations for action arising from control are properly followed-up. The Commission must retain both regulation and control if it is to discharge the responsibilities placed upon it under the Treaties.

Thirdly, an Authority with regulatory power could not be created under the current institutional arrangements of the European Union, and would require modification of the existing provisions of the EC Treaty.

For these reasons, it is not proposed to transfer risk management competencies to the Authority.

34. **Risk communication** is a key element in ensuring that consumers are kept informed, and in reducing the risk of undue food safety concerns arising. It requires scientific opinions to be made widely and rapidly available, subject only to the usual requirements of commercial confidentiality, where applicable. In addition, consumers need to be provided with easily accessible and understandable information relating not only to these opinions, but also to wider issues touching upon consumer health protection.

*The advantage of an Authority*

The broadest acceptance of scientific risk assessment is essential to ensure that action is effective, appropriate and rapid.
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35. The responsibilities of the Authority would consist of the preparation and provision of scientific advice, the collection and analysis of information required to underpin

both that advice and the Community's decision making processes, the monitoring and surveillance of developments touching upon food safety issues and the communication of its findings to all interested parties.

Through the manner in which it discharges its functions, the Authority would have to demonstrate the highest levels of independence, of scientific excellence and of transparency in its operations. In this fashion it should be in a position rapidly to establish itself as the authoritative point of reference for consumers, the food industry, Member State authorities and on the wider world stage.

36. An Authority would be ideally placed to develop the flexible, rapid, response that the new challenges require. It would provide a single, highly visible, point of contact for all concerned. It would not only act as a point of scientific excellence, but would also be available to consumers to provide advice and guidance on important food safety developments. It would undertake information actions with a view to ensuring that consumers can make informed choices, and are better informed on food safety issues.
37. The Authority needs to work in close co-operation with national scientific agencies and institutions in charge of food safety. The creation of a network of scientific contacts throughout Europe and elsewhere, with the Authority at its centre, is designed to ensure that all concerned become associated with the analytical process, and have a clearer understanding and greater acceptance of the basis for the opinions that are generated.

The Commission and the other EU institutions will have a vital role to play in supporting the Authority and ensuring that the Authority is adequately resourced and staffed, and by taking full account of the opinions that the Authority generates.

#### ***Objectives of a European Food Authority***

The principal objective of a European Food Authority will be to contribute to a high level of consumer health protection in the area of food safety, through which consumer confidence can be restored and maintained.

38. The Authority must meet the fundamental principles of independence, excellence and transparency to be successful in its mission. As an integral part of these principles, the Authority must demonstrate a high level of accountability to the European institutions and citizens in its actions.

Therefore the Authority must

- be guided by the best science,
- be independent of industrial and political interests,
- be open to rigorous public scrutiny,
- be scientifically authoritative and
- work closely with national scientific bodies.

39. This White Paper draws upon the Commission's experience of operating scientific advice, and an examination of a number of models already in place, such as the EU's European Medicines Evaluation Agency (EMA) and the US's Food and Drug Administration (FDA). Account has also been taken of the report of Professors James, Kemper and Pascal on the 'Future of scientific advice in the EU'.

The Commission believes that a European Food Authority should have a legal existence and personality separate from the current EU Institutions in order to carry out independently its role in terms of risk assessment and risk communication, so as to maximise its impact on consumer health protection and confidence building.

40. As indicated earlier, the existing Treaty provisions impose constraints on the activities that can be attributed to the Authority, but this should not be taken to mean that a possible future extension of its competencies should be discounted. Such an extension should only be considered in the light of the experience with the functioning of the Authority and the confidence gained in its operation, including the possible need to change the Treaty.

41. **Independence:** The existing situation where scientists involved in the provision of advice are required to respect strict rules concerning their independence must continue into the new Authority. If consumer confidence is to be regained, the Authority will need not only to act independently of outside pressures, but to be accepted as doing so by all parties concerned. Nevertheless the Authority will need to be representative and accountable. The Commission will examine the range of options to ensure that the Authority strikes the correct balance in terms of independence and accountability, taking into account the views of the other institutions and stakeholders. Particular attention will need to be paid to the selection of the head of the Authority.

42. **Excellence:** To allow the Authority to act as a point of scientific excellence and reference, and to resolve disputes on scientific issues, it will need rapidly to establish its international pre-eminence. In addition to ensuring the excellence of independent scientists, this will require the identification and recruitment of the highest calibre of personnel, and the best use of available information systems. Particular attention will be paid to the staffing of the Authority, to ensure that it employs suitably qualified specialists, who can provide the necessary support for the independent scientists responsible for the generation of the scientific opinions, as well as collecting and analysing data relevant to its functions. In addition, systems will need to be established so that the best scientists in the different fields can be identified and called upon as required.

It will also be important that the Authority can respond with sufficient speed and flexibility to deal with food safety emergencies, as well as longer term projects.

43. **Transparency** involves not only the rapid, open, presentation of the findings and recommendations of the Authority, but also implies that the processes followed in reaching them are as open as possible, in order to respond to the fundamental right of access of citizens as laid down in the Treaty. This requires clear procedures, publicly available, governing the operation of the Authority. In addition, details of the Authority's working programme would be made widely available.

Although the discussions by which scientific opinions are reached will need to respect issues of confidentiality, their presentation and explanation must be undertaken as openly as possible. These opinions will continue to be made available to the Commission and the Parliament by the Authority as soon as they are available and, at the same time, published on the internet so that all interested parties are kept fully informed.

### *The tasks of the Authority*

44. It is envisaged that the Authority would embrace scientific advice, the gathering and analysis of information and the communication of risk. These issues are dealt with in Chapters 3 and 7 of this White Paper.
45. **Scientific advice:** The scope of the Authority should be to provide scientific advice and information to the Commission on all matters having a direct or indirect impact on consumer health and safety arising from the consumption of food. Thus it will cover primary food production (agricultural and veterinary aspects), industrial processes, storage, distribution and retailing. Its remit will encompass both risk and nutritional issues. The Authority will also cover animal health and welfare issues, and will take into consideration risk assessments in other areas, notably the environmental and chemical sectors where these overlap with risk assessment in relation to food.

The Commission believes that the scientific work currently undertaken by the Scientific Committees related to food safety should be a core part of the proposed Authority. In this context, the structure and mandates of the existing Scientific Committees will be reviewed to ensure that scientific advice responds to the full range of responsibilities attributed to the Authority. The Committee(s) will provide opinions upon request by the Commission. In a proactive capacity, the Committee(s) should also signal new health hazards or emerging health problems and the Authority will have to follow-up such concerns.

46. The Authority will establish means for the rapid identification of scientific experts in the European Union, and elsewhere. In this manner, the Authority will need to access a world-wide network of scientific excellence, with the flexibility to respond rapidly to changing situations.
47. The Authority must be able to keep up-to-date with the most recent scientific developments and to identify gaps in on-going research or topics where it feels that rapid targeted work is necessary. The Authority would have its own budget for the commissioning of ad-hoc targeted and immediate research in response to unforeseen health emergencies, in liaison with the Commission Joint Research Centre, national scientific agencies and international organisations. Account should also be taken of the work of the networks established through the Community research programmes; mechanisms to enhance a two-way interaction between these Community research programmes and the Authority will need to be established.
48. The Scientific Committee(s) must be able to concentrate on the core task of preparing the scientific opinions. The Committee(s) will be supported by a scientific secretariat, which will be responsible for the interface between them and the risk managers. In addition, it will be necessary to establish in-house scientific support which will undertake much of the preparatory work for the Committee(s).

49. **Information gathering and analysis:** There is a pressing need to identify and use the information currently available throughout both the Community and world-wide on food safety issues. This would be a key task for the Authority, and represents an area where great scope for improvement exists. If properly exploited, this information can form a major element in ensuring that potential problems are identified as quickly as possible and that scientific advice addresses the wider health picture.
50. The Authority will be expected to take a proactive role in developing and operating food safety monitoring and surveillance programmes. It will need to establish a network of contacts with similar agencies, laboratories and consumer groups across the European Union and in third countries.

The Authority must be able to guarantee a real-time evaluation and response of the outcome of these programmes, ensuring that real or potential hazards are rapidly identified. In addition, the Authority will need to develop a predictive system that will allow the early identification of emerging hazards, so that crises can be avoided where possible.

51. **Communication:** The ability to communicate directly and openly with consumers on food issues will give the Authority a high public profile. The Authority will need to make special provision for informing all interested parties of its findings, not only in respect of the scientific opinions, but also in relation to the results of its monitoring and surveillance programmes.

The Authority must become the automatic first port of call when scientific information on food safety and nutritional issues is sought or problems have been identified. It will also need to ensure that appropriate information on these issues is published, as part of its commitment to re-establishing consumer confidence. Clearly the Commission will continue to be responsible for communicating risk management decisions.

#### ***Reacting to crises***

52. Where a food safety emergency occurs, the Authority will collect, analyse and distribute relevant information to the Commission and Member States, and will mobilise the necessary scientific resources to provide the best possible scientific advice. The Authority will have to respond rapidly and effectively to crises, and will take a key role in supporting the EU response. This will promote improved planning and handling of crisis situations at the European level, and will demonstrate to consumers that a pro-active approach is being taken to deal with problems.
53. The Authority will operate the Rapid Alert System, which allows the identification and rapid notification of urgent food safety problems. The Commission will be part of the network and will therefore be informed on a real-time basis. Depending on the nature of a crisis, the Authority may be requested to carry out follow-up tasks, including monitoring and epidemiological surveillance.

#### ***Networking with national agencies and scientific bodies***

54. The European Food Authority must be a value-added structure: it should work in close co-operation with national scientific agencies and institutions in charge of food

safety and build upon their expertise. This would result in the creation of a network, designed to ensure the best and most effective use of existing structures and resources. One of the tasks of the European Food Authority will, therefore, be to link centres of excellence, allowing its in-house scientific staff to draw from the leading-edge scientific expertise in all the relevant disciplines across the European Union and at international level. Similarly, national bodies will be able to have access to a scientific base of the highest possible calibre. Through their dynamic two-way exchange, the role of the Authority will be progressively enhanced. This will lead, over time, to reliance on the Authority as the most authoritative source of knowledge on food safety matters in the EU.

55. Within the network system, best use of the existing scientific and technical capabilities and infrastructures of the Commission Joint Research Centre (JRC) should be ensured.

#### ***Interface with Commission services***

56. The Authority and the Commission services must work very closely together from the moment that the Authority assumes its functions. This will concern, in particular, those charged with the preparation of legislation, law enforcement and the operation of controls and inspections (FVO), as well as the Joint Research Centre and those in charge of Community R&D. This will ensure that the Authority's findings can be used to the best effect possible, and that it is kept informed of issues of direct consequence for its own activities. At the same time, it will allow the Authority to be responsive to the needs of the Commission services. This interface should of course not blur the distinctive role assigned to the Authority.

#### ***Resources***

57. The resource implications of setting up and operating the scientific advisory systems, information collection and analysis, and effective networks with scientific bodies in Member States should not be underestimated. In addition to its scientific and communication tasks, the Authority will have to carry a heavy workload in terms of administrative and financial management. The Authority will make extensive use of information and communication technologies, and promote their use by national agencies and institutions in charge of food safety. The efficacy of the Authority will ultimately depend on the adequacy, in terms of both size and quality, of the human, financial and physical resources allocated. It will only be possible to define the resources needed in the light of decisions taken after the consultation process and detailed feasibility studies. The detailed figures in this regard will be presented with the Commission's definitive proposal for the establishment of the Authority and take account of the forthcoming Commission debates concerning political priorities and the related allocation for operational and human resources.

#### ***Location of the Authority***

58. The Authority will need to develop very close working links with the Commission services involved in food safety issues, and with the other EU institutions if it is to carry out its functions effectively and to be available for rapid consultation in crises situations. The Authority also needs to be easily accessible, not only for the scientists called upon to develop the scientific opinions, but also for all other stakeholders who need to seek the views of the Authority. This is not only important for the best use of

resources, but also to demonstrate the openness and availability of the Authority, in particular in its role in communication. In light of these considerations, the Commission considers that the Authority must be established in an easily accessible location.

### *Candidate countries*

59. The candidate countries will be associated to the work of the Authority in line with the conclusions of the Luxembourg European Council which underlined the importance for these countries to become familiar with the working methods and policies of the Union. Specific arrangements will be developed in the up-coming work on the establishment of the Authority.

### *Implementation Timetable*

The Commission believes that it is essential to have a very rapid implementation schedule for the establishment of the Authority.
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60. The following timetable is foreseen for the formal establishment of the new Authority:
- White Paper published : January 2000
  - Consultation period : end of April 2000
  - Commission proposal : September 2000
  - Enabling legislation : December 2001
  - Authority starting operations : 2002
61. While the timetable set out is ambitious, particularly given the scale of the task, the Commission considers that it is achievable given its experience in establishing the EMEA. Not alone will it be necessary to have a rapid start up schedule for the new Authority, but it will also be necessary, in parallel, to improve the functioning of the existing system. The Commission will establish a dedicated team to ensure that there is rapid action on the range of issues identified in this Chapter of the White Paper.
62. The reinforcement of the present system of risk assessment and communication will be a key part of the range of measures necessary to ensure that the Authority can really become operational within two years. Having regard to the availability of resources over the next two years, the Commission will evaluate the possibility of reinforcing the existing scientific support and advice structures in the lead-in phase to the establishment of the Authority.

## CHAPTER 5: REGULATORY ASPECTS

63. In Chapter 4, the Commission has highlighted why risk management must be left to an institutional framework with full political accountability. Notwithstanding the proposed creation of a European Food Authority, the drafting and making of legislation will remain the responsibility of the Commission, the Parliament and the Council.
64. The European Union has a broad body of legislation which covers primary production of agricultural products and industrial production of processed food. The legislation has evolved over the last thirty years, reflecting a blend of scientific, societal, political and economic forces, in particular in the framework of creating the Internal Market, but no overall coherence has been guiding this development. For this reason, the Green Paper on the general principles of food law in the European Union (COM(97) 176 final) already foresaw the need for a major review of food legislation.
65. Food production is extremely complex. Products of animal and plant origin present intrinsic hazards, due to microbiological and chemical contamination. Nevertheless, the current legal framework and operational set-up has in general afforded the EU consumer a high level of health protection. The real problem is not necessarily due to a lack of legal instruments, but the broad disparity in the means to respond to situations in specific sectors, or the multiplicity of actions which need to be triggered in the case where a problems spills over from one sector to another. One of the weakest links in the system is the lack of a clear commitment from all interested parties to give an early warning about a potential risk, so that the necessary scientific evaluation and protective measures can be triggered early enough to ensure a proactive rather than reactive response at EU level.

The full range of measures proposed is presented in the Annex with an indication of the priority measures and likely timing, though resource constraints may affect the finalisation of some initiatives.

### *New legal framework for food safety*

There is a need to create a coherent and transparent set of food safety rules.
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66. The Commission intends to make proposals for a new legal framework laying down the principles to ensure a coherent approach and to fix the principles, obligations and definitions that apply in this field. The aim of these proposals will be to reflect the outcome of the extensive consultation which the Commission initiated in 1997 with the publication of its Green Paper on food law, to lay down the common principles underlying food legislation and to establish food safety as the primary objective of EU food law.
67. The Commission will make proposals including a General Food Law, which will embody the principles of food safety referred to in Chapter 2. These proposals will be subject to the fullest consultation with all interest groups at the earliest possible stage in their development and impact analysis of legislative proposals will be undertaken as appropriate. Individual legislation needs to be clear, simple and

understandable for all operators to put into effect. There also needs to be close co-operation with the competent authorities at the appropriate levels in the Member States to ensure proper and consistent compliance and enforcement and to avoid unnecessary administrative procedures.

68. These proposals will also provide the general frame for those areas not covered by specific harmonised rules but where the functioning of the Internal Market is ensured by mutual recognition, as developed by the European Court of Justice in its “Cassis de Dijon” jurisprudence. Under this principle, in the absence of Community harmonisation, Member States may only restrict the placing on the market of products lawfully marketed in another Member State when and to the extent that this can be justified by a legitimate interest such as the protection of public health and that the measures taken are proportionate. In this context, the Commission will continue to use all means at its disposal, either formal (infringement procedures) or informal (networks of Member States representatives and meetings, etc) in order to resolve disputes on obstacles to trade. Action for measures at Community level will be envisaged where a barrier to trade is found to be justified on food safety grounds.

#### *New legal framework for animal feed*

The safety of food from animal origin begins with safe animal feed.
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69. Although legislation cannot prevent all incidents affecting the feed and food chain, it can set up appropriate requirements and controls allowing for early detection of problems and speedy corrective action. In this respect, the action needed in the **animal feed** sector is illustrative. The principles of food safety mentioned in Chapter 2 should become applicable to the feed sector, in particular to clarify responsibilities of feed producers and to provide a comprehensive safeguard clause. More specifically, the materials which may or may not be used in animal feed production, including animal by-products, need to be clearly defined. A positive list of feed materials would give the clearest response to the current lack of definition of feed materials but this task is complex and time-consuming. In the short term, the current negative list needs to be rapidly expanded. However the Commission is committed to working towards a positive list over the medium term. In addition, a revision of Community legislation will be proposed in order to exclude fallen animals (cadavers) and condemned material from the feed chain. The only material allowed to be used in animal feed would then be material derived from animals declared fit for human consumption.

A legislative proposal for the evaluation, authorisation and labelling of **novel feed**, in particular of genetically modified organisms and feeding stuffs derived therefrom, will be put forward.

Clarification between the different categories of products used in animal nutrition (additives, medicinal products, supplements) is necessary in order to avoid grey zones and to clarify which requirements apply in each case. The Commission will also pursue the prohibition or phasing-out of antibiotics used as growth promoters in the EU depending on their potential use in human and veterinary medicine as part of its broad strategy to control and contain antibiotic resistance.

Now that the origins and consequences of the dioxin crisis are becoming clearer, it has become obvious that the feed manufacturing industry should be subjected to the

same rigorous requirements and controls as the food producing sector. Lack of internal controls (good manufacturing practice, own-checks, contingency plans) and lack of mechanisms for traceability allowed the dioxin crisis to develop and expand throughout the whole food chain. Legislation will be proposed in order to correct these anomalies, including official approval of all feed producing plants as well as official controls at national and EU level. To align the framework for the feed sector with that of the food sector, a rapid alert system for feed shall be integrated into the rapid alert system for food.

### *Animal health and welfare*

The health and welfare of food producing animals is essential for public health and consumer protection.

70. **Animal health** is also an important factor in food safety. Some diseases, the so-called **zoonoses**, such as tuberculosis, salmonellosis and listeriosis can be transmitted to humans through contaminated food. These diseases can be particularly serious for certain categories of the population. Listeriosis may cause encephalitis and spontaneous abortions; salmonellosis is an emerging public health problem. The availability of a correct picture of the situation is a pre-requisite for action. Therefore Community monitoring for food borne diseases and zoonoses is needed and harmonised reporting requirements need to be introduced. The information derived therefrom will facilitate the Commission in setting targets and in taking more effective measures to reduce the prevalence of zoonotic diseases.

Existing eradication and disease control programmes, such as those for tuberculosis and brucellosis, should be continued and where possible re-enforced; in particular, in those Member States whose status with regard to these diseases remains problematic. Particular attention should be devoted to the control of hydatidosis and *Brucella melitensis* in Mediterranean regions. Information on zoonoses monitoring needs to be better exploited in order better to define programmes at EU level.

This White Paper makes proposals specifically designed to promote the health and welfare of animals only in so far as Food Safety policy is directly concerned. The Commission acknowledges that animal health and welfare issues in a broader context are important. In the context of this White Paper, it is recognised that **animal welfare** questions need to be integrated more fully with regard to food policy. In particular the impact on the quality and safety of products of animal origin intended for human consumption needs to be reflected in the legislation.

71. Most of the legislation relating to **BSE/TSE** has been adopted in the form of safeguard measures, taken on an ad hoc basis. By definition, the adoption of such measures does not involve all Community institutions. They also do not provide for a fully consistent approach. The Commission has addressed this problem in proposing to the Council and the European Parliament a comprehensive proposal based on Article 152 of the Treaty, which covers all measures to control BSE and other transmissible spongiform encephalopathies (TSEs). Until the adoption of this proposal, emergency measures will be taken to ensure a high level of protection during the interim period. The most important measures will be rules on removal of specified risk materials in combination with a provisional classification according to BSE status, reinforcement of the epidemiosurveillance system on the basis of testing

certain higher risk animals (fallen stock, emergency slaughtered cattle), updating of the feed ban and embargoes in the light of recent scientific advice.

In addition the Commission takes the view that further testing to establish the incidence of BSE across the Union is desirable. This will of course depend upon the availability of suitable post mortem tests. The Commission will keep this under active review and will make proposals for a suitable testing programme in the light of developments.

### *Hygiene*

A co-ordinated and holistic approach towards hygiene is an essential element of food safety.
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72. Over time, the Community has developed extensive requirements relating to **hygiene** of food. These include over twenty legal texts, which are designed to ensure the safety of food produced and placed on the market. However, these requirements were adopted as a scattered response to the needs of the Internal Market, taking into account a high level of protection. This has resulted in a series of different hygiene regimes according to whether the food is of animal or plant origin, which can only be justified for historical reasons. It has also left some areas out of the scope of the requirements, such as production of food of plant origin at the level of the farm (primary production). A new comprehensive Regulation will be proposed recasting the existing legal requirements to introduce consistency and clarity throughout the food production chain. The guiding principle throughout will be that food operators bear full responsibility for the safety of the food they produce. The implementation of hazard analysis and control principles and the observance of hygiene rules, to be applied at all levels of the food chain, must ensure this safety. The Commission shall examine how best to assist small and medium enterprises in implementing these requirements, in particular by supporting the development of guidance documents. In addition, a procedure for laying down microbiological criteria and, where necessary, food safety objectives will be introduced.

### *Contaminants and residues*

Limits of contaminants and residues must be set and controlled.
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73. The term “**contaminants**” traditionally covers substances which are not intentionally added to food. They can be the result of environmental contamination; they also can result from agricultural practices, production, processing, storage, packaging, transport or from fraudulent practices. Specific EU requirements only exist for a few contaminants, although many measures exist at national level. This is de facto leading to disparity in consumer health protection throughout the EU, but also to practical difficulties for control authorities and industry. The serious nature of this gap was highlighted during the dioxin crisis, where ad hoc limits, only valid for products of Belgian origin, were set in the framework of a safeguard measure. There is therefore an obvious need to define standards for contaminants throughout the chain leading from feed to food. The scientific basis for setting these limits needs to be addressed as a matter of priority.
74. Some substances are found in food as a result of intentional use. This concerns **residues of pesticides** in food of plant and animal origin and **veterinary medicines**

in food of animal origin. Community legislation has laid down rules for the establishment of maximum residue limits of these substances in food and agricultural products. Member States have an obligation to monitor compliance with these limits but there are no harmonised requirements and the monitoring activities vary among them. Moreover there is a limited number of accredited laboratories capable of carrying out monitoring in the Member States. As far as pesticides are concerned, the Commission aims at progressively setting limits for all pesticide/commodity combinations. Action to correct deficiencies with regard to monitoring and laboratory testing will be taken.

At present, there is a large number of **pesticides** on the market that have not yet been evaluated at Community level. In the meantime, new pesticides are being presented for obtaining a market authorisation. The approval procedure of new pesticides needs to be accelerated. In parallel, the review of the approval of existing pesticides needs to be streamlined so as to eliminate very rapidly products for which safety data are lacking or for which safety concerns have been identified. This will therefore promote the use of safer pesticides.

However, the performing of risk assessments for approving pesticides and setting maximum residue limits is hampered by the absence of sufficient accurate data about diets. In order to fill this gap, a major study to establish a database on diets will be carried out; this database will also be an essential tool for risk assessment of any other contaminant, additive, etc.

75. Legislation on the **radioactive contamination** of food and feed is taken on the basis of Article 31 of the Euratom Treaty, and in case of imports, on the basis of Article 133 of the Treaty. In this context, the post-Chernobyl legislation will be kept under constant review.

#### *Novel Food*

The Community provisions governing **novel foods** have to be tightened and streamlined.

76. The procedure for authorising the placing on the market of novel foods (i.e. foods and food ingredients which have not yet been used for human consumption, in particular those containing or derived from genetically modified organisms) should be clarified and made more transparent. Exemptions from these provisions need to be reviewed. Therefore, the Commission will adopt an implementing regulation to clarify the procedures laid down in the Novel Food Regulation (EC) N° 258/97 and will in due course also present a proposal to improve this Regulation in accordance with the revised regulatory framework for the deliberate release of GMOs under Directive 90/220/EEC. Furthermore, the labelling provisions have to be completed and harmonised.

#### *Additives, flavourings, packaging and irradiation*

There is a need to up-date and complete existing Community legislation with regard to additives, flavourings, packaging and irradiation.

77. The provisions relating to **food additives** and **flavourings** need to be amended in several respects. Firstly, implementing powers should be conferred on the

Commission to maintain the Community lists of authorised additives and the status of enzymes should be clarified. Secondly, the Community lists of colouring matters, sweeteners and other additives need to be updated. Thirdly, the purity criteria for sweeteners, colours and other additives have to be amended and appropriate purity criteria for food additives made from novel sources have to be laid down. The Commission will further publish a report on the intake of food additives. Specific action concerning flavourings has so far concentrated on chemically defined substances. More work is needed to reflect innovation in this field and new insight in toxicological effects of substances naturally present in flavourings. The Commission will update the register of flavouring substances, establish a programme for their evaluation and lay down a list of additives authorised for use in flavourings.

78. The Commission will also consider changing the Community framework for **materials that come into contact with food** in order to enhance the administration of this sector and to improve the labelling requirements. The structure and transparency of the Directives on plastic materials will be improved and consideration will be given to an extension of these provisions to surface coatings. As regards the materials not yet under harmonisation (paper, rubber, metals, wood, cork), the Commission will continue to collaborate with the other European bodies active in this field (CEN, Council of Europe).
79. The Commission will further propose a Directive to complete the list of foodstuffs authorised for **irradiation** treatment, and publish the details of the irradiation facilities operating in the Member States, as well a list of third countries' facilities which are approved as equivalent. It will also elaborate a Directive on constituents of **natural mineral waters** and on the conditions of use for the treatment of certain natural mineral waters with ozone enriched air.

#### *Emergency measures*

The possibility for taking safeguard measures is an essential tool for managing food safety emergencies.
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80. The dioxin crisis has demonstrated the lack of consistency of the present framework for the adoption of **safeguard measures** in response to an identified risk to consumer health. The Commission does not at present have a legal instrument to adopt a safeguard measure upon its own initiative either for feed or for a processed food of non-animal origin originating from one of the Member States. According to the sector, the mechanisms for adoption of safeguard measures are different. The adoption of a single emergency procedure applicable to all types of food and feed, whatever their geographical origin, is the only means to remove the disparities and close the loopholes. In this regard, the Commission will be making a comprehensive legislative proposal.

#### *Decision making process*

The decision making process needs to be streamlined and simplified in order to ensure efficacy, transparency and rapidity.
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81. The EU food legislation can be based on various provisions of the EC Treaty: Article 95 in the case of measures for the completion of or the functioning of the Internal Market (taking as a basis a high level of consumer and health protection), Article 152

for measures in the veterinary and phyto-sanitary fields which have as their direct objective the protection of public health, Article 153 relating to consumer protection and Article 37 where agricultural aspects are preponderant. Depending on the legal basis, measures are adopted by the Council in co-decision with the European Parliament or after consultation of the European Parliament on proposal by the Commission.

Article 202 of the EC Treaty provides that in the instruments which it adopts, the Council shall confer on the Commission powers for the implementation of the rules which the Council lays down, save in specific cases where it may reserve the right to exercise directly implementing powers itself. Such transfer of competence should normally allow the Commission to transform rapidly the scientific advice it receives by amending the appropriate legislation or adopting appropriate decisions. In some cases however (in particular for food additives) implementing powers have not yet been conferred on the Commission with the undesirable result that updating positive lists of authorised substances (whether this is necessary to authorise a new substance, to ban the use of an authorised substance, or to modify the conditions of use of an authorised substance) can take several years after the formulation of the scientific advice.

82. Where implementing powers have been conferred on the Commission (for example flavourings, extraction solvents, contaminants, pesticide residues, materials in contact with food, diet foods, irradiated foods or quick-frozen foods), the current decision-making process for transforming scientific advice into legislation or decision is in some cases not satisfactory: the procedures applicable are disparate and cumbersome; different committees are involved; different modalities apply; resources are scarce and scattered.
83. All the procedures laid down by the EU food legislation for its implementation and its adaptation to technical and scientific progress need to be reviewed. In this respect the number of committees dealing with delegated legislation and the adoption of individual decisions should be reduced and streamlined. Better co-ordination should be introduced to ensure that food safety issues are addressed as a continuum from farm to table through the application of a single regulatory procedure for delegated legislation, a single management procedure for the adoption of individual decisions and an emergency procedure for all urgent matters of food safety. The new procedures should be in conformity with the recent Decision on comitology.
84. Clear and strict deadlines should be fixed for the Commission to prepare an amendment or decision, for the Standing Committee to reach an opinion and for the Commission to finalise an amendment or decision. Greater transparency should be considered at all stages of the regulatory process. Information and communication technologies should be used extensively to automate the production and tracking of amendments and decisions and to accelerate their circulation between all the parties involved.

## CHAPTER 6: CONTROLS

A comprehensive piece of legislation will be proposed in order to recast the different control requirements. This will take into account the general principle that all parts of the food production chain must be subject to official controls.

### *Development of EU legislation*

85. Legislative requirements setting out official controls at both national and EU level have been established in different pieces of Community legislation over a period of more than 30 years. Although these legislative acts have the same objective, their approach to the operation of these controls is different. They also contain anomalies, resulting in an incomplete legal basis for carrying out official controls in both Member States and third countries. There is a need to clarify and update existing food control legislation and to ensure that it covers all steps in the production. Furthermore, certain detailed meat inspection requirements need to be reviewed as they are no longer in line with modern food safety management practices.
86. Existing legislation includes a system whereby Member States can collect fees to cover the costs of controls for products of animal origin. Member States may levy charges on importers for the control of a certain number of products of animal and non-animal origin for compliance with post-Chernobyl legislation. There are differences in the level of fees charged between, and within, the Member States. In addition, there is no legal basis for a similar system to be applied to controls of feed and food of non-animal origin.
87. The lack of uniformity in setting and charging control fees, and the extension of this principle to the areas not presently covered, will be included in this legislative review. Common objectives should be fixed at EU level with regard to the staff and equipment requirements, whilst guarantees should be introduced to ensure that fees are used only for the financing of controls.

### *Controls over the operation of EU legislation*

88. Responsibility for safe food production is shared between operators, national authorities and the European Commission. Operators are responsible for compliance with legislative provisions, and for minimising risk on their own initiative. National authorities are responsible for ensuring food safety standards are respected by operators. They need to establish control systems to ensure that Community rules are being respected and, where necessary, enforced. These systems need to be developed at Community level, so that a harmonised approach is followed.
89. To ensure that these control systems are effective, the Commission, through the Food and Veterinary Office (FVO), carries out a programme of audits and inspections. These controls evaluate the performance of national authorities against their ability to deliver and operate effective control systems, and are supported by visits to individual premises to verify that acceptable standards are actually being met.
90. Recent food safety crises have highlighted deficiencies in national systems of control. At the heart of the problem is the lack of harmonised Community approach to the design and development of national control systems.

91. There is therefore a clear need for a **Community framework of national control systems**, which will improve the quality of controls at Community level, and consequently raise food safety standards across the European Union. The operation of such control systems would remain a national responsibility. This Community framework would have three core elements.
- The first element would be **operational criteria set up at Community level**, which national authorities would be expected to meet. These criteria would form the key reference points against which the competent authorities would be audited by the FVO, thereby allowing it to develop a consistent, complete, approach to the audit of national systems.
  - The second element would be the development of **Community control guidelines**. These would promote coherent national strategies, and identify risk-based priorities and the most effective control procedures. A Community strategy would take a comprehensive, integrated, approach to the operation of controls. These guidelines would also provide advice on the development of systems to record the performance and results of control actions, as well as setting Community indicators of performance.
  - The third element of the framework would be enhanced **administrative co-operation** in the development and operation of control systems. There would be a reinforced Community dimension to the exchange of best practice between national authorities. This would also include promoting mutual assistance between the Member States by integrating and completing the existing legal framework. Furthermore, this would cover issues such as training, information exchange and longer term strategic thinking at Community level.
92. Development of this overall Community framework for national control systems would clearly be a task for the Commission and the Member States working together. The experience of the FVO will be an essential element in its development.
93. Since the establishment of the Single Market, the importance of having effective and harmonised health controls at the external borders of the European Union has become very clear. The current system, based on border inspection posts (BIPs) under the control of individual Member State authorities, only covers products of animal origin. Furthermore it fails to provide a sufficiently well co-ordinated approach to border checks. The legal basis for border checks needs to cover all products, and to identify a more effective Community-level control system.
94. It is necessary to consider whether the Commission needs to be given additional powers, in support of existing infringement procedures, where controls reveal significant non-compliance with EU rules. This must allow, in particular, rapid action to be taken in the face of immediate consumer health risks, and be based upon an effective and transparent follow-up of FVO inspection reports. As appropriate, it should also be possible to withhold Community financial support, or to reclaim funding already allocated.

## CHAPTER 7: CONSUMER INFORMATION

### *Risk communication*

Risk communication should not be a passive transmission of information, but should be interactive, involving a dialogue with and feedback from all stakeholders.

95. Risk communication consists of information exchange between concerned parties on the nature of the risk and the measures to control this risk. This is a fundamental responsibility for public authorities when managing public health risks. This can only function correctly if risk assessments and risk management decisions are transparent and public. Since 1997, the Commission has implemented a new approach to ensure transparency by making available to the public all information on scientific advice and on inspections and controls. This policy is a key element in risk communication and public confidence and has therefore to be actively pursued.
96. In all aspects related to food safety, it is essential that the consumer is a fully recognised stakeholder and that consumer concerns are taken into account by
- consulting the public on all aspects of food safety
  - providing a framework for discussions (public hearings) between scientific experts and consumers
  - facilitating trans-national consumer dialogue both at European and at global level.
97. It is important that all steps in policy making are taken in full openness. However good a new system may be, without this transparency the consumers will not be able to follow the development of the new measures and fully appreciate the improvements which they bring. Transparency will result in the necessary public scrutiny and ensure democratic control and accountability.
98. Finally, a more pro-active approach needs to be introduced concerning the communication of unavoidable risks for certain parts of the population. For instance women of childbearing age, pregnant women, infants, the elderly and immunodeficient people should be warned more actively about the possible risks of certain foods.

### *Labelling and advertising*

Consumers are to be provided with essential and accurate information so that they can make informed choices.

99. Binding labelling rules must, therefore, ensure that the consumer has the information on the product characteristics that determines choice, composition and storage and use of a product. Operators should be free to provide more information on the label, provided this information is correct and not misleading.

Within the WTO, labelling has become a trade policy issue in many different fields, including food safety, in relation to both the TBT and the SPS agreements. The Community has therefore indicated that it will pursue multilateral guidelines on

labelling. The guidelines should serve to avoid unnecessary disputes. This is of particular interest for the Community given our position on the consumer's right to know.

100. Further to the ongoing **codification of the Labelling Directive**, the Commission intends to propose a new amendment which would remove the current possibility not to indicate the components of compound ingredients, where they form less than 25% of the final product. Full ingredient labelling will not only ensure optimal consumer information as to the composition of a food product but will at the same time ensure the necessary information for those consumers who for health or ethical reasons have to, or want to, avoid certain ingredients. In this context, the problem of carry-over of additives still needs to be considered. Furthermore, for ingredients that are known allergens, but where only the name of the category needs to be indicated, an indication as to the presence of such allergens will be considered in order to enable susceptible consumers to avoid such products.
101. The Labelling Directive prohibits the attribution to any foodstuff of the property of preventing, treating or curing a human disease or reference to such properties. The Commission continues to consider that labelling and advertising of a foodstuff should not contain such health claims. It is indeed true that a good balanced diet is a prerequisite for good health, but claims that the intake of food can prevent, treat or cure one disease or another could in fact lead consumers to unbalanced dietary choices. The Commission will however consider whether specific provisions should be introduced in EU law to govern "functional claims" (for example claims related to beneficial effects of a nutrient on certain normal bodily functions) and "nutritional claims" (such as claims which describe the presence, absence or the level of a nutrient, as the case may be, contained in a foodstuff or its value compared to similar foodstuffs). Furthermore, the Commission will consider the need of bringing the requirements of the Nutrition Labelling Directive into line with consumer needs and expectations.
102. Complementary to the approach to labelling of foodstuffs, the means of redress that consumers and competitors enjoy against **misleading advertising messages** should be extended to allegations related to the above-mentioned types of claims. The Commission will make a proposal in this respect to amend the Misleading Advertising Directive and will ensure that advertising and labelling provisions in respect of claims provide for a coherent legislative framework.
103. The Commission will further consider the opportunity to revise or introduce specific labelling provisions for certain categories of foods. Specific rules, such as the obligatory indication of place of origin for fresh fruit, which provide better information to the consumer on these products, are not in contradiction with the general rules. The Commission will also clarify the provisions governing the labelling of **novel food**, and, in particular, products derived from genetically modified organisms, and will take an initiative with regard to the labelling of additives produced through genetic engineering and to the labelling of food and food ingredients produced without genetic engineering (so-called "GMO-free food").

## *Nutrition*

Consumers show a rising interest in the nutritional value of the food they purchase, and there is a growing need to avail consumers of correct information about the food they consume.

104. Ensuring the protection of public health is not restricted to chemical, biological and physical safety of food. It should also aim at ensuring the intake of essential nutrients while limiting intake of other elements in order to avoid adverse health effects, including anti-nutritional effects. Scientific information has shown that an adequate and varied diet are very important factors in maintaining good health and overall well being. This may be particularly true now that new types of products are appearing on the market with modified nutritional value, which can influence the behaviour and well being of consumers either favourably or unfavourably. In addition, the information which would allow the consumer to make the correct choices is not systematically available in a clear and accessible way.
105. In respect of **dietetic foods** (i.e. foods intended to satisfy the particular nutritional requirements of specific groups of the population), the Commission will elaborate a specific Directive on foods intended to meet the needs resulting from intense muscular effort. It will also prepare a report on foods intended for persons suffering from diabetes, and define the conditions for making the claims “low-sodium” or “sodium-free” and “gluten-free”. The Commission will also submit to Council and Parliament two proposals for Directives on **food supplements** (i.e. concentrated sources of nutrients such as vitamins and minerals) and **fortified foods** (i.e. and foods to which nutrients have been added). Finally, purity criteria will have to be laid down for nutritional substances which are added to food for particular nutritional use or which are present in food supplements and foods to which nutrients are added.
106. A number of actions at Community level have been organised in the context of the “Fourth and Fifth Research and Development Framework Programme”. These actions provide some of the components which should be relevant to a nutritional policy. The Commission is considering the development of a comprehensive and coherent **nutritional policy** and will present an action plan for that purpose.
107. A number of aspects that have already been raised in this White Paper also apply to the establishment of a policy in this field. Successful implementation of a nutritional policy requires in particular efficient monitoring, data collection and data analysis. Information on food intake, diets and nutritional status should therefore be included in national and Community data collection systems. In addition, research and studies on nutrition should be promoted, scientific advice should be actively sought and the results thereof be made available in full transparency. Another important aspect of a nutritional policy is efficient and correct consumer information; in this respect, the Nutrition Labelling Directive plays a role. A special effort to establish appropriate information tools, including nutritional labelling but also information campaigns, should be put in place. Council Recommendations for dietary guidelines will be proposed. Appropriate communication to consumers will have to be ensured.

## CHAPTER 8: INTERNATIONAL DIMENSION

The key principle for imported foodstuffs and animal feed is that they must meet health requirements at least equivalent to those set by the Community for its own production.

108. The Community is the world's largest importer/exporter of food products, and trades with countries all over the world in an increasing diversity of food products. With this extensive trade in food products, food safety cannot be seen as solely an internal policy question. Exactly the same concerns as regards zoonoses, contaminants and other concerns apply to food products in international trade, whether these products are to be imported into the Community or exported from the Community. In order to ensure that these requirements are met, our WTO obligations require either that we base those measures on international standards or in so far as they are not based on international standards, that the measures are scientifically warranted. In cases where scientific evidence is insufficient, provisional measures may be adopted on the basis of available pertinent information.
109. The international framework as regards food safety has developed significantly through the enhanced role of certain international organisations such as the Codex Alimentarius and the International Office of Epizootics (OIE) under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO).
110. The Community plays an active role in the SPS Committee, and in other WTO committees, to ensure that the international framework encourages and defends the rights of countries to maintain high public health standards for food safety. In this context, the Community has the objective to clarify and strengthen the existing WTO framework for the use of the precautionary principle in the area of food safety, in particular with a view to finding an agreed methodology for the scope of action under that principle. The adoption of a global approach towards food safety as set out in the present White Paper will contribute to re-enforce the role of the Community in WTO.

Some third countries use sanitary and phyto-sanitary arguments without scientific justification in order to refuse the access of Community food products to their market. The SPS Agreement provides the right to obtain the risk assessment on which a third country measure is based. Such risk assessment should be carefully analysed in due time, in order to detect inconsistencies and weaknesses and to open the procedure of consultation foreseen by the SPS Agreement.
111. Work on the accession of the European Community to the Codex Alimentarius and the International Office of Epizootics will be pursued rapidly.
112. Consumers all over the world have the right to expect exported Community products to meet the same high standards that apply within the Community. The level of food safety required for products exported from the Community should therefore be at least that required for products placed on the market within the Community. The

need to establish Community export certification arrangements to ensure this will be examined.

113. The Community has already negotiated a number of bilateral international agreements on sanitary measures, which include the recognition of the equivalence of the sanitary measures applied by third countries. The possibility of negotiating further agreements will be explored. This includes the need for technical co-operation as well as co-operation on RTD with third countries. In order to meet the obligations laid down in the SPS agreement, the Community must ensure that all legislation concerning SPS measures provides for the possibility to recognise equivalency also on a case-by-case basis.
114. The process of negotiating agreements with neighbouring countries and territories, for example Norway, Switzerland, Andorra, under which they take on the Community 'acquis' for food safety and other sanitary and phyto-sanitary requirements, shall be continued.
115. As regards the future enlargement of the Community, it is essential that the candidate countries have implemented the basic principles of the Treaty, food safety legislation and control systems equivalent to those in place within the Community. This represents a significant challenge to those countries, both in terms of the upgrading of their production and processing facilities, and the implementation of the necessary legislation and control arrangements. The existing framework of Community assistance will assist, where necessary, the candidate countries to adopt the necessary legislation, including the establishment of relevant institutions to implement and enforce this legislation, in accordance with the priorities identified in the Accession Partnerships.

## CHAPTER 9: CONCLUSIONS

116. The implementation of all the measures proposed in this White Paper will enable Food Safety to be organised in a more co-ordinated and integrated manner with a view to achieving the highest possible level of health protection.

Legislation will be reviewed and amended as necessary in order to make it more coherent, comprehensive and up-to-date. Enforcement of this legislation at all levels will be promoted.

The Commission believes that the establishment of a new Authority, which will become the scientific point of reference for the whole Union, will contribute to a high level of consumer health protection, and consequently will help to restore consumer confidence.

117. The success of the measures proposed in this White Paper is intrinsically linked to the support of the European Parliament and the Council. Their implementation will depend on the commitment of the Member States. This White Paper also calls for strong involvement of the operators, who bear the prime responsibility for the daily application of the requirements for food safety.

Greater transparency at all levels of Food Safety policy is the golden thread throughout the whole White Paper and it will contribute fundamentally to enhancing consumer confidence in EU Food Safety policy.

## ANNEX

### Action Plan on Food Safety<sup>3</sup>

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
<b>I. Priority measures</b>					
1.	Proposal for setting up a European Food Authority	To set up an independent European Food Authority.	29	September 2000	December 2001
2.	Proposal for laying down procedures in matters of food safety	To introduce a comprehensive safeguard measure covering the whole food chain, including feed.  To establish a comprehensive Rapid Alert System covering all feed and food emergencies with harmonised requirements and procedures, including third countries on the basis of reciprocity.	80	September 2000	December 2001
3.	Proposal for a General Food Law Directive	To establish food safety as the primary objective of EU food law.  To lay down the common principles underlying food legislation (in particular: scientific basis, responsibility of producers and suppliers, traceability along the food chain, efficient controls and effective enforcement).	67	September 2000	December 2001

<sup>3</sup> This action plan does not include all of the on-going actions resulting from the obligations in EU legislation.

<b>No</b>	<b>Action</b>	<b>Objective</b>	<b>REF. IN WP</b>	<b>Adoption by Commission</b>	<b>Adoption by Council/ Parliament</b>
		To increase transparency, consistency and legal security.			
4.	Proposal for a Regulation on official food and feed safety controls	<p>To establish a Community framework for official controls on all food and feed safety aspects along the feed and food chain by:</p> <ul style="list-style-type: none"> <li>-merging and completing existing rules for national controls and Community controls and inspections within the EU, at the borders and in third countries.</li> <li>-integrating existing monitoring and surveillance systems so as to establish a comprehensive and effective food safety monitoring and surveillance system from farm to table.</li> <li>-establishing a framework for organising consolidated annual programs for controls of foodstuffs.</li> <li>-merging existing Community rules on mutual assistance and administrative co-operation.</li> <li>-creating a Community approach towards a financial support for official controls.</li> </ul>	Ch. 6	December 2000	December 2001
5.	Proposal for a Regulation on feed	To establish animal and public health as the primary objective of EU feed legislation	69	December 2001	December 2002
		To lay down common principles underlying feed legislation (in particular: scientific basis, responsibility of producers and suppliers, systematic implementation of hazard analysis and			

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		critical control points (HACCP), traceability, efficient controls and enforcement). To recast all existing measures on feedingstuffs so as to create a comprehensive legislative tool increasing transparency, consistency and legal security.			
6.	Proposal for a Regulation on novel feed	To put into plan a centralised system for the authorisation of use in animal nutrition of non conventional products, in particular of GMOs and GMO derived feedstuffs.	69	September 2000	December 2001
7.	Amendment to the Annex of Directive 96/25/EC on the circulation of feed materials	To amend the definitions of feed materials listed in the Annex to Decision 96/25/EC, particularly with regard to oils and fats and animal products	69	September 2000	-
8.	Proposal for a Regulation on hygiene	To recast horizontal and vertical Directives on hygiene of food of plant and animal origin. To clarify responsibility of food operators and to introduce the systematic implementation of HACCP. To apply hygiene rules at all levels of the food chain, including primary production.	72	June 2000	June 2002
9.	Amendment to Decision 98/272/EC on epidemio-surveillance of transmissible spongiform encephalopathies (TSEs)	To reinforce TSE surveillance including a study on mandatory testing (rapid post-mortem test) on targeted groups of cattle. To reinforce TSE surveillance in small ruminants	71	March 2000 September 2000	- -
10.	Decision on the Member State and	To ensure efficacy of residue testing in Member States and	74	December 2000	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
	third country residue programmes	third countries.			
11.	Proposal for amending Directive 89/107/EEC on food additives	To confer implementing powers for maintaining the lists of permitted food additives and to lay down specific provisions in respect of enzymes	77	December 2000	December 2001
12.	Proposal for amending Directive 95/2/EC on food additives other than colours and sweeteners	To update and revise the list of food additives other than colours and sweeteners	77	December 2000	December 2001
13.	Proposal for amending Directive 88/388/EEC on flavourings for use in foodstuffs	To clarify the scope and update definitions, to set maximum limits for toxic substances and to confer implementing powers to the Commission	77	December 2000	December 2001
14.	Proposal for amending Regulation 258/97 on novel foods and novel food ingredients	To make the necessary adaptations in the light of the conclusions of the report on the implementation of the Regulation and in accordance with the new regulatory framework of Directive 90/220/EEC	76	December 2001	December 2002
15.	Regulation on the labelling of GMO-free foodstuffs	To give operators the possibility to use labelling claims referring to the absence of use of genetic engineering techniques for the production of foodstuffs	76 103	September 2000	-
16.	Proposal for amending Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs	To remove the possibility not to indicate the components of compound ingredients forming less than 25 % of the final product and lay down a list of allergenic substances	100	December 2000	December 2001

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
17.	Proposals for Commission Directives to fix maximum residue levels (MRLs) of pesticides in food and agricultural commodities	To fix MRLs for pesticides residues for, inter alia: 36 pesticides with existing open positions in the residues directives that will automatically go to zero in July 2000 unless the Commission adopts other values To set MRLs at zero for 8 pesticides that were excluded from Annex I to Directive 91/414/EEC To set MRLs for new active substances included in Annex I to Directive 91/414/EEC	74	June 2000  September 2000  Continuous process	-
18.	Communication on an action plan on nutrition policy	To develop a comprehensive and coherent nutrition policy	106	December 2000	-
<b>II. Feedingstuffs</b>					
19.	Proposal for amending Directive 70/524/EEC concerning additives in feedingstuffs	To consolidate the Directive. To fix maximum residue limits for additives. To clarify certain aspects of the procedure (evaluation reports) and the authorisation (generic versus specific).	69	July 2001	December 2002
20.	Amendment to Decision 91/516/EEC on the list of ingredients the use of which is forbidden in compound feedingstuffs	To introduce the changes deemed necessary to the list of feed materials the use of which must be prohibited in compound feedingstuffs, with particular reference to certain by-products from fat processing.	69	June 2000	-
21.	Amendment to the Annex of Directive 1999/29/EC on the undesirable substances and products	To fix the maximum limits of dioxins for oils and fats, and for other or all feed materials. To collect information on background contamination of PCB and dioxin-like PCB,	69	December 2000	-

<b>No</b>	<b>Action</b>	<b>Objective</b>	<b>REF. IN WP</b>	<b>Adoption by Commission</b>	<b>Adoption by Council/ Parliament</b>
	in animal nutrition	MRLs for other potential contaminants of feedingsstuffs will also be fixed.			
22.	Proposal for amending Directive 96/25/EEC on the circulation of feed materials	Following reflection to decide whether an exclusive positive list of authorised feed materials should be established	69	December 2002	December 2003
23.	Proposal for amending Directive 95/53/EEC fixing the principles governing the organisation of official inspections in the field of animal nutrition	To foresee a legal basis for a safeguard clause in case of appearing or spreading hazards related to feedingsstuffs likely to pose a risk to human health. To introduce an obligation for Member States to carry out a monitoring programme for contaminants in feedingsstuffs. To introduce a Rapid Alert System for feed to be integrated in the Rapid Alert System for food. (to be integrated in action 2)	69	March 2000	March 2001
24.	Proposal for amending Directive 79/373/EEC on the marketing of compound feedingsstuffs	To review current provisions for the labelling of compound feedingsstuffs	69	January 2000	March 2001
25.	Proposal for amending Directive 95/69/EEC laying down the conditions and arrangements for approving and registration of certain establishments and intermediaries operating in the feedingsstuffs sector	To introduce provisions for: – Approval or registration of manufacturers of compound feedingsstuffs – Approval of manufacturers of certain feed materials – Improving traceability of feed materials and identification of critical points – Establishing a code for good manufacturing practice for	69	December 2000	December 2001

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		animal feeding			
<b>III. Zoonoses</b>					
26.	Proposal for amending Directive 92/117/EEC on zoonoses	To improve monitoring and reporting system for diseases transmissible from animals to man and to reduce prevalence of specified zoonoses (e.g. salmonella)	70	June 2000	June 2002
27.	Decision on Member State and third country programmes for the control of zoonotic agents on animal products exported to the Community	To ensure that Member States implement adequate measures to control zoonotic agents To ensure that third country products are controlled to the same level as Community products	70	December 2002	-
<b>IV. Animal health</b>					
28.	Proposal for a Regulation on animal health requirements for products of animal origin	To recast existing animal health rules for products of animal origin	70	June 2000	June 2002
29.	Increase budgetary allocation for actions provided for in Council Decision 90/424/EEC on expenditure in the veterinary field	To enable actions necessary to improve animal disease eradication (brucellosis, tuberculosis etc) To create a task force for monitoring disease eradication in the Member States	70	May 2000	December 2000
<b>V. Animal by-products</b>					
30.	Proposal for amending Directives 90/667/EEC and 92/118/EEC on animal waste and derived products	To recast existing measures of animal by-products not destined for human consumption (meat and bone meal, rendered fats, manure etc.) To ensure that only animal by-products derived from animals declared fit for human consumption can enter the animal feed	69	June 2000	December 2001

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		chain. To clarify responsibility of animal by-products operators To tighten up official control and to improve traceability			
<b>VI. BSE/TSE</b>					
31.	Decision on classification according to BSE status	Classification of individual countries in view of changes in BSE status (post-mortem tests)	71	June 2000	-
32.	Amendment to Decision 94/381 (feed ban) Decision on the removal of specified risk materials (SRMs) replacing Decision 97/534/EC.	To amend the Decision in the light of recent scientific opinions  To replace Decision 97/534/EC laying down the rules on the prohibition of the use of materials that present risks as regards TSEs. Amendment of the TSE framework proposal accordingly.	71	March 2000	-
33.	Decision on the harmonisation of BSE rules for imports of live animals and products from third countries	To harmonise the BSE import rules for other third countries	71	September 2000	-
<b>VII. Hygiene</b>					
34.	Report on the testing of residues in Member States and third countries	To evaluate the performance of national and third country residue programmes.	74	December 2000	-
35.	Modification of the Annex to Council Directive 96/23/EC on residue monitoring	To re-enforce the monitoring and detection of PCBs and dioxines in food of animal origin.	74	June 2000	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
36.	Proposal for a Decision to review the ante-and post-mortem procedures for animals and meat	To make ante- and post-mortem inspections risk based, and to review inspection methods applied at present	72	September 2001	December 2002
37.	Decision on microbiological standards on certain foods	To fix the maximum limits of undesirable micro-organisms in foodstuffs, after risk assessment.	72	December 2001	-
<b>VIII. Contaminants</b>					
38.	Amendment to Regulation No 194/97 setting maximum limits for certain contaminants	To set up limits for several contaminants : ochratoxin A, cadmium, lead, 3-MCPD, dioxin and, possibly, PCBs.	73	December 2000	-
<b>IX. Food additives and flavourings</b>					
39.	Report on the intake of food additives	To provide an overview of the intake of food additives in the European Union	77	June 2000	-
40.	Proposal for amending Directive 94/35/EC on sweeteners	To update and revise the list of sweeteners for use in foodstuffs	77	December 2000	December 2001
41.	Amendment to Directives 95/31/EC, 95/45/EC and 96/77/EC on purity criteria for food additives (including sweeteners and colours)	To update and complete existing provisions. To introduce a general requirement for a new safety evaluation for permitted additives made from new sources or with new methods.	77	September 2000	-
42.	Amendment 81/712/EEC to laying down Community methods of analysis for Directive	To replace existing provisions with a set of general principles and a reference to other similar provisions	77	June 2001	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
	the respect of purity criteria				
43.	Decision amending the Community register of flavouring substances used in or on foodstuffs	To update the register	77	December 2000	-
44.	Regulation establishing a programme for the evaluation of flavouring substances	To set priorities and time limits for evaluation	77	June 2000	-
45.	Proposal for a Regulation on additives used in flavourings	To lay down a list of additives authorised for use in flavourings	77	June 2001	December 2002
46.	Proposal for a Regulation on smoke flavourings	To lay down the conditions for the production of smoke flavourings	77	June 2001	December 2002
<b>X. Materials in contact with food</b>					
47.	Proposal for amending Directive 89/109/EEC on food contact materials	To allow the update of specific Directives through regulatory procedure and to change or add provisions on the labelling of contact materials	78	December 2000	December 2001
48.	Amendment to Directive 90/128/EEC on food contact plastics	To update the list of authorised food contact plastics	78	December 2000	-
49.	Practical guide on food contact materials	To provide guidance on the application of Community provisions relating to contact materials	78	December 2000	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
<b>XI. Novel foods/Genetically modified organisms</b>					
50.	Regulation clarifying the authorisation procedure for novel foods and novel food ingredients	To clarify and make more transparent the procedure laid down in Regulation 258/97 for the authorisation of novel foods and novel food ingredients	76	September 2000	-
51.	Report on the implementation of Regulation 258/97 on novel foods and novel foods ingredients	To examine the application of the "novel food" legislation and assess its impact on public health, consumer protection and information, and the functioning of the internal market	76	December 2001	-
52.	Regulation on the labelling of food containing or derived from genetically modified organisms	To further harmonise the provisions governing the labelling of food, additives and flavourings containing or derived from GMO material	76 103	September 2000	-
<b>XII. Irradiation of food</b>					
53.	Proposal for amending Directive 1999/3/EC on foods and food ingredients treated by irradiation	To complete the Community list of foods and food ingredients which may be treated with ionising radiation	79	December 2000	June 2002
54.	Decision establishing the list of irradiation facilities	Publication of the list of irradiation facilities authorised in the Member States and those in third countries which have been approved by the EU	79	December 2000	-
<b>XIII. Diabetic foods/food supplements/fortified foods</b>					
55.	Directive on foods intended for intense muscular effort	To lay down specific provisions for foods intended to meet the expenditure of intense muscular effort, especially by sportsmen	105	December 2001	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
56.	Report on foods intended for persons suffering from diabetes	To assess the need for specific provisions for food for people with carbohydrate-metabolism disorders	105	December 2001	-
57.	Proposal for amending Directive 89/398/EEC on dietetic foods	To define the conditions for making the claims "low-sodium" or "sodium-free", and "gluten-free".	105	December 2001	December 2002
58.	Directive on purity criteria for nutritional substances in food for particular nutritional use	To lay down purity criteria for nutritional substances which are added to food for particular nutritional use or which are present in food supplements and foods to which nutrients are added	105	December 2002	-
59.	Directive on substances added for nutritional purposes in foods for particular nutritional uses	To establish a positive list of the various substances which may be added for nutritional purposes in foods for particular nutritional uses	105	June 2000	-
60.	Proposal for a Directive on food supplements	To lay down common criteria for marketing concentrated source of nutrients (vitamins and minerals)	105	March 2000	March 2001
61.	Proposal for a Directive on fortified foods	To lay down provisions for marketing foods to which nutrients such as vitamins and minerals have been added	105	September 2000	September 2001
62.	Amendment to Directive 91/321/EEC on infant formulae and follow-on formulae	To set up a list of pesticides not to be used in agricultural products intended for use in these formulae	105	November 2000	-
63.	Amendment to Directive 96/5/EEC on processed baby foods	To set up a list of pesticides not to be used in agricultural products intended for infants and young children	105	November 2000	-
64.	Amendment to Directive 80/777/EEC on mineral waters	To lay down a list of constituents of mineral waters and the conditions of use for the treatment of certain mineral waters with ozone enriched air	79	September 2000	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
<b>XIV. Labelling of food</b>					
65.	Proposal for amending Directive 79/112/EEC on the labelling, presentation and advertising of foodstuffs	To specify the conditions under which “functional claims” and “nutritional claims” may be made	101	July 2001	July 2002
66.	Proposal for amending Directive on nutrition labelling	To bring the provisions on nutrition labelling into line with consumer needs and expectations	101	July 2001	July 2002
67.	Proposal for amending Directive on misleading advertising	To clarify the scope of the Directive with regard to claims concerning in particular food, health and the environment	102	December 2000	July 2002
<b>XV. Pesticides</b>					
68.	Regulation on monitoring of pesticide residues in food	To improve co-ordination and quality of monitoring of pesticides in foods	74	March 2000	-
69.	Recommendation for a co-ordinated Community Monitoring Programme for pesticides residues in Foods for the year 2001	Recommendation for a co-ordinated Community Monitoring Programme for pesticides residues in Foods for the year 2001	74	December 2000	-
70.	Commission Decisions for pesticide active substances including in or excluding from Annex I to Directive 91/414/EEC	Pesticides active substances evaluated in the framework of Directive 91/414/EEC need, after the evaluation to be either included in Annex I or withdrawn from the market.	74	Continuous process	-
71.	Regulation on the evaluation of existing pesticides active substances	To fix a priority list of substances for evaluation at Community level; to introduce a notification procedure for all remaining	74	December 2000	-

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
		substances To lay out the ground rules for the final stage of the Community evaluation of active substances		September 2001	
72.	Proposal for amending Directive 91/414/EEC	<i>Inter alia</i> , to <ul style="list-style-type: none"> <li>- extend competence to include genetically modifies organisms,</li> <li>- allow a harmonised Community regime to charge fees for the evaluation of new pesticides active substances</li> <li>- develop a fast-track procedure for low-risk substances,</li> <li>- clarify problems relating to data protection, work-sharing, parallel imports, classification and labelling, borderlines with biocides legislation etc.</li> </ul>	74	June 2002	June 2003
73.	Directive to develop and adopt the Annexes to Directive 91/414/EEC	To develop Community data requirements for non-GMO microbial plant protection products To develop a harmonised set of risk and safety phrases To establish uniform principles for assessment of safety of micro-organisms as plant protection products	74	December 2000 December 2001 December 2001	-
<b>XVI. Nutrition</b>					
74.	Proposal for Council Recommendations on European dietary guidelines	To support the Member States in their development of nutrition policy at the national level To streamline the flow of information to enable consumers to make informed choices	107	December 2000	December 2001

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
<b>XVII. Seeds</b>					
75.	Proposal for a Regulation concerning environmental risk assessment in respect of genetically modified plant varieties	To lay down the specific conditions for the conduct of the risk assessment applicable to genetically modified varieties of agricultural and vegetable plant species, as required under Council Directive 98/95/EC, as required under Council Directive 98/95/EC.	69 76	March 2001	March 2002
76.	Directives on environmental risk assessment and the assessment principles laid down in Regulation 258/97, in respect of genetically modified plant varieties	To provide for technical and scientific guidance for the conduct of the assessment applicable to genetically modified varieties of agricultural and vegetable plant species.	69 76	June 2001	-
77.	Directives amending the Annexes of the Directives on the marketing of seeds	To lay down the details of the labelling requirement as established by Council Directive 98/95/EC for seeds of genetically modified plant varieties of agricultural and vegetable plant species. To lay down the growing conditions and other requirements for purity concerning the adventitious presence of genetically modified seeds in seed lots of traditional plant varieties	69 76	December 2000	-
78.	Proposal for a Directive amending Directive 68/193/EEC on the marketing of material for the vegetative propagation of the vine.	To lay down assessment procedures and labelling requirements for propagating material of genetically modified varieties of the vine	69 76	January 2000	June 2001
<b>XVIII. Supporting measures</b>					
79.	Proposal for a Regulation on the	To provide for a uniform legal basis to ensure adequate	Ch. 3	December 2000	December 2001

No	Action	Objective	REF. IN WP	Adoption by Commission	Adoption by Council/ Parliament
	financial support for food safety actions at Community level	Community financial support of actions necessary to enhance food safety (liaison and reference laboratories, exchange of officials, training of officials etc.)			
80.	Proposal for a Decision establishing a data base of dietary intakes across the whole EU population.	To create a basis of exposure data used in risk assessments and nutrition	74	December 2000	December 2001
81.	Decision on an Advisory Committee on Food Safety	To improve involvement of all stakeholders in the Community food safety policy by streamlining the existing Advisory Committees.	11	December 2000	-
<b>XIX. Third country policy/ international relations</b>					
82.	Proposals for agreements with third countries	To establish further agreements with third countries on veterinary and/or phyto-sanitary issues	113	Continuous process	-
83.	Proposal for accession of the European Community to Codex Alimentarius	To reinforce the participation of the European Union in the elaboration of international food standards	111	May 2000	December 2000
84.	Proposal for accession of the European Community to OIE	To reinforce the participation of the European Union in the elaboration of international animal health standards.	111	December 2000	December 2001

**Appendix 7**  
**European Union**  
**Regulation on Food Safety**  
歐盟食物安全監管規條

## I

(Acts whose publication is obligatory)

**REGULATION (EC) No 178/2002 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 28 January 2002  
laying down the general principles and requirements of food law, establishing the European Food  
Safety Authority and laying down procedures in matters of food safety**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 37, 95, 133 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

Having regard to the opinion of the Committee of the Regions <sup>(3)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(4)</sup>,

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.
- (4) There are important differences in relation to concepts, principles and procedures between the food laws of

the Member States. When Member States adopt measures governing food, these differences may impede the free movement of food, create unequal conditions of competition, and may thereby directly affect the functioning of the internal market.

- (5) Accordingly, it is necessary to approximate these concepts, principles and procedures so as to form a common basis for measures governing food and feed taken in the Member States and at Community level. It is however necessary to provide for sufficient time for the adaptation of any conflicting provisions in existing legislation, both at national and Community level, and to provide that, pending such adaptation, the relevant legislation be applied in the light of the principles set out in the present Regulation.
- (6) Water is ingested directly or indirectly like other foods, thereby contributing to the overall exposure of a consumer to ingested substances, including chemical and microbiological contaminants. However, as the quality of water intended for human consumption is already controlled by Council Directives 80/778/EEC <sup>(5)</sup> and 98/83/EC <sup>(6)</sup>, it suffices to consider water after the point of compliance referred to in Article 6 of Directive 98/83/EC.
- (7) Within the context of food law it is appropriate to include requirements for feed, including its production and use where that feed is intended for food-producing animals. This is without prejudice to the similar requirements which have been applied so far and which will be applied in the future in feed legislation applicable to all animals, including pets.
- (8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.

<sup>(1)</sup> OJ C 96 E, 27.3.2001, p. 247.

<sup>(2)</sup> OJ C 155, 29.5.2001, p. 32.

<sup>(3)</sup> Opinion delivered on 14 June 2001 (not yet published in the Official Journal).

<sup>(4)</sup> Opinion of the European Parliament of 12 June 2001 (not yet published in the Official Journal), Council Common Position of 17 September 2001 (not yet published in the Official Journal) and Decision of the European Parliament of 11 December 2001 (not yet published in the Official Journal). Council Decision of 21 January 2002.

<sup>(5)</sup> OJ L 229, 30.8.1980, p. 11. Directive repealed by Directive 98/83/EC.

<sup>(6)</sup> OJ L 330, 5.12.1998, p. 32.

- (9) It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.
- (10) Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.
- (11) In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production.
- (12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.
- (13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety.
- (14) For the same reason, it is necessary to consider other practices and agricultural inputs at the level of primary production and their potential effect on the overall safety of food.
- (15) Networking of laboratories of excellence, at regional and/or interregional level, with the aim of ensuring continuous monitoring of food safety, could play an important role in the prevention of potential health risks for citizens.
- (16) Measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
- Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.
- (17) Where food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis — risk assessment, risk management, and risk communication — provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.
- (18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
- (19) It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
- (20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.
- (21) In those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community.
- (22) Food safety and the protection of consumer's interests is of increasing concern to the general public, non-governmental organisations, professional associations, international trading partners and trade organisations. It is necessary to ensure that consumer confidence and the confidence of trading partners is secured through the open and transparent development of food law and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health.

- (23) The safety and confidence of consumers within the Community, and in third countries, are of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.
- (24) It is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.
- (25) It is necessary to establish the general principles upon which food and feed may be traded and the objectives and principles for the contribution of the Community to developing international standards and trade agreements.
- (26) Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.
- (27) It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.
- (28) Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.
- (29) It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.
- (30) A food business operator is best placed to devise a safe system for supplying food and ensuring that the food it supplies is safe; thus, it should have primary legal responsibility for ensuring food safety. Although this principle exists in some Member States and areas of food law, in other areas this is either not explicit or else responsibility is assumed by the competent authorities of the Member State through the control activities they carry out. Such disparities are liable to create barriers to trade and distort competition between food business operators in different Member States.
- (31) Similar requirements should apply to feed and feed business operators.
- (32) The scientific and technical basis of Community legislation relating to the safety of food and feed should contribute to the achievement of a high level of health protection within the Community. The Community should have access to high-quality, independent and efficient scientific and technical support.
- (33) The scientific and technical issues in relation to food and feed safety are becoming increasingly important and complex. The establishment of a European Food Safety Authority, hereinafter referred to as 'the Authority', should reinforce the present system of scientific and technical support which is no longer able to respond to increasing demands on it.
- (34) Pursuant to the general principles of food law, the Authority should take on the role of an independent scientific point of reference in risk assessment and in so doing should assist in ensuring the smooth functioning of the internal market. It may be called upon to give opinions on contentious scientific issues, thereby enabling the Community institutions and Member States to take informed risk management decisions necessary to ensure food and feed safety whilst helping avoid the fragmentation of the internal market through the adoption of unjustified or unnecessary obstacles to the free movement of food and feed.
- (35) The Authority should be an independent scientific source of advice, information and risk communication in order to improve consumer confidence; nevertheless, in order to promote coherence between the risk assessment, risk management and risk communication functions, the link between risk assessors and risk managers should be strengthened.

- (36) The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide-ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. However, it is necessary to ensure that the Authority focuses on food safety, so its mission in relation to animal health, animal welfare and plant health issues that are not linked to the safety of the food supply chain should be limited to the provision of scientific opinions. The Authority's mission should also cover scientific advice and scientific and technical support on human nutrition in relation to Community legislation and assistance to the Commission at its request on communication linked to Community health programmes.
- (37) Since some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be assessed by the Authority in accordance with the relevant legislation.
- (38) In order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC<sup>(1)</sup> and without prejudice to the procedures established therein.
- (39) The Authority should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.
- (40) The confidence of the Community institutions, the general public and interested parties in the Authority is essential. For this reason, it is vital to ensure its independence, high scientific quality, transparency and efficiency. Cooperation with Member States is also indispensable.
- (41) To that effect the Management Board should be appointed in such a way as to secure the highest standard of competence, a broad range of relevant expertise, for instance in management and in public administration, and the broadest possible geographic distribution within the Union. This should be facilitated by a rotation of the different countries of origin of the members of the Management Board without any post being reserved for nationals of any specific Member State.
- (42) The Authority should have the means to perform all the tasks required to enable it to carry out its role.
- (43) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations, appoint members of the Scientific Committee and Scientific Panels and appoint the Executive Director.
- (44) The Authority should cooperate closely with competent bodies in the Member States if it is to operate effectively. An Advisory Forum should be created in order to advise the Executive Director, to constitute a mechanism of exchange of information, and to ensure close cooperation in particular with regard to the networking system. Cooperation and appropriate exchange of information should also minimise the potential for diverging scientific opinions.
- (45) The Authority should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence. It is necessary to reorganise these Committees to ensure greater scientific consistency in relation to the food supply chain and to enable them to work more effectively. A Scientific Committee and Permanent Scientific Panels should therefore be set up within the Authority to provide these opinions.
- (46) In order to guarantee independence, members of the Scientific Committee and Panels should be independent scientists recruited on the basis of an open application procedure.
- (47) The Authority's role as an independent scientific point of reference means that a scientific opinion may be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Authority should be able to refuse or amend a request providing justification for this and on the basis of predetermined criteria. Steps should also be taken to help avoid diverging scientific opinions and, in the event of diverging scientific opinions between scientific bodies, procedures should be in place to resolve the divergence or provide the risk managers with a transparent basis of scientific information.

<sup>(1)</sup> Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

- (48) The Authority should also be able to commission scientific studies necessary for the accomplishment of its duties, while ensuring that the links established by it with the Commission and the Member States prevent duplication of effort. It should be done in an open and transparent fashion and the Authority should take into account existing Community expertise and structures.
- (49) The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the Authority should therefore be set up, in the form of a network coordinated by the Authority. A review of Community data collection networks already existing in the fields covered by the Authority is called for.
- (50) Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in the exercise of its policies. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention.
- (51) The establishment of the Authority should enable Member States to become more closely involved in scientific procedures. There should therefore be close cooperation between the Authority and the Member States for this purpose. In particular, the Authority should be able to assign certain tasks to organisations in the Member States.
- (52) It is necessary to ensure that a balance is struck between the need to use national organisations to carry out tasks for the Authority and the need to ensure for the purposes of overall consistency that such tasks are carried out in line with the criteria established for such tasks. Existing procedures for the allocation of scientific tasks to the Member States, in particular with regard to the evaluation of dossiers presented by industry for the authorisation of certain substances, products or procedures, should be re-examined within a year with the objective of taking into account the establishment of the Authority and the new facilities it offers, the evaluation procedures remaining at least as stringent as before.
- (53) The Commission remains fully responsible for communicating risk management measures. The appropriate information should therefore be exchanged between the Authority and the Commission. Close cooperation between the Authority, the Commission and the Member States is also necessary to ensure the coherence of the global communication process.
- (54) The independence of the Authority and its role in informing the public mean that it should be able to communicate autonomously in the fields falling within its competence, its purpose being to provide objective, reliable and easily understandable information.
- (55) Appropriate cooperation with the Member States and other interested parties is necessary in the specific field of public information campaigns to take into account any regional parameters and any correlation with health policy.
- (56) In addition to its operating principles based on independence and transparency, the Authority should be an organisation open to contacts with consumers and other interested groups.
- (57) The Authority should be financed by the general budget of the European Union. However, in the light of experience acquired, in particular with regard to the processing of authorisation dossiers presented by industry, the possibility of fees should be examined within three years following the entry into force of this Regulation. The Community budgetary procedure remains applicable as far as any subsidies chargeable to the general budget of the European Union are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors.
- (58) It is necessary to allow for the participation of European countries which are not members of the European Union and which have concluded agreements obliging them to transpose and implement the body of Community law in the field covered by this Regulation.
- (59) A system for rapid alert already exists in the framework of Council Directive 92/59/EEC of 29 June 1992 on general product safety<sup>(1)</sup>. The scope of the existing system includes food and industrial products but not feed. Recent food crises have demonstrated the need to set up an improved and broadened rapid alert system covering food and feed. This revised system should be managed by the Commission and include as members of the network the Member States, the Commission and the Authority. The system should not cover the Community arrangements for the early exchange of information in the event of a radiological emergency as defined in Council Decision 87/600/Euratom<sup>(2)</sup>.
- (60) Recent food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. Such a comprehensive approach to emergency food safety measures should allow effective action to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed.

<sup>(1)</sup> OJ L 228, 11.8.1992, p. 24.

<sup>(2)</sup> OJ L 371, 30.12.1987, p. 76.

- (61) Recent food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information. Therefore, revised procedures should take into account the Authority's responsibilities and should provide for its scientific and technical assistance in the form of advice in the event of a food crisis.
- (62) In order to ensure a more effective, comprehensive approach to the food chain, a Committee on the Food Chain and Animal Health should be established to replace the Standing Veterinary Committee, the Standing Committee for Foodstuffs and the Standing Committee for Feedingstuffs. Accordingly, Council Decisions 68/361/EEC <sup>(1)</sup>, 69/414/EEC <sup>(2)</sup>, and 70/372/EEC <sup>(3)</sup>, should be repealed. For the same reason the Committee on the Food Chain and Animal Health should also replace the Standing Committee on Plant Health in relation to its competence (for Directives 76/895/EEC <sup>(4)</sup>, 86/362/EEC <sup>(5)</sup>, 86/363/EEC <sup>(6)</sup>, 90/642/EEC <sup>(7)</sup> and 91/414/EEC <sup>(8)</sup>) on plant protection products and the setting of maximum residue levels.
- (63) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission <sup>(9)</sup>.
- (64) It is necessary that operators should have sufficient time to adapt to some of the requirements established by the present Regulation and that the European Food Safety Authority should commence its operations on 1 January 2002.
- (65) It is important to avoid confusion between the missions of the Authority and the European Agency for the Evaluation of Medicinal Products (EMA) established by Council Regulation (EEC) No 2309/93 <sup>(10)</sup>. Consequently, it is necessary to establish that this Regulation is without prejudice to the competence conferred on the EMA by Community legislation, including powers conferred by Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin <sup>(11)</sup>.
- (66) It is necessary and appropriate for the achievement of the basic objectives of this Regulation to provide for the approximation of the concepts, principles and procedures forming a common basis for food law in the Community and to establish a European Food Safety Authority. In accordance with the principle of proportionality as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve the objectives pursued,

HAVE ADOPTED THIS REGULATION:

## CHAPTER I

### SCOPE AND DEFINITIONS

#### Article 1

#### Aim and scope

1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

<sup>(1)</sup> OJ L 255, 18.10.1968, p. 23.

<sup>(2)</sup> OJ L 291, 19.11.1969, p. 9.

<sup>(3)</sup> OJ L 170, 3.8.1970, p. 1.

<sup>(4)</sup> OJ L 340, 9.12.1976, p. 26. Directive as last amended by Commission Directive 2000/57/EC (OJ L 244, 29.9.2000, p. 76).

<sup>(5)</sup> OJ L 221, 7.8.1986, p. 37. Directive as last amended by Commission Directive 2001/57/EC (OJ L 208, 1.8.2001, p. 36).

<sup>(6)</sup> OJ L 221, 7.8.1986, p. 43. Directive as last amended by Commission Directive 2001/57/EC.

<sup>(7)</sup> OJ L 350, 14.12.1990, p. 71. Directive as last amended by Commission Directive 2001/57/EC.

<sup>(8)</sup> OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 2001/49/EC (OJ L 176, 29.6.2001, p. 61).

<sup>(9)</sup> OJ L 184, 17.7.1999, p. 23.

<sup>(10)</sup> OJ L 214, 24.8.1993, p. 1. Regulation amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

<sup>(11)</sup> OJ L 224, 18.8.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1553/2001 (OJ L 205, 31.7.2001, p. 16).

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption.

#### Article 2

##### Definition of 'food'

For the purposes of this Regulation, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC <sup>(1)</sup> and 92/73/EEC <sup>(2)</sup>;
- (e) cosmetics within the meaning of Council Directive 76/768/EEC <sup>(3)</sup>;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC <sup>(4)</sup>;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
- (h) residues and contaminants.

#### Article 3

##### Other definitions

For the purposes of this Regulation:

1. 'food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution

<sup>(1)</sup> OJ 22, 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

<sup>(2)</sup> OJ L 297, 13.10.1992, p. 8.

<sup>(3)</sup> OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2000/41/EC (OJ L 145, 20.6.2000, p. 25).

<sup>(4)</sup> OJ L 359, 8.12.1989, p. 1. Directive as last amended by Directive 92/41/EEC (OJ L 158, 11.6.1992, p. 30).

of food, and also of feed produced for, or fed to, food-producing animals;

2. 'food business' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;
3. 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
4. 'feed' (or 'feedingstuff') means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
5. 'feed business' means any undertaking whether for profit or not and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing, processing or storing feed for feeding to animals on his own holding;
6. 'feed business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control;
7. 'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
8. 'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
9. 'risk' means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
10. 'risk analysis' means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
11. 'risk assessment' means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
12. 'risk management' means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;

13. 'risk communication' means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
14. 'hazard' means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
15. 'traceability' means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution;
16. 'stages of production, processing and distribution' means any stage, including import, from and including the primary production of a food, up to and including its storage, transport, sale or supply to the final consumer and, where relevant, the importation, production, manufacture, storage, transport, distribution, sale and supply of feed;
17. 'primary production' means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products;
18. 'final consumer' means the ultimate consumer of a food-stuff who will not use the food as part of any food business operation or activity.

## CHAPTER II

### GENERAL FOOD LAW

#### Article 4

##### Scope

1. This Chapter relates to all stages of the production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.
2. The principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken.
3. Existing food law principles and procedures shall be adapted as soon as possible and by 1 January 2007 at the latest in order to comply with Articles 5 to 10.
4. Until then, and by way of derogation from paragraph 2, existing legislation shall be implemented taking account of the principles laid down in Articles 5 to 10.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community.

#### Article 6

##### Risk analysis

1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.
2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

#### SECTION 1

### GENERAL PRINCIPLES OF FOOD LAW

#### Article 5

##### General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

*Article 7***Precautionary principle**

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

*Article 8***Protection of consumers' interests**

1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of:

- (a) fraudulent or deceptive practices;
- (b) the adulteration of food; and
- (c) any other practices which may mislead the consumer.

## SECTION 2

**PRINCIPLES OF TRANSPARENCY***Article 9***Public consultation**

There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it.

*Article 10***Public information**

Without prejudice to the applicable provisions of Community and national law on access to documents, where there are reasonable grounds to suspect that a food or feed may present

a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk.

## SECTION 3

**GENERAL OBLIGATIONS OF FOOD TRADE***Article 11***Food and feed imported into the Community**

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

*Article 12***Food and feed exported from the Community**

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. Where the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

*Article 13***International standards**

Without prejudice to their rights and obligations, the Community and the Member States shall:

- (a) contribute to the development of international technical standards for food and feed and sanitary and phytosanitary standards;
- (b) promote the coordination of work on food and feed standards undertaken by international governmental and non-governmental organisations;
- (c) contribute, where relevant and appropriate, to the development of agreements on recognition of the equivalence of specific food and feed-related measures;
- (d) give particular attention to the special development, financial and trade needs of developing countries, with a view to ensuring that international standards do not create unnecessary obstacles to exports from developing countries;
- (e) promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Community is not reduced.

## SECTION 4

**GENERAL REQUIREMENTS OF FOOD LAW***Article 14***Food safety requirements**

1. Food shall not be placed on the market if it is unsafe.
2. Food shall be deemed to be unsafe if it is considered to be:
  - (a) injurious to health;
  - (b) unfit for human consumption.
3. In determining whether any food is unsafe, regard shall be had:
  - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
  - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

- (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
- (b) to the probable cumulative toxic effects;
- (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

*Article 15***Feed safety requirements**

1. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.
2. Feed shall be deemed to be unsafe for its intended use if it is considered to:
  - have an adverse effect on human or animal health;
  - make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety requirement.

4. Feed that complies with specific Community provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

5. Conformity of a feed with specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. Where there are no specific Community provisions, feed shall be deemed to be safe when it conforms to the specific provisions of national law governing feed safety of the Member State in whose territory the feed is in circulation, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

#### Article 16

### Presentation

Without prejudice to more specific provisions of food law, the labelling, advertising and presentation of food or feed, including their shape, appearance or packaging, the packaging materials used, the manner in which they are arranged and the setting in which they are displayed, and the information which is made available about them through whatever medium, shall not mislead consumers.

#### Article 17

### Responsibilities

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other

monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

#### Article 18

### Traceability

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed.

To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

#### Article 19

### Responsibilities for food: food business operators

1. If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

#### Article 20

### Responsibilities for feed: feed business operators

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the

feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

#### Article 21

### Liability

The provisions of this Chapter shall be without prejudice to Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products <sup>(1)</sup>.

## CHAPTER III

### EUROPEAN FOOD SAFETY AUTHORITY

#### SECTION 1

### MISSION AND TASKS

#### Article 22

### Mission of the Authority

1. A European Food Safety Authority, hereinafter referred to as the 'Authority', is hereby established.

2. The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks.

3. The Authority shall contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market.

<sup>(1)</sup> OJ L 210, 7.8.1985, p. 29. Directive as last amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

4. The Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

5. The mission of the Authority shall also include the provision of:

- (a) scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme;
- (b) scientific opinions on other matters relating to animal health and welfare and plant health;
- (c) scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

6. The Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.

7. The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

8. The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

9. The Member States shall cooperate with the Authority to ensure the accomplishment of its mission.

#### *Article 23*

#### **Tasks of the Authority**

The tasks of the Authority shall be the following:

- (a) to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;
- (b) to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission;
- (c) to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;

- (d) to commission scientific studies necessary for the accomplishment of its mission;
- (e) to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;
- (f) to undertake action to identify and characterise emerging risks, in the fields within its mission;
- (g) to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;
- (h) to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;
- (i) to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving cooperation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;
- (j) to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;
- (k) to express independently its own conclusions and orientations on matters within its mission;
- (l) to undertake any other task assigned to it by the Commission within its mission.

#### SECTION 2

#### **ORGANISATION**

#### *Article 24*

#### **Bodies of the Authority**

The Authority shall comprise:

- (a) a Management Board;
- (b) an Executive Director and his staff;
- (c) an Advisory Forum;
- (d) a Scientific Committee and Scientific Panels.

#### *Article 25*

#### **Management Board**

1. The Management Board shall be composed of 14 members appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of candidates substantially higher than the number of members to be appointed, plus a representative of the Commission. Four of the members shall have their background in organisations representing consumers and other interests in the food chain.

The list drawn up by the Commission, accompanied by the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and within three months of such communication, the European Parliament may make its views available for consideration by the Council, which will then appoint the Management Board.

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and, consistent with these, the broadest possible geographic distribution within the Union.

2. Members' term of office shall be four years, and may be renewed once. However, for the first mandate, this period shall be six years for half of the members.

3. The Management Board shall adopt the Authority's internal rules on the basis of a proposal by the Executive Director. These rules shall be made public.

4. The Management Board shall elect one of its members as its Chair for a two-year period, which shall be renewable.

5. The Management Board shall adopt its rules of procedure.

Unless otherwise provided, the Management Board shall act by a majority of its members.

6. The Management Board shall meet at the invitation of the Chair or at the request of at least a third of its members.

7. The Management Board shall ensure that the Authority carries out its mission and performs the tasks assigned to it under the conditions laid down in this Regulation.

8. Before 31 January each year, the Management Board shall adopt the Authority's programme of work for the coming year. It shall also adopt a revisable multi-annual programme. The Management Board shall ensure that these programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Before 30 March each year, the Management Board shall adopt the general report on the Authority's activities for the previous year.

9. The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities <sup>(1)</sup> and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the Chair of the Scientific Committee to attend its meetings without voting rights.

## Article 26

### Executive Director

1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the *Official Journal of the European Communities* and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. Before appointment the candidate nominated by the Management Board shall be invited without delay to make a statement before the European Parliament and answer questions put by members of this institution. The Executive Director may be removed from office by a majority of the Management Board.

2. The Executive Director shall be the legal representative of the Authority and shall be responsible for:

- (a) the day-to-day administration of the Authority;
- (b) drawing up a proposal for the Authority's work programmes in consultation with the Commission;
- (c) implementing the work programmes and the decisions adopted by the Management Board;
- (d) ensuring the provision of appropriate scientific, technical and administrative support for the Scientific Committee and the Scientific Panels;
- (e) ensuring that the Authority carries out its tasks in accordance with the requirements of its users, in particular with regard to the adequacy of the services provided and the time taken;
- (f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Authority;
- (g) all staff matters;
- (h) developing and maintaining contact with the European Parliament, and for ensuring a regular dialogue with its relevant committees.

3. Each year, the Executive Director shall submit to the Management Board for approval:

- (a) a draft general report covering all the activities of the Authority in the previous year;
- (b) draft programmes of work;
- (c) the draft annual accounts for the previous year;
- (d) the draft budget for the coming year.

The Executive Director shall, following adoption by the Management Board, forward the general report and the programmes to the European Parliament, the Council, the Commission and the Member States, and shall have them published.

4. The Executive Director shall approve all financial expenditure of the Authority and report on the Authority's activities to the Management Board.

<sup>(1)</sup> OJ L 356, 31.12.1977, p. 1. Regulation as last amended by Regulation (EC, ECSC, Euratom) No 762/2001 (OJ L 111, 20.4.2001, p. 1).

## Article 27

**Advisory Forum**

1. The Advisory Forum shall be composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority, on the basis of one representative designated by each Member State. Representatives may be replaced by alternates, appointed at the same time.
2. Members of the Advisory Forum may not be members of the Management Board.
3. The Advisory Forum shall advise the Executive Director in the performance of his duties under this Regulation, in particular in drawing up a proposal for the Authority's work programme. The Executive Director may also ask the Advisory Forum for advice on the prioritisation of requests for scientific opinions.
4. The Advisory Forum shall constitute a mechanism for an exchange of information on potential risks and the pooling of knowledge. It shall ensure close cooperation between the Authority and the competent bodies in the Member States in particular on the following items:
  - (a) avoidance of duplication of the Authority's scientific studies with Member States, in accordance with Article 32;
  - (b) in those circumstances identified in Article 30(4), where the Authority and a national body are obliged to cooperate;
  - (c) in the promoting of the European networking of organisations operating within the fields of the Authority's mission, in accordance with Article 36(1);
  - (d) where the Authority or a Member State identifies an emerging risk.
5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the invitation of the Chair or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.
6. The Authority shall provide the technical and logistic support necessary for the Advisory Forum and provide the Secretariat for its meetings.
7. Representatives of the Commission's departments may participate in the work of the Advisory Forum. The Executive Director may invite representatives of the European Parliament and from other relevant bodies to take part.

Where the Advisory Forum discusses the matters referred to in Article 22(5)(b), representatives from competent bodies in the Member States which undertake tasks similar to those referred to in Article 22(5)(b) may participate in the work of the Advisory Forum, on the basis of one representative designated by each Member State.

## Article 28

**Scientific Committee and Scientific Panels**

1. The Scientific Committee and permanent Scientific Panels shall be responsible for providing the scientific opinions of the Authority, each within their own spheres of competence, and shall have the possibility, where necessary, of organising public hearings.
  2. The Scientific Committee shall be responsible for the general coordination necessary to ensure the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonisation of working methods. It shall provide opinions on multisectoral issues falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels.
- Where necessary, and particularly in the case of subjects which do not fall within the competence of any of the Scientific Panels, the Scientific Committee shall set up working groups. In such cases, it shall draw on the expertise of those working groups when establishing scientific opinions.
3. The Scientific Committee shall be composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any of the Scientific Panels.
  4. The Scientific Panels shall be composed of independent scientific experts. When the Authority is established, the following Scientific Panels shall be set up:
    - (a) the Panel on food additives, flavourings, processing aids and materials in contact with food;
    - (b) the Panel on additives and products or substances used in animal feed;
    - (c) the Panel on plant health, plant protection products and their residues;
    - (d) the Panel on genetically modified organisms;
    - (e) the Panel on dietetic products, nutrition and allergies;
    - (f) the Panel on biological hazards;
    - (g) the Panel on contaminants in the food chain;
    - (h) the Panel on animal health and welfare.

The number and names of the Scientific Panels may be adapted in the light of technical and scientific development by the Commission, at the Authority's request, in accordance with the procedure referred to in Article 58(2).

5. The members of the Scientific Committee who are not members of Scientific Panels and the members of the Scientific Panels shall be appointed by the Management Board, acting upon a proposal from the Executive Director, for a three-year term of office, which shall be renewable, following publication in the *Official Journal of the European Communities*, in relevant leading scientific publications and on the Authority's website of a call for expressions of interest.

6. The Scientific Committee and the Scientific Panels shall each choose a Chair and two Vice-Chairs from among their members.

7. The Scientific Committee and the Scientific Panels shall act by a majority of their members. Minority opinions shall be recorded.

8. The representatives of the Commission's departments shall be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups. If invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

9. The procedures for the operation and cooperation of the Scientific Committee and the Scientific Panels shall be laid down in the Authority's internal rules.

These procedures shall relate in particular to:

- (a) the number of times that a member can serve consecutively on a Scientific Committee or Scientific Panel;
- (b) the number of members in each Scientific Panel;
- (c) the procedure for reimbursing the expenses of members of the Scientific Committee and the Scientific Panels;
- (d) the manner in which tasks and requests for scientific opinions are assigned to the Scientific Committee and the Scientific Panels;
- (e) the creation and organisation of the working groups of the Scientific Committee and the Scientific Panels, and the possibility of external experts being included in those working groups;
- (f) the possibility of observers being invited to meetings of the Scientific Committee and the Scientific Panels;
- (g) the possibility of organising public hearings.

### SECTION 3

#### OPERATION

##### Article 29

#### Scientific opinions

1. The Authority shall issue a scientific opinion:
  - (a) at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted;
  - (b) on its own initiative, on matters falling within its mission.

The European Parliament or a Member State may request the Authority to issue a scientific opinion on matters falling within its mission.

2. Requests referred to in paragraph 1 shall be accompanied by background information explaining the scientific issue to be addressed and the Community interest.

3. Where Community legislation does not already specify a time limit for the delivery of a scientific opinion, the Authority shall issue scientific opinions within the time limit specified in the requests for opinions, except in duly justified circumstances.

4. Where different requests are made on the same issues or where the request is not in accordance with paragraph 2, or is unclear, the Authority may either refuse, or propose amendments to a request for an opinion in consultation with the institution or Member State(s) that made the request. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

5. Where the Authority has already delivered a scientific opinion on the specific topic in a request, it may refuse the request if it concludes there are no new scientific elements justifying the re-examination. Justifications for the refusal shall be given to the institution or Member State(s) that made the request.

6. The implementing rules for the application of this Article shall be established by the Commission after consulting the Authority, in accordance with the procedure provided for in Article 58(2). These rules shall specify in particular:

- (a) the procedure to be applied by the Authority to the requests referred to it;
- (b) the guidelines governing the scientific evaluation of substances, products or processes which are subject under Community legislation to a system of prior authorisation or entry on a positive list, in particular where Community legislation makes provision for, or authorises, a dossier to be presented for this purpose by the applicant.

7. The Authority's internal rules shall specify requirements in regard to format, explanatory background and publication of a scientific opinion.

##### Article 30

#### Diverging scientific opinions

1. The Authority shall exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body in question to ensure that all relevant scientific information is shared and in order to identify potentially contentious scientific issues.

3. Where a substantive divergence over scientific issues has been identified and the body in question is a Community agency or one of the Commission's Scientific Committees, the Authority and the body concerned shall be obliged to cooperate with a view to either resolving the divergence or presenting a joint document to the Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

4. Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

#### Article 31

### Scientific and technical assistance

1. The Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission. The tasks of providing scientific and technical assistance shall consist of scientific or technical work involving the application of well-established scientific or technical principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and also assistance to the Commission in the development of technical guidelines.

2. Where the Commission refers a request for scientific or technical assistance to the Authority, it shall specify, in agreement with the Authority, the time limit within which the task must be completed.

#### Article 32

### Scientific studies

1. Using the best independent scientific resources available, the Authority shall commission scientific studies necessary for the performance of its mission. Such studies shall be commissioned in an open and transparent fashion. The Authority shall seek to avoid duplication with Member State or Community research programmes and shall foster cooperation through appropriate coordination.

2. The Authority shall inform the European Parliament, the Commission and the Member States of the results of its scientific studies.

#### Article 33

### Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the

fields within its mission. This shall involve in particular the collection of data relating to:

- (a) food consumption and the exposure of individuals to risks related to the consumption of food;
- (b) incidence and prevalence of biological risk;
- (c) contaminants in food and feed;
- (d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.

5. Within one year following the date of entry into force of this Regulation, the Commission shall publish an inventory of data collection systems existing at Community level in the fields within the mission of the Authority.

The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular:

- (a) for each system, the role which should be assigned to the Authority, and any modifications or improvements which might be required to enable the Authority to carry out its mission, in cooperation with the Member States;
- (b) the shortcomings which should be remedied to enable the Authority to collect and summarise at Community level relevant scientific and technical data in the fields within its mission.

6. The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

#### Article 34

### Identification of emerging risks

1. The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.

2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. The Member States, the Community agencies concerned and the Commission shall reply as a matter of urgency and forward any relevant information in their possession.

3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.

4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

#### Article 35

### Rapid alert system

To enable it to perform its task of monitoring the health and nutritional risks of foods as effectively as possible, the Authority shall be the recipient of any messages forwarded via the rapid alert system. It shall analyse the content of such messages with a view to providing the Commission and the Member States with any information required for the purposes of risk analysis.

#### Article 36

### Networking of organisations operating in the fields within the Authority's mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.

4. Within one year following the entry into force of this Regulation, the Commission shall publish an inventory of Community systems existing in the fields within the mission of the Authority which make provision for Member States to carry out certain tasks in the field of scientific evaluation, in particular the examination of authorisation dossiers. The report, which shall be accompanied, where appropriate, by proposals, shall indicate in particular, for each system, any modifications or improvements which might be required to

enable the Authority to carry out its mission, in cooperation with the Member States.

#### SECTION 4

### INDEPENDENCE, TRANSPARENCY, CONFIDENTIALITY AND COMMUNICATION

#### Article 37

### Independence

1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.

3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda.

#### Article 38

### Transparency

1. The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

- (a) agendas and minutes of the Scientific Committee and the Scientific Panels;
- (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;
- (c) without prejudice to Articles 39 and 41, the information on which its opinions are based;
- (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;

- (e) the results of its scientific studies;
- (f) the annual report of its activities;
- (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

#### Article 39

##### Confidentiality

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2.

#### Article 40

##### Communications from the Authority

1. The Authority shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions.

2. The Authority shall ensure that the public and any interested parties are rapidly given objective, reliable and easily accessible information, in particular with regard to the results of its work. In order to achieve these objectives, the Authority shall develop and disseminate information material for the general public.

3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

4. The Authority shall ensure appropriate cooperation with the competent bodies in the Member States and other interested parties with regard to public information campaigns.

#### Article 41

##### Access to documents

1. The Authority shall ensure wide access to the documents which it possesses.

2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions' documents.

#### Article 42

##### Consumers, producers and other interested parties

The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties.

#### SECTION 5

##### FINANCIAL PROVISIONS

#### Article 43

##### Adoption of the Authority's budget

1. The revenues of the Authority shall consist of a contribution from the Community and, from any State with which the Community has concluded the agreements referred to in Article 49, and charges for publications, conferences, training and any other similar activities provided by the Authority.

2. The expenditure of the Authority shall include the staff, administrative, infrastructure and operational expenses, and expenses resulting from contracts entered into with third parties or resulting from the financial support referred to in Article 36.

3. In good time, before the date referred to in paragraph 5, the Executive Director shall draw up an estimate of the Authority's revenue and expenditure for the coming financial year, and shall forward it to the Management Board, accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward them to the Commission, and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft, the Commission shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.

6. After the adoption of the general budget of the European Union by the budgetary authority, the Management Board shall adopt the Authority's final budget and work programme, adjusting them where necessary to the Community's contribution. It shall forward them without delay to the Commission and the budgetary authority.

#### Article 44

### Implementation of the Authority's budget

1. The Executive Director shall implement the Authority's budget.
2. Control of commitment and payment of all expenditure and control of the existence and recovery of all the Authority's revenue shall be carried out by the Commission's financial controller.
3. By 31 March each year at the latest, the Executive Director shall forward to the Commission, the Management Board and the Court of Auditors the detailed accounts for all the revenue and expenditure in respect of the previous financial year.

The Court of Auditors shall examine the accounts in accordance with Article 248 of the Treaty. It shall publish each year a report on the Authority's activities.

4. The European Parliament, acting on a recommendation from the Council, shall give a discharge to the Authority's Executive Director in respect of the implementation of the budget.

#### Article 45

### Fees received by the Authority

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty and for other services provided by the Authority.

#### SECTION 6

### GENERAL PROVISIONS

#### Article 46

### Legal personality and privileges

1. The Authority shall have legal personality. In all Member States it shall enjoy the widest powers granted by law to legal

persons. In particular, it may acquire and dispose of movable and immovable property and institute legal proceedings.

2. The Protocol on the privileges and immunities of the European Communities shall apply to the Authority.

#### Article 47

### Liability

1. The contractual liability of the Authority shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Authority.

2. In the case of non-contractual liability, the Authority shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or its servants in the performance of their duties. The Court of Justice shall have jurisdiction in any dispute relating to compensation for such damage.

3. The personal liability of its servants towards the Authority shall be governed by the relevant provisions applying to the staff of the Authority.

#### Article 48

### Staff

1. The staff of the Authority shall be subject to the rules and regulations applicable to officials and other staff of the European Communities.
2. In respect of its staff, the Authority shall exercise the powers which have been devolved to the appointing authority.

#### Article 49

### Participation of third countries

The Authority shall be open to the participation of countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by this Regulation.

Arrangements shall be made under the relevant provisions of those agreements, specifying in particular the nature, extent and manner in which these countries will participate in the Authority's work, including provisions relating to participation in the networks operated by the Authority, inclusion in the list of competent organisations to which certain tasks may be entrusted by the Authority, financial contributions and staff.

## CHAPTER IV

**RAPID ALERT SYSTEM, CRISIS MANAGEMENT AND EMERGENCIES**

## SECTION 1

**RAPID ALERT SYSTEM***Article 50***Rapid alert system**

1. A rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed is hereby established as a network. It shall involve the Member States, the Commission and the Authority. The Member States, the Commission and the Authority shall each designate a contact point, which shall be a member of the network. The Commission shall be responsible for managing the network.

2. Where a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information shall be immediately notified to the Commission under the rapid alert system. The Commission shall transmit this information immediately to the members of the network.

The Authority may supplement the notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States.

3. Without prejudice to other Community legislation, the Member States shall immediately notify the Commission under the rapid alert system of:

- (a) any measure they adopt which is aimed at restricting the placing on the market or forcing the withdrawal from the market or the recall of food or feed in order to protect human health and requiring rapid action;
- (b) any recommendation or agreement with professional operators which is aimed, on a voluntary or obligatory basis, at preventing, limiting or imposing specific conditions on the placing on the market or the eventual use of food or feed on account of a serious risk to human health requiring rapid action;
- (c) any rejection, related to a direct or indirect risk to human health, of a batch, container or cargo of food or feed by a competent authority at a border post within the European Union.

The notification shall be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued. It shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn.

The Commission shall immediately transmit to members of the network the notification and supplementary information received under the first and second subparagraphs.

Where a batch, container or cargo is rejected by a competent authority at a border post within the European Union, the Commission shall immediately notify all the border posts within the European Union, as well as the third country of origin.

4. Where a food or feed which has been the subject of a notification under the rapid alert system has been dispatched to a third country, the Commission shall provide the latter with the appropriate information.

5. The Member States shall immediately inform the Commission of the action implemented or measures taken following receipt of the notifications and supplementary information transmitted under the rapid alert system. The Commission shall immediately transmit this information to the members of the network.

6. Participation in the rapid alert system may be opened up to applicant countries, third countries or international organisations, on the basis of agreements between the Community and those countries or international organisations, in accordance with the procedures defined in those agreements. The latter shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Community.

*Article 51***Implementing measures**

The measures for implementing Article 50 shall be adopted by the Commission, after discussion with the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

*Article 52***Confidentiality rules for the rapid alert system**

1. Information, available to the members of the network, relating to a risk to human health posed by food and feed shall in general be available to the public in accordance with the information principle provided for in Article 10. In general, the public shall have access to information on product identification, the nature of the risk and the measure taken.

However, the members of the network shall take steps to ensure that members of their staff are required not to disclose information obtained for the purposes of this Section which by its nature is covered by professional secrecy in duly justified cases, except for information which must be made public, if circumstances so require, in order to protect human health.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant to the effectiveness of market surveillance and enforcement activities in the field of food and feed. The authorities receiving information covered by professional secrecy shall ensure its protection in conformity with paragraph 1.

## SECTION 2

### EMERGENCIES

#### Article 53

#### **Emergency measures for food and feed of Community origin or imported from a third country**

1. Where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures, depending on the gravity of the situation:

- (a) in the case of food or feed of Community origin:
  - (i) suspension of the placing on the market or use of the food in question;
  - (ii) suspension of the placing on the market or use of the feed in question;
  - (iii) laying down special conditions for the food or feed in question;
  - (iv) any other appropriate interim measure;
- (b) in the case of food or feed imported from a third country:
  - (i) suspension of imports of the food or feed in question from all or part of the third country concerned and, where applicable, from the third country of transit;
  - (ii) laying down special conditions for the food or feed in question from all or part of the third country concerned;
  - (iii) any other appropriate interim measure.

2. However, in eMERGENCIES, the Commission may provisionally adopt the measures referred to in paragraph 1 after consulting the Member State(s) concerned and informing the other Member States.

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred to in Article 58(2), and the reasons for the Commission's decision shall be made public without delay.

#### Article 54

### **Other emergency measures**

1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member State may maintain its national interim protective measures until the Community measures have been adopted.

## SECTION 3

### CRISIS MANAGEMENT

#### Article 55

#### **General plan for crisis management**

1. The Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as 'the general plan').

2. The general plan shall specify the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54.

The general plan shall also specify the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy.

*Article 56***Crisis unit**

1. Without prejudice to its role of ensuring the application of Community law, where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated or reduced by existing provisions or cannot adequately be managed solely by way of the application of Articles 53 and 54, it shall immediately notify the Member States and the Authority.

2. The Commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary.

*Article 57***Tasks of the crisis unit**

1. The crisis unit shall be responsible for collecting and evaluating all relevant information and identifying the options available to prevent, eliminate or reduce to an acceptable level the risk to human health as effectively and rapidly as possible.

2. The crisis unit may request the assistance of any public or private person whose expertise it deems necessary to manage the crisis effectively.

3. The crisis unit shall keep the public informed of the risks involved and the measures taken.

## CHAPTER V

## PROCEDURES AND FINAL PROVISIONS

## SECTION 1

## COMMITTEE AND MEDIATION PROCEDURES

*Article 58***Committee**

1. The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the 'Committee', composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.

2. Where reference is made to this paragraph, the procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Articles 7 and 8 thereof.

3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

*Article 59***Functions assigned to the Committee**

The Committee shall carry out the functions assigned to it by this Regulation and by other relevant Community provisions, in the cases and conditions provided for in those provisions. It may also examine any issue falling under those provisions, either at the initiative of the Chairman or at the written request of one of its members.

*Article 60***Mediation procedure**

1. Without prejudice to the application of other Community provisions, where a Member State is of the opinion that a measure taken by another Member State in the field of food safety is either incompatible with this Regulation or is likely to affect the functioning of the internal market, it shall refer the matter to the Commission, which will immediately inform the other Member State concerned.

2. The two Member States concerned and the Commission shall make every effort to solve the problem. If agreement cannot be reached, the Commission may request an opinion on any relevant contentious scientific issue from the Authority. The terms of that request and the time limit within which the Authority is requested to give its opinion shall be established by mutual agreement between the Commission and the Authority, after consulting the two Member States concerned.

## SECTION 2

## FINAL PROVISIONS

*Article 61***Review clause**

1. Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level.

The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

2. Before 1 January 2005, the Commission shall publish a report on the experience acquired from implementing Sections 1 and 2 of Chapter IV.

3. The reports and recommendations referred to in paragraphs 1 and 2 shall be forwarded to the Council and the European Parliament.

#### Article 62

#### References to the European Food Safety Authority and to the Standing Committee on the Food Chain and Animal Health

1. Every reference in Community legislation to the Scientific Committee on Food, the Scientific Committee on Animal Nutrition, the Scientific Veterinary Committee, the Scientific Committee on Pesticides, the Scientific Committee on Plants and the Scientific Steering Committee shall be replaced by a reference to the European Food Safety Authority.

2. Every reference in Community legislation to the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs and the Standing Veterinary Committee shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

Every reference to the Standing Committee on Plant Health in Community legislation based upon and including Directives 76/895/EEC, 86/362/EEC, 86/363/EEC, 90/642/EEC and 91/414/EEC relating to plant protection products and the setting of maximum residue levels shall be replaced by a reference to the Standing Committee on the Food Chain and Animal Health.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 January 2002.

For the European Parliament

The President

P. COX

For the Council

The President

J. PIQUÉ I CAMPS

3. For the purpose of paragraphs 1 and 2, 'Community legislation' shall mean all Community Regulations, Directives and Decisions.

4. Decisions 68/361/EEC, 69/414/EEC and 70/372/EEC are hereby repealed.

#### Article 63

#### Competence of the European Agency for the Evaluation of Medicinal Products

This Regulation shall be without prejudice to the competence conferred on the European Agency for the Evaluation of Medicinal Products by Regulation (EEC) No 2309/93, Regulation (EEC) No 2377/90, Council Directive 75/319/EEC<sup>(1)</sup> and Council Directive 81/851/EEC<sup>(2)</sup>.

#### Article 64

#### Commencement of the Authority's operation

The Authority shall commence its operations on 1 January 2002.

#### Article 65

#### Entry into force

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Communities*.

Articles 11 and 12 and Articles 14 to 20 shall apply from 1 January 2005.

Articles 29, 56, 57 and 60 and Article 62(1) shall apply as from the date of appointment of the members of the Scientific Committee and of the Scientific Panels which shall be announced by means of a notice in the 'C' series of the Official Journal.

<sup>(1)</sup> OJ L 147, 9.6.1975, p. 13. Directive amended by Directive 2001/83/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 67).

<sup>(2)</sup> OJ L 317, 6.11.1981, p. 1. Directive amended by Directive 2001/82/EC of the European Parliament and of the Council (OJ L 311, 28.11.2001, p. 1).

**Appendix 8**  
**Food and Agriculture**  
**Organisation**  
**Global Forum on**  
**Food Safety Regulators**

聯合國糧農組織

世界食物安全

監管人員大會文件



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS



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**GF/PROCEEDINGS**

**FAO/WHO**  
**GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28 – 30 January 2002*

*Improving Efficiency and Transparency in Food Safety Systems*  
*Sharing Experiences*

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**PROCEEDINGS OF THE FORUM**

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FAO  
Rome, April 2002

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**FAO/WHO**  
**GLOBAL FORUM OF FOOD SAFETY REGULATORS**

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Sharing Experiences*

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**PROCEEDINGS OF THE FORUM**

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## **INTRODUCTION**

The Global Forum of Food Safety Regulators was the first opportunity for food safety regulation officials from 110 countries to meet and discuss food safety issues of international importance. The Forum was also attended by 17 international organizations, NGOs and observers having an interest in food safety matters. The list of all participants is attached as Appendix 1.

The Forum was jointly opened by H.E. Touhami Khiari, the Minister of Health of Morocco and Mr. Ahmed Sbihi representing the Minister of Agriculture, Rural Development, Water Resources and Forestry of Morocco (see Appendix 2 for both presentations in the original language). Both stressed the need to consider and adopt new approaches to ensure safe food. They further noted that food safety must be balanced with economic concerns and market requirements. They agreed that capacity building for developing countries is now a necessity.

The Directors-General of FAO, Dr. Jacques Diouf, and of WHO, Dr. Gro Harlem Brundtland, welcomed the Forum participants by video (Appendix 3). Both noted the alarming number of deaths from food-borne diseases that occur each year, world-wide, particularly among children. Food safety is the responsibility of all and new ways must be found to prevent and respond to food-borne hazards. The entire food chain must be considered where food safety concerns are involved.

Dr. David Heymann, Executive Director, Communicable Diseases, WHO, described various emerging food-borne diseases and their impacts on human health, economics and trade. He demonstrated how risk analysis can be used as a guide for appropriate international response to food crises, particularly for developing countries. He underlined the value of international surveillance systems in these efforts (Appendix 4).

Dr. Hartwig de Haen, Assistant Director-General, Economic and Social Department, FAO, stressed the vital importance of ensuring the quality and safety of food to all countries and all people. He noted that food safety control systems must be adapted to national needs and that there must be a balance between food safety and other important aspects of food quality. Dr. de Haen also underlined the urgency of international co-operation in emergency response, communication and capacity building (Appendix 5).

The Forum elected Mr. Abdelrahman Hilali, Directeur de la Protection des Végétaux, du Contrôle Technique et de la Répression des Fraudes, Ministry of Agriculture and Rural Development of Morocco, and Mr. Jaouad Mahjour, Directeur de l'Epidémiologie, Ministry of Health of Morocco, as co-Chairmen. The Forum further elected Mrs Catherine Geslain-Lanéelle of France and Mr. Ronald Doering of Canada as co-Vice Chairpersons.

The Chairmen formally opened the Forum and the participants adopted the Provisional Agenda of the Forum (Appendix 6). Dr Mamdouh Gabr, Professor of Pediatrics, Cairo University, Egypt, was introduced to present the Global Forum Keynote Address (Appendix 7). Dr Gabr noted the continuing massive number of illnesses and deaths from food-borne disease world-wide. The problem is especially acute in developing countries. He outlined some of the key challenges that face national regulators when considering food safety issues. For example, although a quantitative approach to risk assessment is needed, it should be tempered by subjective considerations. He discussed the difficulties in both establishing and implementing food safety regulations. National policy on food safety is increasingly affected by public opinion. Dr Gabr stressed that a public information system is needed. He noted that more co-ordination is needed

both internationally and nationally to avoid unnecessary controversy in food safety control. Dr Gabr concluded by outlining some future trends and research needs in the food safety area.

The Chairmen reminded the participants that the Global Forum was not intended to lead to recommendations or to decisions and that the Forum Proceedings would summarize the main issues discussed, as well as identify new developments in food safety and areas in which more dialogue and cooperation is considered necessary.

In order to focus the Forum discussions four major themes were identified, each of which involved a global food safety issue. The themes selected were *Regulatory Issues*, *Risk Management*, *Capacity Building* and *Communication and Participation*. Each theme had two key topics representing specific areas of concern within that theme. The themes and their topics were presented by food safety experts in four Discussion Groups that met separately to consider, discuss and exchange views. Conference Room Documents outlining national experiences or food safety problems encountered were provided by many countries for each Group to consider when discussing specific topics. A Discussion Summary from each Discussion Group was presented to and discussed by the entire Forum in plenary session for inclusion in these Proceedings. The following Discussion Summaries for each theme reflect the plenary comments.

## **REGULATORY ISSUES**

The Discussion Group on Regulatory Issues was chaired by Sr. Don Angel Sartori Arellano of Chile. The Vice Chair was Dr. Piergiuseppe Facelli of Italy. Dr. Mitsuhiro Ushio of Japan's Ministry of Health, Labour and Welfare (MHLW) introduced the Regulatory Issues theme by providing an overview of Japan's food safety regulatory system and presenting important regulatory issues that all countries should consider.

The MHLW and the Ministry of Agriculture, Forestry and Fisheries (MAFF) share responsibility for the provision of safe food in Japan at the central level. MHLW and local authorities implement food safety regulation based on the Food Sanitation Law.

Japan uses a comprehensive sanitary control system based on the Hazard Analysis and Critical Control Points (HACCP) System. The MHLW approves food manufacturing or processing facilities if it is confirmed that the appropriate level of hygiene is achieved.

Food safety continues to be a challenge. Further improvement of hygiene levels, public education, and coordination of epidemiological and laboratory investigations are required.

Dr Ushio raised several regulatory issues for consideration. He indicated that a farm-to-table approach could most effectively reduce risk through the principle of prevention. This approach is hard to implement because of the time lag, geographical differences in practices, and the variety of stakeholders. The type and size of the organization(s) that are necessary to implement the food safety strategy is an important issue. Experiences with a "single food safety agency" were elicited.

Dr Ushio asked participants to share thoughts on how the safety of imported foods could be ensured by highlighting several strategies. Attendees were also reminded that they are faced with the challenge of regulating newly developed food and food derived from modern technologies. Options for motivation and implementation of an effective food safety system were presented. Strategies suggested were 1) appeal to an individual moral sense and ethics; 2) economic incentives; 3) education and communication; and 4) regulatory procedures.

## NATIONAL AND TRANSBOUNDARY FOOD SAFETY EMERGENCIES

Dr. Richard Harding of the United Kingdom's Food Standards Agency presented the first of the two topics under the main theme. He discussed the chronology of events in the UK associated with Bovine Spongiform Encephalopathy (BSE) and the application of food safety control measures. Controls have resulted in a drastic reduction of detected cases of BSE in the UK, and effective protection of public health.

### Lessons Learned

There was benefit in a co-ordinated European approach. The UK learned that effective control measures must be rigorously applied. This supported the need to match policy with practice, a point made in the keynote address. Mr Harding observed that risk assessments must be based on best scientific data available. Areas such as this are characterized by uncertainty, and in practice this meant that different experts sometimes reached different conclusions, and that control measures were then set at a precautionary level to take this uncertainty into account.

### Follow-up Discussion

A concern was raised that importing countries may not have the necessary resources to verify the safety of their imports. It was noted that both importing and exporting countries must ensure that appropriate controls are in place to address BSE and other food safety concerns. Another concern expressed was export by developed countries of products with standards lower than their own domestic standards. A number of countries reported that laws were in place that required exports to meet domestic standards.

It was noted that the science-based assessment of an identified risk can lead to the identification of other potential risks. Along these lines, other specific aspects about BSE were raised that merit proactive risk assessment.

An issue was raised as to the quantity of food that is lost due to burdensome regulations. There was a general agreement on the need for science-based risk assessments, and the value and need for international co-operation in the development of risk assessments. It was stressed that the measures should be proportional to the risk to public health, and that it was important to involve all stakeholders.

Recognition of the equivalence of foreign inspection systems was suggested as a means of facilitating trade. Developed countries were urged to take concrete steps in concluding such equivalence agreements with developing countries, as many difficulties seem to have been experienced in this regard. Industry was recognized as having a role and a responsibility in ensuring the safety of food. The need for even more co-operation and communication between industry and government was highlighted.

Some countries noted that regulation development is a capacity building issue. Countries where street food is a major component of the daily diet raised the question of what regulatory guidance or experiences on the subject could be shared. Codex indicated that guidelines on the safe preparation of street food were recently approved.

The issue of the safety and quality of complementary foods for infants in developing countries was raised. Concern was also expressed on the compliance to the international Code of Marketing of breast milk substitutes.

## **NEW INSPECTION APPROACHES AND TECHNIQUES – IMPLICATIONS FOR FOOD SAFETY REGULATIONS**

Mr. Greg Roche of the Australia New Zealand Food Authority (ANZFA) presented the second topic. He discussed the challenging, but ultimately successful, efforts to develop and implement the new Australian Food Safety Standards.

The success story showed that mixed regulatory approaches combining mandatory requirements with voluntary prescriptive guidelines can accommodate the specific requirements of a spectrum of food related businesses. Classifying food businesses by relative levels of risk ensured resources were effectively allocated.

### **Lessons Learned**

The ANZFA experience showed that:

- Creating a single, uniform and simpler system of food safety laws takes time. (It took six years to get the least controversial elements introduced. The future of mandatory HACCP food safety programs is still uncertain.);
- Lengthy, exhaustive consultations with stakeholders are essential;
- Anticipate resistance from small businesses to the introduction of mandatory food safety programs;
- The basis for food safety regulation is hampered by the low amount of high-quality data - specifically, on the method and pattern of transmission of food-borne pathogens to humans and the extent and cost of food-borne illness.

### **Follow-up Discussion**

To achieve maximum prevention it is essential that safety should be built into food products from production through to consumption. This calls for a comprehensive and integrated farm-to-table approach. In this context, some countries felt that it is necessary to consider conditions under which animals are raised (including animal feeding practices and use of veterinary medical drugs) or vegetable primary products are produced (use of pesticides etc.).

In recent years, many countries have changed the structure of organizations and their philosophy of control to a more systematic application of risk analysis and use of HACCP principles. Strict co-operation is necessary between various stakeholders in the development and implementation of safe food production measures, particularly between industry and public authorities.

It was stressed that there was a need for more co-operation at the international level, and even at the regional level. It was reported that FAO/WHO have recently produced a new publication entitled '*Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems*'. Some countries stressed the importance of information exchanges, particularly between countries with similar conditions, to ensure effective regulatory measures.

The creation of an early and rapid alert system by FAO and WHO in the Codex framework was suggested. Some barriers such as shortage of human and financial resources were noted. In this context, existing experiences in the European Union, the USA and other countries would help to achieve a global network system.

The issue of food safety regulation regarding food aid was raised. In this connection, Article 9 of the WTO SPS Agreement on Technical Assistance for the developing countries was referred to.

It was noted that consumers in some developing countries had not received full benefits of domestic food safety regulatory control, since limited resources had to be devoted to quality control of exports in order that demands of importing countries in this area are fulfilled.

***N.B.** The theme and both topic presentations under Regulatory Issues as well as a summary of each of the CRDs submitted for each topic, are attached as Appendix 8.*

## **RISK MANAGEMENT**

The Discussion Group on Risk Management was chaired by Dr Zeinab Abd El-Haleim Hewidy of Egypt. The Vice Chair was Dr Hataya Kongchuntuk of Thailand. Mrs. Catherine Geslain-Lanéelle, Directrice générale de l'alimentation, France, introduced the Risk Management theme by presenting an overview of risk management issues that all countries need to consider. She provided specific examples from France.

The 1999 dioxin crisis in Europe was used to illustrate the precautionary principle in risk management. Bearing in mind the recognized carcinogenic effect of dioxin and the absence of specific information on the extent of contamination associated with feed containing Belgian fat, temporary precautionary measures were taken. The European Commission banned certain products of Belgian origin and restrictive measures were applied to likely contaminated flocks identified in a French traceability study. Protective measures were amended, and progressively lifted, as more precise information became available.

All aspects of food production from farm-to-table have an impact on food safety. Socio-economic changes over the last 30 years call for an integrated approach. This approach facilitates the circulation of information, allows better coherence and effectiveness of epidemiological surveillance networks and allows the traceability of foods. Traceability was presented as an important food safety management option .

Risk managers must be prepared for emergencies and emerging risks. Health surveillance is vital. It was suggested that effective regulation must be based on scientific evaluation but also requires taking account of socio-economic concerns.

There is a risk management role for food chain professionals. They are responsible for the safety of foods, provide guidance in hygiene practices, meet voluntary certification requirements, set and meet standards, and contribute information to permit traceability.

## **REDUCTION OF FOODBORNE HAZARDS, INCLUDING MICROBIOLOGICAL AND OTHERS, WITH EMPHASIS ON EMERGING HAZARDS**

Mr. Ron Hicks of the Food Safety and Inspection Service of the United States presented the first topic under the main theme. He shared the US approach to risk management, which includes:

- Transparent development of risk management strategies;
- Strategies are based on best available information;
- Strategies evolve to address emerging risks; and

- Strategies evolve to utilize advances in technology and new scientific data.

The tools utilized by the US in its risk management approach include (1) regulations; (2) guidance to industry; (3) education; (4) surveillance; and (5) use of any or all available research.

This risk management approach was illustrated by the measures taken in regard to *Listeria monocytogenes* (LM). A 1985 illness outbreak associated with LM in soft cheese led to increased monitoring, improvements in plant sanitation procedures including voluntary HACCP systems, and a substantial government education campaign. Annual illness rates from LM declined by 44 percent. A 1998 illness outbreak associated with ready-to-eat meat products was a reminder that risk management strategies must be reassessed based on the best available information. A new risk analysis led to multiple new risk management measures, including:

- Education of at-risk populations, the medical community, and care-givers;
- Guidance on post-processing contamination controls;
- Training for regulators and industry;
- Enhanced disease surveillance;
- Projects with retail operations;
- Coordinated research; and
- Proposing regulations to detect and prevent contamination in meat plants.

The implementation of mandatory HACCP systems in meat and poultry plants was also highlighted. The prevalence of *Salmonella* in meat and poultry products in the US has been dramatically reduced with a corresponding decrease in foodborne illnesses.

### Lessons Learned

Risk management is most effective when it is based on sound scientific information or on the best available data. Strategies must evolve over time to address emerging risks or better handle known risks. Strategies should also evolve to make optimal use of technological and scientific advances. Lastly, it must include the effort of all those involved along the farm-to-table continuum.

## **INTEGRATED APPROACHES TO THE MANAGEMENT OF FOOD SAFETY THROUGHOUT THE FOOD CHAIN**

Dr. Stuart Slorach, Deputy Director-General of Sweden's National Food Administration, presented the second topic within the theme. He discussed a holistic, risk-based, "prevention is better than the cure" approach in managing food safety throughout the food chain.

The role of the supervisory authorities is to prescribe safety standards and to ensure that producers, processors and traders, who are identified as having primary responsibility for food safety have adequate internal control system based on HACCP principles. This could be accomplished best by having a single agency with responsibility for the whole food chain or close co-ordination if more than one agency is involved. Consumers have responsibility for food hygiene in the home and for dietary habits.

Sweden's approach to controlling *Salmonella* in broilers illustrated the holistic approach (1) the breeding pyramid and the feed are kept free of *Salmonella*; (2) Production facilities, flocks and

carcasses are monitored; (3) Controls are carried out at the retail level and consumers and caterers are educated; (4) There is follow up of food poisoning outbreaks.

### **Lessons Learned**

- Food safety strategies should be risk-based and cover the entire food chain.
- The follow-up and reporting of foodborne disease outbreaks should be improved.
- An integrated, multidisciplinary approach to food safety, that addresses problems at the source, should be adopted.
- In-house control systems based on the HACCP approach are needed.
- Food inspection and monitoring results should be made public.
- Training of catering personnel and the education of consumers in food hygiene should be improved.
- Contacts between food safety and environmental protection officials should be improved.
- Adequate resources should be assigned for the detection of emerging risks.

### **Follow-up Discussion**

***N.B.*** The discussion was delayed until after presentation of the second topic paper. The following therefore reflects the combined discussion of both topics.

Many countries described their systems for risk management, including regulatory aspects, control programs, agencies involved, crisis management, sanitary surveillance and food monitoring, and networking among others.

Specific hazards discussed included deteriorated sugar cane food poisoning in China, *Escherichia coli* outbreaks in Japan and the United Kingdom, the “Dioxin crisis”, and *Salmonella* control in Sweden.

During the discussions, the following observations were made:

- National food safety management systems are different and co-operation among competent bodies was recognized as essential;
- Co-operation and effective partnership among governments, farmers, industries and consumers in sharing responsibilities to address food safety issues is needed;
- Risk managers have employed various strategies. These include:
  - risk assessment using available data and continuous revision;
  - support by some that precaution is a tool in the case of incomplete risk assessment;
  - support by some for the use of traceability or trace-back systems;
  - strategies that deal with all aspects of food protection from farm-to-table including relevant cooling and freezing systems; and
  - emphasis on prevention by implementing systems such as HACCP;
- It was recognized that research on food safety hazards was important to fill data gaps and provide practical tools for reducing food-borne hazards and also necessary to

assess the risk management strategies. The involvement of universities and research institutes is vital.

- Surveillance and reporting systems were considered as the base for the timely detection of illness outbreaks and emerging food-borne hazards.

Concerns were expressed on the following main issues:

- lack of a specific food safety policy or the consideration that such a policy is of low priority;
- lack of data on food-borne illness while trying to maintain a high level of vigilance for food-borne hazards;
- the need to sensitize food handlers and consumers to the relationship between hygienic practice, food safety and food-borne disease;
- the need to train officials and upgrade laboratories to accomplish food safety control;
- the safety of imported foods is a major concern for some countries due to lack of facilities for laboratory testing;
- the difficulty of reducing hazards when the educational level of the audience is low.

***N.B.** The theme and both topic presentations under Risk Management, as well as a summary of each of the CRDs submitted for each topic, are attached as Appendix 9.*

## **CAPACITY BUILDING**

The Discussion Group on Capacity Building was chaired by Dr Junshi Chen of China with Dr Svetlana Borislavova Tcherkezova of Bulgaria serving as Vice-Chair. Mr. Gregory Orriss of the Canadian Food Inspection Agency introduced the Capacity Building theme by presenting an overview of international capacity building and technical assistance. He emphasized the importance of food safety capacity in the context of public health and access to international markets. WHO estimates that in 1998 2.2 million people, mostly children, died from diarrhoeal diseases, many attributable to contamination of food and drinking water. Developing countries face challenges due to population growth, growth in the number of immuno-compromised individuals, increased urbanization, and inadequate infrastructure.

Developing countries have opportunities to expand markets due to worldwide reductions in tariffs and subsidies, new rights and obligations under the SPS Agreement, and increased demand for a variety of foods. Still, developing countries that export food face significant challenges in meeting importing country health and safety requirements. Developing countries need capacity building to be able to take full advantage of their SPS rights and obligations. The capacity and technical assistance needs of developing countries can be summarized as: (1) Basic infrastructure, (2) National food control strategy; (3) Food legislation and regulatory framework; (4) Food inspection services; (5) Food control laboratories and equipment; (6) Disease surveillance systems; (7) Participation in international standard-setting organizations; (8) Implementation of food quality and safety assurance systems by the industry; (9) Collaboration and cooperation of food control agencies; and (10) Scientific and technical expertise.

While there has been considerable technical assistance provided over the recent years, it has not been effectively coordinated and has been inadequate for many developing countries to meet their public health and market access needs. Recently, in Doha, FAO, OIE, WHO, WTO and the World Bank pledged to work together to strengthen the capacity of developing countries to establish and implement science-based sanitary and phytosanitary measures.

Suggested approaches for capacity building included: (1) Building alliances; (2) Communication and exchange of information; (3) Coordination of activities; (3) Preparation of an assessment of needs and a country profile; (4) Identifying financing sources; (5) Initiating technical cooperation between countries and institutions; (6) Sector specific activities; and (7) Regional approaches. Solutions will require the concerted efforts of developing countries, FAO, WHO, other international organizations, and developed countries.

## **TECHNICAL ASSISTANCE TO DEVELOPING COUNTRIES**

Dr. Leo Hagedoorn of the Ministry of Agriculture of The Netherlands presented the first topic under the main theme. He shared the Netherlands' experience in technical assistance and capacity building efforts. The Netherlands supports the efforts of international organizations in capacity building. Further, the Netherlands is a Member State of the European Union, which over the past 10 years has tripled external assistance programs to reach 12.3 billion Euros in year 2000.

Three assistance activities of the Netherlands were highlighted including (1) the Center for Promotion of Imports from developing countries, which has initiated a program to enhance the fresh fruit and vegetable sector in selected African countries - the aim is to address some of the critical technical non-tariff barriers to trade and to build up local institutional capacity; (2) the Europe/SADC Initiative, which is a Dutch initiative aimed at achieving further regional cooperation in the area of agriculture between countries in the EU and the South African Development Community - areas for cooperation are food security, food safety, trade in agricultural products, and sustainable agriculture; and (3) the ASEM (Asia-European Meeting) seminars, which promotes the use of risk analysis as the basis for establishing SPS measures.

### **Lessons Learned**

The Netherlands' experience in technical assistance and capacity building suggests that support should be given for longer periods and that more emphasis should be given to regional approaches. Capacity building provided by international organizations should be integrated and co-ordinated.

### **Follow-up Discussion**

Many developed countries described their specific technical assistance activities. However, many developing countries, while appreciating that assistance, expressed concerns that the assistance did not adequately meet their public health and market access needs.

Specific concerns included the lack of focus and co-ordination of assistance received. Several countries and international organizations provided further information on their technical co-operation programmes. While recognizing the logic of regional approaches, a number of countries expressed the view that careful consideration should be given to specific national needs.

## **NEW APPROACHES AND BUILDING ALLIANCES IN CAPACITY BUILDING AND TECHNICAL ASSISTANCE**

Mr. Deepak Gupta, Joint Secretary and Chairman, National Codex Committee at India's Ministry of Health gave the second topic presentation. He discussed new approaches and building alliances in capacity building and technical assistance. He emphasized that progress in taking food safety measures will only come when capacity is created to design and effectively implement those measures.

Capacity building must reflect the needs, priorities and conditions of developing countries. Some problem areas were identified as:

- While much has been done in capacity building, efforts have been sporadic and critical mass and multiplier effects have not been achieved.
- Technical assistance has been largely focussed in food export areas and is seminar driven, which is expensive and has limited reach.
- Technical assistance under the SPS Agreement has been largely notional even when developing countries have incurred substantial costs to meet import requirements.
- Increasing sophistication of laboratory instrumentation and methods of food analysis
- Codex standards primarily based on information provided by developed countries on the principle of 'highest' not 'appropriate' levels of protection, thus acting as non-tariff barriers to some developing country exports.
- Capacity building required to enable developing countries to take part fully in the standard setting process including physical attendance at Codex meetings
- Poor response by developed countries in concluding Equivalence Agreements

### **Lessons Learned**

Specific areas of action were identified as: (1) the development of a National Action Plan based on a needs assessment; (2) the strengthening of national food control systems; (3) collaborative projects for capacity building within the National Plan; (4) improving laboratory infrastructures; (5) preparation of GMP / HACCP / GHP norms for medium and small businesses, with special attention to street food/catering establishments; (5) sustainable education and training; (6) a national alliance of scientific and academic institutions, professional associations, and trade bodies; (7) strengthening existing institutions to Centres of Excellence and Collaborating Centres; and (8) improved foodborne disease surveillance.

Some topics deserving further consideration include (1) consideration by FAO, WHO and other international organizations to co-ordinate all technical assistance at the country level; (2) preparation of national HACCP training and implementation programmes; (3) consideration by WHO to strengthen WHO Regional Offices; (4) provision of technical support in the form of experts at National Food Safety Control points; (5) preparation of Internet-based training and sensitization programmes; (6) improvement of data generation from developing countries for Codex standard setting; (7) preparation of a database of import requirements of developed countries; (8) setting up a Global Food Safety Fund or other funding mechanism to support developing countries; and (9) identification of appropriate instrumentation and methods of food analysis.

### **Follow-up Discussion**

Several key issues were identified for capacity building based on country experiences and problems. Channels of communication and mechanisms for collaboration are needed for co-ordinating efforts and building partnerships. Existing research and academic institutions could be used for specific tasks related to food safety. This will promote co-ordination and sustainability.

Several countries suggested that food safety should be integrated into primary and secondary school education. Networking of laboratories was proposed by several countries as a means to improve efficiency and share laboratory expertise.

A number of countries emphasized the need for communication and co-operation among international, regional and national organizations. These communications may have several mechanisms such as periodic meetings, inventories of actions and needs, information on seminars and workshops (e.g. venue and content), and creation of a database related to technical assistance. Co-operation between all involved organizations was considered essential for an optimal programme of work. Participants were informed of ongoing efforts to better co-ordinate technical assistance and capacity building activities among the FAO, WHO, OIE, World Bank and WTO.

The participants placed a great emphasis on an inventory of needs. It was felt that such an evaluation should be undertaken by the candidate countries themselves with the assistance of international organizations.

It was noted that through ongoing technical assistance programmes, national expertise in developing countries has been established. However, quite often this expertise is not acknowledged at an international level. Engagement of local expertise along side of international experts was seen as an important contribution to capacity building in developing countries as well as being of extreme value in binding alliances between developing countries, by contributing to better adjustment of the technical cooperation to the beneficiary countries through better insight into national specifics.

Many countries emphasized the fact that, in order for technical co-operation activities to be effective and sustainable in the long term, all other stakeholders should be involved in addition to professional capacity building. Special emphasis should be given to appropriate sensitization of key persons, such as policy makers, and to the development of public education programmes related to food safety, such as school health education and the development of consumer awareness.

***N.B.*** *The theme and both topic presentations under Capacity Building as well as a summary of each of the CRDs submitted for each topic, are attached as Appendix 10.*

## COMMUNICATION AND PARTICIPATION

Dr. C.J. Kedera of Kenya chaired the Discussion Group on Communication and Participation. Dr Azriman Rosman of Malaysia was the Vice Chair. Mr José Luis Flores of the Secretariat of Health of Mexico presented an overview of the theme of Communication and Participation using the experience of Mexico as an example. He explained the roles of the various officials involved in food control and noted that Mexico's efforts to communicate during the development of food safety laws and regulations raised issues for all countries to consider. These included:

- Establishment of a General Office for Consumers' Communication;
- Basic education on food safety is required at the elementary school to foster communication and participation;
- Forming a Master Plan on Food Safety for the promotion of GAP, GMP, SSOP and HACCP;
- Offering a training program for housewives to foster hygiene practices and handling of food in the home;
- Creation of a single food safety system through a consultation with all stake holders;
- Promoting awareness programs with producers' associations to facilitate the process of establishing risk reduction systems.

## **COMMUNICATING FOOD SAFETY REGULATIONS AND RISK MANAGEMENT – INVOLVEMENT AND PARTICIPATION OF CONSUMERS AND OTHER STAKEHOLDERS**

Ms. Antonia Maria de Aquino, Ministry of Health, Brazil introduced the first topic under the general theme. She shared Brazil's experience in the implementation of risk analysis.

She related two experiences highlighting Brazil's methods of communicating food safety information. The first involved botulism associated with canned palm heart. A risk analysis was initiated and a technical group comprised of all stakeholders was formed. Initially, a temporary product label was used to warn consumers. In addition, a "Warning to the Population" was announced in popular newspapers and on television. Products associated with the outbreak were recalled.

In second instance, a survey of salt samples showed large deviations in levels of added iodine. New requirements were established for the iodized salt industry. The Service for Industrial Learning was enlisted to help disseminate the new requirements. Advertising campaigns by the mass media was done and information materials were delivered to schools to inform consumers about risks from iodine deficiency. Health community agents, of whom there are 144,000 members, took part in the risk communication through housecalls.

### **Lessons Learned**

Ms. Aquino's presentation identified a number of communication options, including:

- Warning labels;
- Notification through newspapers and television;
- Use of Internet;
- Enlisting organizations in communications with industry, schools and direct visits to homes.

### **Follow-up Discussion**

It was clear during the ensuing discussion that communication has an all-important role in many aspects of food safety, including:

- Controlling and managing food safety crises;
- Safety standards of food as well as new regulations;
- Informing and educating consumers and public at large;
- Getting feedback from consumers and other stake holders.

Communications with consumers and other stakeholders has improved the quality of risk management decisions, allayed public fears and reduced panic when food safety emergencies have occurred.

Several possibilities were suggested to accomplish effective communications. These included:

- Information in relation to risk management needs to be shared by the members of an inter-ministerial body to address public comments and concerns;
- Establishment of consumer forums and public meetings to discuss food safety;
- Enacting national laws which require governments to consider consumer participation and contribution;
- Use of existing groups such as Codex National Committees.

It was noted that the characteristics of effective communications are multi-channelled dialogues with all stake holders that are complete and factual, that note and acknowledge uncertainties, and that ensure that communications are timely, clear, specific and understandable.

### **ENSURING EFFICIENT COMMUNICATION AND INTERACTION BETWEEN FOOD SAFETY RISK ASSESSORS AND RISK MANAGERS**

Dr. Hans Dieter Boehm, Germany's Federal Ministry of Consumer Protection, Food and Agriculture introduced the second topic under the general theme. He discussed a paper based on the WHO Expert Consultation *The Interaction between Assessors and Managers of Microbiological Hazards in Food* held during March 2000 in Kiel, Germany. This Expert Consultation made the following principle comments and proposals:

- Food safety systems should be structured on a risk-based approach with appropriate interaction between risk assessors, risk managers, and stakeholders;
- A functional separation of risk assessment and management is essential;
- Independence, transparency, and robustness of scientific analyses are essential for credibility. Nonetheless, dialogue among assessors, managers, and stakeholders is essential to maximize utility of assessment findings;
- National governments should acknowledge the importance of functional risk assessment and risk management while ensuring transparent and appropriate interactions.

#### **Follow-up Discussion**

It was generally noted that risk assessors and risk managers were separate groups. However, some countries were of the opinion that both functions could be combined especially where the documentation is publicly available. The functional separation of risk assessment and risk management contributes to increasing the transparency of the risk analysis process. Where both the risk assessment and risk management processes are documented and transparent, the integrity of the risk assessment process can be maintained. In addition, there are several other benefits that can be derived from this separation:

- Maintenance of scientific independence
- Facilitation of an open dialogue and open communication between risk assessors and risk managers
- Clarification of communications with the public on scientific issues as well as other relevant factors considered in the risk assessment

It was noted that risk assessment need not be a long or expensive process. The final consideration being that any use of the risk assessment process will improve risk management decisions. The use of the risk analysis paradigm will ensure the effective use of limited resources in the food safety area.

Several countries expressed the need for generic risk assessment. It was noted that generic risk assessment framework is available and is used at the international level. However, application at the national level requires local data on intake and exposure to be included into the generic risk assessment to reflect the realities of the local conditions.

Some concerns were expressed that the mass media may misreport a food safety emergency and cause public panic. It was suggested that in order to avoid this circumstance and build trust there must be complete transparency in the risk assessment process and open, direct communication with the media.

It was noted that capacity building and development activities must include information, education and training for consumers and other interested parties who may be involved in the risk assessment and risk management processes.

***N.B.*** *The theme and both topic presentations under Communication and Participation, as well as a summary of each of the CRDs submitted for each topic, are attached as Appendix 11.*

## **FUTURE GLOBAL FORA**

There was general agreement among the participants that a second forum with possible succeeding fora should be held. The Global Forum is not designed to compete with or replace other ongoing international meetings. As the participants are primarily food regulators, many are involved with Codex activities. The Codex Alimentarius Commission (CAC) meets on alternate years with the next session scheduled for 2003. It was therefore suggested and agreed that the next Global Forum meet in 2004, with any succeeding fora meeting during those years that the CAC does not meet.

The joint secretariat provided two suggested themes for the next Global Forum, for consideration by the participants. These were:

### **1. Application of risk analysis in food safety**

The Global Forum is a forum to share information and experiences. Several countries have in recent years started adopting new thinking in food safety and are producing their first experiences in the application and use of risk-based food safety management systems.

These changes generate new regulations that will affect the safety of the food supply along the whole food chain not only domestically but also in other countries when traded goods enter the food chain. Thus, even countries that do not yet have a risk-based food safety system will undoubtedly also be affected by the actions of countries adopting risk-based regulations. They will therefore also have experiences to share. Since this is a new area, most countries will be in dire need of information and experiences from which they can learn and from which they will eventually be able to improve the functioning of food safety systems.

## 2. Building effective food safety systems

The Global Forum is a forum to share information and experiences. In all countries the area of food safety is defined by the interplay of government, private sector, consumers and other partners such as the academia and the media. It has been demonstrated that the effectiveness of food safety systems relies heavily on coordination, collaboration and communication of all activities, not only to be cost-effective but also to increase confidence. The role and responsibilities of each partner in a food safety system should be clearly defined, the overall functioning of the system should be based on a number of agreed principles, and it is felt that the aim of the forum could be to share information on the structure of existing food safety systems, their strengths and weaknesses, in order to find ways of improving the present systems throughout the world with a view to directly improving the food safety situation, and to increase subsequently the confidence of all stakeholders.

There was considerable discussion over the choice of the central theme for the next forum. Most countries supported the second suggested theme (building effective food safety systems). Several countries also supported a possible theme of development of a worldwide food safety information system. One country pointed out that a future forum would benefit from regional conferences to discuss food safety needs held in advance of the forum. It was decided that the final decision would be left to the joint FAO/WHO Secretariat. It was also suggested that a scoping meeting may be convened by FAO and WHO to decide on the theme for the 2004 Global Forum. Several countries requested that the topics selected for the next forum be practical and pragmatic with a narrow scope allowing greater focus during discussions. It was also suggested that more time be allowed as it was felt that the present Forum was too short. It was further suggested that the next forum venue again be in a developing country.

The secretariat summarized the points agreed to by the participants as:

- The next Global Forum to be held in 2004 with any succeeding fora held during years that the CAC is not in session;
- The next Forum theme to be *Building effective food safety systems*;
- Selected topics under the main theme to be limited in scope as well as being practical and pragmatic;
- Additional time to be considered;
- The next Forum venue to be held in a developing country.

## CLOSING THE GLOBAL FORUM

Prior to the closing of the Global Forum the Chairman of the Codex Alimentarius Commission, Mr. Tom Billy, was invited to make a presentation regarding the present and future activities of Codex. Mr. Billy noted that at the last Commission session in 2001, the Codex adopted both a Strategic Vision statement and a Strategic Framework with Objectives. The Framework established six strategic objectives and priorities of Codex. These were:

- Promotion of sound national food control and regulatory systems from farm to table;
- Promotion of the widest application of risk analysis;
- Promotion of seamless linkages between Codex and multilateral bodies;
- Increased efficiency and stronger management oversight of Codex work;
- Full participation by Codex members and interested parties;
- Promote the maximum use of Codex standards, nationally and internationally.

He advised the participants that the work on the new objectives has already begun. FAO and WHO are designing a Codex Participation Trust Fund for developing countries. Also, a FAO/WHO management review and evaluation of the work of Codex has been initiated.

H.E. Ismail Alaoui, The Minister of Agriculture, Rural Development and Forests of Morocco, officially closed this first Global Forum of Food Safety Regulators on behalf of the Government of Morocco and H.R.H. King Mohammed VI. He stressed the importance of international meetings such as this to focus the attention of the world on food safety matters. He noted that the Forum opened new horizons for co-operation between institutions and organizations responsible for food safety. He thanked the participants for their efforts over the previous three days and stated that Morocco was pleased to have been the host of this most important activity.

The Chairmen provided the Forum participants with a general statement and summary of the deliberations and findings of this first FAO/WHO Global Forum of Food Safety Regulators (see the following page).

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS****Chairmen's Summary****ANNEX I**

This Global Forum was held to exchange experiences, both good and bad, on the efforts of governments to assure the safety of their food supplies. The Forum was characterized by very active participation of all delegates. The meetings were held in an atmosphere of conviviality and countries were willing to learn from each other and openly discuss all experiences presented.

All of the Forum discussions were based on the principle that regulations must be science-based and built on risk assessment as appropriate to circumstance. These discussions demonstrated a global recognition that actions need to be taken throughout the food production chain from farm and fishing boat to the consumer.

The Forum held the view that all stakeholders should be involved in the regulatory process and that its implementation should be based on the risk analysis paradigm.

In the process of sharing experiences, countries learned that it is possible to use food safety regulations to reduce foodborne illness and improve the overall health of their populations. This also helps countries develop their trade opportunities and strengthen consumer confidence in the safety of their food supply.

Nevertheless, many areas require further discussion in appropriate fora to clarify the application of the risk analysis paradigm in all situations. There is also a need for further dialogue and interaction between countries to deal with food safety issues where there is uncertainty or lack of agreement on the science.

It was recognized that further application of the risk analysis approach in developing countries requires additional investigation and more transfer of knowledge and information, as well as an efficient sharing of relevant data between countries. The pivotal role of international organizations in mediating this development was stressed.

Many of the discussions were based on practical examples, included in the more than 90 country papers submitted to the Forum. Such examples include the resolution of the dioxin crisis and efforts underway in several countries to reduce microbiological risks, such as *Salmonella* and *Campylobacter*, in some cases quite significantly.

The Forum also shared examples on how food safety systems are being adapted to ensure a more sustainable consultation and involvement of consumers and other stakeholders in the regulatory process.

Because food safety should no longer be the luxury of the rich, actions need to be taken urgently to develop the capacity in particular in developing countries to assure the safety of the food supply to their populations. Building such capacities will also assist in building export capacity, improving public health and reducing poverty. It improves the confidence of all consumers in the foods that they buy in the global marketplace.

The Forum had a vibrant exchange of views on the assistance needs of developing countries and how capacity building efforts can be more effectively utilized. There was recognition that an assessment of needs and priorities of developing countries concerning technical assistance is necessary. Many countries reported ongoing efforts of capacity building and called for more information, communication and consultation to enhance the effectiveness of these activities.

It was recognized that communication and consumer involvement both need further development in many national food safety systems. Improved emergency response systems, especially at the international level, will assist in improving communication and understanding of food safety emergencies and assist in better and more targeted response at the national level.

With the risk analysis approach, improved communication, and increased capacity building efforts there is a bright prospect of improvements in food safety both nationally and internationally.



## APPENDIX I

**LIST OF PARTICIPANTS  
LISTE DES PARTICIPANTS  
LISTA DE PARTICIPANTS**

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**APPENDIX II**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28–30 January 2002*

**OPENING REMARKS OF THE MINISTERS OF HEALTH AND AGRICULTURE  
OF THE KINGDOM OF MOROCCO**

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**Mr Ahmed Sbihi**  
**Representative for H.E. Minister of Agriculture, Rural Development, Water, and Forestry**  
**The Kingdom of Morocco**

Your Excellency,  
Mr. Governor,  
Distinguished participants,  
Mr. Director-General of the FAO,  
Mr. Director-General of the WHO,  
Honourable Regional Representatives of these two organizations,  
Distinguished Ambassadors, Experts, Ladies and Gentlemen;

Allow me first of all to welcome, in my name and on behalf of the Government of His Majesty King Mohammad VI, the delegates of the Member States of the Food and Agriculture Organization of the United Nations and the World Health Organization, the experts in these two organizations, and the representatives of all other organizations participating in this scientific event. This gathering aims, as you all know, at exchanging experiences and identifying cooperation opportunities for more efficient and transparent food safety evaluation and system measures world wide.

It is a great honour for the Kingdom of Morocco to host this Global Forum in Marrakesh where the World Trade Organization (WTO) came into being in April 1994. Hosting the Forum is an embodiment of His Majesty King Mohammad VI's sublime volition that was expressed during the audience of FAO's Director-General, Mr. Jacques Diouf with His Majesty during his visit to Morocco last year. His Majesty showed great interest in this Forum given his concern about this field.

Ladies and gentlemen,

What makes this Forum so important to us? First of all, because food safety is nowadays a strategic priority for all states and international organizations, such as the FAO, WHO, WTO and others, due to the economic globalization, the freedom of exchange, and the ensuing increase in production and expanded use of technology.

Therefore, we are all requested in such a gathering to build on the Rome Declaration which came as a result of the 1996 World Food Summit. All leaders participating in the Summit stressed the right of all to have access to sufficient and safe food.

The idea of holding such an international event emerged during the G8 Summit in Okinawa in 1999. During its Conference in Genoa, Italy in 2001 the G8 emphasized the need to include the food security issue among the urgent issues to be discussed at the global level, in order to come up with an efficient health crisis prevention mechanism based on scientific data.

In fact, in view of the recent health-related crises, such as bovine spongiform encephalopathy (BSE) or the presence of high levels of dioxin in food products of animal origin, which had severe economical and social repercussions in most developed and underdeveloped countries, major efforts are needed to satisfy the consumers' needs in facing health-related hazards.

We see this Forum as an appropriate platform for those responsible for food safety in over 150 countries, to freely express their concerns and exchange their expertise and experiences in this regard.

Ladies and gentlemen,

The importance of this Forum stems also from the nature of the issues on its agenda. These are important and complex issues as they compare varying procedures according to each country, culture and means, but all aim at a unique objective, i.e. ensuring the safety of consumers.

I would like to discuss in particular the issue of “capacity building” which is, in our view, a practical framework to promote international cooperation in order to assist developing countries in the implementation of food safety mechanisms.

Although most developed countries have reached a high level of food safety, most developing countries are still lagging behind due to limited financial resources and lack of expertise.

In developed countries, globalization and the liberalization of markets occurred in a framework of highly-processed agricultural and animal products. Another characteristic is the increase in the consumers’ needs and the existence of more tighter laws and more sophisticated monitoring techniques. All these factors make the access of the developing countries’ exports to the markets of these countries extremely complicated and difficult.

However, in developing countries, the globalization and the freedom of exchange occurred with an unsophisticated production system with limited marketability and informal trade. Also, the majority of citizens in these countries are more concerned about their basic subsistence needs; while the control mechanisms lack the necessary financial and human resources, therefore making the national markets the main target of likely hazardous and unsafe products. These structural impediments, in addition to the lowering of customs tariffs, will certainly lead to imbalances in trade exchanges in favour of developed countries.

This shows us the valuable role of the global community as a whole in setting a framework of solidarity enabling all people to have access to sufficient and safe food products. The international organizations concerned also play a vital role, in particular FAO and WHO, in filling the gap among countries in terms of plant sanitary control systems. In this regard, it is necessary to establish an international fund with the sufficient financial resources in order to finance framework-setting, elaboration, and rehabilitation programmes for developing countries. At the same time, FAO and WHO play a crucial role in finalizing diagnosis and premonitory studies and in participating in the elaboration of action plans that will satisfy the needs of these states. Developing countries should be enabled to participate in the setting of international standards and measures such as the international sanitary reference code or Codex Alimentarius, in order for them to preserve their interests with equal opportunities in terms of trade exchange. This will provide the international law with an unsuspected legitimacy thanks to the preservation of the interests of all countries around the world.

Ladies and gentlemen,

Morocco is fully aware of the importance of food for the Moroccan consumers’ health and for the reputation of its food exports. Therefore, we introduced a package of in-depth reforms to the national sanitary safety system.

In this regard, a network of laboratories was set up covering the entire territory and satisfying most of the needs in terms of analysis; this in addition to a special rehabilitation programme which trained a large number of specialised human personnel. On the border check-points, a newly created unified network is in charge of sanitary control. A broad-based programme was also launched to create self-control regulations at the production units’ level, based on sophisticated techniques such as the “Forestry check-points for risk assessment technique” (HACCP) and the “Good production procedures technique” (BPF).

We were also able, with FAO’s support, to reform and modernize the basic law on fraud fighting. We are currently working on the creation of a neutral scientific assessment agency for sanitary hazards in food, in addition to a structural reform study to cope with these hazards.

In the same context, we included the food traceability issue on our list of priorities. We are also trying to make a clear distinction between risk assessment and risk prevention operations in order to optimize the control's transparency and autonomy with regard to public authorities, industrialists and non-industrialists. The control institutions and those responsible for risk prevention should coordinate their efforts to reach a high level of food safety. All kinds of cooperation - whether bilateral or multilateral - are welcome in this regard in order to work on a common basis which will ensure the sanitary safety of food both on the regional and the international levels.

Ladies and gentlemen,

Given the high-level participation in this Forum, its activities will certainly lead to practical results and recommendations which will contribute to the elaboration of new working trends and plans to provide the needed protection and prevention for all people.

Finally, I would again like to thank FAO and WHO for choosing the Kingdom of Morocco to host the First Global Forum of Food Safety Regulators. I would like to welcome you all to Morocco and to extend my best wishes for the success of our Forum.

Thank you.

***H.E. Touhami Khiari  
Minister of Health  
The Kingdom of Morocco***

Distinguished Representatives of FAO and WHO,

Your Excellencies the Ambassadors,

Ladies and gentlemen,

First of all, I would like to express my thanks and appreciation to FAO and WHO for choosing Morocco to host this important Forum and I wish all participants a pleasant stay among us.

Ladies and gentlemen,

Such meetings make Marrakesh the capital of international gatherings and conferences and enhance its reputation as the city where important decisions are taken. Our city has been the birthplace of World Trade Organization in 1994. Recently, countries around the world agreed here to take important steps towards combating pollution at the 7<sup>th</sup> Conference on Climate Change.

Apart from its beauty, cultural heritage and history, Marrakesh has always been a welcoming place that brings people together. That is why Marrakesh has been chosen for this meeting with the hope of adopting decisions which will improve human life.

Ladies and gentlemen,

In spite of the technological revolution we enjoy today, we are still confused regarding certain issues. These issues are related to unprecedented changes and developments in our societies which make us wonder how human brains can assimilate and accommodate such new ideas and technologies. Among these issues are the way we behave, our patterns of living and how to achieve our aspirations.

The theme of your meeting is within one of these issues. The way we handle such a theme is contrary to what we might have imagined not very long ago. The recent events and the way they were handled politically and at the media level would not have the same effect had they occurred twenty or even ten years ago. The ever changing needs of the world population, the development of their rights and the struggle to maintain them have not limited the pressures to institutional bodies, but have extended to include the media, the civil society and other means. Politicians are subjected to greater pressures other than the responsibilities they have been entrusted with.

To find solutions to all these problems and to respond to the needs of our citizens, we have to first identify them and then find real solutions.

Ladies and gentlemen,

The theme of today's meeting reflects these conditions under which we live in. Let us take, for example, BSE, which was the major international event that led to severe actions at the international level, even without any scientific proof to justify them. A new concept has been introduced in our terminology related to precautionary measures. While a clear definition of such measures were absent, they were applied blindly and in many cases in an exaggerated way.

The most striking example is the withdrawal of the suture used in surgical operations extracted from cows. The reason given was that it could cause possible damage in the long run. Instead an artificial and expensive one was introduced with the consequences of such action. Now the question is how to accept these consequences in order to avoid possible dangers which could be subjective in nature?

Adopting such measures has financial implications which burden the budget of every state. It is not a secret to tell you that an action such as this is detrimental to our people's needs and creates problems to our development programmes.

In the meantime, the complexity of the problem remains within conflicting economic interests and preoccupation of a human dimension. If we have to create wealth, it should not be at the expense of human interest and acceptance of the status quo. The integration of world economy would create comparative advantages to individuals, groups and societies. However, it would lead to food dependence on a global level.

Your meeting is important as it tackles problems related to changes and shifts in our societies, which require new methods and solutions to ensure food security to our people.

The last years ten years have witnessed the increase of food-related diseases world wide. These diseases have social, psychological and economic implications that go beyond the individual, the family and society to reach an international level. No state is isolated from such problems, however, the most affected are the developing countries which lack resources, mechanisms, technologies, legal and logistic capabilities to address such problems. These problems are doubled as these countries import food and commodities to satisfy the basic needs of their population.

Although the number of mad cow cases declared by developing countries does mean much, this epidemic indirectly reached Europe and it was obliged to destroy huge numbers of animals and animal products and use alternative and expensive products.

Ladies and gentlemen,

During the last century, food-related diseases have been brought under control, however, their economic, social or cultural implications could not be identified or assessed. Therefore, strategies in food safety should concentrate on sustainable actions. Efforts in this field should also be coordinated at the national and international levels. I would like to take this opportunity to congratulate consumer societies which played an important role in improving the standard of food safety.

Your meeting is an occasion to exchange information on problems related to food safety, identifying shortfalls and developing strategies. I believe that the aim of this meeting is to give a scientific dimension to the question of food safety and to find logical and realistic solutions. Scientists are requested to clarify the problem so as countries, especially developing countries, can take necessary actions without wasting their resources. These actions should be taken without any external pressures, especially from developed countries, within new equilibrium and globalization.

Ladies and gentlemen,

There is a need for an approach based on identifying risks in food safety to improve the detection of food-related diseases and to develop national infrastructures to analyze them, especially in developing countries.

As you know, science and technology are developing rapidly, however, the gap between developed and developing countries is widening to the detriment of the latter as they lack analytical techniques in this field.

We have, therefore, to think of an international system in the form of an agency or observatory to coordinate food safety and identify food risks among countries at the international level. Assistance has to be provided to developing countries to strengthen their systems of control for food safety.

Finally, I would like express my congratulations to the organizers of this meeting especially those from FAO and WHO and to extend my thanks to the participants who share their knowledge and experience with us. I wish your meeting every success and the best of luck.

APPENDIX III

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28 – 30 January 2002*

**INAUGURAL STATEMENTS FROM FAO AND WHO**

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Excellencies,

Ladies and Gentlemen,

First of all, I should like to express my gratitude to His Majesty King Mohammed VI and his Government for having kindly invited us to hold the Global Forum of Food Safety Regulators in this lovely historical city of Marrakech.

Food security is one of FAO's top priorities. Feeding - and feeding properly - the hundreds of millions of people who suffer from hunger and malnutrition requires attention not only to calorie needs but also to quality concerns.

Several million people suffer or die each year from foodborne diseases. This unacceptable situation calls for prompt and effective remedial action. It is not only a health and economic imperative but also a moral responsibility.

Food safety concerns all participants in the food chain, from primary producers to consumers, as food can be contaminated by pathogens at any link of this chain. The most effective and often least expensive actions should therefore aim to prevent such contamination at source.

The latest food crises have highlighted the responsibility of farming and farmers in consolidating food safety. Their involvement in resolving the problem is therefore more than a requirement; it is a duty. Responsibility for food safety must also be shared by the private sector, consumers and public authorities who need to work together to put in place adequate regulations, appropriate institutions, proven capacities and effective controls.

Finally, food safety is a shared responsibility of developed and developing countries. With the increasing globalization of trade in food products, health requirements applied by importing countries must seek to protect consumers and not to raise technical barriers to trade. Food safety is thus clearly the responsibility of all. I therefore urge the developed countries to provide the developing countries with their technical and financial support.

FAO is ready to play a major role in setting up an integrated international food safety system, in cooperation with WHO and the other international agencies concerned. Food safety and food security are inseparable. Food safety is an inalienable right of each individual and requires an effort of understanding, communication and cooperation.

I am convinced that this Forum will produce real progress towards ensuring that everyone has access to safe food. I therefore wish you every success in your deliberations.

***Dr Gro Harlem BRUNDTLAND***

***Director-General  
World Health Organization***

Honourable Ministers and Dear Participants,

I am very happy to address you at the opening of this first ever Global Forum of Food Safety Regulators.

This is a pioneering and exciting event. Food safety is an essential public health priority all over the world. It is one of WHO's present priorities. Not long ago, food safety - like tobacco - was regarded as a luxury problem of the industrialized world, not something worth spending precious international funding on. Luckily, that misperception has changed for tobacco; and you are helping to also set the picture straight for food safety.

WHO estimates that annually 2,1 million people die from diarrhoea, mainly caused by food or water, and that even in developed countries up to one third of the population suffers from food-borne disease every year. Food safety is a global priority, not only because the problems are shared globally, but because these problems have significant influence on both health and development world-wide.

Many countries are reporting significant increases in food-borne disease. This tells us that food safety systems are not keeping up with changes in microbiological and chemical hazards, shifting food consumption patterns and growing urbanization, new production methods and new technology or even the globalization of food trade.

We must reflect on these trends. We must improve our systems and avoid repeating the mistakes of the past. WHO, together with FAO and our Member States are working hard to develop new, evidence-based, preventative strategies to lower risk of disease. This work focuses on the whole food production chain. We promote an open and transparent risk-analysis framework and especially a dialogue with consumers. We encourage interdisciplinary collaboration all the way from farm to table.

But theory is not enough. The national experience in implementing new ways of prevention and response to food hazards will be the yardstick by which to measure success. This is where the Global Forum comes in. We need to share our experiences, good or bad, so that future food safety systems can improve and leap-frog over past mistakes. I am heartened by the broad, global interest for this meeting, both in participation and in the presentation of country reports.

I wish you a successful Forum, and look forward to continue working with you in the future in this critical area of public health.

**FAO/WHO GLOBAL FORUM FO FOOD SAFETY REGULATORS**

*Marrakesh, 28-30 January 2002*

**INTRODUCTORY REMARKS**

*by*

*Mr David HEYMANN*

*Executive Director, Communicable Diseases  
World Health Organization*

## **FOOD SAFETY, AN ESSENTIAL PUBLIC HEALTH PRIORITY**

### **INTRODUCTION**

Food safety was in the past often but not always addressed as a public health issue. In recent years, because of a chain of events comprising large-scale food related crises of various degrees of severity, the public perception of the safety of our food supply has been shaken. However, the real burden of disease related to food presents an even more important reason why food safety has recently been increasingly identified as an essential public health priority. This is reflected in the acceptance of food safety as priority for WHO in the year 2000.

### **MICROBIOLOGICAL CONTAMINATION AND SURVEILLANCE**

The estimated annual mortality of food and water-borne infectious diseases in developing countries amounts to the sad high of 2.1 million deaths, mainly of infants and children. In industrial countries microbiological food borne illnesses affect up to 30 percent of the population. Every year 20 out of each million inhabitants die from food borne disease. There are a number of examples of increased problems over the last decades. The increase in the incidence of Salmonella enteritidis infections in humans in the years between 1980 and 2000 amounts to a factor of 20 for many of the countries in Europe and North America. Another example of globally emerging problems is antimicrobial resistance. Data from the US show that the percentage of multi-drug resistant Salmonella Typhimurium, type (DT) 104 in cattle has risen from a mere 2 percent in 1982 to 43 percent in 1996, while at the same time the percentage in humans rose from 0 percent to 35 percent. The curves of both human and cattle percentages are almost similar, time-wise; suggesting transmission from cattle to humans through food.

Our chains of food supply are often composed of many steps, and at each stage there are numerous possible occasions for contamination of the food. Many food production methods have been developed without adequate foresight into the possible consequences of the application of non-traditional techniques. This has for instance led to the spread of the BSE epidemic, an epidemic for which we cannot predict the expected course.

Some examples of the economic impact of infectious food borne disease outbreaks show that the consequences of cost reduction measures can be grave. An outbreak of cholera in Peru in 1991 cost 770 million dollars, a similar outbreak in Tanzania in 1998 36 million dollars. The costs, or rather losses, are caused by for instance declining tourist revenues and exports of food commodities. Simple preventive measures and effective surveillance systems at a fraction of these costs might have prevented these outbreaks, or would have definitely reduced the impact thereof.

From the outbreak in Tanzania a valuable lesson in risk analysis was learnt. Immediately after the notification of a human cholera outbreak in January 1998, various importing countries posed a ban on the importation of freshwater and marine fish imports. After a risk assessment undertaken by WHO on the actual transmission of human cholera, the ban was lifted. However, in the interim Tanzania had lost a lot of revenue through the halted export of fish. Had risk analysis been undertaken based on adequate information, the international response would have been more appropriate, and the ban would never have been posed. It is thus in the interest of all trading partners, be they the exporter, often developing countries, as well as developed countries, to have an adequate risk analysis performed.

### **CHEMICAL CONTAMINATION AND STANDARD SETTING**

The human health effects of chemical contaminants of food, such as dioxins, range from various cancers, damage to the nervous system, diseases of the immune system, and reproductive disorders to interference of infant and child development. Various monitoring programmes have taught us that even in countries where the food supply is supposedly safe, chemical contamination

remains a problem. Dietary exposure to dioxin and dioxin like PCB's in various Western countries is higher than the provisional tolerable monthly intake, the average level of DDT in human breast milk in all but one of the WHO Regions is well over the provisional tolerable monthly intake. Various similar or smaller scale studies regrettably complement this picture.

WHO, through a number of food safety activities, has been contributing to food safety on a global level for a number of years. Much has been achieved in the areas of disease surveillance and response, risk assessment and surveillance of chemicals and chemical contamination, capacity strengthening, and standard setting. Most of these activities have been undertaken in collaboration with FAO.

## **GLOBAL SURVEILLANCE OF INFECTIOUS DISEASE**

A network of networks: WHO has, through a network of networks, joined all presently existing networks that are active in the area of infectious disease surveillance. This task is undertaken by using important partners in the area of collection of information on disease incidence and outbreaks, such as the Ministries of Health, the UN sister agencies, NGOs, the media, epidemiology and military training networks. Examples of partners in this network of networks are described in the paragraph below.

The Global Public Health Intelligence Network, GPHIN, is a web-based global network that automatically scans all news publications on the Internet for infectious disease outbreaks. This way, a number of important outbreaks have been identified, that would only have been discovered in a much later stage if the usual surveillance systems would have been the only mechanism of recognition. As an example, over a ten-day period in the year 2000, through screening for human infectious disease outbreaks related to food animals, GPHIN found a total of ten outbreaks. Of these outbreaks 5 affected less than 5 patients, three were in the range between 20 and 50, and two were large-scale. The rapid detection of these outbreaks allows for an early launch of control measures, and thus reduces the eventual size of the outbreaks.

The global surveillance of human influenza, in which 84 countries are involved, through either collaborating laboratories or national networks, has led to the early detection of the Influenza A (H5N1) virus, or Hong Kong virus, which allowed for effective risk management and pandemic planning. The existence of a network, joining all collaborating laboratories and institutions, allowed for start of vaccine production as early as 4 months after the initial detection of the virus.

The global surveillance of salmonella infections, a joint project of WHO, CDC and the Danish Veterinary Institute, which surveys salmonella infections in animals and humans is another global programme in which a network of laboratories has been set up to monitor the global incidence of salmonella infections. The programme is also active in expanding the network through technical assistance to laboratories in sero-typing analysis and quality assurance.

In the area of monitoring and surveillance of chemical contaminants, WHO has been collecting data on chemical food contamination and human exposure for global evaluation through its Global Environment Monitoring System, or GEMS, for a number of years. The focus is on population based dietary exposure to major food contaminants, and presently more than 80 countries are participating in the system.

## **RISK ASSESSMENT**

For many years, chemical risk assessment has been the first focus of activities. Through the work of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), risk assessments and advice have been provided to Codex Alimentarius and Member States.

In the area of global risk assessment, the studies into potential exposure to Bovine Spongiform Encephalopathy through trade, which focussed on the spread of the actual sources of BSE contamination world wide, animal feed and live bovines, has allowed for the development of scenarios and projections on the incidence of BSE and human variant Creutzfeldt Jacob disease.

Currently FAO and WHO are performing a number of microbiological risk assessments, the first ever to be performed at the international level. The food-pathogen combinations that have been identified through various expert consultations as deserving immediate attention are *Listeria* in ready to eat foods, *Campylobacter* in poultry, *Vibrio cholera* in seafood, and *Salmonella* in eggs and poultry.

## **THE WHO GLOBAL FOOD SAFETY STRATEGY**

Through the adoption of food safety as one of WHO's priorities in the World Health Assembly in 2000, it became imperative for WHO to develop a global strategy on food safety. This strategy has recently been evaluated and approved by the Executive Board, and will serve as the basis for the WHO food safety activities in the medium and long term. In this strategy, technical capacity building and international cooperation are incorporated in the areas of food borne disease surveillance, risk assessment, the safety of new technologies, the public health role in the work of Codex Alimentarius, and risk communication.

## **CONCLUSION**

The opportunities for partnership in food safety are presently good. In industrialised countries the present atmosphere creates wariness in consumers vis-à-vis food safety, and a severely compromised confidence of these consumers in the existing food control systems. This leads to a large willingness to put food safety on the political agenda. The hidden burden of food safety is still not fully understood, but present knowledge already alarms by mere facts. In developing countries the visible and endemic burden is large. Regretfully, mainly due to a lack of awareness both on the side of the consumers and on the side of politicians, there is often a low political will to address the issues adequately.

There is at this precise moment in time a great opportunity to create the necessary partnerships between industrialized and developing countries to benefit from current and past experience in strengthening national and global food safety. Let us grasp that opportunity as strive for safer food for all.

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28 – 30 January 2002*

**INTRODUCTORY REMARKS**

*by*

*Mr Hartwig DE HAEN*

*Assistant Director-General  
Economic and Social Department  
Food and Agriculture Organization of the United Nations*

Your Excellencies, honoured guests and Forum participants, ladies and gentlemen !

Welcome to this first-ever Global Forum of Food Safety Regulators. This is an opportunity for food safety regulators from every region of the world to sit together and share experiences on what has worked and what has not to improve food safety throughout the food chain.

## **INTRODUCTION**

Ensuring the quality and safety of the food we eat is vitally important. Food safety is everyone's responsibility - those involved in production, processing, marketing, handling, cooking and eating. But, the legal responsibility for food safety rests with governments. The key people in any national program to control food quality and safety are those gathered here today – the national food safety regulators.

I would like to emphasize a few concepts that are fundamental to the issues that you will be discussing over the next few days. First, food safety is a serious matter for all countries and all people. Second, food safety control systems need to be adapted to national needs. Thirdly, we must strive to find the right balance between food safety and other important aspects of food quality. Finally, I want to highlight the importance of three global issues –capacity building, the need for international cooperation and, communication and participation.

## **FOOD SAFETY IS A SERIOUS MATTER FOR ALL COUNTRIES AND FOR ALL PEOPLE**

In many parts of the world, food safety systems desperately need improving. Safer food has many benefits: less human suffering from food borne diseases, lower cost of public health, fewer barriers to world trade, lower loss of labour productivity and better overall food security. Food safety could indeed be considered one of the most important concerns of our time.

Today we know better than ever how to control the safety and quality of foods. We know how to harvest and process foods safely. We have advanced food inspection and analysis technology and we also have sophisticated procedures of risk analysis. I dare say that, at least in developed countries, most of the food we eat has never been safer than it is today. So why are we gathered here to discuss food safety and why is it so important? The answer is simple but sad: because several million suffer from food-borne diseases every year, sometimes even dying from them. This is unacceptable because most of these illnesses are preventable.

The threat to public health from food-borne microbial pathogens occurs in both developed and developing countries, with the greatest impact on children, pregnant women, the poor and the elderly. Chemical hazards are another significant source of food-borne illness. Public concern has been heightened by recent episodes of new microbiological and chemical contamination of foodstuffs. Threats such as salmonella, mycotoxins, BSE, dioxin and residues from antibiotics affect more than one country and in some cases more than one continent.

In developed countries, consumers are constantly raising their expectations with regard to food safety. In developing countries the main problem remains hunger and malnutrition. Almost 800 million people suffer from insufficient dietary intake, but unsafe food is of increasing concern to them as well. Although developed countries have had some widely publicised cases of food contamination recently, the level of food safety is generally much lower in developing countries, with negative implications not only for the well-being of their people, the poor in particular, but also for their access to export markets. This disparity needs to be remedied. Food safety can no longer be the luxury of the rich; it must become a universal right for all.

## **OUR FOOD SAFETY CONTROL SYSTEMS NEED TO BE ADAPTED**

Our food safety control systems need to be better adapted to the needs of the countries and to the state of the art. The gap between our knowledge and the practical reality is too wide.

For example, the traditional way to control the safety of foods has been to examine the finished food product. However, concentrating on just the last link in the chain has sometimes been rather costly

when food was found to be contaminated and had to be rejected or disposed of. The less costly options are often those that prevent contamination at the source and apply production and processing technologies that bear less risk of contamination.

One more appropriate approach is to consider how to enhance the safety of food throughout the entire food chain. The monitoring and control of food safety is a continuum from the original production of the food, through harvest, processing, storage and transport, until its final destination in the hands of the consumer. In this approach, sometimes referred to as “farm to table”, the food producers, processors and handlers are all partners with consumers and the national food control agencies. It promises to be more cost-effective than approaches that concentrate mainly on the sector of food transformation. The most recent food threats have highlighted the vital role of agriculture, animal husbandry and fisheries in ensuring food safety. This is why we call on all regulators to work with farmers and other primary producers in building food safety, in developing as well as developed countries.

We in FAO observe that most of the traditional food control systems have had a sectorial or fragmented structure, with different ministries or agencies being responsible for food control. Even if such a system puts emphasis on the necessary multi-disciplinary approach to food safety, it can face difficulties in co-ordination or uneven regulation. The challenge is to establish more integrated systems, which provide increased consistency in assuring food safety. Such integrated systems could go a long way toward improving the confidence of consumers and foreign buyers. FAO and WHO have just produced guidelines for strengthening national food control systems that include reference to these necessary changes. You will hear more about these Guidelines during this Forum.

A word of caution should be voiced here: establishing and upgrading food safety control systems is often a costly undertaking. Low-income countries have no other choice than to proceed step-by-step and to invest first where there is a pressing need to guarantee compliance of their export products with international standards. Care should be taken, however, that this does not result in dual systems permanently. In the long run, domestic consumers should not be discriminated against having to eat food that is less safe than the food exported from their country. Food safety is the right of people everywhere.

## **BALANCE FOOD QUALITY AND DIVERSITY WITH SAFETY**

Today, the diversity and richness of our global food supply is greater than at any time in the past. However, while some consumers enjoy new and exotic foods in their markets, others do not want to lose their traditional foods - foods identified with particular cultures or production areas. Keeping this in mind, we must seek to maintain a diversity of high quality foods without higher risk. An example is cheese made from unpasteurized milk. Ideally, we must find improved processing, handling and monitoring techniques so as to permit production of a safe product even with traditional methods.

The connection between food safety and quality was also expressed in one of the objectives of the Plan of Action of the World Food Summit, which states the aim to “..ensure that food supplies are safe, physically and economically accessible, appropriate and adequate to meet the energy and nutrient needs of the population”.

## **CAPACITY BUILDING**

For many years now, FAO has worked with developing countries to establish and improve their existing food control systems. FAO is prepared to continue and even intensify this assistance in capacity building, ranging from food legislation to food inspection and risk analysis through training, provision of expert advice and purchase of necessary equipment and supplies.

Many developing countries, the poorer, least developed countries in particular, still have an insufficient capability to control the safety of foods. In this regard, I am glad to recall the Joint Statement by the Heads of FAO, WHO, OIE, WTO and the World Bank at the recent Ministerial Conference of WTO in Qatar, in which they confirm their commitment to support developing countries in their capacity building efforts. Indeed, these agencies are currently working on a major initiative to

establish a common framework to assist developing countries in the three dimensions of biosecurity: food safety, animal and plant health, and, therefore, better compliance with the WTO Agreement on Sanitary and Phytosanitary Measures.

### **INTERNATIONAL COOPERATION IN EMERGENCIES**

It is common to hear references to the “globalization of world trade.” and in fact the number of countries trading in food on the world market has increased dramatically in recent years. For some developing countries the export of foods – notably agricultural products – is key to earn foreign exchange. Because of this, it is no longer sufficient to consider food safety to be mainly a local concern. Today, food safety is a transboundary issue. International cooperation in food safety management, including response to food safety emergencies, is more essential than ever before. FAO calls on all countries, and is itself ready, to support the establishment of a system for better, more rapid and more concerted response to food safety emergencies. This would cover early identification and rapid characterisation of problems and a system of information exchange among affected countries.

Building and strengthening such an international system to respond to transboundary food safety emergencies can also effectively increase preparedness and response to international bioterrorism, which unfortunately is of particular concern today.

### **COMMUNICATION AND PARTICIPATION**

It is said that rumour travels faster than fact. This can also be said of rumour about food-borne disease – it very often travels faster than the disease itself. An informed and active public and a knowledgeable industry are the cornerstones of an effective risk management system. One of the key issues to be discussed at this Forum is communication. Communication and knowledge are the only ways to deal effectively with consumer concerns and fears. Systems and procedures must be established to ensure that consumers, as well as the industry, are properly informed when a food safety emergency occurs. These procedures should involve all stakeholders in the response to such emergencies. This, of course, also applies to the more routine food safety and quality matters, especially when new regulations are issued.

### **CONCLUSION**

Many circumstances and issues interconnect the nations of the world, not the least of which is global food trade and food safety considerations. The time has come for those involved in regulating food safety throughout the world to come together, learn from each other and consider what might be done to improve global food safety and quality. FAO and WHO have jointly convened this Global Forum for exactly that purpose.

I want to thank you in advance for your efforts in addressing the many important issues you will face during the next three days. I wish you all the best in your deliberations and I look forward eagerly to the results of those deliberations. Thank you.

## FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS

*Marrakesh, Morocco, 28-30 January 2002*

## AGENDA OF THE GLOBAL FORUM

Agenda Item	Subject matters
<i>OPENING OF THE FORUM</i>	
<b>1</b>	<b>Election of Officers</b>
<b>2</b>	<b>Adoption of the Agenda and Timetable</b>
<b>3</b>	<b>Keynote address: “Improving efficiency and transparency in food safety systems – sharing experiences”</b>
<b>4</b>	<b>Exchange of information</b>
<b>4.1</b>	<b><i>Regulatory Issues</i></b>
4.1 a)	<i>National and Transboundary food safety emergencies</i>
4.1 b)	<i>New inspection approaches and techniques – implications for food safety regulations</i>
<b>4.2</b>	<b><i>Risk Management</i></b>
4.2 a)	<i>Reduction of food-borne hazards, including microbiological and others, with emphasis on emerging hazards</i>
4.2 b)	<i>Integrated approaches to the management of food safety throughout the food chain</i>
<b>4.3</b>	<b><i>Capacity Building</i></b>
4.3 a)	<i>Technical assistance to developing countries: experiences and lessons learned</i>
4.3 b)	<i>New approaches to consider in capacity building and technical assistance – building alliances</i>
<b>4.4</b>	<b><i>Communication and Participation</i></b>
4.4 a)	<i>Communicating food safety regulations and risk management – involvement and participation of consumers and other stakeholders</i>
4.4 b)	<i>Ensuring efficient communication and interaction between food safety risk assessors and risk managers</i>
<b>5</b>	<b>Other matters</b>
<b>6</b>	<b>Presentation of the Summary Report of the Global Forum</b>
<i>CLOSING OF THE FORUM</i>	

Working documents will be available on the Internet Global Forum Home Page at the following address: <http://www.foodsafetyforum.org/global>

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**NOTES TO THE PROVISIONAL AGENDA**


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**OPENING OF THE GLOBAL FORUM:** The Global Forum will be opened by a high-level Moroccan official.

- Item 1 Adoption of the Agenda:** The first item on the Provisional Agenda will be the adoption of the Agenda. At this stage, any additional matters to be discussed in plenary may be proposed to be examined under Agenda Item 5.
- Item 2 Election of Officers:** Delegates will proceed to the designation of a Chairperson and a Vice-Chairperson to lead the plenary meeting of the Global Forum.
- Item 3 Keynote address: “Improving efficiency and transparency in food safety systems – sharing experiences”:** The Forum will be presented with a keynote address on the main theme and how the Forum will proceed to the discussions.

Food Safety Regulators from four different regions of the world will introduce the four themes identified for the Forum, *i.e.* Regulatory Issues, Risk Management, Capacity Building, and Communication and Participation.

In order to facilitate exchange of information among Delegates, each theme will be examined within one Discussion Group. The Forum will nominate one Chairperson and one Vice-Chairperson for each Discussion Group. The Forum will receive information on the way in which the debate should be carried out and any other practical aspects, *i.e.* meeting schedule, duration, location and expected nature of output.

Prior to dividing into Discussion Groups, the Forum will receive a brief introduction on the eight topics prepared by several participants. These presentations will be made at the beginning of each Discussion Group’s meeting of the Forum. The written lectures will be distributed as Conference Room Documents.

**Item 4 Exchange of information:**

The Chair of each Discussion Group will report in plenary the summary records of the different key elements outlined during the exchange of information on food safety sub-topics. Discussions will have been conducted focusing on the following elements:

- 4.1 a) *National and Transboundary food safety emergencies:* Recent history has shown that national food safety emergencies can suddenly become international. Coping with such transboundary regulatory issues becomes a global concern and the exchange of information and views at the Forum will be invaluable.
- 4.1 b) *New inspection approaches and techniques – implications for food safety regulations:* Advances in food inspection techniques and the laboratory sciences can have a profound effect on food safety regulations. How individual governments change or create new regulations to address these advances are of considerable interest.
- 4.2 a) *Reduction of food-borne hazards, including microbiological and others, with emphasis on emerging hazards:* The reduction of food-borne hazards is the ultimate risk management goal of food safety regulators. New hazards are constantly emerging, however, making risk management a continuously changing process. Regulators will be encouraged to discuss the ways in which this process may be improved.

- 4.2 b) *Integrated approaches to the management of food safety throughout the food chain:* The management of food safety is not just of concern at the consumer level, it must also be considered throughout the food chain, from production through processing, distribution and consumption. Food regulators need to consider integrated approaches to such management and what role(s) the food industry and consumers can play.
- 4.3 a) *Technical assistance to developing countries: experiences and lessons learned:* Capacity building is an integral part of assistance offered to developing countries in need of establishing or strengthening their food safety/food control systems. Over the years, many donor countries or agencies, both national and international, have provided technical assistance in the food safety area to developing countries. The Global Forum will share experiences from both developed and developing countries and discuss what lessons can be learned. This can provide valuable guidance on how such assistance should proceed.
- 4.3 b) *New approaches to consider in capacity building and technical assistance – building alliances:* Traditional approaches to technical assistance and capacity building may no longer be sufficient with today's rapidly changing global technology. The Forum will discuss these changes and what new approaches should be considered.
- 4.4 a) *Communicating food safety regulations and risk management – involvement and participation of consumers and other stakeholders:* Information on food safety regulations and routine risk management decisions must be widely disseminated, especially to industry and consumers, if they are to be effective. The Forum will consider what practical approaches can be taken to improve such communications.
- 4.4 b) *Ensuring efficient communication and interaction between food safety risk assessors and risk managers:* Risk assessors and risk managers must be able to effectively and efficiently communicate and interact with each other if the food safety risk analysis process is to be successful. Many of the food regulators attending the Forum will be risk assessors as well as risk managers. The Forum will provide the means to discuss ways to ensure such communication and interaction.
- Item 5 Other matters:** Other matters will be discussed on the basis of the proposals made during the adoption of the Provisional Agenda (Item 1).
- Item 6 Presentation of the Summary Report of the Global Forum:** The Chairperson of the Forum will present the summary report of the discussions drafted by the Secretariat. This summary report will fully reflect the different points of view and approaches expressed during the Forum.

**CLOSING OF THE FORUM:** The Global Forum will be closed by a high-level Moroccan official.

APPENDIX VII  
(GF/CRD 1)

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28 – 30 January 2002*

**KEYNOTE ADDRESS: “IMPROVING EFFICIENCY AND TRANSPARENCY  
IN FOOD SAFETY SYSTEMS – SHARING EXPERIENCES”**

*Food Safety Issues, An International Concern*

*by*

*Mamdouh GABR*

*M. D., F. R. C. P.*

*Professor of Pediatrics, Cairo University, Egypt*

*Former President, International Union of Nutrition Sciences*

*Former President, International Pediatric Association*

## **INTRODUCTION**

Food safety has been of great concern to mankind since early civilization. Fermentation, a primitive method of food safety, still practiced until now, has been known to both Egyptian and Chinese civilizations. Elaborate food storage systems such as grain “silos” were built. It is amazing in the absence of scientific knowledge, ancient Egyptians when building these “silos” attempted to control humidity and avoid human and animal contamination through using an opening in the lower part of the “silos” to allow withdrawal of grains poured in it from above.

In recent history, the discovery of microorganisms, the wide use of pesticides and fertilizers, the advances in food industry and the rapidly expanding world food trade necessitated the establishment of various food safety measures.

The United Nations system recognized the crucial role of food safety with its health and economic consequences. The Codex Alimentarius was established in 1963 with the aim of protecting health of consumers, and to ensure fair practice in food trade. Various committees and subcommittees were formed. International agreements and declarations were announced. Innovative prevention approaches to insure food safety were developed. Foremost among these are the risk analysis framework and the hazard analysis critical control points approach (HACCP). In spite of these efforts, it is estimated that one third of the population in developed countries are affected by food borne illness each year. The situation is even worse in developing countries where reported cases represent the tip of the iceberg. Water borne and food borne diarrheal disease kills approximately three million people each year. Two to three percent of food borne disease leads to long-term ill health.

Several challenging issues exist. More will appear in the future. I shall briefly touch upon some of these challenges.

## **THE QUANTITATIVE RISK ASSESSMENT APPROACH**

Historically food safety evaluation has been qualitative rather than quantitative. Many decisions were based on subjective observations and evaluations. Scientific advances led to efforts to quantify the risk associated with food. In deciding priorities the cost benefit approach is usually adopted. The use of quantitative risk assessment implies a vigorous scientific base, which may be lacking specially in developing countries. A number of the costs and benefits of food safety regulations are intangible and difficult to convert into monetary amounts. It is frequently difficult to compare between risks, which might be expressed in subjective terms to benefits, which can be expressed in economic terms. Can we quantify the quality of life or more dramatically the cost of the human life?

Although the concept of quantitative risk approach has to be maintained it has to include a subjective consideration of non-quantifiable issues as well as the various determinants affecting food safety.

## **SETTING AND IMPLEMENTING FOOD SAFETY REGULATIONS**

Whichever food safety policy is adopted, the barrier is implementing the policy and enforcing the related laws and regulations. There is a need to bridge the gap between policy and practice, between theory and reality. Biases in prioritization are not infrequent, being driven by politicians seeking public support or by competing agencies or scientific institutions. In developing countries the situation is worse. Infrastructure may be lacking. There are many other competing health, social and economic priorities. How can you convince a decision maker in a poor country to spend, from a limited health budget, on the control of a food contaminant with a potential long-term carcinogenic hazard, when the majority of the population will die from other causes before they develop cancer?

International organizations and world scientists have to support developing countries in order to create the will and develop the skill to implement food safety control taking into consideration existing barriers and capabilities. They should assist them to conduct epidemiological studies on the prevalence of food borne disease, up date their food laws and regulations and establish national or regional training centers and appropriate laboratories. United Nations organizations must sensitize policy makers not to give low priority to food safety issues.

## **PUBLIC AWARENESS**

Public opinion is increasingly becoming a driving force influencing government decisions on food safety. In developed countries, the public is pressing on more stringent safety measures, which are often not scientifically justified. Public fear of food environment is an unwanted consequence of increasing knowledge. Media frequently exploit fear than evaluate facts. Occasionally debates within the scientific community may be misinterpreted by the public to represent uncertainties.

It is the responsibility of the scientific community to develop its own dynamic proactive and timely public information system in order to keep the public aware of sound scientific information regarding food safety and alleviate unnecessarily costly concerns.

In many developing countries it is the other way round. Public awareness of the dangers and consequences of unsafe food is low. People react indifferently to safety control measures. Socio-cultural factors, poverty, illiteracy, and resistance to certain endemic food borne pathogens are among many causes that contribute to this indifference. Because of economic or political factors, decision makers may be reluctant to take action to raise public awareness.

The scientific community should develop a public information campaign to overcome these barriers specially since it enjoys greater credibility than the government in developing countries.

## **COORDINATION**

United Nations agencies involved in food safety can play a greater role in overcoming differences at the regional or the national level without jeopardizing the freedom of various partners. The conflicting reaction to mad cow disease (BSE) is an example. The differences in adopting the precautionary principle between Europe and US is another.

United Nations organizations should foster the “regulatory rapprochement approach” to overcome differences in safety regulations between countries through coordination, mutual recognition or harmonization. Because of political, economic and social reasons this is not an easy task it should be set as a goal to be achievable within the next decade.

Interdisciplinary coordination at the national domestic level has to be strengthened. In the US responsibility for regulating the safety of food supply is divided among various agencies (USDA, FDA, EPA, etc.) with occasional unnecessary controversies. In developing countries, a national codex committee should be authorized to coordinate responsibilities of the various ministries involved in food safety control. A prerequisite for risk-based strategies is an interdisciplinary approach involving strong collaboration among all sectors dealing with food borne diseases surveillance and safety.

## **INTERNATIONAL FOOD TRADE**

Food exports represent a major proportion of the income of many food exporting developing countries. It is of crucial economic interest to these countries to achieve quality and safety of their food at the international level. On the other hand, unnecessary food safety restrictions, not based on sound scientific evidence, may impede food exports and consequently their economic development, increasing poverty. The priority for the poor who cannot afford to purchase food is food availability rather than food safety. Combating poverty in food exporting countries in itself will contribute greatly to food

safety control measures both at the domestic and international level. These concerns were specifically addressed in the agreements on Sanitary and Phytosanitary measures (SPS) and the Technical Barriers to Trade (TBT). Countries were allowed to adopt different food safety standards, provided they are justified by current available scientific evidence and will not create unnecessary technical barriers for international trade. How can this balance be achieved? The Codex Alimentarius committees have no authority over its members to oblige them to implement Codex standards. After the SPS agreement, CAC standards were recognized to serve as a yardstick or benchmark for national requirements. There is a need for further international negotiations to render Codex Alimentarius Committee recommendations more binding either on voluntary or mandatory bases.

## **FOOD COMPANIES**

Government food control services are increasingly adopting the approach of industry self-quality control measures. Official monitoring is carried by the concerned governmental authorities in order to insure that it is in compliance with regulations on the national level as well as across multiple countries. The share of multinational food companies in food consumption is increasing. Food companies are keen to keep their reputation through providing high quality safe food. Many of these companies established food processing factories in developing countries where food safety control measures may be less rigid than in developed countries and where the ability of the government to perform proper monitoring may be limited. Multinational companies should maintain the highest standard they adopt wherever their factories are.

Another concern is the patency issue. Under Trade Related aspects of Intellectual Property Rights agreement (TRIPS) most multinational companies hold patency rights on genetically engineered foods or plant varieties. Farmers in developing countries may have to pay fees to the concerned company before reusing their own harvested seeds, adding an economic burden on the farmers, which may be reflected on the national food safety system.

There is a need to strengthen the partnership between governments and the private sector along mutually agreed fair guidelines.

## **FUTURE TRENDS**

Advances in transportation and the rapidly expanding food trade will necessitate stricter regulations on transnationally transported food and food products. A single source of contamination can have global consequences.

Food safety measures will benefit from advances in information and communication technology through timely interchange of information at the scientific and managerial level. Proper public education measures, however, should be taken to insure that the ease of public access to information does not contribute to public uncertainty.

As man made and natural disasters continue safety measures for emergency feeding programs have to be further perfected. The tragic events of 11 September 2001 raised international concern regarding the threat of possible biological chemical or radiological contamination of food. Proper preventive, monitoring and intervention measures have to be established and integrated within the existing food safety control systems.

Preference to fresh and minimally processed foods may challenge the industry to use less harsh processing regimens necessitating greater care in preparation and storage.

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## **RESEARCH NEEDS**

Basic research is required to cope with newly recognized food hazards; new pathogens, zoonotic diseases, toxic agents, irradiation hazards, and the possible side effects of genetically engineered food or new food processing techniques. More research will also be needed to judge the potential long term teratogenic, mutagenic or oncogenic effects of certain food contaminants.

Scientific advances during the next few years will hopefully lead to more efficient food safety control measures, which will impose less burden on the food business. There is concern, however, that as we learn more, we develop more costly sophisticated techniques that are beyond the financial capabilities of many countries. Applied research should focus on developing more accurate, scientifically based methodologies; which are feasible, affordable, sensitive and timely responsive to the rapidly advancing scientific knowledge.

We are looking forward for your free and valuable deliberations, which will discuss these and other issues. Your deliberations will enhance international cooperation to safeguard the health of mankind.



**APPENDIX VIII**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakech, Morocco, 28 – 30 January 2002*

**THEME AND TOPIC PAPERS**

**WITH SUMMARIES OF APPLICABLE CONFERENCE ROOM DOCUMENTS FOR**

***REGULATORY ISSUES***

## FOOD SAFETY REGULATORY ISSUES

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### 1. INTRODUCTION

First of all, I would like to express my respect for their efforts to the Government of Morocco, the secretariat of the FAO and WHO, and all those who were engaged in preparing for the first Global Forum. Also, I would like to thank the organizer of this Forum for this opportunity to speak to all of you here today about food safety regulation in Japan.

As you know, the Global Forum was established, in response to the Communiqué of the Kyusyu/Okinawa G-8 Summit in 1999. The purpose of the Forum is to encourage FAO and WHO to organize periodic international meetings of the food safety regulators to advance the process of science-based public consultations. The Japanese government strongly hopes that the Forum will be a great success.

Needless to say, it is important to take comprehensive action to keep food safe in all processes covering farm to table. In this sense, the Ministry of Health, Labour and Welfare (MHLW) shares the responsibility of the provision of safe food with the Ministry of Agriculture, Forestry, and Fisheries (MAFF). Both ministries individually regulate food based on related laws. The MAFF is responsible for food production and quality assurance and the MHLW is responsible for stable food distribution and food safety.

As an expert of food safety, I will discuss the current regulatory status of food in Japan.

### 2. OUTLINE OF FOOD SAFETY REGULATION IN JAPAN

Food safety regulation is carried out based on the Food Sanitation Law. This law was enacted in 1947 and revised several times as circumstances demanded. The law is a comprehensive food law consisting of 36 articles.

Here, I will outline four major points of the law which may help you understand the current regulatory situation in Japan.

First, the law covers a wide range of targets.

The law stipulates that the purpose of the law is to prevent the occurrence of health hazards arising from human consumption of food. The law covers not only foods and drinks, but also additives including natural flavouring agents, and equipment and containers/packages that are used for handling, manufacturing, processing or delivering food. The equipment and containers/packages are limited to products that come into direct contact with foods. The law also covers persons who carry out food-related business such as food manufacturing and food import. The law, however, does not apply to medical drugs and quasi-drugs.

Second, the law gives authority to the Ministry of Health, Labour and Welfare.

This authority enables the MHLW to take legal action toward prior issues smoothly and quickly. If the authority is not given, the MHLW has to revise the law, in order to give legal force to MHLW's actions or to apply penal regulations to offenders. The revision of the law is however time-consuming, due partly to the delay of discussion at Diet resulting from social and political factors.

For example, the law stipulates that the Ministry of Health, Labour and Welfare, from the viewpoint of public health, may establish standards and specifications for food or additives intended for

sale. The law authorizes the MHLW to establish necessary standards and specifications, as needed, without revising the law itself. Lately, genetically modified foods, or GM foods, became the target of regulation under the law. This is also a good example of the provision of authority. The MHLW may regulate GM foods by establishing standards without revising the law. We have prepared a country report on the regulation of GM foods. If you are interested in details, please consult the report.

Third, the law gives important roles to local governments in regulating food and the MHLW shares responsibility with local governments.

From beginning to the present, the purpose of the law has been focused on the prevention of food poisoning. In this viewpoint, the law regulates a wide range of food-related businesses. The number of targeted facilities rises to about 4 million nation-wide. About 2.6 million of them are required to obtain a business license from the Minister of Health, Labour and Welfare. In order to carry out regulatory work for a large number of facilities, many employees are necessary. However, the central government has only 62 employees in the section that is responsible for these businesses. You can easily imagine that the number of employees is not enough to conduct daily inspections for all facilities and give guidance to them. The law authorizes each local government to take necessary measures to businesses in the location under the jurisdiction of the government. The measures include establishing necessary standards for business facilities, giving or revoking licenses, giving guidance, and discontinuing or suspending the business. Also, Japan has another type of administrative organizations that are exclusively responsible for regional health and hygiene. These organizations, called health centres are taking important roles in safety assurance of food in the region concerned.

Fourth, Japan uses a comprehensive sanitary control system based on the Hazard Analysis and Critical Control Points (HACCP) system.

Japan established this comprehensive system in 1995 when the Food Sanitation Law was revised. Under the system, the Ministry of Health, Labour and Welfare gives approval to individual manufacturing or processing facilities, according to food groups, if the Ministry confirms, after due examination, that hygiene is controlled appropriately for these foods. In the system, manufactures or processors establish manufacturing or processing methods of the target foods and sanitary-control methods, based on the HACCP system. Then, the Minister confirms whether these established methods comply with the approval standards. The manufacturing or processing methods approved under the system is considered to meet the standards for manufacturing or processing under the law. This means that the system enables the application of a wide variety of methods to food production without following the uniform standards. Currently, there are six food categories as targets of the system. These categories include milk, dairy products, meat products, fish-paste products, non-alcoholic beverages, and foods, which were packed into a container or package and pasteurized under pressure, such as canned foods and retort foods.

Japan started to implement a new law in 1998 in order to encourage food-related businesses to introduce the HACCP system. This law financially supports businesses. They may receive a long-term, low-interest loan necessary to improve their facilities and equipment and may obtain preferential taxation. This law is under the jurisdiction of the Ministry of Agriculture, Forestry and Fisheries. The MHLW shares the responsibility of the sanitary-control management with the MAFF.

### 3. ISSUES OF FOOD SAFETY

I briefly explained some important points of Japanese food safety programme, based on the Food Sanitation Law. Unfortunately, health hazards are not completely controlled, despite comprehensive and intensified regulation.

Take food poisoning, which is a long-standing challenge in food safety regulation. The number of incidents has not decreased in the past several years. Some 1,960 incidents and some 40 thousand patients were reported in 1997, some 3 thousand incidents and some 46 thousand patients reported in 1998, and some 2.7 thousand incidents and some 35 thousand patients reported in 1999. Especially, the following two cases drew much attention at home and abroad. One is a case caused by enterohaemorrhagic *Escherichia coli* O-157, or EHEC O-157. The other is a case caused by powdered skim milk contaminated with enterotoxin. The former occurred in 1996, ending up with around 10 thousand patients and eight deaths. The latter occurred in 2000 and the number of incidents rose to 15 thousand.

Also, the hottest current issue is mad cow disease, or BSE. As many of you here already know, Japanese authorities announced September 10 that a suspected case of BSE was found. The news promptly spread in and outside Japan. Now, the case is under investigation to identify the cause and the scope of spread.

The BSE case taught us a lot. One, consistent approaches covering farm to table are necessary for safety assurance of food. Two, when an issue occurs somewhere in the world, we should not overlook the fact that a large quantity of food and feed are globally distributed. Three, we need a certain method or system to trace problems that have occurred, in order to identify the cause and conditions.

### 4. TOWARD SAFER FOOD

I would like to raise issues to be considered as food safety regulators and discuss with all of you. I hope my talk sparks a great discussion in the forum.

#### 1) “Farm to Table” Food Safety Control System

The objective of reduced risk can be achieved most effectively by the principle of prevention throughout the production, processing and marketing chain. To achieve maximum consumer protection it is essential that safety should be built into food products from production through to consumption. This calls for a comprehensive and integrated *farm-to-table* approach in which the producer, processor, transporter, vendor, and consumer all play a vital role in ensuring food safety and quality.

Conceptually the importance of this approach has been recognized by food safety regulators in Japan. I think the current BSE problem in Japan gave me a feeling of reality. In order to ensure meat safety, at the farm level, farmers and workers must control safety of feed, pesticide and other chemical inputs and recognize potential sources of microbial contaminants from water, soil, animals and humans, while regulators take responsibility for auditing performance of the food system through monitoring and surveillance activities.

It is not difficult to express this concept into words. However, it is extremely difficult to implement this concept in the current real world. For example, I can list some difficulties to be overcome; such as

- 1) there could be several years difference from feed production, farm operation, procession, distribution and consumption
- 2) there could be geographical difference between feed production, farm operation, procession, distribution and consumption
- 3) a lot of experts with different backgrounds must be involved

In order to implement effective, efficient and uniform control measures across the whole food chain throughout the country, it is important to consider the type and size of the organization(s) that are

necessary to implement the food safety strategy. Where it has not been possible to have a single unified structure or an integrated food control system, for various historical and political reasons, it is necessary for this strategy to clearly identify the role of each agency, to avoid duplication of effort, and to bring about a measure of coherence between them. It should also identify areas or segments of the food chain that require special attention and need additional resources for strengthening.

I acknowledged that recently some countries restructured food safety administrative structure into “single food safety agency” and I have heard that the consolidation of all responsibility for protecting public health and food safety into a single food safety agency with clearly defined terms of reference has considerable merit. I would like to hear those experiences and share with all the participants.

## **2) Safety of Imported Food**

With an expanding world economy; liberalization of food trade; growing consumer demand; developments in food science and technology; and improvements in transport and communication, international trade in fresh and processed food is increasing rapidly. Regarding food and feed, I can safely say that borders no longer exist.

It goes without saying that a country like Japan, which relies on imported food for more than 60% of food supply (calorie bases), must consider the safety of imported food. Any countries, which import more or less of food, need to think about how they can enhance the safety of imported food. Meanwhile, access of countries to food export markets will continue to depend on their capacity to meet the regulatory requirements of importing countries.

Now I would like to ask all of the participants how the safety of imported foods are ensured. There are some strategies such as, sampling and testing of imported food at the port of entry, requiring attachments of test results and/or inspection certificate with food, allowing the importation of food only from establishments recognized as compliant with requirements established by importing countries, or visiting exporting countries and educating and training food inspectors and workers in food industries.

Further, in order to examine the safety of imported food, first food safety standards must be established at a national level in accordance with Codex standards, guidelines or based on risk assessment.

In the future, if the Codex standards are widely accepted, and audit methods, procedure and criteria are internationally agreed, then audit results from Country A conducted by country B or an internationally recognized audit Organization could be shared globally, and reduce the cost of audit by different countries.

## **3) Countermeasures to newly developed food and food derived from modern technologies**

Talking of newly developed food; I should start from food derived from biotechnology or GMOs. Because this issue is not only new, but also safety assessment of these food is substantially different from “traditional” food safety assessment, I can say a large number of countries still grope in the dark on how governments can cope with this issue. The Japanese government has submitted a country paper on this issue, so I would like you to read it for your further information. To be short, I think there are political and technical discussions on both safety assessment and labelling.

Because of the increase of allergic diseases and increasing consumer concerns of allergies caused by food consumption in Japan, the mandatory labelling requirement of major allergic food has just implemented in Japan. It's critical for people who have food allergies to identify them and to avoid foods that cause allergic reactions. Some foods can cause severe illness and, in some cases, a life-threatening allergic reaction (anaphylaxis) that can constrict airways in the lungs, severely lower blood pressure, and cause suffocation by the swelling of the tongue or throat. I believe there are some common foods that cause allergies internationally, and some food to cause allergies in specific countries and/or areas. I think we should take some action against at least those foods that may cause a life-threatening allergic reaction.

With the extension of the average life expectancy, the increase in cancer patients and death from cancer, and antipathy against medical treatment, increasing requests have been made for allowing the distribution of vitamins, etc. as foods, which have been used for medical purposes. If the product has a clear labelling of reducing health risk, it will be considered as a medicine and regulated under Pharmaceutical law in Japan. Recently those food with intermediate labelling between medicine and food are becoming popular among those who are interested in health, have a high level of education, have accumulated information through eating experience, and so on. So, at least in Japan, ensuring intermediate food between medicine and food would be one new challenge in the food safety area, and at this occasion I would like to hear some experiences in other countries.

The new issues I raised above could be the tips of an iceberg. In the future we might be faced with difficult brand-new problems. At that occasion how will the national governments in your countries cope with the new problems?

#### **4) Ensuring the effectiveness of food safety system**

In order to achieve certain objectives in the regulatory purpose and to encourage/guide people forward in the right direction, generally speaking, the strategies could be; 1) appeal to an individual moral sense and ethics, 2) economical inducements 3) education and communication, and 4) regulatory procedures including guidance, recommendation and legal action with penal regulations.

Government regulatory systems can provide a framework for maintenance of food safety across the food continuum “from farm to table.” Food safety laws, regulations, directives, standards, policies and procedures form a foundation for food control systems. Regulatory requirements establish limits and responsibilities, but are of little value without effective complements by all the stakeholders.

Assurance of food safety is a combined effort. Food producers at all levels of production bear a responsibility for the production of safe foods. At the farm level, farmers and workers must control pesticide and other chemical inputs and recognize potential sources of microbial contaminants from water, soil, animals and humans. The food processing and transportation industries must assess where food safety may be jeopardized at critical points in food production and transport and take appropriate measures to control these potential hazards. Retail establishments, restaurants and other food vendors must also understand how to ensure proper sanitary practices and temperature controls. The consumer’s role may be the most important in that s(he) controls food safety at the point closest to food consumption. The consumer needs the knowledge, understanding and incentive to prepare and store safe foods for family and friends. So each stakeholder must fulfill each responsibility in order to ensure safer food.

In Japan, education for the school children on food safety and voluntary food safety activities by food industries are recognized as extremely important for food safety, therefore these programmes are supported by the government. I would like to know about various programmes in your countries on this aspect.

### **5. CONCLUSION**

Needless to say, foods are essential for our lives and safety should come first.

Food hygiene is a classical area in the public health programme, and today it is still a globally significant issue, as the WHO mentions.

We, those responsible for food safety, are expected to take appropriate measures not only for long-standing issues such as food poisoning but also for newly emerging issues, such as GM foods and BSE. In handling such issues, we have to make a decision based on sound science and provide information in an appropriate and timely manner to related people, especially consumers. It is what is called risk communication. Also, each member country should harmonize its own regulations with international standards and specifications from the viewpoint of smooth food trade. Thus, since Codex Alimentarius Commission’s programme is growing important, I expect the progress of the programme

and your cooperation. Also, we should learn many things from not only positive but also negative instances in member countries through such a forum.

Japan, as the presidency holder, is working to prepare for the third session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Modern Biotechnology scheduled for next March in Yokohama. As the development of GMOs is progressing, the Japanese government would like to complete standards for the safety assessment under international consensus as soon as possible. I expect that many of you here will participate in the session and make a contribution to consensus building.

In closing, on behalf of the participants here, I would like to thank the Government of Morocco again for hosting the forum. Thank you very much.

GF 01/7

## BSE AS A NATIONAL AND TRANS-BOUNDARY FOOD SAFETY EMERGENCY

*Paper submitted by the United Kingdom*

### 1. OUTLINE AND BACKGROUND

A new cattle disease, Bovine Spongiform Encephalopathy (BSE) was first identified in 1986. This belongs to a group of diseases known as a Transmissible Spongiform Encephalopathies (TSE). Although initially the infective agent for BSE was not thought to be capable of infecting humans, there is now evidence to suggest that BSE and a variant of the human TSE, Creutzfeldt-Jacob Disease (vCJD), are the same infective agent. These diseases are invariably fatal.

The agent that causes BSE is extremely resistant to the controls that would normally kill infectious agents such as bacteria and viruses, including cooking. Normal food hygiene measures are therefore ineffective against BSE. The only effective control in relation to human health is therefore to remove the infective agent from the food chain.

### 2. BSE AS A PRION DISEASE

BSE is one of a group of diseases that affect a number of different mammals. These diseases, known as TSEs, or prion diseases, result from the build-up of abnormal prion proteins in the brain and nervous system and eventually cause death. BSE has a long incubation period. This means that it usually takes four to six years for cattle infected with BSE to show signs of the disease.

#### 2.1 CASE NUMBERS OF BSE

By 6 September 2001 there had been a total of 179,950 cases of BSE in cattle in the UK, with the peak number occurring in 1992. (See Figure 1.)

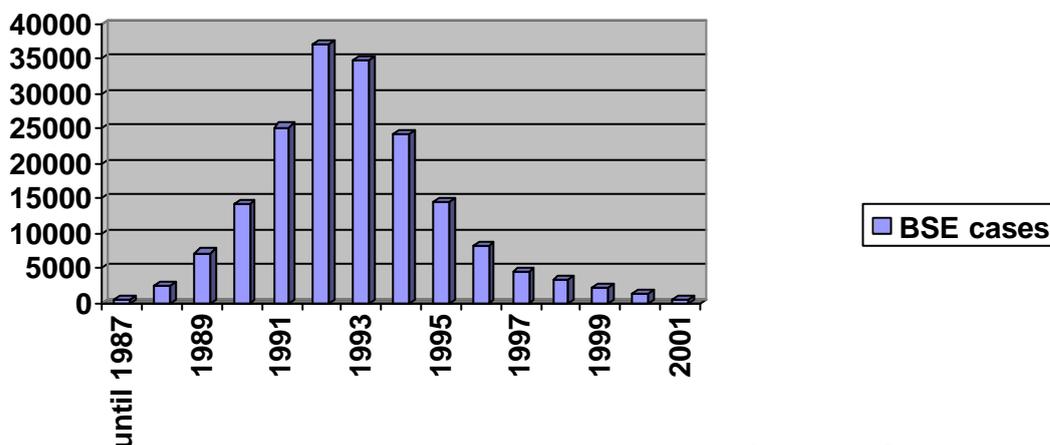


Figure 1: Cases of BSE in the UK

Although the vast majority of BSE cases world-wide have occurred in the UK, other countries have also been affected, mainly within Europe. Including:

Ireland	688 cases by 09/01	Spain	63 cases by 09/01
Portugal	581 cases by 07/01	Belgium	40 cases by 08/01
Switzerland	388 cases by 08/01	Italy	27 cases by 09/01
France	345 cases by 09/01	Netherlands	19 cases by 07/01
Germany	107 cases by 08/01		

Denmark, Greece, Luxembourg, Czech Republic and Liechtenstein have also had a few cases.

## 2.2 ASSOCIATED HUMAN DISEASE

The most commonly known human prion disease is Creutzfeldt-Jacob Disease (CJD). A new strain of CJD that occurs predominantly in younger people was discovered in 1996. More recent evidence has shown that the protein that accumulates in the brains of individuals with this new form of CJD is similar to the protein found in cattle infected with BSE, rather than that found in classical CJD. The new illness in humans is known as variant CJD, or vCJD.

The occurrence of a new form of CJD in the UK, where there is a high incidence of BSE, suggested that there might be a direct link between the two diseases. There is compelling evidence that the cause of vCJD is consumption of BSE contaminated meat. Researchers concluded that the most likely origin of this new disease was human exposure to the BSE agent.

Like BSE in cattle, vCJD is always fatal in people. As of August 2001 the total number of definite and probable cases of vCJD in the UK was 106. Figure 2 shows the breakdown of numbers by year. (Figures for 2001 up to and including August.)

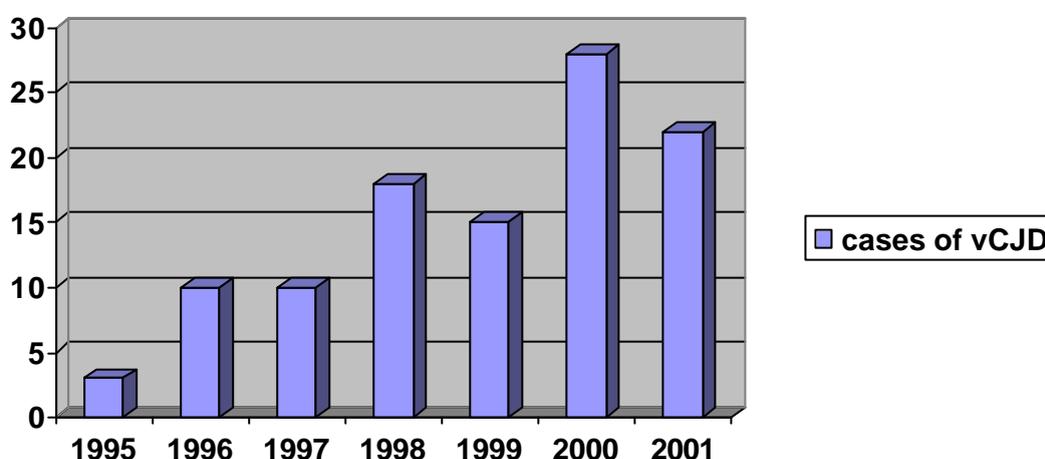


Figure 2: Cases of vCJD in the UK, definite and probable, by year.

## 2.3 WHERE DOES BSE COME FROM?

BSE was first confirmed in cattle in 1986. Despite much research, however, no-one can say with certainty where BSE came from. It may have been the result of a spontaneous genetic mutation in a cow or other animal during the 1970s. The normal practice in the UK at the time was to recycle animal protein, including cattle offal, back into meat and bone meal incorporated into cattle feed. This could have led to the cycling of BSE within the cattle population and its spread. One of the early theories about why BSE spread within the cattle population was linked to a change in the rendering process to produce meat and bone meal. However, given that no rendering process will effectively destroy the BSE agent it is highly unlikely that this was a key factor.

## 2.4 RISK AND UNCERTAINTY

Perhaps more than any other area of food safety, BSE is characterised by scientific uncertainty. Even now the precise nature of the causative agent and how it spreads in the host is not known for certain. The scientific uncertainty, which characterises BSE, means that throughout the BSE crisis the risk management options for protecting the health of the public have been precautionary in nature and aimed at risk reduction in the light of current knowledge. Risk can never be completely eliminated and the options have needed to be continually reassessed in light of emerging knowledge.

Throughout the Government has used expert scientific advisory committees to assess scientific evidence. This started with the Southwood Working Party in 1988, which developed into the Tyrrell Committee in 1989. The current committee is the Spongiform Encephalopathy Advisory Committee (SEAC) established in 1990.

## **2.5 CHRONOLOGY OF EVENTS IN THE UK AND APPLICATION OF FOOD SAFETY CONTROL MEASURES**

**November 1986** - BSE was identified in cattle.

**December 1987** - Initial epidemiological studies in cattle were completed. These concluded that ruminant derived meat and bone meal was the only viable hypothesis for the cause of BSE. This conclusion was crucial in terms of control measures for both animal health and for protection of humans.

**June 1988** - The use of ruminant derived meat and bone meal for feeding to ruminants was banned.

**August 1988** - A slaughter policy was introduced, including compensation to farmers for slaughtered animals. An animal health measure but it indirectly impacted on human health by helping to reduce potential exposure.

**December 1988** - BSE was designated a zoonoses, enabling legal powers to be used to reduce the risk to human health. This was a highly precautionary measure at the time as there was little indication that BSE would affect humans.

**November 1989** - Specified bovine offal was banned from human food. The specified offal included those parts of the animal thought to have the highest likelihood of carrying the BSE agent. A crucial human health protection measure, even though it was highly precautionary at the time and exceeded even expert scientific advice.

**September 1990** - Following reports that 5 antelopes and a cat had succumbed to a spongiform encephalopathy, and the experimental transmission of BSE to a pig, a ban was placed on specified bovine offal in all animal feed, including pet food. An animal health protection measure, but indirectly provided additional protection for humans.

**March 1991** - The first case of BSE in offspring born after the ruminant feed ban (June 1988) was announced. This could have indicated that the feed ban was not being as effectively applied as it should have been. Subsequently many such cases occurred. (See Figure 3.) Of course, the case could also have indicated vertical transmission through cattle. Whilst some cases of vertical transmission are thought to have been possible, most cases in cattle born after the ruminant feed ban are now thought to have been because continued use of banned feed, or cross contamination with other animal feed. The 1990 ban on specified bovine offal in all animal feed was important to control cross contamination.

**November 1994** - The ban on the use of specified bovine offal in animal feed was extended. All mammalian protein was banned in ruminant feed.

**December 1995** - An additional measure to protect human health was enacted prohibiting the use of bovine vertebral column in the manufacture of all mechanically recovered meat. Spinal cord had already been included in the specified offal ban. However, it had proven difficult to remove the spinal cord completely from all carcasses. It was therefore decided to avoid the problem of fragments of spinal cord remaining by prohibiting the use of the vertebral column altogether.

**March 1996** - The first cases of vCJD were announced.

**March 1996** - The sale for human consumption of any meat from bovine animals over thirty months old was banned. Very few animals show signs of BSE onset by that age and infectivity is similarly only just emerging in infected animals. The over thirty months rule was therefore designed to prevent BSE infected cattle from entering the food chain.

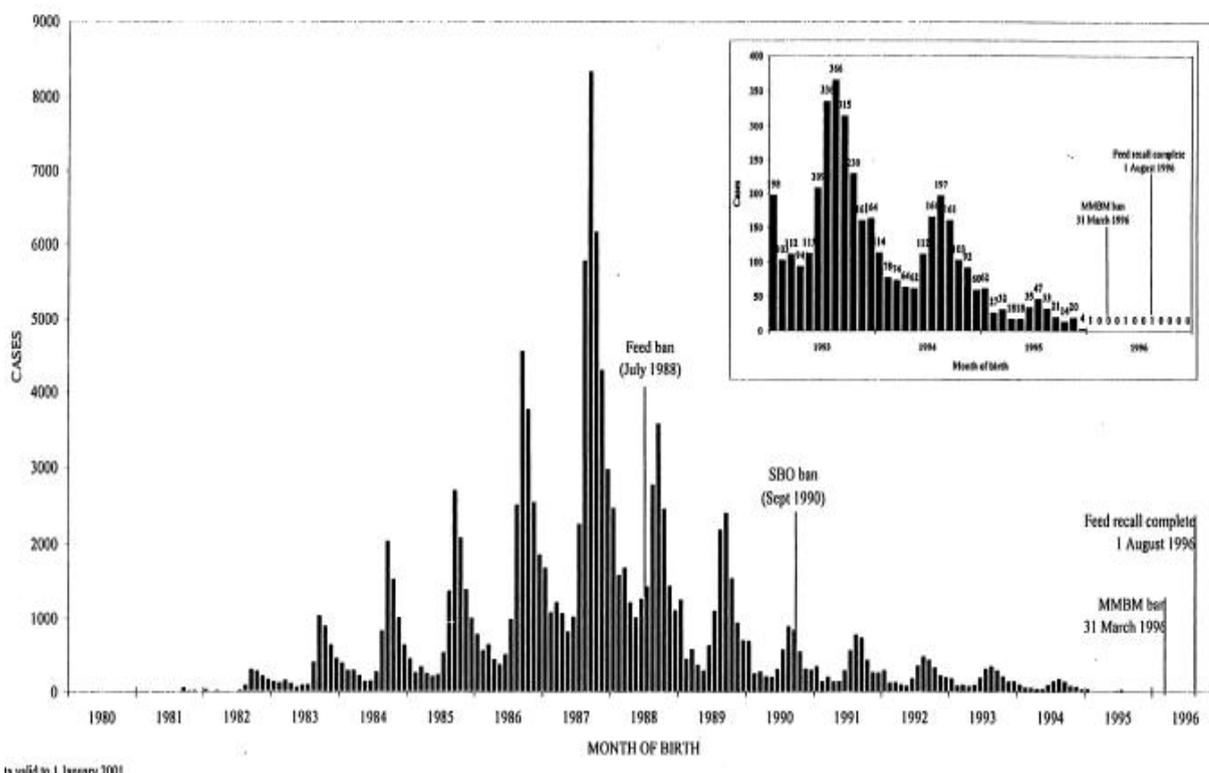
**April 1996** - The feeding of mammalian meat and bone meal to all farmed livestock was prohibited.

**June 1996** - A feed recall scheme was launched (completed by October 1996) to collect and dispose of any meat and bone meal and feed containing it. This was to remove this possible source of infection entering the food chain.

**January 1997** - Introduction of a selective cull of cattle most at risk of BSE.

**December 1997** - Legislation came into force requiring the deboning of all beef derived from cattle, both home-produced and imported, aged over 6 months at slaughter before it is sold to customers. This was to control a very small risk of infectivity in bone marrow and dorsal root ganglia. (Later lifted once the risk was thought to have reduced.)

### CONFIRMED CASES OF BSE WITH KNOWN DATES OF BIRTH, PLOTTED BY MONTH OF BIRTH



**Figure 3: Confirmed cases of BSE with known dates of birth, plotted by month of birth.**

The controls outlined above have been very successful in relation to reducing the number of cases of BSE in cattle. As mentioned previously the size and shape of the epidemic on vCJD in humans is impossible to predict at this time with any certainty. However, the control measures taken, especially :

- Removal of specified bovine offal (later Specified Risk Material) from the food chain;
- Banning of mechanically recovered meat from the spinal column, now extended under EU law to all ruminant bones;
- The over thirty months rule.

These measures are thought to mean that risk from consuming UK beef is at a very low level.

### 3. EUROPEAN AND WIDER PERSPECTIVE

As noted in paragraph 5, the BSE emergency has not affected only the UK. It has also had significant impacts on our trading partners. This is particularly so within Europe, but there have also been wider ramifications throughout the world. About 0.5% of all cases of BSE have occurred outside the UK. Initial spread of the disease to other countries is thought to have been due to export of feed or live animals, but cases now appearing in other countries are probably due to the recycling of the disease in those countries.

Ireland, in 1989, was the first country outside of the UK to have cases of BSE. Cases then followed in Portugal and Switzerland (from 1990), France (1991), and Germany and Denmark (1992). Italy had its first 2 cases in 1994 and Belgium, Luxembourg and The Netherlands had their first cases in 1997. (See table 1.)

	Germany	Belgium	Denmark	Spain	France	Ireland	Italy	Luxembourg	The Netherlands	Portugal	Switzerland
1989	0	0	0	0	0	15	0	0	0	0	0
1990	0	0	0	0	0	14	0	0	0	1	2
1991	0	0	0	0	5	17	0	0	0	1	8
1992	1	0	1	0	0	18	0	0	0	1	15
1993	0	0	0	0	1	16	0	0	0	3	29
1994	3	0	0	0	4	19	2	0	0	12	64
1995	0	0	0	0	3	16	0	0	0	14	68
1996	0	0	0	0	12	74	0	0	0	29	45
1997	2	1	0	0	6	80	0	1	2	30	38
1998	0	6	0	0	18	83	0	0	2	106	14
1999	0	3	0	0	31	95	0	0	2	170	50
2000	7	9	1	2	162	152	0	0	2	136	33
2001 until Summer	94	21	3	58	103	108	25	0	11	72	22

**Table 1:** Cases of BSE by country. Note that the figures for 1999/ 2000 onwards include those detected through monitoring.

### 4. EUROPEAN RESPONSE

At the time of the formal identification of BSE in the UK in late 1986 the disease was regarded as an animal health problem. Because of this the UK imposed controls in relation to removing meat and bone meal from ruminant feed in 1988. However, this was followed in the UK in 1989 by the requirement to remove specified bovine offal from human food, as a precautionary measure, despite the fact that there was no evidence for the disease being able to affect humans.

In May 1990 control measures were introduced in other European Community countries. At that time two European countries banned the import of beef from the UK. This ban was lifted in June 1990 following the intervention of the European Commission, which undertook to propose stricter animal health measures.

The next European wide measures were introduced in 1994 when the feeding of mammalian protein to ruminants was banned. They also introduced the first rendering standards to try to minimise BSE in meat and bone meal. Further measures followed in 1996, immediately after the announcement of the first case of vCJD in the UK and the recognition of BSE as a food safety issue. The first action at this

time was taken at a European level with a Europe-wide ban on exports of beef and beef products from the UK.

Some European Member States also took other precautionary measures to protect their consumers from all risks of contamination on an individual state basis between 1996 and 1998. These precautionary measures included the ban on specified risk material in human food and animal feed. These national measures were extended in October 2000 into a Europe-wide ban.

The banning of the export of beef from the UK was clearly a measure to protect consumers in other countries from possible food safety risks. However, the UK was also concerned to ensure that its consumers were protected from possible risks posed by imported beef. Introduction at a European level of the ban on the use of specified risk materials in human food was particularly important in this respect, although there has been, some concern over the effectiveness of its implementation (see paragraphs 28–29 below).

By the time of the European ban on UK beef significant measures had already been in place in the UK to protect human health for some time. These included the banning of specified risk material from human food and animal feed. Immediately following the March 1996 announcement of the first case of vCJD a further measure was introduced, the over thirty months rule.

June 1996 saw the first moves towards lifting the European export ban on UK beef – known as the Florence agreement. This set out 5 conditions for the gradual lifting of the ban. These were:

- Withdrawal of all meat and bone meal from farms or from establishments manufacturing animal feed;
- Stepping-up of checks in slaughterhouses;
- Introduction of a passport system for all cattle and setting-up of a computerised system for the identification and monitoring of animals;
- Removal of cattle aged more than 30 months from the human and animal food chains;
- Application of a selective culling programme.

Compliance with these conditions resulted in export of beef and beef products to Europe being allowed from Northern Ireland from June 1998 under the Export Certified Herd Scheme. This was followed in July 1999 by a decision to allow the export of UK beef produced under a Date Based Export Scheme applying to animals born after August 1996.

## **5. ACTIONS TAKEN BY NON-EUROPEAN COUNTRIES**

BSE has also had implications for countries outside of Europe. One of the earliest controls applied by a third country was in 1989 when the USA banned the import of live cattle or beef and beef products from the UK. This was later extended to any country with confirmed cases of BSE. The stated aim of the USA controls related to protection of their herds from BSE infection. Many other countries followed with their own bans. By 1996 a great many non European countries had also banned UK beef, including Australia, New Zealand and South Africa all of whom were important markets for UK beef.

The European ban on specified risk materials used in human food also applies to third country imports except from countries classified as highly unlikely to present a BSE risk (see paragraph 26). When meat and meat products are imported from third countries they must be accompanied by a certificate to the effect that the specified risk materials have been removed and that the animals have been slaughtered in accordance with required European Union standards. Similarly the UK ban on the sale of cattle over 30 months for human food (in place since 1996) applies to all imported beef except from 14 countries (Argentina, Australia, Botswana, Brazil, Mauritius, Namibia, New Zealand, Paraguay, Poland, South Africa, Swaziland, Uruguay, USA, Zimbabwe).

A further European initiative is the classification of countries into risk categories. In July 2000, the European Union Scientific Steering Committee adopted an opinion on the geographic risk of BSE in all Member States and certain third countries. It determined four categories of risk and allocated countries to one of the four categories as shown below:

- Category I (Highly unlikely to present a BSE risk)
- Category II (Risk of BSE is unlikely but cannot be excluded)
- Category III (Likely to present a BSE risk, even if not confirmed, or presenting a low level of confirmed BSE risk)
- Category IV (Confirmed, at a higher level)

There is provision for the categories to be reassessed. Factors other than confirmed cases that were also taken into account included:

- Imports of contaminated feed;
- Imports of infected animals;
- Possibility of cross contamination of cattle feed with other feeds that contain mammalian meat and bone meal.

## **6. EFFECTIVENESS OF CONTROLS**

Europe has clearly benefited from a European approach to tackling the problem of BSE. While control measures taken in the UK prior to 1996 were significant in reducing levels of BSE in the UK, it was clearly important also to implement controls throughout Europe because of the extent of international trade.

However, to be effective control measures must be rigorously applied and enforced through an effective inspection regime. This was certainly a lesson that the UK learnt in the early to mid 1990s when it was found that practices in slaughter houses had to be very closely monitored if the removal of all specified risk material was to be ensured. Action taken by the Meat Hygiene Service (set up in 1995) led to a great improvement in the UK. It is equally important to monitor imports for compliance. During 2001, up until August, 19 seizures of imported meat had been made because of the presence of prohibited spinal cord.

## **7. CONCLUSIONS AND LESSONS TO BE LEARNED**

BSE was a new hazard. Not only had it not been encountered before but it belonged to a group of diseases, TSEs, that are still poorly understood. This led to unprecedented difficulties in risk assessment. Risk assessments must always be based on the best scientific data available. When key data (for example, the infective dose for animals and humans) are unavailable a great deal of uncertainty is introduced.

Uncertainty also has two important implications. The first is that it is quite likely that different groups of experts may deliver different assessments based on the same evidence, as actually happened between different expert committees in Europe. The second implication is that decisions about areas of considerable uncertainty tend to lead to more precautionary policies, on occasions going further than current expert advice.

BSE has clearly caused considerable trans-national problems in both the trade of live animals and meat. These have been mainly, but not exclusively, in Europe. Within Europe we have had the advantage of a co-ordinated approach to control, underpinned by the advice of the European expert scientific committees. Co-ordination of action has been essential in bringing BSE under control.

Finally, consumer protection continues to depend on both continued efforts to eradicate the disease as well as the controls further down the food chain. Effective enforcement of required controls is obviously essential as well.

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## THE DEVELOPMENT AND IMPLEMENTATION OF THE NEW AUSTRALIAN FOOD SAFETY STANDARDS<sup>i</sup>

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### 1. INTRODUCTION – HOW FOOD IS REGULATED IN AUSTRALIA

Australia is a federation, and the separate State public health systems in Australia were developed prior to the formation of the federal government in 1901. The federal government steadily increased its power and influence over most areas of human activity in Australia through the course of the 20<sup>th</sup> century, not least because of the financial powers granted to it as an emergency measure in World War Two. By 2001 the federal government had become the source of funding for most public health activities in Australia, but most of the administration of public health activities in Australia continues to be carried out by the six State, two Territory and numerous local government authorities.

Until 1990 food regulation was a combination of State and Territory activity and the work of a small national advisory committee that made recommendations on food standards. The committee did not consider food safety issues<sup>ii</sup>. As a result major differences arose between the States and Territories. This cumbersome state of affairs could not continue, and in 1991 a national body, the National Food Authority (NFA), came into existence. It was a statutory authority established to, amongst other things, prepare food standards, co-ordinate surveillance of the food supply and advise the Australian Quarantine and Inspection Service on imported food issues. It reported to a ministerial council, the Food Standards Council, which had the ultimate say over the content of food standards.

Australia and New Zealand have two of the most closely integrated economies in the world, so it came as no surprise that in 1996 the NFA was recast as the Australia New Zealand Food Authority (ANZFA). ANZFA is the only bi-national food regulator in existence, with two offices: one in Canberra and a smaller office in Wellington. It currently has approximately 130 staff, most of whom have a scientific or technical background, including microbiology, food technology, chemistry, genetics, toxicology and law. The ministerial council was recast as the Australia New Zealand Food Standards Council (ANZFSC), consisting of the Australian and New Zealand Ministers for Health, the 6 State and 2 Territory Ministers for Health. Under the terms of the treaty with New Zealand on joint food standards, issues of food safety were specifically excluded, and New Zealand and Australia continue to have separate food safety systems. The model of food regulation outlined in this paper applied throughout the 1990s, and it is worth noting that it is now in the process of change, however those changes are outside of the scope of this paper<sup>iii</sup>.

It is necessary to note that the model I have described above is only that of a policy and standard-setting framework. Administration of food safety, and in particular inspection of food businesses, is carried out by environmental health officers employed by either a State or Territory or one of the 700 local government bodies. ANZFA consults with relevant State and Territory officials through a Senior Food Officers (SFOs) forum, and at a higher policy level with the Australia New Zealand Food Authority Advisory Committee (ANZFAAC). They can be distinguished by remembering that SFOs know what is happening on the street, and ANZFAAC members know what is happening in the Minister's office. Having the support of both groups has been critical to the successful passage of the food safety reform package.

### 2. THE PROBLEMS WITH THE EXISTING LEGISLATION

The rest of the *Food Standards Code*, which covers composition and labelling of food, additives and contaminants, residue levels and some microbiological standards, applies uniformly across

Australian food businesses. It appeared illogical that requirements for food safety were not also uniform.

The existing State and Territory laws also created difficulties. Some of the legislation reflected recent developments in regulatory policy, however this was not true for all legislation, the oldest of which dated back to 1928, with its attendant redundancies – for example, one jurisdiction required every place where food was handled to have a manure receptacle for the daily deposit of animal droppings and stable cleanings<sup>iv</sup>. The legislation could be extremely prescriptive, for example one jurisdiction had a requirement that window sills had to be at least 300 millimetres above any bench on which food was handled<sup>v</sup>. This type of legislation tended to focus on process, rather than on the desired outcome, namely a safe food business.

Australia has in the past ten years embraced the concept of ‘minimum effective regulation’ and the area of food safety has not been immune from the trend.

ANZFA was aware that Australian legislation lagged behind that of our trading partners, and did not reflect modern food regulation, particularly in the emphasis on HACCP. In addition, there has been growing awareness of the importance of the ‘paddock – to – plate’ approach to managing food safety, which means managing the whole of the food chain: first class handling and processing requirements are of little use where material with a high pathogenic load enters the food chain. In part for this reason, and as part of the changes to the food regulatory changes mentioned elsewhere, all Australian governments decided in 2000 that ANZFA will assume responsibility for food standards in the area of primary production, with the object of achieving an integrated regulatory approach.

Finally, and of greatest importance, has been the need to reduce the incidence of foodborne illness in Australia. Figures on the level of foodborne illness are notoriously imprecise, due to widespread under-reporting, however ANZFA has estimated that there are approximately 4,000,000 cases of foodborne illness every year in Australia, or one case for every 5 Australians<sup>vi</sup>. This is slightly lower than reliable estimates of foodborne illness in the United States.

This particular objective was given particular impetus by some widely reported individual outbreaks of foodborne illness which have galvanised public and political opinion on the issue.

In summary, the Food Safety Standards were developed for the following reasons:

- to provide more effective food safety regulations and reduce the level of food-borne illness in Australia;
- to provide nationally uniform food safety standards for Australia so businesses operating in more than one State or Territory have only one set of requirements;
- to replace existing food hygiene regulations that were sometimes significantly out-of-date; and
- to introduce less prescriptive regulations, that are simpler to comply with and give businesses more flexibility to determine the best way for them to comply with the requirements – providing food safety is not compromised.

### **3. FOOD SAFETY REFORM – EARLY YEARS**

Efforts to create a set of uniform, simple and flexible food safety laws have a long genesis. In 1975 Health Ministers endorsed a proposal for a *Model Food Act* and complementary food standards, including on food hygiene. A *Model Food Act* was released in 1980, however its acceptance was limited. Between 1981 and 1986 *Model Food Hygiene Regulations* were drafted, however again there was little acceptance.

#### **ANZFA becomes involved**

The current round of food safety reform can be said to have begun in 1994 with the release by the NFA (now ANZFA) of a discussion paper, *Safe Food Handling – Australia*, which advocated a more preventative approach to food safety. It suggested national food hygiene legislation and

supporting codes of practice and guidelines. In particular, it advocated food safety programs based on HACCP principles.

An early issue in framing the food safety standards arose out of the heterogeneous nature of the food industry in Australia. At one end of the spectrum are a small number of large corporate conglomerates who are well aware of the importance of food safety in protecting their brand. They understand the outcomes that must be achieved and have the technology and resources to achieve those outcomes in a variety of ways. At the other end of the spectrum are a very large number of small businesses who prefer a highly prescriptive approach to regulation – ‘just tell us what we have to do’. The obvious dilemma for the policy maker is: which approach to adopt. Eventually ANZFA opted, correctly, for a mix of the two. The standards contain a mix of prescription and a general proviso that, if an alternate method can guarantee the same level of safety, it could be utilised.

Following the release of the discussion paper for public comment, the NFA held consultation meetings in each Australian State capital between October and December 1994.

Fate then intervened. In early 1995 there was an outbreak of *Escherichia coli* 0111 from contaminated mettwurst. One hundred and seventy people became ill, of whom 23 children developed Haemolytic Uraemic Syndrome and one child died. The public demand for something to be done about improving food safety became deafening. In June 1995 the ministerial council, ANZFSC, asked ANZFA to develop, in consultation with the States and Territories, new standards for food safety which would then be implemented in a nationally uniform way. The following year ANZFSC asked ANZFA to draft a new *Model Food Act*, to, amongst other things, ensure uniform application and enforcement of the food safety standards. This eventually bore fruit in a model Bill, divided into a Part A which every jurisdiction had to adopt without amendment, and which contained critical material, such as definitions of food and ‘sell’; and a non-mandatory Part B, which contained desirable but not essential elements. This dual approach was eventually adopted by the jurisdictions in 2000 and the *Model Food Act* is now in the process of enactment in the States and Territories.

In September 1996, having reviewed the results of its previous round of consultation on food safety, and having consulted widely with various stakeholders, ANZFA released an Information Paper, *Proposal to Develop a National Food Hygiene Standard*, and invited comment on the proposals outlined. This was regarded by ANZFA as the commencement of a formal process under the *ANZFA Act* to amend the *Food Standards Code* to, for the first time, explicitly incorporate food safety requirements through separate food safety standards. Again, ANZFA raised the prospect of mandatory food safety programs, which would require all food businesses that could identify one or more potential safety hazards to develop and implement food safety programs based on HACCP principles. The details and scope of the programs would vary according to the size and nature of the business and the level of risk it posed to the community. It was proposed that the standards would be phased in over 6 years.

Responses to the Information Paper indicated that there was support for development of standards on both general food hygiene requirements and for the design and construction of premises, to replace existing regulations in the area. As a result, ANZFA decided to progress work on these two areas (which eventually became Standards 3.2.2 and 3.2.3 of the *Food Standards Code*) as a matter of urgency, as implementation of these two standards was regarded as a necessary precursor to the introduction of a requirement for mandatory food safety programs (which eventually became known as Standard 3.2.1). A preliminary paper on the draft standards was released for public comment in July 1997.

ANZFA formed a Working Group, mainly consisting of officials from the food area of State and Territory Health Departments, to rework the draft standards that had been in the preliminary paper. A further draft of the revised standards was released to a meeting of officials and industry and consumer representatives on 15 October 1997, and following further consideration by the Working Group, a further revised version of the standards was released for public comment in March 1998. Following receipt of 280 formal submissions, ANZFA held 17 workshops across Australia with approximately 600 attendees to discuss the standards. Although ANZFA had intended to only have one formal round of

public consultation, in light of the level of interest a further round of public consultation was held in October 1998, when it released a further revision of the general standards (which had in the interim grown to three, to include a standard on application and interpretation). By now the consultation document had grown to over a hundred pages in length, although the standards themselves remained commendably short. In retrospect, it can be seen that this seemingly endless process of consultation was invaluable in creating a constituency in favour of reform, which understood the issues and became committed to the proposed new approach to regulating food safety.

The three general standards were endorsed by the Board of ANZFA in November 1998 – ANZFA is an independent statutory authority, and at the time major policy and strategic decisions for ANZFA were taken by a ten member Board<sup>vii</sup>, consisting of a number of academics with a background in public health, food science and public administration, as well as representatives of consumers and industry, together with three New Zealand nominees. The Board approved the revised standards and recommended their adoption together with a food safety program standard, to the ministerial council, ANZFSC.

At its December 1998 meeting, ANZFSC agreed to the standards in principle, subject to the completion of a Regulatory Impact Statement, and further discussions with State and Territory officials on implementation. ANZFA completed a Regulatory Impact Statement and released it for comment in May 1999. The Regulatory Impact Statement estimated that foodborne illness cost Australia \$A2.6 billion a year.

### 3.1 THE FOOD SAFETY PROGRAM STANDARD IN TROUBLE

By this stage, there was considerable unease in some sectors of the food industry concerning the introduction of mandatory food safety programs, i.e. Standard 3.2.1. Although the major food processors supported the food safety reforms, including food safety programs, and the Australian Food and Grocery Council and major retailers in particular were and remain prominent champions of the reform package, the food service sector in particular grew increasingly strident in its criticism of the proposed food safety program requirement. The Australian Hotels Association and the Restaurant and Catering Association were particularly prominent critics. They claimed that many of their members were small businesses who would have to contend with an expensive and cumbersome bureaucratic system that would not deliver better food safety outcomes. They also claimed that ANZFA's Regulatory Impact Statement had overstated the extent of foodborne illness in the Australian community. There was also concern from the primary industry sector that, despite their current exemption, the requirement for mandatory food safety programs would eventually be imposed 'on farm'. ANZFA only became belatedly aware of the high-level lobbying that had been occurring on this issue.

By October 1999 the food safety program standard was in deep trouble. At its meeting at that time, ANZFSC recommended to the Council of Australian Governments (a committee commonly known as COAG, and which consists of the Australian Prime Minister, the Premiers of the 6 Australian States and the Chief Ministers of the Australian Capital Territory and the Northern Territory) that it defer consideration of the food safety program standard until the federal Department of Health and Aged Care (ANZFA's 'parent' department) had obtained better data on the incidence of foodborne illness, and the cost and impact of the mandatory food safety program standard. The federal government allocated over \$A4 million for this exercise. At the same time, ANZFSC recommended that the other three general standards be endorsed by COAG. The three general standards were endorsed by COAG and ultimately approved by ANZFSC in July 2000. They were gazetted into the *Food Standards Code*, as a new Chapter 3, on 24 August 2000. States and Territories were required to begin the process of incorporating the standards into their own food hygiene laws from February 2001, and New South Wales was the first to do so, in May 2001. A table on implementation dates is attached as Appendix One to this paper.

There has been one further development concerning the food safety program standard. The decision in October 1999 to defer its adoption caught a number of jurisdictions by surprise. One State,

Victoria, had already begun to introduce a food safety programs requirement, following a serious episode of foodborne illness that killed two people. Other jurisdictions were considering the introduction of mandatory food safety programs in high-risk food businesses, such as hospitals and nursing homes. There was a danger that jurisdictions would introduce differing versions of food safety programs, undermining one of the key elements of the reform package, namely uniform legislation. Therefore ANZFA proposed as a compromise approach, and ANZFSR accepted in October 2000, that although the food safety program standard would not be compulsory, if a jurisdiction did choose to introduce food safety programs, it would have to comply with the requirements of Standard 3.2.1. The Department of Health and Aged Care has commissioned external consultants to advise it on the cost and efficacy of food safety programs and has funded, with the co-operation of ANZFA, the creation of Oz Food Net, to improve the epidemiological data on foodborne illness. Consideration of the outcomes of these exercises will be a lengthy process.

Out of that convoluted policy and political process, what emerged? Has it been worth it? To answer that question requires, amongst other things, an examination of the standards themselves.

### ***3.1.1 Standard 3.1.1 Interpretation and Application***

This is the introductory standard. It explains the main terms that are used within the Food Safety Standards, such as the meaning of ‘safe and suitable food’. It also applies the standards to all food businesses in Australia, with the exception of primary food production businesses, unless those businesses are also involved in the processing or retail sale of food. It requires food businesses generally to comply with the standards and in addition requires food handlers to comply with those requirements which are relevant to them.

### ***3.1.2 Standard 3.2.1 Food Safety Programs***

If a food business is required to have a food safety program, it must examine all of its food handling operations in order to identify those food safety hazards that might reasonably be expected to occur and prepare a written food safety program to control these hazards. The program must include controls for the identified food safety hazards, ways to monitor that the controls are working and steps to be taken when a hazard is not under appropriate control. Records must be kept by businesses to ensure that there is evidence that the business complies with the program requirement. Finally, each food business’s food safety program will be regularly audited by a suitably qualified food safety auditor to ensure compliance. Auditing lies at the heart of the new approach of the food safety program standard. Instead of an occasional inspection by an environmental health officer to determine whether prescriptive requirements are being complied with, the auditor is considered someone who assists a food business to identify possible hazards, controls and monitoring mechanisms. The standard is silent as to whether this auditor is an environmental health officer, i.e. a public servant, or a qualified industry food safety auditor, as approaches to enforcement are likely to differ on this issue. In conjunction with a number of stakeholders, including the Australian Institute of Environmental Health, which represents environmental health officers, ANZFA has developed a national audit system for food safety programs. This sets out the requirements for the approval of auditors, including a three-level auditor system, the audit process and methodology, mechanisms for determining audit frequency and finally the development of policies and procedures to ensure the integrity of the audit system.

To assist in determining audit frequency, ANZFA has also developed a national priority classification system for food business, which classifies businesses into risk categories, based on the type of food, the activity of the business, the method of processing and the customer base. The three levels (high, medium and low) then determine the initial frequency of audit. The system may also be used by government when considering the phased introduction of a food safety program requirement.

One further document which should be considered when considering Standard 3.2.1 is that of ANZFA’s framework for the development of food safety program tools. A frequent criticism of the concept of mandatory food safety programs is the cost involved in having to write an individual plan for each food business. The framework document addresses this criticism by providing a guide for the

production of tools, such as templates, models, software and printed materials which can be utilised to create individual food safety programs.

### **3.1.3 Standard 3.2.2 Food Safety Practices and General Requirements**

This standard sets out specific food handling controls related to the receipt, storage, processing, display, packaging, transportation, disposal and recall of food. Other requirements relate to the skills and knowledge of food handlers and their supervisors, the health and hygiene of food handlers, and the cleaning, sanitising, and maintenance of the food premises and equipment within the premises. There are also requirements to have a thermometer on the premises (a new requirement, so that the food handler can utilize time/temperature controls), controls on single use items, and of pests. If complied with, these requirements should ensure that food does not become unsafe or unsuitable. The standard applies to all food businesses, whether operating from a permanent building, a vehicle, boat or plane or at temporary market premises.

A notable new approach is that the standard permits food businesses to deviate from temperature requirements provided they can demonstrate they have a safe alternate system in place. For example, the standard requires potentially hazardous food to be either 5°C or colder, or 60°C or hotter when it is received, displayed, transported or stored. However, businesses can safely deviate from these temperature requirements by using time to control the safety of the food, provided the total times does not exceed safe limits and records are kept. This would, for example, enable food to be displayed, unrefrigerated, for short periods.

There are two further major changes introduced by this standard that do not formally commence until after February 2002.

Firstly, there is now a requirement on each food business to notify the relevant authority, usually the local government council, of its existence. The notification requirement applies to almost every food business in Australia. A food business is any business or activity that involves the sale of food or the handling of any type of food for sale in Australia, with the exception of some primary food production activities.

This means that the notification requirement applies to activities undertaken for charitable or community reasons, as well as to commercial ventures and once-off projects that involve the handling and sale of food. It includes businesses that may not think of themselves as food businesses, like cinemas, corner stores, petrol stations and swimming pools, if they sell packaged or any other type of food.

The second new requirement is that the owners of food businesses will be responsible for ensuring that people who handle food or food contact surfaces in their business, and the people who supervise this work, have the skills and knowledge they need to handle food safely. The only exception to this requirement is for charitable or community fundraising events, which sell food that is not potentially hazardous or that will be properly cooked and then eaten straightaway.

### **3.1.4 Standard 3.2.3 Food Premises and Equipment**

Standard 3.2.3 specifies requirements for the:

- Overall design and construction of food premises, including water supply, sewerage, garbage, ventilation and lighting
- Floors, walls and ceilings of food premises;
- Fixtures, fittings, and equipment within buildings, including handwashing facilities; and
- Food transport vehicles.

If food businesses comply with these requirements, they will find it easier to meet the food safety requirements of the food practices standard. Again, these requirements apply regardless of which particular structure the businesses is housed in.

#### 4. SUPPORT MATERIAL AND ACTIVITIES

ANZFA has produced a wide variety of material to explain both the intent and the content of the new standards. In particular, it has published two editions of *Safe Food Australia*, a 200-page guide to the three general standards. As the new standards are more outcome – based than the hygiene regulations they replaced, *Safe Food Australia* emphasises the choices available to food businesses, within the overall requirement to produce safe food. There have also been a number of technical and general fact sheets on the new standards and how to apply them. ANZFA staff have been regularly invited to present workshops, particularly to the environmental health officers who are responsible for putting the new standards into effect. Many environmental health officers at the local level are very comfortable with a high level of prescription, and many food businesses (particularly small businesses) likewise. In these circumstances, ANZFA has prepared a wide variety of written material (most of which is on the ANZFA website) in order to ease the transition into amore outcomes-based system. Small business has been a particular focus of ANZFA’s support activities, in view of its limited access to resources. ANZFA has also convened an Implementation Working Group of Senior Food Officers from all jurisdictions, to discuss issues which have arisen from implementation and ensure a common consistent approach. Given that there are usually only 8 staff in the food safety area at ANZFA, and there are other calls on their time, the output has been considerable.

#### 5. LESSONS FOR OTHER COUNTRIES – GOOD AND BAD

The intention of this Forum is to allow us to compare experiences, and there is a wealth of material lessons learned the hard way from ANZFA’s work on the food safety standards. First, it is not a quick process. The idea of creating a single, uniform and simpler system of food safety laws was not a radical one. It had widespread community and political support, and most elements of the food industry supported it. It promised to reduce the regulatory burden on industry while generally raising the standard of care in the industry. Nevertheless, the process took 6 years just to get the least controversial elements introduced, and the future of mandatory food safety programs is still uncertain.

Secondly, if change is to be introduced, lengthy consultation is essential. The consultative process was exhaustive, but certainly succeeded in enlisting critical support in the jurisdictions, in industry and among the community at large. ANZFA’s use of a number of consultation documents, working groups and public forums ensured that there was significant stakeholder support for the standards when they finally reached the approval stage.

Thirdly, advocating the widespread introduction of mandatory food safety programs is a very problematic activity. ANZFA failed to build a strong constituency for HACCP, for food safety programs generally and the approach we were advocating. ANZFA always considered the introduction of food safety programs to be a long-term objective, requiring years of work on implementation of the general food safety standards before moving to food safety programs. This was not understood by those who feared the overnight introduction of a bureaucrat-driven change that would only involve more paperwork for overstretched small business. The timing was not helpful, in that the Australian government was at the time introducing a value added tax which applied to most Australian businesses, which resulted in much higher sensitivity than usual about the introduction of a new regulatory requirement.

Fourthly, the area continues to be bedeviled by a paucity of high- quality data. There is a general scientific consensus on what pathogens are likely to contaminate food. There is much less known about the method and patterns of transmission to humans, and the extent and cost of preventable foodborne illness.

Fifthly, major and well-publicised outbreaks of foodborne illness can transform the climate on the issue of food safety reform. Major outbreaks of foodborne illness, particularly involving fatalities, have driven a large part of the political response to food safety issues in Australia. When polled, Australian consumers have regularly cited foodborne illness as their major food issue, rather than, as some have suggested, genetically modified or irradiated food. The general food safety standards were, in

retrospect, assured of passage because otherwise there would have been an outcry that years of work on new national laws on food safety had achieved nothing.

Finally – the exercise is worth it. Although we are still a long way from full implementation of the entire food safety reform package, Australia now has a single set of food safety laws which are shorter, clearer, more flexible, more fairly allocate responsibility and set a new bench mark for food safety.

## APPENDIX 1 TO GF 01/8

Current position in relation to each State and Territory in implementing the Model Food Bill and the Food Safety Standards

<b>State/Territory</b>	<b>Model Food Bill</b>	<b>Standards 3.1.1, 3.2.2 and 3.2.3</b>	<b>Standard 3.2.1 (Food Safety Programs)</b>
Northern Territory	The proposal for a new Food Act will need to be considered by the new Territory Government. Aiming for Autumn 2002 sittings.	The Standards will not be enforceable prior to the introduction of a new Food Act.	Awaiting outcome of Federal government's Department of Health and Aged Care (DHAC) study on costs and benefits of food safety programs.
WA	The new Food Act is likely to be considered during the Autumn session of 2002.	The Standards will become enforceable following the passing of the new Food Act and will operate in conjunction with the existing food hygiene regulations until they are repealed. Consultation with stakeholders groups is currently taking place on the legislative changes.	WA is not opposed to the introduction of mandatory food safety programs and is likely to initially require programs for producers of smallgoods, the dairy sector and food businesses within public hospitals.  Stakeholders groups are strongly pushing for the new Food Act to obligate the Minister to consult with industry sectors and obtain substantial agreement prior to requiring food safety programs within a sector.
Qld	Amendments to the Qld Food Act on Annex A are pending. Public consultation on Annex B is expected Feb/Mar 2002.	Came into effect by amendment to existing regulations on 1 July 2001.	Awaiting outcome of DHAC study on costs and benefits of food safety programs, but may be further announcement before that date.
South Australia	A new Food Act has received Royal Assent and proclamation date early 2002.	Will commence on proclamation i.e. early 2002.	Awaiting outcome of DHAC study on costs and benefits of food safety programs.

State/Territory	Model Food Bill	Standards 3.1.1, 3.2.2 and 3.2.3	Standard 3.2.1 (Food Safety Programs)
New South Wales	Amendments to the NSW Food Act are likely to be considered either Spring 2001 or early 2002.	Came into effect by regulation on 16 May 2001 with a modification to exempt funding raising events from the notification requirement.	<p>Proposing to require 3.2.1 for high risk businesses. Comment on this approach is currently being sought through a NSW Information Paper, <i>A new approach to Food Safety in New South Wales</i>, June 2001.</p> <p>NSW Health is also conducting, with DHAC funding, a National Risk Validation project. The project will utilise outbreak data together with data from Food Science Australia and cost/benefit analysis to assess the hazards associated with industries and the potential food safety risks to the consumer.</p>
Tasmania	New Food Act to be considered at the end of 2001 or early 2002.	Came into effect by regulation on 24 Sep 2001.	Awaiting outcome of DHAC study on costs and benefits of food safety programs.
ACT	The new Food Act was gazetted on 10 September but has not yet taken effect. Expected to take effect early 2002 but no later than 10 March 2002	Expected to commence early 2002 but no later than 10 March 2002.	Awaiting outcome of DHAC study on costs and benefits of food safety programs.

State/Territory	Model Food Bill	Standards 3.1.1, 3.2.2 and 3.2.3	Standard 3.2.1 (Food Safety Programs)
Victoria	Amended Food Act passed April 2001. It will take effect from 2 Jan 2002.	Will apply from 2 January 2002.	<p>Has not yet applied Standard 3.2.1 to any food business.</p> <p>All food businesses with the exception of minimal risk businesses are required to have a food safety program by 1 Jan 2003 in accordance with the Vic Food Act.</p> <p>High risk businesses are required to have an independently developed and audited food safety program (referred to as an Independent System).</p> <p>Moderate risk businesses have the choice of an Independent System or a food safety program developed from a DHS registered template and compliance checked by local government.</p>

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- i I am grateful for the contributions of Ms Tania Martin of the Food Safety Program, ANZFA, towards the preparation of this paper. The views expressed in it are completely the author's own.
- ii For the purposes of this paper 'food safety' covers those activities which deal with food hygiene, and in particular the requirements concerning handling, processing, transport and storage of food in a safe manner.
- iii In short, ANZFSC will, with the addition of Ministers for Agriculture and Industry from all the jurisdictions, become the Food Regulation Ministerial Council, which will set broad policy guidelines in the area of food regulation. Regulations will be made by ANZFA, renamed Food Standards Australia New Zealand. There is also provision for a new policy advisory and implementation framework to support the new structure. The new arrangements, subject to applicable treaty changes between Australia and New Zealand, should come into effect in mid 2002.
- iv ACT Public Health (Sale of Food and Drugs) Regulations 1928 Reg 40.
- v Queensland Food Hygiene Regulations 1989 Reg 9.
- vi Food Safety Standards, Costs and Benefits, ANZFA 1999. p28.
- vii Following the commencement next year of recently approved changes to the food regulatory model in Australia and New Zealand, the Board will be expanded and its role redefined.

**SUMMARIES OF CONFERENCE ROOM DOCUMENTS FOR THEME 1****REGULATORY ISSUES****▪ CANADA-1**

Canada's food safety system operates in a multi-jurisdictional setting involving federal, provincial, territorial and municipal authorities. Under such shared jurisdiction, a comprehensive agreement has been established entitled *Food-borne Illness Outbreak Response Protocol* outlining the roles and responsibilities of all governments involved in the investigation of food safety emergencies and detailing an integrated approach in response to national and regional food-borne illness outbreaks. For transboundary situations, Canada endorses and follows the *Codex Guidelines for the Exchange of Information in Food Control Emergency Situations*. As for domestic products, the *Protocol* serves as the guidance document to address a national food safety emergency involving an imported product. New initiatives to improve food safety emergency procedures involve projects to enhance early detection and investigation of a food-borne illness. Health Canada has developed a program entitled "*Skills Enhancement for Health Surveillance*" which is an internet-based training initiative for local and regional public health departments across Canada to increase skills in epidemiology, surveillance and information management. A national reporting system is also being developed entitled "*Outbreak Investigation*" to improve notification of all food-borne illness outbreaks in Canada.

**▪ EUROPEAN COMMUNITY-1**

On 21<sup>st</sup> January 2002 the EU Council of Ministers took the last steps towards the adoption of a Parliament and Council Regulation establishing the European Food Safety Authority (EFSA) and laying down a new framework for Food Safety in the European Union. The new Regulation establishes the principles, definitions and requirements on which all future food law in Europe will be based and defines the terms '*food*' for the first time at the European level harmonizing differences that did exist between some of the Member States. It also defines the term '*food law*' which covers a wider range of provisions beyond those relating solely to food (e.g. measures relating to materials and substances in contact with food, measures which may have a direct or indirect impact on food safety). Furthermore, the Regulation establishes the rights of consumers to safe food and to accurate and honest information. Future food law will be based on an integrated approach from the farm to the final consumer, including measures applicable on the farm. The Regulation establishes the principles of risk analysis in relation to food law and establishes the structures and mechanisms relating to the scientific and technical evaluation to be principally undertaken by the European Food Safety Authority. In addition, the Regulation formally establishes the Precautionary Principle as an option open to risk managers where decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way. The new Regulation provides for traceability of all food and feeds as they move between businesses, with information being made available to the competent authorities upon request. The document includes a description of the technical structure of the future European Food Safety Authority.

**▪ EUROPEAN COMMUNITY-3**

This CRD provides a description of the European Union's rapid alert system put in place since 1978 amongst its Member States. The Member States have a duty to provide as a matter of urgency, information in the case of a serious risk to the health of consumers. It is applicable to all consumer products, food and non-food, insofar as these products are not already covered by specific equivalent provisions in other Community acts. In legal terms, Member States are only obliged to inform the

Commission in cases where the dangerous product could be placed on the market outside the territory of the Member State that has identified the specific risk. But in practice, as the single market becomes ever more integrated, it is becoming increasingly difficult to be sure that a product will not go beyond the borders of a given Member State and therefore, notification is useful in any case. There are currently two networks : the food network and the non-food products network. These networks are supported by the latest available computerised information technology. The document details the procedures for the functioning of the Community Rapid Alert System and describes it's modernization as effectuated through a regulation entered into force during mid-February 2002 and established under a new network linking up the Member States, the Commission and the new European Food Safety Authority.

#### ▪ IACFO-1

This paper discusses new food safety challenges posed by the growth of the international food trade; public health implications of the World Trade Organization's (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS); and the role of the World Health Organization's (WHO) International Health Regulation's (IHR) in promoting food safety. Reviews concerning various shortcomings of the current leading international agreement in the area of food safety and trade (i.e. the WTO SPS Agreement), are addressed and it is stated that the globalization of the food industry necessitates not only reform of an *international trade agreement* that protects business interests, but also an *international food safety agreement* to protect consumer interests. This paper concludes that this need could be served by supporting the revision of the WHO IHRs as they apply to food in international trade and recommends that developed countries should provide the WHO with extra-budgetary resources to promptly complete this effort. Such steps will help restore public confidence in the safety of the food supply and promote further steps towards trade liberalization in the food sector. Such steps will thus benefit producers as well as consumers.

#### ▪ INDONESIA-2

The document summarises food safety regulation in agriculture in Indonesia. The lack of food safety awareness in farmers is stressed as is the consequential result that Indonesian agricultural products are below the standard required by consumers and the international market. The Indonesian National Standard (SNI) is the only authorized standard applied nationally in Indonesia. Issued by the National Standardization Institution, the SNI promotes effective production, increased productivity and quality assurance on safe food production. The HACCP system is adopted nationally under SNI No. 4852-1998 and applied in the agriculture industry as the main tool in establishing food safety in agricultural products. The implementation of the HACCP system in the agricultural sector is recognized by the Ministry of Agriculture Decree No. 303/1996 which acts as a technical regulation on the National Standardization System for the agricultural sector. However, for implementation by small-scale farmers, HACCP requires modification in addressing specific local conditions. Indonesia needs to promote food safety programs within the agriculture industry are in policy development; food safety assurance; food safety promotion; training and education; information dissemination and these programs would need support from developed countries through both bilateral and multilateral cooperation.

#### ▪ ITALY-1

The contamination (*dioxin crisis*) of food of animal origin occurred in Europe during 1999 and represented an opportunity to evaluate the food control system in Italy. The experience of the crisis highlighted deficiencies in the control system and the existence of an efficient traceability system for animal and product consignments from other EU Member State, thereby permitting the tracing of most animal and product consignments coming from Belgium over the period in question. The dioxin crisis urged the European Union to improve the feed control system, through the establishment of an effective traceability system and a strengthening of the rapid alert system of the EU Member States. The

experience of the European Union fosters the creation of a permanent international observatory in charge of alerting all countries worldwide of occurring food emergencies. The management by the FAO or the WHO of a computerized system (through the Codex Alimentarius) for the gathering and circulating of notifications pertaining to food health emergencies, has been suggested.

#### ▪ **LAO'S PDR-1**

The document provides information on national agriculture and food regulation in Lao's PDR-1. The Food Law is enforced primarily by the Ministry of Health. Good manufacturing practices and a number of essential standards (i.e. for drinking water, ice cream, tomato sauce, iodization salt, mineral water and ice) have been issued based on the Codex Alimentarius Commission guidelines. Codex standards are used as a reference for inspection purposes of other food products for which Laos food standards are not available. The Food Control Authority is led by the Food and Drug Administration Commission which was established in 1991 and is managed by the Ministry of Health. Difficulties are highlighted in running the three official laboratories of the country. In the case of food export, the Food and Drug Department and the Food and Drug Quality Control Center under the Ministry of Health, are responsible for controlling and delivering certificates of food analysis and quality assurance of these foods. The control of domestic food products is a multidisciplinary activity which requires the involvement and cooperation of all concerned. The document contains a list of requirements necessary to strengthen national food control systems and capacity building on food safety.

#### ▪ **MOROCCO-1**

Morocco's food inspection is currently conducted under two main laws (adopted in 1977 and 1984) and a series of complementary regulations related to the safety and trade aspects of food products. The basic legal text governing the inspection of exported and imported live animals and of food products of animal origin is the law adopted in 1989 and which explicitly delegates powers to the Ministry of Agriculture in decisions concerning the banning of products which present a risk to human health. Food control in Morocco is carried out by specialised units in several Ministries (Agriculture, Health, Interior, Industry). Their interventions are not always coordinated despite the legal establishment, since 1968, of an Inter-Ministerial Coordinating Commission. The main responsibility for ensuring food safety rests, however, with the Ministry of Agriculture. Following reported delays in responses to inquiries from international organizations (e.g., Codex, OIE, OMC, FIL), it was suggested that guidance be developed to designate appropriate contact points able to provide prompt responses to various enquiries. Further developments in Morocco include: risk management options chosen during two emergency food safety situations (i.e., ESB, Dioxin); proposals towards greater flexibility to publish a decree in cases of food safety emergencies; the examination for future endorsement of a food law and of a draft law to create a Moroccan Food Safety Agency; the extension of a national quality management programme (established primarily for fish and fisheries products) to all food sectors. A national Sanitary Monitoring and Survey Unit and national biosecurity commission have been established. National recommendations have been issued to create a structure in charge of assessing risks in order to establish a functional split between risk assessors and risk managers; establish a rapid alert system; elaborate a coordination system amongst all stakeholders involved in food safety; split processing and development aspects from official food safety control; and lighten procedures to adopt legal texts regarding food safety.

#### ▪ **PERU-1**

This paper presents figures and analysis of the 1991 cholera outbreak that led to 322,562 contaminated people and 2,909 victims and concludes that water (particularly stagnant water), is the main route of transmission of *Vibrio cholerae*. The outbreak of this epidemic raises concerns of environmental health threats and the lack of adequate sanitary measures for the evacuation of waste waters, highlighting the problem of sanitary education and preventive and curative action to control Cholera spread. The need for surrounding countries to coordinate their efforts is imperative since

cholera-like disease has a transboundary infection nature and a multi-sector National Commission to fight against cholera has been established, as has a Coordinating Technical Group by Brazil, Colombia and Peru. Multi-sector collaboration of all bodies involved nationally in food safety is called for. There is a need for the reinforcement of national sanitary legal requirements in the preparation and handling of street-vended food and beverages. This outbreak initiated the education of young women in the administration of treatment against dehydration. Combining health care-education-community is also felt to be a good preventive pre-requisite.

#### ▪ PHILIPPINES-2

The paper discusses the origins and levels of threat regarding mercury exposure by consumers of fish products in the Philippines. It proposes a series of recommendations to address the problem, including: 1] the establishment of a laboratory to undertake comprehensive inorganic and methyl mercury determination in areas “at risk” to provide the necessary guidelines to the community, with particular reference made to high risk groups (e.g. pregnant women and children); 2] provide education of high risk groups; 3] to request local government units to a) continue in health and environmental monitoring activities in the affected areas, b) require establishments to install anti-pollution devices for air pollution and waste treatment recovery/treatment facilities, c) relocate of ballmilling/refining process into an industrial zone, d) undertake remediation/mitigation measures in the environment to ensure that exposure limits to mercury will be kept at a minimum or within permissible limits, e) conduct monitoring of fish especially those with high levels.

#### ▪ DR CONGO-1

Situated in central Africa, the Democratic Republic of Congo is confronted with many food safety emergency situations, augmented by its location in equatorial and sub-tropical areas subject to many communicable diseases transmissible to humans from animals (zoonoses). The current unstable political situation within the Democratic Republic of Congo has resulted in scarce official monitoring, insufficient food quality control and a lack of financial and logistic means required to review and test food. Priorities include the food production chain, imported food control, risks linked to inappropriate transportation and conservation. Common foodborne diseases (enterobacteriae provoked/caused toxoinfection due to enterobacteriae and to vibrios cholerae among others and emerging diseases (Ebola virus, ESB...) and other food contamination are present in the country. Poor living conditions are the main roots of this decrease of public health in the country. Although national expertise exists to identify hazards, logistic resources (e.g., laboratory equipment) as well as training programmes of technical staff are missing. The technical assistance and financial support of the United Nations are required to establish a real capacity building strategy on food control facilities and procedures within the country.

#### ▪ REP. CONGO-1

Presently, the Congo Republic has no legislation related to food safety. Consequently, the plant protection service has proposed a draft food law currently under discussion and promulgation. Services involved in veterinarian and zootechnical inspections were truly operative up to the 90s thanks to the good management of the Veterinarian and Zootechnical Research Center (VZRC) laboratory. These services are currently paralysed due to a lack of financial support and of equipment (chemical reagents). This is also due to the decision taken to stop meat inspection at borders. The Plant Protection and Phytosanitary Control Service focuses its activities on imported products in checking certificates of origin. Congo is a net importer of the majority of its food. Import levels greatly extend available control capacities on imported food. This imbalance is mainly due to the absence of a national food laboratory. In addressing these problems rapid action is required to establish an efficient food control system, to review and adapt current legislation to foster food safety control, to carry out training of staff involved in food control and to increase coordination on food control provisions at sub-regional and regional levels. All provisions have the objective to reduce undue exposure of consumers to foodborne hazards.

The Congo-Brazzaville Republic is a disabled country shocked by several consecutive civil wars and is slowly starting to build up its economy. The drafting of comprehensive food legislation should be urgently undertaken by the national authorities. Thus, the proposed draft food law on zootechnic and zoosanitary regulations is most welcome, its application utilitarian to all operators (including rural areas) involved in food control.

#### ▪ TANZANIA-1

This paper describes the main regulatory framework in place to assure food safety in Tanzania. In particular, the responsibility for carrying out food safety and quality control functions in Tanzania is assumed by Ministries of Health, Agriculture and Food Security, Natural Resources and Tourism, and Ministry of Industries and Trade. Laws empowering these ministries had been considered to be adequate for monitoring and control of transboundary food safety emergencies. These laws include: a Food (Quality) Control Act (establishing the National Food Control Commission (NFCC) and the general mandate of the Ministry of Health); a Plant Protection Act (empowering the Minister for Agriculture and Food Security to regulate the import and export of plant products to and from the country with the view to controlling diseases and pests and also the control of export/import of food products of plant origin in coordination with the NFCC); a Fisheries Act (empowering the Minister for Natural Resources and Tourism to regulate and to ensure safety and quality of all fishery products produced and processed in the country); a Radiation Control Act (establishing a National Radiation Control Commission in charge of controlling the presence of radioactive material including in food trade); a Standards Act (empowering the Minister for Industries and Trade, through the Tanzania Bureau of Standards to promulgate national standards including standards for food products); and a Tropical Pesticides Research Institute Act (1979) (establishing the Tropical Pesticides Research Institute, which is responsible for registration and approval of pesticides for use in the country).

#### ▪ USA-8

This paper presents several cases-studies in food-borne disease outbreaks which occurred in the USA with food contamination particularly through E. Coli O157:H7, Listeria Monocytogenes or Cyclospora. Lessons learned from these outbreaks include the need for interaction of government, industry and academia to address emerging public health issues. Even in the presence of large uncertainties, such collaboration can protect the public's health on an interim basis while targeted research begins to answer the most important questions. As new information becomes available, the collaborative framework facilitates the rapid integration of the new information into the evolving control effort. Response to food safety emergencies requires the ability to recognize unusual health events, to identify the cause with adequate specificity to permit categorization of the agent, to investigate the possible sources of exposure sufficiently well to determine if food is a likely source of the agent, to refine the food exposure data sufficiently well to permit a reasonable reaction, and to effectively and quickly segregate potentially contaminated food to prevent its consumption. For food safety emergencies that involve well-recognized foodborne hazards in characteristic food vehicles (e.g. Salmonella in eggs, Campylobacter in poultry meat, Vibrio in seafood) a rapid effective response generally requires enhancing the public health and regulatory infrastructure and improving interagency interactions and government-industry-consumer cooperation and communications. It is mentioned that the same systems may be used for addressing unintentional foodborne disease and for identifying and addressing intentional contamination of foods (bioterrorism), but this would necessitate adaptation of the existing food safety systems.

#### ▪ WHO-1

The potential for terrorists to deliberately contaminate foods must be taken seriously. On 17 January 2002, the WHO Executive Board adopted a resolution (EB109.R5) which recognized the importance of safeguarding food in a global public response to the deliberate use of biological and chemical agents and radionuclear attacks intending to cause harm. Reducing these threats of sabotage will require an

unprecedented degree of co-operation among health, agriculture, and law enforcement government agencies; the food industry; other private sector bodies and the public. Systems to rapidly and effectively detect and respond to disease outbreaks resulting from contamination and other causes are critical. The potential for contamination and interruption of food supplies as acts of terrorism should be considered in the assessment of food safety assurance systems. Planning must include consideration of communication with the press and the public in order to manage fear and unfounded rumours. Panic and hysteria may result in far more serious consequences to public health, as well as industry and commerce, than the threat itself. Existing systems for public health surveillance and food safety should be strengthened; separate systems for terrorism concerns should not be developed. Allocation of resources should be relative to the nature and likelihood of the threats, whether they are inadvertent or deliberate. FAO and WHO are strengthening their disease surveillance and response operations to include food sabotage and to provide guidance to Member States in the development of their programmes for prevention, detection and response to terrorist threats to food. Appropriate consideration must be given to the possibility that information on threat agents and system vulnerability could be used by terrorists.

#### ▪ **CÔTE D'IVOIRE-1**

This paper presents a historical summary of the regulatory framework implemented in Côte d'Ivoire from independence to date. The 1990s represent an important period during which there occurred an increased concern in food safety issues due to demographic and development factors and to a major international foodborne disease crises (BSE). Furthermore, the increased pressure put on national food producers from the exporting market authorities which request higher quality and safety standards in fish products and pesticide residues is stressed including difficulties faced by the government in complying with certain safety management options chosen by countries importing Ivorian food products and the impudent weight of certain sanitary measures on the national economy.

#### ▪ **NIGERIA-1**

In addition to the presentation of the national regulatory framework in Nigeria, the document recognises that amongst the major contributors to the success of any food safety programme are education and alleviation of poverty. The government has introduced the Universal Basic Education programme, which assures a free and compulsory education up to the secondary school level. The Government has also introduced various programmes for the training of school leavers, to prepare them for employment and to start small-scale industries. As the government continues to strive to improve the basic infrastructure in terms of electricity, potable water, telecommunication, adequate accommodation and environmental sanitation, it also recognises the need for improvement in the implementation of the national food hygiene and safety policy in the following areas: 1) Review, harmonization and effective enforcement of the existing laws relating to food safety; 2) Strengthening infrastructure and managerial capacity in risk analysis; 3) Forging closer inter-ministerial collaboration, cooperation and coordination; 4) Involvement of all stakeholders in policy formulation as a key to the success of the food safety programme; 5) Strengthening the capacity of states and local governments in promoting safe and hygienic practices by street food vendors and catering establishments.

#### ▪ **AUSTRALIA-1**

This document copies an advertising brochure which presents SAFEMEAT. This is a national system implemented in Australia involving a strong partnership between industry and the federal and regional governments. To date, SAFEMEAT has implemented a national livestock identification scheme to ensure domestic consumer information and international markets requirements on meat products. SAFEMEAT initiates research and development projects particularly in relation to microbiology and foodborne pathogens. It also develops communication linkages and monitors the status of meat products and their conformity to appropriate standards. Future action and development will be carried out in the

following areas: in establishing meat standards and regulation; in promoting research and development in the meat industry; in improving emergency management; in monitoring/reducing residues and pathogens; in implementing further management of national systems; and in planning communication and education programs in order to improve awareness in the general public and amongst operators on all aspects of food safety in meat and meat products.

#### ▪ CANADA-2

National and international awareness of the importance of food safety is increasing as a result of the identification of emerging foodborne pathogens and new hazards from imported and domestically produced foods. New approaches for regulatory inspection and enforcement activities and new technologies are being implemented as part of Canada's integrated approach to enhancing food safety. In Canada, change is being driven by industry-wide adoption of Hazard Analysis Critical Control Point (HACCP) based practices. From a regulatory perspective, HACCP based risk management approaches are providing a basis for the strategic investment of inspection resources to maximize the effectiveness of inspection activities based on a better understanding of food safety risks and the management of those risks by industry. Canada has made considerable progress and the implementation of HACCP programs such as the Quality Management Program, Food Safety Enhancement Program and Meat Inspection Reform have resulted in important lessons learned. Key lessons include: successful implementation of HACCP based inspection programs involves the commitment of regulatory resources from initial program design and consultation through to ongoing program maintenance; the recognition of stakeholder *ownership* essential to the success of HACCP programs; the introduction of HACCP programs through careful planning with implementation staged over a reasonable transition period; and the significant impacts attained through the implementation of the HACCP programs on regulatory strategies, inspection activities and staff, resulting from the substitution of *hands-on* inspection responsibilities to verification activities.

#### ▪ EUROPEAN COMMUNITY-2

This paper presents the roles and functions of the Food and Veterinary Office (FVO) of the European Commission. The main task of the FVO is to carry out on-the-spot inspections to evaluate the food safety control systems operated by national authorities in Member States and third countries, to report its findings **and** conclusions, **to** make recommendations and to follow up the actions taken by these authorities in response to its reports. It also has responsibility for monitoring control activities on animal health, animal welfare and plant health. In addition, the results of the FVO's inspections can contribute to the development of community legislation by identifying areas of existing legislation which may need to be amended or where new legislation is required. The FVO is required to verify that the competent authorities in food exporting countries are capable of ensuring that community requirements are met in respect of all products exported to the EU; in the case of certain products, to inspect individual production establishments, of which there are currently around 15,000 approved for export to the community; and to monitor on a regular basis the operation of around 290 inspection posts that carry out specified checks on all imports of animals, animal products and food of animal origin at the point of entry into the EU including the individual approval of new inspection posts. A new approach for Member States under which the three aspects of control – verifying transposition, receiving reports from Member States, and the carrying out of on-the-spot inspections – will be combined into one integrated control process, involving a food control cycle based on four main stages. The new framework will also apply to third countries.

#### ▪ INDONESIA-1

This document presents the national inspection system for traditional foods in Indonesia. It sets out the basic problems, constraints and difficulties in reducing foodborne illnesses throughout the country and the food chain. Most traditional foods are in general home-made or, if produced industrially,

involve small scale enterprises. It is reported that most traditional food entrepreneurs do not have sufficient skill or knowledge of food processing hygiene. Moreover, the capability of managers is still limited to registering their products. To strengthen their capacity they should be guided by education programmes which, to the benefit of the government, are easy to monitor and control. The quantity of contaminated foods is still described as high and is recognised as a heavy social and economic burden on the nation. In 2000, 30 cases of foodborne diseases were registered including 13 mortalities and 2,762 morbidities. The origins of these diseases were mainly due to chemical contaminants, microbial pathogens, and natural poisoning, but most cases could not be identified due to late information, unrepresentative samples, weak coordination among agencies, difficulties in getting supportive data. Most of the unsafe foods originated in street-vended foods, meals served in restaurants, home industries and household practices.

#### ▪ **MONGOLIA-1**

Food safety is an emerging issue in Mongolia as its international food trade expands and the numbers of food premises increase. This article aims to introduce the changes in food safety in Mongolia and makes comparisons before and after 1990, when the country made a dramatic socioeconomical change from a centralized economy to a free market economy. The food safety situation in Mongolia is presented from the end users health outcome, or from the end of the food chain till food supply, storage and point of purchase. Some facts are tabulated, having been collected by the local inspection agencies within their current capacity of analysis and monitoring. Positive changes include advances in the legislative environment and technological improvements in small food enterprises over recent years. Reference is made to the objectives of the National Plan of Action on Food Security, Safety and Nutrition (NPAN) for which there exists strong international support. Implementation of the NPAN is principally required for advocacy; the training of different stakeholders; the establishment of training programmes; and the strengthening of laboratory capacity. Changing economic circumstances contribute significantly to the food safety situation in Mongolia. Vulnerability of traders and poor people to the different kinds of inspection penalties is very high, with destroyed foods and the labour of traders contributing to national values. Therefore, inspection agencies must work towards prevention rather than control. Great endeavours must be made towards building national consensus and to consolidate different food safety agencies using more radical approaches by both government and international agencies.

#### ▪ **NEW ZEALAND-2**

Cattle can be a host to *Taenia saginata* infection which is presented as tapeworm in humans. It is not of large public health significance in New Zealand and is of equally small significance in the Nation's beef production. A range of treatments – including proper cooking – are effective for meat potentially carrying undetected cysts. Medical treatment is also readily available in New Zealand for any human infection. Studies have shown that a (theoretical) suspension of post-mortem inspection for the parasite would make little impact on public health outcomes. Many importing country requirements still require this check to be part of the processing procedures. There are grounds for reassessing the reasons for this inspection in New Zealand's case and for considering better use of scarce resources. Other countries may wish to consider the New Zealand model in ranking their public health priorities. As the Codex Alimentarius Commission considers its work on food safety objectives (and the Codex Committee on Meat and Poultry Hygiene recommences work), there may be lessons with wider relevance than just their application to the New Zealand situation.

#### ▪ **RUSSIA-1**

This paper describes the regulatory framework established in the Federation of Russia through federal laws and government decrees covering all aspects of food safety (i.e. the epidemiological population survey, food quality, health nutrition policy, food control, food registration, genetically

modified food, analysis and sampling methods). The creation of a computerized accounting system of results of food safety monitoring is also noted. The Russian Federation proposes the establishment of a Joint FAO/WHO Expert Committee at the international level to review and classify the different sources of production and application of genetically modified food and related standard acts. It is suggested that the scope of this Committee be broadened in the future to evaluate all new industrial technologies and biotechnologies applied to raw materials and food products. The Russian Federation has also proposed the creation of an International Center of Analysis of Food Products under the joint responsibility of FAO, WHO and other appropriate international organizations. This Center would also include a “fast-response group” to face food safety emergency situations and collect and publish in a worldwide database all data relating to contamination of food and food rejections in order to prevent trans-boundary food hazards.

#### ▪ **SENEGAL-1**

This document presents the food safety regulatory framework presently in force in Senegal, including the various national competent authorities responsible for the control and inspection of domestic and imported food. A list is presented of national laws and decrees which establish basic principles and structures such as the National Codex Committee. The paper recommends that more resources be allocated to food quality promotion and control; that food safety legislation be reviewed, harmonized and updated; and that food control authorities be evaluated and reinforced. It also raises the need for quality assurance manuals for the control of pesticide residues in food to be established and distributed to official laboratories. The paper calls for improved regional coordination among countries of West Africa in harmonizing their national food legislation in order to share resources and strengthen regional capacity building. The need for staff training in food control services and national laboratories is also stressed.

#### ▪ **TURKEY-1**

In Turkey, responsibility for food safety is shared between the Ministry of Health (MH) and the Ministry of Agriculture (MARA). The MH inspects food production establishments, issues working licenses and conducts inspections of food sold on the market as well as food catering establishments. The MARA inspects food products produced in these establishments and is responsible for food control of imports and exports. The responsibilities of the two ministries are given in the Main Food Law and they are supported by their own regulations. Within the harmonization process of the European Union, the national legislation on food is being revised for certain main topics such as official control of foodstuffs. The regulation of the MARA on Food Production, Consumption and Inspection of Foodstuffs, involved the introduction of HACCP principles and brought a new approach to the food inspection system. Codes of hygiene, in addition to HACCP systems are part of the new plans for the food control systems of the MH permitting greater efficiency and effectiveness in food control through cooperation with the MARA.

#### ▪ **USA-1**

The U.S. Department of Agriculture’s landmark rule, the “Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP)” (1996) forms the cornerstone for the U.S. food safety strategy for meat and poultry products. However, the PR/HACCP rule did not extend HACCP concepts to slaughter. A new approach to food safety, the HACCP-Based Inspection Models Project (HIMP), was initiated. The new system enables establishments to fully integrate their production processes. Establishment employees conduct sorting activities based on initial anatomical and pathological examination of carcasses, followed by government inspection of each carcass and verification of the establishment HACCP and slaughter process controls. The U.S. Department of Agriculture contracted with an independent private corporation to measure the organoleptic and microbiologic accomplishments of the traditional inspection system in young chickens, market hogs, and young

turkeys. The Department developed new science based organoleptic performance standards from this data collection. Establishments in the HIMP initiative were provided flexibility in how best to meet those performance standards. Data collected in the project to date, by both the independent contractor and in-plant inspectors, show important improvements in both food safety and non-food safety conditions. The Department intends to propose the appropriate regulatory changes that adopt the new inspection system.

- **USA-2**

Americans consume an average of 234 eggs per person per year. Some of these eggs will contain *Salmonella enteritis* (SE) bacteria, capable of causing illness if the eggs are eaten raw or are used in foods not thoroughly cooked. Because eggs can become contaminated internally from the hen, many common egg-handling practices, (e.g. holding eggs and egg-containing foods at room temperature instead of under refrigeration, inadequate cooking and the pooling of eggs to prepare a large volume of an egg-containing food that is then subject to temperature abuse or inadequately cooked) are now considered to be unsafe. As a result, in an effort to reduce eggs as a source of SE illnesses in the United States, the Egg Safety Task Force is developing a regulatory plan to eliminate egg-associated SE illnesses. The Task Force is composed of designees of the Federal food safety agencies responsible for egg safety, including the Food Safety and Inspection Service, United States Department of Agriculture, and the Food and Drug Administration, United States Department of Health and Human Services. The plan developed by the Task Force is the basis for the new eggs and egg products inspection approaches and techniques described in this conference room document. After a large outbreak of *Escherichia coli* O157:H7 linked to fresh apple juice products in the western United States, FDA held a public meeting on juice safety that was attended by the Fresh Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Following discussions on how best to ensure the safety of juices, the NACMCF recommended the use of HACCP principles in processing juice. On April 24, 1998, FDA issued proposed rules to require (1) the use of HACCP for all juice and juice products, and (2) warning label statements on untreated fresh juice. The warning label statement requirement is currently in effect and the HACCP rule (published in final form on January 18, 2001) will become effective over the next three years, based on the size of the firm.

**APPENDIX IX**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakech, Morocco, 28 – 30 January 2002*

**THEME AND TOPIC PAPERS**

**WITH SUMMARIES OF APPLICABLE CONFERENCE ROOM DOCUMENTS FOR**

***RISK MANAGEMENT***

GF 01/04

## SHARING INFORMATION ON NATIONAL EXPERIENCES IN THE GENERAL FIELD OF RISK MANAGEMENT

*Paper submitted by the Delegation of France*

It must now be acknowledged that food safety is a priority for consumers. They want safe, healthy food which will keep them healthy.

It is the responsibility of food safety authorities to meet consumers' expectations and to guarantee them a high level of health protection, by adopting the necessary measures.

Risk management is one of the essential tools for setting up food safety systems and it seems appropriate to share experiences in this field so that all the countries have access to information which will allow them to adopt the necessary measures to protect the health of consumers.

The subject of risk management is a broad one; the discussion group on "Sharing information on national experiences in the general field of risk management" is to discuss two specific topics in detail: "Reduction in foodborne hazards, including microbiological and others, with emphasis on emerging hazards" and "Integrated approaches to the management of food safety throughout the food chain". I would like to go beyond that in introducing the discussion group debates by touching on the various aspects of this subject and the ways in which risk managers and policy makers can approach it.

### **I. Firstly, what is risk management?**

It is primarily one of the three aspects of risk analysis, the others being risk evaluation and risk communication. The Codex Alimentarius has adopted the following definition: risk management is the process of weighing up the various possible policies, taking account of the evaluation of risks and other factors involved in the health protection of consumers and the promotion of fair trade practices, and taking decisions accordingly, i.e. choosing and implementing the appropriate prevention and monitoring measures.

The management of food-related risk is therefore a political prerogative which involves balancing the recommendations formulated by the experts commissioned to scientifically evaluate the risks, and the resources of all types that social and commercial groups and manufacturers can set aside for dealing with these risks.

### **II. How can food safety regulators manage a known or future risk to protect the health of consumers?**

#### **1. By basing policies and measures adopted on an evaluation of the risks**

This is not merely a recommendation but a duty for member countries of the World Trade Organization (WTO). The WTO Agreement on the Application of Sanitary and Phytosanitary measures (SPS Agreement) states, in fact, that WTO members should base their sanitary and phytosanitary measures on risk evaluation.

It should be noted, in this respect, that risk evaluation is a scientific process consisting of stages of identifying and characterizing the dangers, then evaluating exposure to these dangers in order to characterize the risk (probability that the danger will be expressed in real terms).

Risk evaluation is a particularly important process in the case of new or emerging risks.

**Example:** 2-3 years ago import controls in France frequently detected germs of the genus *Vibrio parahaemolyticus* on shrimps. Up to that time the discovery of those microbes led to the implementation of protective measures (destruction of batches) owing to the pathogenic nature of *V. parahaemolyticus* (one of the major causes of gastroenteritis from seafood). The discovery of an increase in the appearance of this germ led the risk manager to order a risk evaluation of this specific problem. This evaluation enabled the risk manager to define his position as follows:

only strains of *V. parahaemolyticus* producing a toxin, haemolysin, are pathogenic;

*V. parahaemolyticus* microbes producing haemolysins can be detected by molecular techniques.

In the light of these conclusions, the risk manager altered his approach to the risk represented by *V. parahaemolyticus* as follows:

destruction of any batch contaminated by a strain of *V. parahaemolyticus* with a gene for haemolysin;

market distribution of other batches (on which non-haemolysin-producing strains of *V. parahaemolyticus* have been detected).

Risk evaluation should also help to achieve a high level of consumer health protection. It is therefore important for risk evaluation which, it should be remembered, is used to draw up food safety regulations, to meet several criteria:

excellence, i.e. a very high level of scientific expertise;

independence, i.e. the greatest possible objectivity, and in particular no interaction with economic lobbies;

transparency;

useful, available scientific and technical information as a basis.

In order to guarantee the independence and transparency of this high-quality scientific and technical information, some countries or regional interest groups have decided to separate risk evaluation from risk management, while considering interaction to be essential only from a pragmatic point of view. This strategy has, moreover, been recognized internationally since according to the Codex Alimentarius, there should be a functional separation between risk evaluation and management.

**Example:** In France, a scientific body, the “Agence française de sécurité sanitaire des aliments”- the French agency for food safety - (Afssa) was set up by law in 1998, with responsibility for evaluating the health and nutritional risks which could affect food intended for humans and animals, including possible risks from water intended for human consumption. It had the further task of providing the scientific and technical support necessary for drafting regulations.

This body has broad scientific powers applied to food safety, ranging from the production of raw materials (animal and plant products) to distribution to the end consumer.

It is organized around committees of experts specializing in nutrition, microbiology, biotechnology, transmissible subacute spongiform encephalopathies, physical and chemical contaminants and residues, animal feed, contact materials, additives, technological auxiliary substances and flavours, animal health, and water supplies.

The Afssa comes under the supervision of three ministries (agriculture and fishery; economy, finances and industry; and solidarity and employment); it issues independent scientific opinions.

In order to guarantee its independence, the members of its specialized expert committees were appointed after a public call for candidates.

*Furthermore, along with 13 national specialized laboratories the Afssa constitutes a centre for research and technical support for French risk managers working in the field of food safety.*

*Risk managers work closely with the agency. It is compulsory to consult the Afssa on any change in regulations related to food safety, and the Afssa can propose any measure it considers appropriate to protect public health.*

*The Afssa is also a watchdog body which must be informative and transparent. Its opinions and recommendations are published. It has no powers of inspection.*

## **2. The principle of precautionary measures, in the absence of sufficient scientific proof**

There is, however, an exception to the obligation to base sanitary and phytosanitary measures on a risk evaluation. This allows governments to adopt sanitary and phytosanitary measures even when the risk evaluation is incomplete and to use precautionary measures to protect their citizens. The SPS agreement (article 5.7) states that in cases where relevant scientific proof is insufficient, a WTO member country may provisionally adopt sanitary and phytosanitary measures based on the relevant information available. Under such circumstances, the countries should then strive to obtain the additional information necessary for a more objective evaluation of the risk and should re-examine the sanitary and phytosanitary measure accordingly, within a reasonable time-frame.

Scientific uncertainty cannot, therefore, serve as an excuse for a decision-maker to fail to act in response to a food-related risk. Thus when a potentially dangerous and irreversible situation begins to emerge, but the scientific evidence is lacking for a full scientific evaluation, risk managers are legally and politically justified in adopting precautionary measures without waiting for scientific confirmation. It is, in fact, the responsibility of decision-makers to adopt the necessary measures to protect consumers. It should be noted once again in this respect that citizens are more demanding today than formerly as regards food safety. They give priority to health safety over other criteria which might have prevailed in the past, in a context in which the food supply is large enough to offer replacements.

In order to explain the concept of the precautionary approach, I am going to give an example of its use in the risk management of the dioxin crisis in Europe in 1999.

**Example:** *This crisis began in late May 1999, when the Belgian authorities alerted the European Commission and other Member States to serious dioxin contamination of certain products of animal origin.*

*The affair had begun in Belgium a few months earlier, in February, with the appearance of unusual clinical signs in poultry stock. The investigations conducted by the Belgian services found that these symptoms were related to poisoning of the stock by dioxin probably present in feed, and identified the animal feed manufacturer concerned as well as the company which prepared the fat used in the feed, which was the cause of the problem.*

*The Belgian authorities then carried out traceability tests to determine the extent of the damage, informed the European Commission and other Member States, and decided to destroy all contaminated eggs and poultry.*

*Bearing in mind the recognized carcinogenic effect of dioxin and the absence of specific information on the extent of the contamination (dioxin concentrations 700 times the limits set by the World Health Organization had been detected by the Belgian authorities in some foods), it was necessary to adopt emergency measures even though the risk evaluation was incomplete in various aspects. Although the danger, namely dioxin contamination, was known,*

- *the risk had not been identified precisely since few data were available concerning acceptable levels of dioxin in foodstuffs in cases of acute contamination by this type of contaminant. There was more documentation on chronic contamination, which is more familiar;*
- *the evaluation of exposure to the risk was incomplete. The exact extent of the contamination, based on information received from the Belgian authorities and supplemented by field studies and samples of products of animal origin gathered to determine the dioxin content, was not known. It should be noted in this respect that the analytical method for detecting dioxin residues is one of the most difficult to perform. 5 to 6 weeks are thus required for the analysis of a sample;*

*The following precautionary measures were consequently adopted:*

- *a ban decided by the European Commission on distribution within the community of products containing milk, eggs, meat and fat originating in Belgium;*
- *withdrawal and destruction of products of Belgian origin on French soil which could be contaminated;*
- *bearing in mind the introduction in France of two batches of fat suspected of originating from the Belgian company which prepared the fat used in the feed which caused the problem, a traceability study was conducted on French soil to detect stock which may have consumed feed likely to have been contaminated. The suspect flocks were subject to restrictive measures;*
- *withdrawal and destruction of products originating from suspect French stock.*

*In accordance with the SPS agreement, the community decision to ban the distribution within the community of products containing milk, eggs, meat and fat from Belgium and the protective measures adopted with regard to French production were amended, then progressively lifted as more precise information became available on the identification of the risk and exposure to the risk (analytical results, scientific opinions).*

*To conclude, although the cost of this crisis was economically very great (384 flocks subject to restrictive measures, more than 9 million tonnes of animals and products of animal origin destroyed), it should be noted that the objective of the measures adopted, namely consumer protection, was understood and accepted by all parties involved. Consumers themselves were constantly kept up to date by decision-makers and did not lose confidence in the policy followed: they did not turn away permanently from the products affected by the crisis. Finally, no harmful effects of this contamination on human health have been identified to date, which tends to prove the effectiveness of the measures implemented.*

The example described shows that the principle of precautionary measures is used in very specific cases in the field of food safety. The risk manager, i.e. the decision-maker, applies this principle when there is a major risk to human health and if all the data necessary to evaluate the risk are not available.

This approach, which is part of risk management, is not static, but evolves as additional scientific data become available within the framework of risk evaluation, in accordance with the provisions of the WTO SPS agreement. Although the application of a precautionary measure can temporarily cause commercial restrictions or hindrances, it cannot be described as protectionism since it is a tool which allows risk managers to implement temporary measures which can evolve as the availability of scientific data evolves, and which have as their sole aim the protection of the health of consumers, animals, or plants, a right recognized by the same agreement.

This is indeed the intention of the resolution adopted by the European Council at Nice. Member States of the European Union focused on setting out in this resolution the guidelines for the use of precautionary measures and management of their application by the relevant State authorities. They recognized that when a multi-disciplinary, adversarial, independent, transparent evaluation, based on the available data, has failed to yield a definite conclusion regarding the risk level, risk management measures must be taken based on a political assessment of the level of protection sought. They also stated that these measures must, where a choice is possible, represent the solutions that are least restrictive for trade, respect the principle of proportionality while taking into account the long- and short-term risks, and be re-examined in the light of evolving scientific knowledge. The Council then emphasized the importance of consultation and adequately informing the general public. It should also be noted that when dealing with a public generally reacting emotionally given the lack of scientific data concerning a risk or the uncertainty of the extent of the risk, the precautionary principle also aims to manage expectations as regards additional scientific information.

It should moreover be emphasized that health risks exist all over the world, they are amplified by the globalization of trade and can pose a serious threat to developed as well as developing countries which may be particularly vulnerable in this respect. The implementation of the precautionary principle should not therefore be confined to the most highly developed countries, but should also be perceived as a factor of development allowing the destructive consequences of potential major health incidents to be avoided.

### 3. The “farm to table” approach

To be sure of the safety of foodstuffs, all aspects of the food production chain in continuity must henceforth be considered, from primary production (including animal protection and health aspects) and the production of animal feed, to the distribution of foodstuffs to the end consumer. Each component may have an impact on food safety.

*Examples: In the 1999 dioxin crisis in Belgium, the high levels of dioxin contamination in some products of animal origin were shown to be due to animals ingesting dioxin in their feed.*

*Elsewhere, the detection of salmonella in food can be caused not only by poor hygiene in agri-food companies, but also by salmonella contamination of the animals from which the foodstuffs are made.*

Socio-economic changes over the last 30 years make for an integrated approach to food safety. The following are of particular relevance:

- the modification of production methods, transformation of sales and consumption of agricultural products;
- the increase in intensive methods and industrialization of stockbreeding, crops and the manufacture of animal feed;
- the appearance of new diseases, such as BSE, and the emergence of foodborne diseases (salmonellosis, diseases due to verotoxic *E. coli* strains for example);
- better consumer information and increased consumer demands, as well as the change in lifestyle (in particular the increased consumption of prepared meals);
- the increase in trade in foodstuffs, which has resulted not only in cheaper and more varied foods, but also in complicating the path taken by products from their place of production to the end consumer.

This integrated approach to risk management has a number of advantages.

The following lessons can be learned from the French experience of the subject. This approach facilitates the circulation of information, the implementation of decisions and the application of checks. It allows better coherence and greater effectiveness not only of epidemiosurveillance networks, i.e. the

gathering of information on human and animal diseases, but also of measures to control zoonotic diseases (salmonellosis for example) and food contaminant surveillance plans. This process monitoring approach has proved to be essential in the management of risks related to bovine spongiform encephalopathy: coherent monitoring from the farm (epidemiological surveillance) to distribution (traceability of meat), via the abattoir (withdrawal of specified hazardous material, for example).

Finally, this approach is one way of guaranteeing the traceability of foodstuffs and also of reassuring the consumer, at a time when consumer demands as regards food safety are increasing and confidence is falling (emerging diseases, extensive industrialization of the process, innovations and new technologies).

I will not dwell on this subject; it will be covered in the discussion group.

#### **4. Traceability**

Traceability is an essential requirement in guaranteeing food safety. When a danger threatens (for example food poisoning), the risk manager should be able to determine the food responsible, rapidly carry out a precise, targeted withdrawal of dangerous products, inform consumers or agents in charge of monitoring foodstuffs, go back along the whole length of the food chain if necessary to identify the source of the problem, and put it right. Traceability studies thus allow risk managers to limit exposure of consumers to the risk and thus the economic impact of the measures by targeting products at risk.

For it to be effective, the traceability system must involve all stages in the pathway, from the live animal or raw material to the product undergoing final processing, from stock-rearing to food sector companies via companies in the animal feed sector.

*Example: All cattle in the European Union are identified. Animal movements within the EU can be followed on a computerized system called the ANIMO network. When the animals are slaughtered, the abattoir keeps a record of the animal's details and has a traceability system which allows it to trace the resulting carcasses to an animal. The carcasses are stamped to identify the abattoir from which they come. Furthermore, when meat is put on the market, it is accompanied by a document stating in particular the source establishment and the destination establishment. This type of system is present at each subsequent level of product processing.*

#### **5. Management of health risks in an emergency and in emerging risks**

Despite the checks carried out by risk managers, incidents are always possible. To ensure consumer safety, it is important that risk managers are informed as soon as possible of an incident and have access to the most precise possible evaluation of the risk in order to be able to implement the necessary measures and avert the danger.

Health surveillance is thus vital, and within this framework the circulation of information is essential. Sources of alarms can be varied. I could mention monitoring services at departmental\* or central level, production or distribution companies, the embassy of another country, or an international organization, or in the particular case of the European Union, the rapid warning network. A Member State which learns of a serious anomaly in the field of food safety can use the rapid warning network to warn all the other Member States and the European Commission so that they can rapidly assess any danger to which they may be exposed.

Scientists, the media, and consumer associations are also sources of warnings.

Furthermore, managing health risks in an emergency or emerging risks requires good cooperation between the monitoring services in charge of food safety and effective procedures for withdrawing suspect products from the market.

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\* Relating to an administrative region or “département” – Translator’s note

**Example:** In France, a health surveillance provision was set up by law in 1998. It involved creating the Institute of Health Surveillance (IVS) which relies on interregional epidemiology cells and departmental\* directorates of health and social affairs. The IVS has 3 tasks:

- health surveillance and observing the health of the general population;
- issuing warnings and recommending all appropriate measures to risk managers;
- identifying the cause of a change in the health of the general population, in particular in an emergency.

*This is the provision whereby, for example, groups of cases of human listeriosis can be identified and action coordinated as rapidly as possible between all the authorities responsible for risk management (the Ministry of social affairs and employment, the Ministry of agriculture and fishery, the Ministry of the economy, finances and industry) to identify the food responsible for the infection.*

## **6. Taking account of socio-economic concerns**

The implementation of regulations aimed at protecting consumer health can be effective only if the risk manager is aware of the resources that companies and manufacturers can set aside for managing risks. One recommendation is thus to bring together professionals involved in drafting regulatory texts to hear their opinions. This is what happens in France. Various bodies are involved, from the purely professional (national association for agri-food industries, trade unions, health defence groups) to the multi-disciplinary (National Food Council and National Consumer Council, for example).

It is recognized, in this respect, that in some cases risk evaluation cannot on its own provide all the information on which to base a risk management decision. In response to the expectations of the general public and consumers, other relevant factors should legitimately also be taken into consideration, notably social and economic factors (technical feasibility, economic impact), traditional and ethical factors (animal well-being) and environmental factors, as well as the feasibility of inspections.

## **III. What is the role of food chain professionals in risk management?**

The first responsibility of professionals is the marketing of their products. They can participate in the policy to improve food safety in various ways.

### **1. Self-monitoring and company laboratory accreditation**

Agri-food companies can monitor the health quality of the foodstuffs they produce by carrying out, on their own initiative, laboratory analyses of their products and by appropriate monitoring of the production processes: this is called self-monitoring. They can thus act immediately, where necessary, in advance of official checks, to remedy a health problem (for example, when a hygiene problem is identified).

These companies can use an external laboratory, or have their own analytical laboratory.

To give their analyses the necessary credibility, companies can seek accreditation of their own analytical laboratory. They can thus give guarantees of reliability and transparency recognized by the regulatory authority and by their clients.

### **2. Guides to good hygiene practice**

In France, several production processes have guides to good hygiene practice recommended by the risk manager (French and Community regulations). These guides, produced by professional organizations and validated by the relevant authority on the scientific advice of the Higher Council of public hygiene of France, are based on the implementation of the HACCP system which defines methods for the monitoring and surveillance of specific identified risks.

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\* Relating to an administrative region or “département” – Translator’s note

### **3. The development of company certification**

This is a voluntary system which involves having the quality management strategy of a company certified. Certification is carried out in France by an independent and accredited organization, such as the French Association for Quality Assurance (AFAQ). More than 1000 French industrial agri-food sites already have a quality assurance certificate resulting from the implementation of ISO 9000 standards. The association suggested by consumers between protecting the environment and the health of the general public has recently led companies to move towards environmental management systems (the ISOI 14000 procedure).

### **4. Product standardization**

Standards signal the will to accept a number of commitments. Many companies are thus setting up technical reference systems which describe the characteristics of products, the manufacturing process or analytical and control methods, as a result of a voluntary strategy. This practice is well established in France; the French Standardization Agency (AFNOR) is coordinating the drafting of these standards.

### **5. Contribution to product traceability**

This involves setting up and keeping up-to-date written procedures concerning information recorded and product or product batch identification, using appropriate methods, in order to trace the origin and determine the production and distribution conditions of these products or product batches.

Traceability is an essential component of product certification or quality assurance certification systems, and increasing numbers of French agri-food sector companies are putting it into practice.

### **6. Distribution**

Self-monitoring and quality management systems can be set up at the distribution stage.

This is not an exhaustive presentation of the subject of risk management. It provides a number of pointers as regards the risk management tools available to food safety regulatory heads and professionals, with a view to meeting consumer concerns and expectations.

GF 01/9

## **REDUCTION OF FOOD-BORNE HAZARDS, INCLUDING MICROBIOLOGICAL AND OTHERS, WITH EMPHASIS ON EMERGING HAZARDS**

*Submitted by the United States delegation: Thomas J. Billy, Administrator, Food Safety and Inspection Service, U. S Department of Agriculture; and Dr. Bernard Schwetz, Acting Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services.*

### **1. INTRODUCTION**

The ultimate risk management goal of food safety regulators is the control or reduction of food-borne hazards and in turn, reduction in the incidence of food-borne illness. Risk management involves weighing policy alternatives in light of available data and selecting and implementing appropriate control options for protecting the public health. To be effective, risk management strategies must be developed with a continual exchange of information by all interested parties, thus ensuring that the process and the strategies are considered transparent and are trusted. In addition, risk management strategies must continually change as new hazards emerge and as scientific and technological advances occur.

The kinds of measures taken to reduce food-borne hazards may vary from country to country and depend on factors such as the hazards of concern, the country's regulatory system, and food storage, preparation, and consumption practices. However, countries will most likely follow a similar set of basic steps to develop their risk management strategies, including identifying the problem, determining contributing factors, evaluating the risks, and selecting risk management measures that are feasible and should yield the best results. These similarities make it worthwhile for regulators to share experiences in developing risk management strategies and discuss ways in which this process may be improved.

### **2. RISK MANAGEMENT STRATEGIES**

In the United States, a variety of risk management strategies are used by the Food Safety and Inspection Service (FSIS), which has jurisdiction over meat, poultry, and processed eggs, and the Food and Drug Administration (FDA), which has jurisdiction over all other foods at the federal level. Among these are regulatory measures, industry guidance, surveillance systems, and outreach activities such as industry training and consumer education.

Both FSIS and FDA have mandated Hazard Analysis and Critical Control Point Systems—FSIS for meat and poultry products, and FDA for seafood and fruit and vegetable juices. HACCP systems are mandated under regulations that are drafted, published for public review and comment, then finalized, taking into account the comments that have been received. Under HACCP, plants identify critical control points at which hazards can occur during their processes, establish controls to prevent or reduce those hazards, and maintain records documenting that the controls are working as intended. HACCP serves to clarify the respective roles of industry and government. Companies are responsible for implementing an effective HACCP program that ensures their products are safe. Government is responsible for verifying that the regulatory requirements have been met, that the HACCP program is working as intended, and that appropriate actions are taken when the HACCP critical controls have not been met.

The United States also has established performance standards for various food safety hazards and tests products to ensure these standards are met. For example, along with mandatory HACCP in

meat and poultry plants, FSIS has in place pathogen reduction performance standards for *Salmonella* that slaughter plants must meet. Such standards provide a basis for plants to calibrate their process control measures. FSIS also has established a 6.5-log pathogen reduction performance standard for *Salmonella* in cooked roast beef and cooked poultry. As another example, FDA has established a 5-log pathogen reduction performance standard in its juice HACCP regulation. Various pathogens have been involved in foodborne illness outbreaks associated with juices, and the processor determines which pathogen is the target of HACCP critical controls. Among the pathogens involved in foodborne illness outbreaks associated with juices are *E. coli* O157:H7, *Salmonella*, and *Cryptosporidium parvum*.

Regulatory requirements are an important, but not the only, risk management strategy available to food safety officials. Less formal than regulations, guidance to the industry can be effective in reducing foodborne illness risks. An example is the FDA's *Guidance for the Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds and Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production*. This type of guidance, although not regulatory, is published for public review and comment. As another example, FSIS published guidance to industry on appropriate intervention measures to use to reduce the risk of *Listeria monocytogenes* (LM) from hot dogs and sliced luncheon meats.

Research is another risk management strategy. Research conducted by government, industry and academia on food safety hazards; data gathering; and technology development also are important in filling existing data gaps and in providing practical tools for detecting, controlling, and reducing foodborne hazards. Risk managers benefit from knowing how human pathogens grow, develop, and colonize in animals and how management practices on the farm may reduce the opportunity for these pathogens to contaminate fresh produce, meat, and other foods. They benefit from comprehensive data on the incidence of foodborne illness and what foods are responsible for these illnesses. And they benefit from having available new technologies such as improved diagnostic tests and vaccines that can be used as potential risk management strategies.

Education is another non-regulatory risk management strategy, and the United States has taken a farm-to-table approach to food safety education. Everyone has a responsibility for food safety, so education is aimed at those involved in producing, transporting, preparing, and consuming foods. For example, at the production level, food safety agencies are working with producers to develop and encourage measures to reduce hazards associated with animals presented for slaughter and fresh produce. The FDA has developed a *Guide to Minimize Microbial Risk in Fresh Fruits and Vegetables* that highlights production practices that will enhance the safety of fresh produce. An extensive outreach and education program for both domestic and international producers in these good agricultural practices is underway. Consumer education is an integral component of this risk management strategy and is provided through a variety of techniques. Methods include school-based educational campaigns, web sites, telephone hotlines, and safe handling labels. A consumer campaign, "Fight BAC!™," has emphasized four simple factors to keep food safe from bacteria: Clean, Separate, Cook and Chill, and has promoted these messages through the media and community-based education activities. Physician awareness programs have highlighted the importance of advising patients, particularly vulnerable patients such as pregnant women, the elderly, and individuals with compromised immune systems, about the impact of microbial hazards on their health.

Risk management strategies must continually change as new hazards emerge and new information becomes available. Regulators must be vigilant to trends in their own countries and abroad and must be open to new paradigms regarding pathogens. New pathogens such as *Salmonella typhimurium* DT104 have emerged in the United States. As another example, scientists learned relatively recently—that is, within the past several years—that *E. coli* O157:H7 is acid-tolerant, and the United States has had to adapt its risk management approach to these new findings.

Fortunately, new, effective tools are available to help keep pace with emerging hazards. For example, in the area of foodborne disease surveillance, the Foodborne Diseases Active Surveillance Network (FoodNet), a collaborative project among Federal, state and local governments, has been in existence since 1995. It currently involves 9 sentinel sites around the U.S., representing more than 25.4 million people. FoodNet provides national estimates of the burden and sources of specific foodborne diseases and includes studies designed to help public health officials better understand the epidemiology of foodborne diseases in the United States. In addition, public health officials are now better able to detect and rapidly respond to foodborne outbreaks through PulseNet—a national computer database that analyzes molecular fingerprints of foodborne pathogens. It has been used many times to link specific food products to specific human illnesses and to link what appear to be sporadic, unassociated cases of foodborne illness to a specific, single source. This enables public health officials at the Federal, State, and local levels to minimize the spread of outbreaks.

We are also seeing improved practices in areas such as steam pasteurization and carcass rinses used to remove pathogens from slaughtered carcasses and technologies to improve the safety of plant, seafood, egg, and dairy products. Irradiation has been approved by the FDA for a variety of food products. Government food safety policies encourage innovation by setting new food safety requirements, by guiding and conducting research that addresses the most critical data and technology gaps, and by implementing expedited reviews of new technologies and food-safety related food additives.

Two examples will be used to illustrate how the United States has used risk management strategies to successfully address food-borne hazards on fresh and processed products. The first example is *Listeria monocytogenes* (LM) in ready-to-eat products. The second example is *Salmonella* in raw meat and poultry products.

## **2.1 LISTERIA MONOCYTOGENES IN READY-TO-EAT PRODUCTS**

The U.S. experience with LM is a very dramatic indication of how risk management strategies can have a significant impact on rates of human disease. It has been only in the past two decades that researchers have recognized the association of LM with foodborne illness, and the impact of the pathogen in terms of human health became clear during the 1980's following a series of outbreaks. Of particular concern is that certain subsets of the population—newborns, the elderly, patients with compromised immune systems—are particularly susceptible to *Listeria* infections. Infections also are a major concern in pregnant women. Even though symptoms may be relatively mild in the mother, the illness can be transmitted to the fetus, causing serious illness or fetal death. One outbreak in 1985 in the State of California resulted in 142 cases of listeriosis, including 46 deaths; 85 percent of the cases involved pregnant women. This particular outbreak was traced to LM in soft, fresh Mexican-style cheese, manufactured with contaminated milk. Data collected by the U.S. Centers for Disease Control and Prevention (CDC) in the late 1980's determined that cases of listeriosis were most often associated with soft, fresh cheese; undercooked poultry; hot dogs not thoroughly reheated; and food purchased from delicatessen counters.

### **2.1.1 How the issue was addressed**

Increasing concerns about LM led U.S. food safety regulatory agencies to take several steps. FSIS and FDA stepped up monitoring and surveillance programs for LM. The agencies worked with processing plants to improve their sanitation procedures, and many companies implemented hazard analysis and critical control point (HACCP) systems to minimize contamination. Government agencies also developed and distributed educational materials on food safety for consumers and special populations at increased risk for listeriosis. As a result of these efforts, between 1989 and 1993, the rate of illness from LM declined 44 percent.

LM is a good example of how risk management strategies must be continually reevaluated as scientific and technological developments occur. In the fall of 1998, CDC reported an increased number of cases of illness due to a specific subtype of LM. The illnesses were associated with ready-to-eat meat products, and FSIS announced a number of initiatives to address the immediate problem. For example, FSIS advised meat and poultry establishments to reassess their HACCP plans to ensure they were adequately addressing LM. The agency provided guidance to industry on practices that have been used successfully by other meat and poultry establishments to prevent LM in ready-to-eat products. FSIS also developed an in-depth verification protocol that is carried out by an interdisciplinary team of experts to evaluate whether plants producing ready-to-eat products have reassessed their HACCP plans to adequately address LM.

In addition, FDA, in cooperation with FSIS, conducted a risk assessment of the potential relative risk of listeriosis from eating certain ready-to-eat foods. The risk assessment supported the findings of epidemiological investigations of both sporadic illness and outbreaks of listeriosis in that it identified pâtés, fresh soft cheeses, smoked seafood, frankfurters, and some foods from deli counters, as potential vehicles of listeriosis for susceptible populations.

In response to findings of the risk assessment, HHS and USDA published a joint action plan, which focused on those ready-to-eat foods identified in the risk assessment as warranting additional control measures. Eight action areas were identified: 1) enhance health care provider and consumer information and education efforts; 2) develop guidance for processors identifying post-process contamination controls; 3) conduct regulator and industry training; 4) redirect inspections and surveillance sampling to firms producing at risk products; 5) propose new regulations and revisions to existing regulations concerning LM controls; 6) enhance disease surveillance and outbreak response to detect illness outbreaks more quickly and accurately; 7) initiate projects with retail operations such as delicatessens and salad bars to study behaviors and practices that control the spread and growth of LM; and 8) coordinate research activities to refine the risk assessment, enhance preventive controls, and support regulatory, enforcement and educational activities.

### **2.1.2 Summary of Findings**

Risk management strategies must be evaluated to determine if they are effective. In the case of LM, as mentioned earlier, actions taken in the 1980's did indeed have a positive effect—a 44 percent decline in illnesses between 1989 and 1993. The success of these efforts can also be evaluated in terms of meeting the food safety objectives stated in *Healthy People 2000*. *Healthy People* is an initiative coordinated by the U.S. Department of Health and Human Services that sets goals every 10 years for a variety of health concerns, including targets for the reduction of foodborne illness. The United States met the food safety objectives for infections caused by key food-borne pathogens stated in *Healthy People 2000*. The incidence of LM decreased from 0.7 cases of infection per 100,000 in 1987 to 0.5 cases in 1996. The target for 2010 is 0.25 cases per 100,000—a 50 percent improvement. However, this target date was changed to 2005 by a presidential directive issued in May 2000.

In addition to illness data, prevalence data collected between 1990 and 1999 indicate a downward trend in LM in ready-to-eat meat products, suggesting that industry has made significant improvements in plant sanitation and control of post-process contamination.

## **2.2 SALMONELLA IN RAW MEAT AND POULTRY PRODUCTS**

Controlling pathogens in raw products required a change in the Nation's mindset about food-borne pathogens. The example provided for raw products focuses on meat and poultry products. Before the early 1990's, the pervasive attitude among industry, and even regulators, was that pathogens are a

natural part of the environment and should be reduced primarily by food preparers through cooking. As scientific support emerged for changes that would better address pathogenic microorganisms in both raw and processed products, there was a growing realization that traditional attitudes towards pathogens in raw meat and poultry products had to change. An outbreak of *E. coli* O157:H7 in late 1993, attributed to undercooked hamburgers, provided the impetus for that change.

### 2.2.1 *How the issue was addressed*

In 1996, FSIS published its rule on Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) systems, which required all plants that slaughter and process meat and poultry to implement HACCP systems as a means of preventing contamination from pathogens and other hazards. The rule, like other HACCP regulations, was based on the principle that prevention must be the first line of defense. HACCP did not address any one particular hazard but provided a flexible framework that could be used to address various hazards.

To make sure HACCP systems are working as intended, the rule also set in-plant, pathogen reduction performance standards for *Salmonella*. This was unique because pathogen reduction performance standards had not in the past been applied to raw products. *Salmonella* was selected as the target organism because it was the most common cause of food-borne illness associated with meat and poultry products, it is present to varying degrees in all major species, and interventions targeted at reducing *Salmonella* are expected to be beneficial in reducing contamination by other enteric pathogens.

FSIS based the current performance standards on what it believed was achievable at that time with current science and technology. Specifically, FSIS proposed that the prevalence of *Salmonella* contamination in carcasses of each of the major species and in raw ground products be reduced by each establishment to a level below the current national baseline prevalence. FSIS collects such data for various pathogens through its Nationwide Microbiological Baseline Data Collection Programs. This was done with the expectation that the performance standards would be revised periodically as new baseline prevalence data became available that reflected progress in pathogen reduction. Ideally, FSIS would have preferred to set such performance standards based on quantifiable risk related to human illness. Unfortunately, because such data are limited, The agency decided to rely on prevalence data and industry averages as its starting point. As more microbial and epidemiological data are collected, more precise, risk-based standards can be established.

### 2.2.2 *Summary of Findings*

Progress in addressing *Salmonella* can be evaluated by looking at both product data and epidemiological data.

In terms of product data, the results of three years of testing—representing aggregate data from all sizes of plants—show that all categories of products showed improvement over baseline studies conducted prior to HACCP implementation. For example, 10.2 percent of young chickens tested were positive for *Salmonella* under HACCP compared to a 20 percent baseline prevalence. Ground chicken averaged 14.4 percent under HACCP, compared to 44.6 percent before HACCP. These were the most dramatic reductions.

In addition, since the implementation of HACCP, the CDC has reported a reduction in the number of food-borne illnesses associated with meat and poultry products, including *Salmonella*. Thus, experience shows that performance standards for *Salmonella*—in concert with other regulatory requirements—have worked extremely well.

As with LM, a variety of risk management approaches have been used to reduce levels of pathogens, such as *Salmonella*, in raw products. The Pathogen Reduction and HACCP rule also mandated standard operating procedures for sanitation and performance criteria for generic *E. coli*—an indicator of fecal contamination. Consumer education programs emphasize the importance of proper food handling in the home, including how to avoid cross contamination between raw and cooked products. And research is ongoing to determine ways to prevent the colonization of pathogens such as *Salmonella* in food animals.

### 3. CONCLUSION

These examples illustrate the challenges and opportunities presented by risk management. To conclude, some lessons learned over the last decade are provided here.

First, no single technological or procedural solution exists that can solve the problem of food-borne illness. Rather, food safety goals are achieved through continuous efforts to improve hazard identification and prevention throughout the farm-to-table chain. Risk management strategies must be continually re-evaluated to keep pace with technological and scientific advances. We must be flexible enough to accept new paradigms when it comes to reducing hazards.

Second, risk management steps can be taken in the absence of formal, quantitative risk assessments. In the real world, risk management steps must be taken on the basis of incomplete information and qualitative data and adjusted as new and more precise information become available.

Third, risk managers need to evaluate the effectiveness of their risk management strategies. This can range from data on pathogens in foods, such as the data on *Salmonella* in raw meat and poultry products collected over the past several years, to consumer surveys of the adoption of safe food handling practices, to public health outcomes such as reductions in food-borne illnesses. The value of such data is that they represent a baseline against which future efforts to improve food safety can be measured.

Fourth, risk management activities should be carried out through a transparent public process. The public consultation process used in the United States for the development of regulations, and the various educational campaigns for producers, processors and consumers, have been described. Public policy that is made without the input of all interested parties is doomed to fail. This does not mean that everyone gets what he or she wants, but the public process, which includes consideration of a sound scientific basis, ensures that all parties are heard. Making risk management decisions through a transparent process also ensures that public trust in the food safety system continues.

Fifth, and finally, government alone cannot solve food safety problems. Government agencies at the Federal, State and local level must work with each other and through partnerships with industry, academic institutions, and the public to implement strategies to meet intended food safety goals.

GF 01/10

## INTEGRATED APPROACHES TO THE MANAGEMENT OF FOOD SAFETY THROUGHOUT THE FOOD CHAIN

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### **Introduction**

Most countries with systems for recording foodborne disease have reported significant increases in the incidence of diseases caused by pathogenic micro-organisms in food over the past few decades. As many as one person in three in industrialized countries may be affected by foodborne illness each year and the situation in most other countries is probably even worse. Apart from the deaths and human suffering caused by foodborne disease, the economic consequences are enormous, running into billions of dollars in some countries. In Europe bovine spongiform encephalopathy (BSE, “Mad cow disease”) and contamination of food with dioxins led consumers to lose confidence in the safety of foods on the market, with severe economic consequences. In many cases, the origins of food safety problems can be traced back to contamination of animal feed or other factors in the early parts of the food chain, an area which until fairly recently had received scant attention from those responsible for food safety.

### **Confident customers**

It is vital that consumer confidence in the food supply be restored and maintained, not by public relations exercises but by actually increasing food safety. Consumers should be able to assume that all food offered for sale is safe for its intended use. It shouldn't be necessary to ask the butcher if the beef is safe this week or the fishmonger if the oysters are safe today! Furthermore, food should be labelled in such a way that consumers can make an informed choice among the variety of products on the market. At the *Food Chain* conference, organized in Uppsala earlier this year during the Swedish presidency of the European Union, the vision for future food production was summarized as *Safe, sustainable and ethical*. Although much progress has been made in recent decades, all who are involved in trying to ensure the safety of the food supply should recognize that we have a long way to go before we can say we have reached this goal.

### **Risk analysis**

The primary goal of food safety risk management is to protect public health from risks associated with food as effectively as possible through the selection and implementation of appropriate measures. Towards the end of the last century, there was a paradigm shift in the food safety area, with the introduction of a risk-based approach to food safety. In order to stimulate the application of risk analysis principles in food safety work, FAO and WHO jointly organized a series of expert consultations on the different components of risk analysis – risk assessment, risk management and risk communication. The second consultation, held in Rome in 1997, dealt with risk management and the report of that consultation contains recommendations on the elements and principles of food safety risk management (1). These recommendations have been used as the starting point for the introduction of risk analysis principles into the Codex system and they have also been used by many government agencies in developing food safety risk management at the national level.

### **General principles of food safety risk management**

The FAO/WHO Expert Consultation recommended the following eight general principles for food safety risk management.

- Risk management should follow a structured approach.
- Protection of human health should be the primary consideration in risk management decisions.
- Risk management decisions and practices should be transparent.
- Determination of risk assessment policy should be included as a specific component of risk management.
- Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment. However, it was recognized that risk analysis is an iterative process, and that interactions between risk assessors and risk managers are essential for practical application.
- Risk management should take into account the uncertainty in the output of risk assessment.
- Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
- Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.

### **Responsibility for food safety**

Primary responsibility for food safety lies with *those who produce, process and trade in food* – farmers, fishermen, slaughterhouse operators, food processors, wholesale and retail traders, caterers, etc. It is their duty to ensure that the food they produce and handle is safe and satisfies the relevant requirements of food law and they should verify that such requirements are met.

The main task of the *supervisory authorities* is to lay down food safety standards and to ensure that the internal control systems operated by food producers, processors and traders are appropriate and operated in such a way that these standards are met. In addition, the authorities should carry out certain direct control activities, for example import control, to ensure compliance with legislation and they should also provide information and advice on a wide range of food-related matters which can affect human health. In recent years, the organization of food control at the national level in many countries has been changed and a single agency has been given responsibility for the whole of the food chain from “farm to fork”. Such a system has many advantages and if responsibility is nevertheless divided among two or more agencies at the national level it is vital that there is close co-ordination between them. Similarly, if responsibility for food control is divided between central and local authorities, then it is important that the central authorities have the power to co-ordinate and audit the work of the local authorities.

*Consumers* are responsible for food hygiene in the home and for ensuring that food storage and preparation recommendations are followed. In addition, it is largely the consumers themselves who decide on the composition of their diet and poor dietary habits are major factor in the causation of food-related disease, especially in industrialized countries. In some cases we are “digging our graves with our teeth” when our intake of certain safe foods is much higher than our needs.

### **Holistic approach to food safety – the whole food chain and beyond**

It is important that care is exercised throughout the whole food production-processing-distribution chain. Previously, food control often concentrated on the examination of end products and on inspection of food processing operations. However, in recent decades there has been a growing awareness of the importance of an integrated, multidisciplinary approach considering the whole of the food chain (and in some cases beyond what is conventionally regarded as the food chain). One result of this change in approach is a much greater awareness of the need for better control on the composition and safety of animal feed. In response to this the Codex Alimentarius Commission established an *ad hoc* Task Force on Animal Feed and in recent years the European Community has introduced much more legislation and control on animal feed. Another result of the paradigm shift is a realization of the need for much closer contact and more interaction between those responsible for food control and those responsible for preventing or reducing environmental pollution. Such pollution, for example with persistent chemicals such as mercury, PCBs and dioxins, can lead to food safety problems. Coupled to this there is now a greater emphasis on source-directed preventive measures. Some examples of this approach are given below.

### **Hazard Analysis and Critical Control Points (HACCP) approach**

Food producers, processors and traders should operate according to the principles of Good Agricultural/Hygienic/Manufacturing Practices. Food production, processing and other handling operations should be analysed with a view to identifying hazards and assessing associated risks. This should lead to the identification of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis and Critical Control Point – “HACCP” approach). The introduction of HACCP-based in-house control may be difficult in small and medium-sized enterprises with limited basic knowledge, experience and resources and is probably best achieved by collaboration between the food industry, education and training organizations and the supervisory authorities. The Codex Alimentarius and its parent organizations FAO and WHO have produced useful guidelines and training and information materials on the application of HACCP in food control.

### **Prevention is better than cure**

Different approaches may be used to try to ensure that the levels of contaminants in foods are as low as reasonably achievable and never above the maximum levels considered to be acceptable/tolerable from the health point of view. Essentially, these approaches consist of:

- measures to eliminate or control the source of contamination
- processing to reduce contaminant levels
- measures to identify and separate contaminated food from food fit for human consumption. The contaminated food is then rejected for food use, unless it can be reconditioned and made fit for human consumption.

In some cases, a combination of the above approaches is used, for example when emissions from previously uncontrolled sources have resulted in environmental pollution with persistent chemicals, which have then entered the food chain.

Previously, most systems for regulating food safety were based on legal definitions of unsafe food, enforcement programmes to remove such food from the market and the application of sanctions on those held responsible for contravening the regulations. Such systems have not been successful in dealing with previous or current problems and are unlikely to be able to deal with emerging risks. Control of final products can never be extensive enough to guarantee contaminant levels below established maximum levels and safety and other aspects of food quality cannot be “inspected into” food at the end of the production chain. In most cases, chemical contaminants cannot be removed from foodstuffs and there is no feasible way in which a batch of contaminated foodstuffs can be made fit for human consumption. The advantages of eliminating or controlling food contamination at source, i.e. *a preventive approach*, is that this is usually more effective in reducing or eliminating the risk of untoward health effects, requires smaller resources for food control and avoids the rejection of foodstuffs and resulting economic and other losses. The use of a preventive and integrated approach to the management of food safety throughout the food chain is illustrated in the following examples.

### **An integrated approach to the control of Salmonella in poultry**

The prevalence of *Salmonella* in feed, live animals and animal products produced in Sweden is very low, less than 0.05% in beef and pork and 0.1% in poultry at slaughter. This has been achieved by a national control strategy which was initiated more than 40 years ago, following a severe domestic outbreak of *Salmonella* in 1953, involving more than 9000 people.

This integrated strategy, which is described in detail in a report (2) on zoonoses in Sweden, covers the different parts of the feed-food chain. The overall goal of the control programme is to ensure that animals sent for slaughter are free from *Salmonella*, thereby ensuring that animal products will be free from *Salmonella*. The strategies to reach this goal are as follows:

- To prevent *Salmonella* contamination in all parts of the production chain.
- To monitor the whole production chain: surveillance programmes for feed, live animals, carcasses, meat and other foods of animal origin are in place.
- If *Salmonella* is found, action is taken to eliminate the *Salmonella* infection/contamination. Any food item contaminated with *Salmonella* is deemed to be unfit for human consumption.

All isolations of *Salmonella* in humans, animals and food of animal origin are notifiable. In addition, findings of *Salmonella* in official samples of food of any origin are notifiable. All primary isolates of *Salmonella* are characterized by sero- and phage-typing the strains and isolates of animal origin are also tested for antibiotic resistance. In order to illustrate how the system works, some details of the measures taken in the poultry area are given below.

Since the frequency of *Salmonella* isolation in Swedish poultry flocks is very low, most of the measures in current control programmes are of a preventive nature. Four factors are of major importance to maintain this favourable situation.

- The breeding pyramid is kept free from *Salmonella*. All grandparent animals are imported and are quarantined and repeatedly tested negative for *Salmonella*.
- Feed is maintained free from *Salmonella*. The control consists of three parts: import control of feed raw materials, mandatory heat-treatment of compound feedingstuffs for poultry and an HACCP-based *Salmonella* control in the feed industry.
- High hygiene and biosecurity standards are in place, preventing the introduction of *Salmonella*.
- Measures are always taken in case of *Salmonella* infection in poultry.

An extensive sampling programme continuously monitors the *Salmonella* situation in poultry. In addition to sampling at the flock level, samples are also collected at all poultry slaughterhouses to monitor the end product.

### **Pesticides and veterinary drugs**

Pesticides and veterinary drugs should be subjected to thorough testing and risk assessment prior to approval for use. In order to minimize the risk of high residue levels in food and also to avoid environmental pollution, they should be used according to the principles of Good Agricultural Practice and Good Veterinary Practice and only by persons who have received adequate training. In order to avoid the development of antibiotic-resistant micro-organisms, the use of antimicrobials in food production should be restricted.

Pesticide levels should be monitored in food (including drinking water) and feed to ensure that they do not exceed established maximum limits (MRLs) and the results of such monitoring should be made public. When residue levels above the MRLs are found, this should trigger increased control of products from the same supplier/grower and to remedial action. Likewise, the levels of residues of veterinary drugs in relevant foods of animal origin should be monitored and the results made public. When residue levels exceeding the MRLs are found, this should lead to an intensification of control and remedial action at the source of the problem, usually the primary producer.

### **Mycotoxins**

The problem of contamination of feed and foodstuffs with mycotoxins, such as aflatoxins, ochratoxin A, patulin and trichotecenes, is best tackled by a systematic examination of the whole production, processing and distribution chain in order to discover the points at which contamination is likely to occur, so that appropriate preventive and control measures can be taken. In Sweden, control of aflatoxins in animal feed components and routine monitoring of aflatoxin M1 in milk back to the individual farmer has enabled us to ensure that aflatoxin levels in milk is kept well below our strict maximum limits. Detailed investigations of post-harvest handling methods have shown that in some cases relatively simple changes may lead to marked decreases in mycotoxin levels. Although a considerable amount of work has been done, there is a need for much more research on mycotoxins in order to provide a sound scientific basis for recommendations for both pre- and post-harvest measures. The Codex Committee on Food Additives and Contaminants (CCFAC) has developed and is developing codes of practice to reduce contamination of food and animal feed with mycotoxins, such as aflatoxins, ochratoxin A and patulin.

### **Persistent environmental pollutants**

Previous emissions of persistent chemicals, e.g. PCBs, dioxins, mercury, cadmium, have led to contamination of foodstuffs, especially foods of animal origin, such as fish and a need for monitoring and control of some products to ensure that they do not contain levels above safe limits. In order to protect public health, my agency has also issued recommendations to susceptible population groups, for example women of childbearing age, advising them to restrict their consumption of certain fish species or fish from contaminated waters.

In order to reduce the levels of environmental contaminants, effective measures must be implemented to reduce emissions from industry and other sources. There are several international conventions aimed at reducing environmental pollution with persistent organic compounds. In recent decades such measures have resulted in marked reductions in pollutant levels in some foods and in human exposure to some environmental pollutants. For example, the levels of lead in human blood have dropped quite dramatically in countries where lead is no longer added to petrol. Likewise, measures to control pollution with dioxins and PCBs and a ban on the use of persistent pesticides, such as DDT, has led to a marked reduction in the levels of these substances in food and in human exposure, as measured by the levels in human milk. This is an example of an area where co-operation between the authorities responsible for food safety and environmental protection has borne fruit. The Codex Committee on Food Additives and Contaminants is developing a code of practice to reduce dioxin contamination of food

### **Revamping meat inspection**

Current meat inspection methods are incapable of detecting the symptomless carriage of pathogenic organisms and many of the components of current meat inspection contribute little or nothing to consumer health protection. It is questionable whether it is worth spending limited inspection resources on routine examination for certain parasites in countries where they have not been found in domestic food animals for many years. The need to revamp meat inspection and make it more risk-based was recognized several years ago in, amongst other places, Australia and New Zealand and intensive discussions on this subject are also underway in the European Union. The Codex Alimentarius Commission has decided to start new work in this field and the Codex Committee on Meat and Poultry Hygiene will meet early next year to discuss the modernizing the current Codes of Practice on Meat Hygiene, including poultry hygiene.

### **Emerging risks – “Looking for trouble”**

We live in a world with rapid developments in science and technology, but also of rapid changes in the risks posed by microbiological and chemical hazards. It is therefore important that agencies responsible for food safety have a “reconnaissance” or “intelligence” function with the task of detecting emerging risks. These risks could be due to emerging pathogens, for example pathogens resistant to a wide range of antibiotics, the use of new feed components, new industrial or domestic chemicals, new production, processing and handling methods or to changes in dietary habits. The detection of emerging risks is one of the tasks that will be assigned to the proposed European Food Authority.

### **Traceability**

In order to be able to identify the source of food safety problems, it is necessary to have systems in place to be able to trace a food product back through the food chain. Such systems are already in place in the European Union for some foods and legislation currently under preparation in the EU will introduce traceability as a general requirement. A good system for tracing food throughout the production and distribution chain is also valuable for the food industry and trade, since it should mean that recalls of faulty products can be restricted.

### **Improved monitoring of foodborne disease and risk assessment**

A risk-based approach to food safety risk management implies that food control resources should be directed towards problems which pose the largest threats to health and where the potential risk reduction is large in relation to the resources used. In order to make our priorities risk-based, we need much better systems for following-up and reporting outbreaks of foodborne disease and better international co-operation in this area. WHO is making a major effort to improve the current situation. Furthermore, we need to spend more resources, preferably at the international level, to speed up and improve expert risk assessment of both microbiological and chemical hazards in food.

### **Transparency**

One of the recommendations of the Expert Consultation on Risk Management was that the risk management process should be as open and transparent as possible. The work of the supervisory authorities should be carried out in a transparent manner, with open communication with consumers, producers, traders and other interested parties. One effective way of increasing compliance with food legislation is to make the results of food control activities public. This applies of course to inspection reports and results of control analyses carried out by the supervisory authorities. In countries where responsibility for food control is divided between different authorities, e.g. central and local authorities, it should also apply to audits carried out by national authorities on the food control work carried out by local authorities. In the European Union the European Commission's Food and Veterinary Office audits of the food control activities carried out in the Member States are available on the Internet and we welcome this approach.

### **Improving food hygiene in commercial catering and in the home**

Hitherto I have dealt mainly with the early parts of the food chain: we must not underestimate the importance of the last part. In Sweden there are indications that a large proportion of the cases of foodborne disease are due to poor hygienic practices in restaurants and other commercial catering establishments and in the home. The food control authorities should ensure that those responsible for the operation of catering establishments train their personnel in food hygiene and that they operate in such a way as to be able to guarantee the safety of the food they serve.

The supervisory authorities also have a duty to try to improve consumers' knowledge about domestic food hygiene and to provide them with information to help them to make their dietary habits consistent with good health.

## **Recommendations**

In summary, I would like to make the following recommendations aimed at increasing food safety:

1. Food safety strategies should be risk-based, giving priority to measures that have the potential to result in the greatest reductions in foodborne disease.
2. The follow-up and reporting of foodborne disease outbreaks should be improved and intensified in order to provide a better base for risk-based food control priorities and remedial measures.
3. An integrated, multidisciplinary approach to food safety should be adopted, covering the whole of the food production, processing and distribution chain. This implies increased control of animal feed and other aspects of primary production.
4. Food producers, processors and distributors should have in-house control systems based on the HACCP approach.
5. In order to decrease the risk of food contamination, a preventive approach should be adopted, tackling problems at source where possible.
6. Meat inspection should be modernized to make it more risk-based.
7. The results of food inspections and other food control activities should be made public.
8. The training of catering personnel and the education of consumers in food hygiene should be improved.
9. Improve contacts at the local, national and international levels between those responsible for food safety and those responsible for environmental protection and pollution control.
10. In order to decrease the risk of future acute food safety problems, food control authorities should assign resources to the detection of emerging risks.

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**SUMMARIES OF CONFERENCE ROOM DOCUMENTS FOR THEME 2****RISK MANAGEMENT****▪ ARGENTINA-1**

The paper describes the 2001 Plan for the Control of Residues and Hygiene. This covers those chemical residues, additives, toxins and microorganisms that represent the highest risk for the consumer. Risks are classified according to two criteria: the hazard nature of a determined chemical in different food items and the consumption patterns of the population of those food items. It also describes the procedure for taking corrective action when a predetermined action level in an identified chemical has been exceeded and led to an excessive exposure of the population to risk. Corrective actions are taken throughout the food chain after having identified the critical entry points of the chemicals into the food.

**▪ BURKINA FASO-1**

The paper describes the food quality and safety objectives and experiences relating to management of food safety risks under specific projects. These projects include production and quality control of locally produced infant food and developing a food safety programme and quality control system. Results obtained show a reduction in cases of infant diarrhoea and adoption of codes of good hygienic practice. Difficulties relate to the low educational level of the mothers and indicate the need for increased awareness raising on the direct link between food safety and foodborne diseases. The paper identifies several specific actions that needed to be taken to improve the situation, including consumer education; review of food control system and of food safety regulations; implementation of food handlers education programmes; review and updating of food legislation and regulation; food legislation enforcement and monitoring programmes.

**▪ BURKINA FASO-2**

The paper describes a project to produce nutritious and safe infant food and follow-up formula by applying good hygienic practices, quality criteria by traditional and semi-traditional production units (woman/mother driven). Formulas are composed of cereal-based flours and enriched flours that are locally produced. Enriched flours lead to a reduction in cases of diarrhoea and showed an improvement in the nutritional status of infants and under-nourished children.

**▪ CHINA-1**

A fatal case of food poisoning caused by altered sugarcane was discovered in the 1970s in the northern part of China. Because of its unknown aetiology and the very high fatality rate, particularly among children, the case was considered one of the major food safety concerns in the country. The Ministry of Health in collaboration with academia conducted a series of field surveys, laboratory tests and clinical studies which led to the elucidation of the aetiology of this specific food poisoning. Based on the findings, specific control measures (i.e. to control the duration and condition of sugarcane storage) were promulgated at the central level and implemented by local health institutions: This resulted in a quick and efficient control of the food poisoning. China's experience in this case demonstrated that: 1) when food poisoning of unknown causes occurs, it is crucial to take proper action quickly and find out its etiology, followed by the development of specific control measures to be implemented by local health workers. This will result in a quick and efficient control of the food poisoning; 2) close collaboration between government food safety officials (risk managers) and

academic food safety experts (risk assessors), as well as between central government agencies and local government agencies is critical in solving food safety emergencies.

▪ **CHINA-2**

Avian influenza (AI) uniquely occurred in the Hong Kong Special Administrative Region (HKSAR) of the People's Republic of China via cross species transmission from live chickens to man. Twenty cases (1997 -1999) resulted for the first time, in six human mortalities. Mass depopulation of poultry from farms, wholesale and retail markets followed to prevent further AI infection in man and to avert a recombination between AI and human influenza strains. Consequently, the SAR government decreed mandatory the testing for H5-AI virus antibodies in all imported and local poultry prior to their release for retail; an end to overcrowding of animals in stalls; segregation at all levels of ducks, geese and quails from all other poultry; an improvement in levels of sanitation and the disinfection of poultry works and stalls. Long term considerations include the centralisation of slaughtering with a suspension on the supply of live chickens.

▪ **ICELAND-1**

The incidence of human campylobacteriosis in Iceland reached epidemic proportions between June 1998 and March 2000. The epidemic was almost exclusively due to an increase in domestically acquired infections, mostly traced to the consumption of fresh chicken. Prior to 1996 it was only permitted to sell frozen poultry in food stores, but with the change of regulations, fresh poultry was allowed and sales increased significantly. Interventions consisting of an educational programme for farmers; an extensive surveillance programme for *Campylobacter* in poultry; freezing all known *Campylobacter*-positive broiler flocks before they go to retail and extensive consumers education were implemented in the beginning of 2000. These measures have resulted in a reduction of domestic and total number of cases of campylobacteriosis between 1999 and 2001.

▪ **IRAN-1**

The development of food safety standards is handled by governmental bodies (e.g. Ministries of Agriculture, Health, Hygiene and Medical Education; Institute of Standards and Industrial Research) through a national food safety programme. National maximum residue limits have been developed (according to Codex norms) and applied during the investigation and monitoring of pesticides and heavy metal residues. A Mycotoxin Unit has recently been established and draft national mycotoxin standards have been developed and are at the final stages of approval. The current 4-year plan at the Iran Veterinary Organization (I.V.O) includes the establishment of a reference laboratory and the application of HACCP system in the production of foods of animal origin. This follows the successful introduction of HACCP in fish processing plants. On the other hand, FAO is assisting the Iran government in the management and control of veterinary drugs and pesticides residues in foods.

▪ **JAPAN-1**

Hydroponically grown radish (*Raphanus sativus*) sprouts served in school lunches were epidemiologically implicated as the causative vehicle of *Escherichia coli* O157:H7 in the largest outbreak which occurred in Sakai City, Japan, in 1996. Laboratory experiments suggested the possibility that *E. coli* O157:H7 had grown during the production of radish sprouts. In order to improve the sanitation level in radish sprout production, the Japanese Ministry of Agriculture, Forestry and Fisheries, in cooperation with the Ministry of Health and Welfare, developed a hygienic practice manual for radish sprouts production in October 1996, most recently revised in March 1998. The manual has adopted the concept of HACCP and identifies supplied water and seeds as critical control points (CCP).

## ▪ JAPAN-2

Japan has prepared an epidemiological investigation and reporting system for foodborne outbreaks at the national level in accordance with the Food Sanitation Law. After the experience of large outbreaks of *E. coli* O157:H7 in 1996, new measures were taken in various field to further improve the hygiene status of foods in Japan. Laws were amended, and new notices have been released. Strict hygiene practices have been introduced to abattoirs and meat processing plants, and long-term food saving program has been applied to institutional cooking facilities. Once enterohemorrhagic *E. coli* or *Salmonella* is isolated, they are subjected to genetic or serological typing, which also helps epidemiological investigations. Development of treatment and diagnostic agents has also been encouraged.

## ▪ MALAYSIA-1

Over a 35-week period (September 1998 to May 1999), 265 cases of viral encephalitis were reported to the Ministry of Health, Malaysia. The cases occurred in four localities, originating in the Kinta district of Perak and spread rapidly with the movement of infected pigs, causing 105 human fatalities. The infection, contracted through 'live' contact with body secretions, was initially treated as an outbreak of Japanese encephalitis, but proved positive for a new virus named 'Nipah' of the Paramyxovirus group of enveloped RNA viruses. Local and international controls of the outbreak followed. Evacuation and quarantine of infected farms, including the extensive culling of pigs, was implemented alongside institutionalised protocols regarding disease prevention and management. With the financial implications to the Malaysian Government and pig rearing industry including a ban in the export of live pigs to Singapore (since March 1999), the establishment of Bio-security level 4 has been approved by the Cabinet in the 8<sup>th</sup> Malaysia Plan.

## ▪ MYANMAR-1

Presently, Myanmar uses agro-chemicals on 80% of national food crops while maintaining significantly low pesticide residue levels (relative to MRLs established by the WHO/FAO Codex Alimentarius Commission). However, this is expected to increase with changes in the pattern of cropping for high rice production and with the extension of food crops. In the early 1990s Myanmar experienced food trade problems, having violated MRLs (national and codex) of Organo Chlorines (OCs), contained in insecticides used on national food crops. Bans and restrictions on the use and import of various OC insecticides followed, causing a decrease in levels, though present use is still high (10% of food crops). Furthermore, the use of Pyrethroids is increasing, while Aflatoxin (*Aspergillus Flavus*) contamination represents another serious food safety concern (present in Peanut, Chilli and Maize crops). Myanmar Agricultural Services aim to improve levels of food safety through the establishment of national MRLs, staff training, the upgrading of food safety facilities and through development of the residue and market surveys.

## ▪ PHILIPPINES-1

Alarmed by the emergence of food borne disease incidence, in 1998 the national government created the National Food Security Council through an Executive Order. Under this, a National Food Safety Committee was organized to formulate a National Food Safety Policy Program. Together with partner agencies, a consultative meeting was convened to discuss and formulate a framework for a National Food Safety initiative. Several issues were raised in the consultative meetings with the committee establishing the following recommendations: 1. the formulation and issuance of a national policy on food safety; 2. the review of critical areas within the food chain, unprotected by laws or regulations and standards; 3. the development of a comprehensive Food Disease Surveillance System; 4. the development of detection methodologies and assessment in the emergence of GMOs. Action plans are formulated to develop strategies for implementation in 3 phases, namely Phase I (2002-2004), Phase II (2005-2007) and Phase III (2005-2007).

**▪ CENTRAL AFRICAN REPUBLIC-1**

Brochure showing the very low nutritional status of the population in the country.

**▪ SWEDEN-1**

Sweden has achieved efficient control of Salmonella, despite the industrialisation of animal production. The prevalence of Salmonella in feed, live animals and animal products produced in Sweden is very low. In beef and pork it is less than 0.05% and less than 0.1% in poultry at slaughter. This unique position has been achieved by a national control strategy from feed to food, which was initiated more than 40 years ago. A severe domestic Salmonella epidemic during 1953, involving more than 9000 people of which a few died, demonstrated the need for a more comprehensive control programme.

**▪ SWITZERLAND-1**

The rate of Listeriosis incidents stabilised in Switzerland in the 1990s due to an endemic level similar to that of other industrialised countries. Between 1990 and 1993, 3 to 6 cases per one million inhabitants were declared yearly, however no grouped cases were noted. In most cases, persons suffering from an immuno compromised system with a severe underlying pathology, generally of the neoplastic type, pregnant women, neonates and the elderly were the most affected. The most onset symptoms were meningitis or encephalo-meningitis, septicaemia and pneumonia. The case-fatality rate among the declared cases was 20%.

**▪ TANZANIA-2**

An outbreak of cholera (vibrio cholera) around Lake Victoria (1997) led to an EU market ban imposed on all respective fish (Nileperch) exports. Opposed by Tanzania, Kenya and Uganda, the ban was justified on the grounds of the 'precautionary principle'. WHO risk analysis revealed that fish from the Lake did not pose a risk of cholera outbreak in Europe and a massive hygiene programme followed (under Recommended Codex Codes for fishery establishments and EU Directives), HACCP systems installed, resulting in a lifting of the EU ban. A second EU ban on Victoria Lake Fish imports (1999) regarded pesticide residues above tolerable levels, yet HACCP systems effectively ensured the safety and quality of fish products with multi-level awareness campaigns implemented. No Lake Victoria fish samples demonstrated the presence of pesticides residues, but over one year passed before the ban was lifted resulting in unrecoverable national economic losses. Consequently, compensation for retrospective economic loss and diligence in applications of the 'precautionary principle' are required at the international level.

**▪ THAILAND-2**

In Thailand, restaurants and street vendors can easily be found in not only the tourist areas but also in other communities in Bangkok and all other provinces. One reason is that there has been a decrease in the number of Thai citizens cooking at home possibly due to smaller families (comprising of two or three family members) and the increasingly fast-pace of city life with street vendors ready at their stalls by four or five in the evening with varieties of ready cooked foods for selection. Consumption of restaurant/street food is also made by thousands of tourists to Thailand each year. Since 1989, the Department of Health of the Ministry of Public Health together with the Tourism Authority of Thailand and the Ministry of Interior who is responsible for all local governments in provinces around the country, have joined forces in a project aimed at assuring the good sanitation of all restaurants and street vendors in Thailand. The "Clean Food Good Taste" Project directly benefits the people of Thailand while also reassuring tourists of Thai food safety. Until now, 5,377 restaurants (of 11,731 applied) and 3,045 vendors (of 6,843 applied) have passed the criteria and been awarded the Clean Food Good Taste logo to be displayed at their businesses. Thirty percent of the awardees are randomly chosen and

assessed twice a year. If good sanitation is not found, the award and logo will be revoked. The success of the Clean Food Good Taste Project is due to the application of four strategies: partnerships and co-ownership; quality assurance; sustainability and public awareness and involvement.

#### ▪ UNITED KINGDOM-1

An outbreak of *Escherichia coli* (E. coli) O157:H7 infectious intestinal disease occurred in Central Scotland in late November 1996. A total of 496 cases were linked to the outbreak. In all there were 21 deaths of infected persons, although some were not as a direct result of the infection. All of those who died were elderly. The cause of the outbreak was traced to contamination of cooked meat at the butchers. Investigations revealed very poor food hygiene practices that allowed cross contamination between raw and cooked meat. This outbreak illustrates the importance of: a) Hazard analysis and implementation of control measures; b) Good management and staff training; c) Effective enforcement.

#### ▪ VANUATU-1

The Republic of Vanuatu has delegated specific government agencies responsible for addressing consumer food safety (e.g. Department of Public Health, Vanuatu Quarantine & Inspection Services), who are authorised to implement necessary procedures through a series of current food legislative acts (e.g. the Food Control Act No. 21 of 1993, Meat Industry Act No.5 of 1991). These government agencies collectively form the Vanuatu National Codex Committee (est.2000), introducing Codex Alimentarius Standards as a guideline to overseeing national food safety issues. Financial difficulties, a lack of qualified human resources and inadequate testing facilities, have been identified as obstacles to the achievement of food safety contributing to a lack of available data on food-borne illnesses in Vanuatu. Further assistance from developed countries and donor agencies (e.g. FAO, WHO) in developing food safety legislation, capacity building etc. is required.

#### ▪ WHO-2

Foodborne disease takes a major toll on health. Thousands of millions of people fall ill and many die as a result of eating unsafe food. Foodborne disease have implications both on health and development. Numerous outbreaks of foodborne disease have attracted media attention and raised consumer concern. However, the major problems are hidden among huge amounts of sporadic cases and smaller outbreaks. Most countries do not have good reporting systems, and a realistic estimation of the true burden of disease is difficult. WHO estimates 2.1 million deaths from diarrhoea worldwide, mainly caused by contaminated food and/or water. It is estimated that annually up to one third of the population, even in developed countries, suffer from foodborne disease. WHO initiatives to develop better methods to evaluate the foodborne disease burden, including strengthening foodborne disease surveillance, will serve to address this issue in the future.

#### ▪ CÔTE D'IVOIRE-2

The paper describes the national approach of the Côte d'Ivoire in the risk management of foodborne diseases and sets out basic needs (e.g. participation in the international standardization committee, WTO committees etc.) and orientations taken at the national level to ensure safer food, both for the domestic market and for foods for export. Assuming that the position of the international community is to implement an international risk management approach in accordance with orientations taken by international standard bodies (i.e. Codex Alimentarius Commission) and to improve the health of all consumers (the majority of which reside in developing countries or LDCs), the following crucial facts must be considered : a) the adoption of a risk-based approach requires a good knowledge of risk analysis and its components; b) implementing these policies requires voluntary, co-ordinated actions and follow-up technical assistance; c) effective participation of representatives from LDCs and developing countries in international standardization bodies is necessary in order to express their specific concerns;

d) elaboration of international standards (e.g. Codex, OIE) should, without prejudice to the level of food safety, have immediate applicability for the majority of countries.

#### ▪ **LIBERIA-1**

The designated national authority on food safety in Liberia, aims to increase public awareness of the risks of food poisoning and of preventive measures practicable throughout the food chain, in order to protect consumer health during consumption of Liberian food both nationally and internationally, whilst helping to maintain and enhance the reputation of Liberian food related industries. Liberia is constricted in its endeavours towards food safety by the absence of a national food analytical laboratory for food quality control, due to the war. Food safety and health protection of consumers have become international issues, forcing most developed countries to examine how they ensure the safety of their food supply. Liberia's integrated approach towards the management of food safety throughout the food chain involves: a) the education of consumers and of risk communication; b) the convincing of industry of its responsibility to produce and provide safe food; c) the development of an effective inspection service from farm to table; d) the aim that every Liberian food business recognizes the importance of food safety and makes it an integral part of their business.

#### ▪ **MAURITANIA-1**

The paper describes national institutions involved in food inspection in Mauritania. As Mauritania is an important meat producing and consuming country in the sub-region, priority was given very early to pre-mortem inspection and post-mortem inspection. Having a large coast on the Atlantic, production of fish and fish products is important and directed to export markets. Inspection is carried out solely on fish intended for export. A national centre for hygiene is responsible for inspections of all foodstuffs intended for sale in Mauritania of animal and vegetable origin. Another body is in charge of the control of cereals and cereal products at entry points determined by law. The paper stresses that despite a significant lack of means, Mauritania is on the way to fostering food safety as a means to reducing food insecurity.

#### ▪ **CANADA-3**

The food safety system in Canada operates in a multi-jurisdictional setting. At the federal level, the system is integrated by Health Canada and the Canadian Food Inspection Agency (CFIA). Within the government, co-operative federal/provincial/territorial structures are in place including targeted funding support from Agriculture and Agri-Food Canada (AAFC). Two major integrated food safety initiatives are described by the Canadian Food Safety Adaptation Program (CFSAP) and the Canadian On-Farm Food Safety Program (COFFSP). Canada is committed to implementing an integrated and science-based approach to enhance food safety. The overall strategy is based on shared responsibility, the use of Hazard Analysis Critical Control Point (HACCP) principles/practices and the introduction of leading technologies and detection methods within government and across the food industry. The goal is to enhance food safety in Canada and to maintain domestic and international recognition of the safety of Canadian products. Implementation of an integrated approach to enhance food safety has resulted in important lessons learned with respect to: the importance of the participation of partners/stakeholders from across the food continuum and the potential benefits such as improved lines of communication, the development of better regulatory policy and interventions and the efficient use of government resources; the practical challenges in working closely with partners/stakeholders to design and implement significant regulatory changes; the level of effort required by industry and other stakeholders to successfully implement changes; and the need for ongoing consultation with regulating staff as new skills and training may be required to meet emerging regulatory changes and the requirements of new science and technologies.

**▪ CI-1**

Consumers International supports the development of comprehensive "working principles for risk analysis," to support transparent food safety decision-making processes at both the international and national levels. Consistent, harmonized principles offer the promise of ensuring a high standard of health protection and food safety for consumers in all parts of the world, while avoiding creating unjustified trade barriers. The Codex Alimentarius Commission and several of its subsidiary bodies are currently developing consensus principles for risk analysis, and completion of that work is an urgent priority. Many opportunities for further progress in advancing risk management through sound principles are identified in this paper. They include spelling out more detailed principles for risk management of specific food safety problems, and expanding the Codex principles to make them useful as guidelines for national governments. A broader consensus is needed on clear principles for the application of precaution and on the roles of science and non-scientific other factors in food safety risk management. And the scientific advisory system on which Codex and many national governments rely for risk assessments needs to be expanded and improved, to increase the quantity and quality of risk assessments to keep pace with demand.

**▪ DENMARK-2**

Since the late 1980s Denmark has implemented three separate pre-harvest programmes to control salmonella in broilers, pigs and layers of table eggs respectively. The programmes differ in the methods employed and to a minor extent in their goals. However, in many important aspects they are very similar. First, they are all based on the credo that if at all possible, foodborne zoonoses should be controlled at source (i.e. on the farm). Their successful implementation has relied to a large extent on co-operation between the authorities and the industry and on the ability to make use of the industry infrastructure, including the ability to unequivocally identify farms of origin. The authorities have delegated responsibility for technical co-ordination of the programmes to committees with representatives from science, government bodies and industry. Secondly, there has been a close involvement of microbiologists and epidemiologists in the planning and implementation of programmes. The parties involved in the undertaking have shown willingness to accept recommendations for the use of novel techniques in routine monitoring, for example, the serological examination of meat juice or egg yolks for salmonella antibodies. Finally, the hallmark of the Danish salmonella programmes has been a very close collaboration between medical and veterinary epidemiologists and microbiologists in monitoring the effect of the programmes on the incidence of human infection.

**▪ EGYPT-1**

In Egypt food control functions are multisectoral. The Ministry of Health and Population administers food control through the Food Safety and Control Administration, the Institute of Nutrition and the Public Health Laboratories. These bodies act through ministerial laws and regulations; food inspectors; the Institute of Nutrition and public health laboratories (technically supervised by the Central Public Health Laboratories-CPHL). The Agricultural Department includes the Reference Laboratory for Safety Analysis of Food of Animal Origin; the Central Laboratory for Food & Feed; the General Organization for Veterinary Services and Egypt's Biosafety system and committee. The Ministry of Industry concerns itself with food safety through the standardization of food commodities; the Ministry of External Trade with food control activities for import and export and the Ministry of Supply with food inspections at local market level. The passing of one basic food law for Egypt is currently under review.

**▪ FAO-1**

In consideration of the complexity of food production; marketing and distribution systems, the multidisciplinary nature of problems of food safety and quality are best addressed at the multi-jurisdictional government levels, and at the international level through the intergovernmental fora of the Codex Alimentarius Commission (Codex) and its committees. At national levels, the administration of

'integrated' food control systems is considered to be the best structure to meet challenges related to food safety, operating as the interface between Government and the various stakeholders. In consideration of the limited function of traditional food systems, developing countries are encouraged to increase their level of participation in Codex work to benefit from the interaction with other countries on issues related to food safety and consumer protection. The FAO/WHO publication, *Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems* which presents these views will shortly become available.

#### ▪ IIR-1

The International Institute of Refrigeration (IIR) supports sustainable development through its involvement in risk management and capacity building involving all refrigeration stakeholders. The establishment of reliable cold chains is recommended with the introduction of Maximum Recommended Temperatures (for food storage and distribution), the use of air-temperature measuring instruments in the improvement of cold chains and implementation of temperature traceability. Stricter monitoring of interfaces between links in the cold chains and of measures governing foods prone to contamination with psychrotrophic bacteria are also recommended, as is incorporation of the HACCP approach for training food safety regulators in good refrigeration practice (and vice versa). The IIR is currently revising the Code of Practice for the Processing and Handling of Quick Frozen Foods of the Codex Alimentarius (Joint FAO/WHO Food Standards Programme) as requested by FAO.

#### ▪ MALI-1

The paper describes the national food control and inspection system and its objectives. This control programme is focused on all imported foods. Conformity assessments are carried out not only on aspects relating to importation/exportation documentation, standard requirements but also on sanitary characteristics (food safety) of foodstuffs (microbiological quality, chemical and biochemical safety etc.). Food industries within the country are subject to regular inspection. In practice, frequency is highly variable and often less than the legal provision of once a year. In 2001, a National Health Laboratory Study showed that 80% of samples taken in small-sized food industries and restaurants did not conform to microbiological standards. However, approximately 10% of all food samples and 23% of water samples were not satisfactory in terms of physico-chemical or bacteriological standards. The paper stressed the importance of educational programmes of food handlers and consumers, through the national network of NGOs and radio-television programmes. Human resources involved in food control and inspection are few, relative to the national area requiring coverage, thereby resulting in insufficient controls of food imports. It is also noted that food contamination is reported from street-vended foods delivery points (gargotes) that are under the decentralized hygienic supervision of municipalities.

#### ▪ NEW ZEALAND-1

This paper outlines the application in New Zealand of a risk-based approach to food safety. It focuses on four key areas within the overall system in place in New Zealand: the roles within the government's regulatory model, the risk management framework, legislation, and measuring the regulatory system's performance. The New Zealand government has taken a partnership approach with food operators, assisting sectors to develop the tools they need to meet the mandatory outcome standards. These include templates and codes of practice to assist operators to implement HACCP-based systems and risk management programmes. The approach has proven successful in contributing to the overarching goal of the food safety regulatory system by ensuring that food reaching the consumers is safe and fit for consumption. The challenges for the future are to further expand application of this approach across the entire food sector and to measure performance of the system.

#### ▪ **SENEGAL-2**

The paper describes the national Codex Alimentarius structure in place in Senegal since 1983. The national food standardization policy is implemented within the Standardization Institute of Senegal (SIN) soon to be replaced by the Senegalese Association of Standardization (ASN). The focus of the new agency is to promote quality and develop quality marks for national products to be exported through certification. It will also implement anti-dumping measures and carry out the control of those standards which are being elaborated of mandatory application by law. The industry and private sectors are to be closely associated to ASN activities as well as consumer associations. The paper gives details regarding national bodies involved in quality management in Senegal. It is recommended that there be a) a standard harmonization be initiated taking those of the Codex Alimentarius as a reference in terms of food quality control; b) reinforcement of capacity building of national institutions (human and material resources), a laboratory network at national, regional and international levels; c) usage of harmonized methods of analysis and sampling; d) consumer information and education programmes; e) interaction and partnerships between public administration and private sector to establish a national quality cultural identity; f) creation of national food safety monitoring committees; g) support for the participation of national food safety regulators to international fora sessions, including Codex Alimentarius; h) focus prioritised on food import control in order to better ensure consumer protection in Senegal.

#### ▪ **SLOVAK REPUBLIC-1**

Slovakian food legislation consists of the Food Act (No. 152/1995) on the basis of which individual directives of Slovakian Food Codex (approved by the Ministries of Agriculture and of Public Health) have been adopted. The Food Act controls food products through the Slovakian Veterinary and Food Administration which functions in cooperation with the Food Research Institute. The National Environment Monitoring Programme (launched 1992) includes the Partial Information System on Food Contaminants (PIS FC) which receives data from the Monitoring of Contaminants in the Food Chain (MCFC), with reliable analytical results guaranteed by the Center for Analytical Quality Insurance (AQA). PIS FC, MCFC and AQA are localised at the Food Research Institute which is responsible for their management and performance. The Slovak Republic bases its approach to risk management on the principles of the EU rapid alert system. A total harmonization of food legislation in line with EU food legislation is expected by the end of 2002.

#### ▪ **SWEDEN-2**

In Sweden the use of antibiotics as growth promoters in animal feed has been prohibited since 1986. Anti-microbials may only be added to feed for veterinary purposes, and always subject to veterinary prescription. When antibiotics were withdrawn from animal feed in 1986 there were no noticeable effects on calves and fattening pigs. There were, however, initially effects on piglet and chicken health, resulting in an increased therapeutic use of antibiotics. Through various measures the health problems in pig and chicken production were largely solved within a few years and the therapeutic use of antibiotics decreased. Since 1988 animal health has constantly improved and the use of antibiotics for animals has decreased. The total use during 2001 was 34 percent of use during 1984.

#### ▪ **UNITED KINGDOM-2**

Enter-net is the international network for the surveillance of human gastrointestinal infections, which monitors salmonellosis and Verocytotoxin producing *Escherichia coli* (VTEC) O157. It involves all 15 countries of the European Union, plus Switzerland and Norway and is funded by the European Commission. International travel and international trade in food play an important role in the occurrence of foodborne infections. Events in one country now have the potential to affect many others. A co-ordinated international response is required to control this threat. Through recognition of outbreaks and investigation, timely exchange of information between experts in different countries can lead to

effective international public health action. Exchange of data internationally can help eliminate potential vehicles of infection allowing authorities to concentrate their resources more effectively. For instance, if a rise in infection occurs only in one country it is likely that the source is in that country and not a result of imported goods.

▪ **USA-3**

The existing US scheme of food safety responsibilities, involving the Food and Drug Administration, US Department of Agriculture, Environmental Protection Agency and other government agencies, is based on laws and regulations that place responsibility for safety on those that produce, process, transport and store the food. In 1997, a new initiative to revamp the regulatory approach extended its scope throughout the food chain entitled, "From Farm to Table." The initiative was needed to address significant outbreaks of foodborne illness and increasing international trade, and was based on extensive consultation with all stakeholders. Actions that were taken to prevent and respond to foodborne illness involved improved recognition of foodborne illnesses and outbreaks; establishment of an outbreak response team; research on new technologies; development of good agricultural practices; food safety education; and increased federal-state partnerships. As a result, food safety is now seen as a shared responsibility between consumers, industry, and government at all levels with better-understood roles for each. Increased transparency and visibility have brought more resources, higher priority and incentives to implement the initiative.

▪ **ZIMBABWE-1**

Agriculture forms the base of the Zimbabwean economy, contributing 45% of export earnings and providing livelihood to over 70% of the population. Food safety is a problem of public health concern and is indicated by recurrent outbreaks of food related diseases. Food control is the responsibility of various government ministries and local authorities. Food control administration is weak due to fragmentation, inadequate resources and limited skills for food inspection. This paper highlights the major food safety challenges faced by Zimbabwe and the contributions through technical co-operation towards the establishment of a comprehensive food control system in Zimbabwe. The technical co-operation project funded by the Food and Agriculture Organization laid the foundation for the establishment of a National Food Control Authority, established policies and procedures for food import inspection and improved quality systems at the Government Analyst Laboratory which is in effect the National Food Control Laboratory.



**APPENDIX X**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakech, Morocco, 28 – 30 January 2002*

**THEME AND TOPIC PAPERS**

**WITH SUMMARIES OF APPLICABLE CONFERENCE ROOM DOCUMENTS FOR**

***CAPACITY BUILDING***

## FOOD SAFETY CAPACITY BUILDING

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### **I. Introduction**

Need and challenge stand out as the two driving forces associated with capacity building and technical assistance: the need for developing countries to improve food safety and quality measures and the challenges of meeting this need. This paper discusses the need for improvement of food quality and safety systems in developing countries in the context of food security, public health protection and international trade and examines means of addressing the associated challenges through new approaches in capacity building and technical assistance.

### **II. Food Security**

It is important to place food safety and quality in the context of food security. In 2020, the world population will most likely reach 7.6 billion, an increase of 31% over the mid-1996 population of 5.8 billion<sup>1</sup>. Approximately 98% of the projected population growth over this period will take place in developing countries. It has also been estimated that between the years 1995 and 2020 the developing world's urban population will double, reaching 3.4 billion<sup>2</sup>. This overall increase in population and in the urban areas in particular, poses great challenges to food systems. Intensification of agriculture and animal husbandry practices; more efficient food handling, processing and distribution systems; and introduction of new technologies may all have to be exploited to increase food availability to meet the needs of growing populations. Some of these practices and technologies may also pose potential problems of food safety and nutritional quality and call for special attention in order to ensure consumer protection.

Rapid urbanization has led urban services to be stretched beyond their limits, resulting in inadequate supplies of potable water, sewage disposal and other necessary services in many countries. This scenario further stresses food distribution systems as greatly increased quantities of food must be transported from rural to urban locations in an environment that is not conducive to hygiene and sanitation. More than 800 million people are today hungry and malnourished with serious impact on growth and learning capacity of children and the ability of adults to lead fully productive lives. Moreover, most of these people are to be found in those parts of the world where such food as they have is often contaminated or adulterated, thus increasing the risk of foodborne illness.

The World Food Summit which took place from 13 to 17 November 1996 brought together close to 10,000 participants, and provided a forum for debate by world leaders on one of the most important issues facing world leaders in the new millennium - food security. The resulting Rome Declaration on World Food Security and the World Food Summit Plan of Action laid the foundations for diverse paths to a common objective - food security, at the individual, household, national, regional and global levels.

Food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and

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<sup>1</sup> United Nations Population Division 1998. *World Population Prospects: The 1996 Revision*. New York.

<sup>2</sup> United Nations Population Division 1998. *World Urbanization Prospects - The 1996 Revision*. New York.

healthy life. In this regard, concerted action at all levels is required. It is important that each nation adopt a strategy consistent with its resources and capacities to achieve its individual goals and, at the same time, cooperate regionally and internationally in order to organize collective solutions to global issues of food security. In a world of increasingly interlinked institutions, societies and economies, coordinated efforts and shared responsibilities are essential.

Coupled with the need to increase the food supply is the need to provide safe food. Food safety is receiving more attention worldwide with the increasing incidence of foodborne illness, concern over known and emerging hazards, and an increase in the international trade in food. Unsafe food is a significant contributor to the burden of disease, particularly in developing countries. Approaches to ensure safety and quality of food therefore form an integral part of food security.

### **III. Public Health Considerations**

Food safety issues vary from country to country, from developed to developing countries, and within these groups of countries as well. Many of the reasons why food safety is becoming a more important issue worldwide are most compelling in developing countries. Increases in population, the growth in the number of immune compromised individuals, increased urbanization, poor sanitation and inadequate potable water supplies generally pose greater challenges in developing countries than in developed ones.

Food-borne diseases are a worldwide problem of great magnitude, both in terms of human suffering and economic costs. The task of estimating with any accuracy the occurrence of food-borne diseases globally is truly formidable as in many countries surveillance systems are inadequate and occurrences are poorly recorded. It is estimated that almost 70% of the estimated 1.5 billion episodes of diarrhoea that occur in the world annually are directly caused by biological or chemical contamination in foods.<sup>3</sup> Even when such diseases are not fatal, they severely increase the effects of poor diet owing to reduced intake, nutrient losses and mal-absorption, which may lead to mental retardation and physical disabilities.<sup>4</sup>

Estimation of the economic consequences of unsafe or poor quality food is complex. It involves consideration of the value of crops and animal products lost as a result of such contamination, value of rejections in the export trade, medical treatment costs, and the loss of output or earnings resulting from morbidity, disability or premature death.

Some studies have been carried out to assess the total costs incurred by society as a consequence of food-borne illnesses. In the USA alone, costs for loss in productivity due to seven specific pathogens have been estimated to range between US\$ 6.5 billion to US\$ 13.3 billion annually.<sup>5</sup>

Developing an effective strategy to reduce foodborne disease requires accurate reporting, epidemiological surveillance and information related to the potential hazards in the food supply. The absence of this information inhibits the implementation of effective food safety control measures and contributes to the failure of governments to commit the necessary resources to address the problems.

Food is also a good indicator of the state of the environment in which it is produced. Monitoring of environmental contaminants in food therefore not only assists in establishing appropriate food safety

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<sup>3</sup> WHO, 1998. Food Safety- A world-wide public health issue. Internet WHO Homepage <http://www.who.ch/>.

<sup>4</sup> FAO/WHO 1984. "The role of food safety in health and development"- A Report of a Joint FAO/WHO Expert Committee on Food Safety.

<sup>5</sup> Buzby J.C.,and Roberts T. 1996. ERS Updates US Foodborne Disease Costs for Seven Pathogens. *Food Review*, 19:3 20-25.

control measures, but can also give early warnings about the state of the environment, such as level of heavy metal contamination, to enable appropriate action for maintaining its productivity.

Food supply systems in developing countries are often fragmented involving a multitude of middlemen. This exposes it to various types of contamination and fraudulent practices. Besides the public health implications, adulteration and fraud are of significant concern. Considering that in developing countries, people spend almost 50% of their earnings on food, and among lower-income households this figure may rise to above 70%, the impact of such fraudulent practices can be quite devastating.<sup>6</sup>

Developing countries have many competing priorities in their health agendas, and food safety has not, in the past, been recognized as a vital public health issue. However, it is becoming clear that foodborne disease has a significant impact on health. The globalization of the food trade and the development of international food standards have also raised awareness of food safety in developing countries. Placing it on the political agenda is the first vital step in reducing foodborne illness.<sup>7</sup>

#### **IV. International Food Trade Considerations**

The value of the world food trade in 1997 was about \$ 458 billion<sup>8</sup>, and is increasing every year, thanks to the expanding world economy, liberalization in food trade, growing consumer demand and developments in food science, technology, transport and communication sectors. International trade in food is also playing an increasingly important role in achieving food security for many countries. The benefits of international trade include the introduction of a wider variety of foods into markets thereby contributing to the availability of a broader choice of nutritious foods. It also provides food exporting countries with foreign exchange contributing to the economic development of those countries, and thus an improvement in the standard of living.

Access by developing countries to food export markets in general, and of the developed world in particular, will depend on their capacity to meet the regulatory requirements of importing countries. The long-term solution for developing countries to sustain or expand the demand for their products in world markets lies in building up the trust and confidence of importing countries in the quality and safety of the exported foods.

An examination of the recent food detentions of imported foods by the U.S. Food and Drug Administration indicates that many of the problems faced by developing countries are not related to highly technical or sophisticated requirements. At the top of the list are food hygiene problems represented by contamination of food with insects and rodent filth. Microbiological contamination comes next, followed by failure to comply with US low acid canned food registration requirements, and then labelling. Over 50% of the rejections are attributable to lack of basic food hygiene, and failure to meet labelling requirements. Dealing with these is well within the means of most developing countries and would go a long way in promoting export trade.

#### **V. World Trade Organization**

The Uruguay Round of Multilateral Trade Negotiations was concluded in April 1994 by the signing of the Marrakesh Agreement and it gave birth to a number of multilateral trade agreements to which all Members of the World Trade Organization, established in 1995, are committed. The Uruguay Round has been described as a turning point in the evolution of agricultural policy. For the first time, a

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<sup>6</sup> Malik R.K. 1981. "Food a priority for consumer protection in Asia and the Pacific region." *Food and Nutrition*, 7:2.

<sup>7</sup> "A Global WHO Food Safety Strategy: Safer food for better health"

<sup>8</sup> WTO 1998. WTO Annual Report 1998.

large majority of countries agreed to a set of principles and disciplines that will help to harmonize both national and international agricultural policies. The Uruguay Round achievement is contained in a series of agreements and ministerial decisions and declarations annexed to the Marrakesh Agreement, which established the World Trade Organization (WTO).

Two WTO Agreements are of particular interest from the perspective of food quality and safety as they introduce a measure of discipline to these areas in international trade. These are the Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement).

The SPS Agreement reaffirms that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirements that these measures are applied only to the extent necessary, are based on scientific principles and are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or as a disguised restriction on international trade. The SPS Agreement encourages Members to base their sanitary and phytosanitary measures on international standards, guidelines and recommendations, where they exist.

The TBT Agreement also recognizes international standards where they exist. It requires that technical regulations on traditional quality factors, fraudulent practices, packaging, labelling etc. (other than standards covered by the SPS Agreement) imposed by countries will not be more restrictive on imported products than they are on products produced domestically. Technical measures applied should not create unnecessary barriers in international trade, should have a legitimate purpose and the cost of their implementation should be proportional to the purpose of the measure. If the proposed measure is considered to violate the provisions of any of the two Agreements, it can be challenged and brought before the WTO dispute settlement mechanism.

There are significant challenges for developing countries related to the implementation of the SPS and TBT Agreements. To fully benefit from the Agreements, developing countries must improve their understanding of the Agreements and develop the necessary capacities to maintain their rights and meet their obligations .

The following is an overview of considerations related to capacity and technical assistance needs of developing countries related to their implementation of specific articles of the SPS Agreement:

#### Article 2 - Basic Rights and Obligations

Many developing countries face resource and capacity challenges to meet their rights and obligations under the SPS Agreement. The right to protect human, animal, or plant life or health goes beyond the potential trade benefits associated with adherence to the SPS Agreement. This right is consistent with the Rome Declaration on World Food Security which reaffirms the right of everyone to have access to safe and nutritious food and the fundamental right of everyone to be free from hunger.

#### Article 3 - Harmonization

Article 3(1) encourages WTO Members to harmonize sanitary and phytosanitary measures on as wide a basis as possible with international standards, guidelines or recommendations developed by international organizations, where they exist. These organizations include for food safety, the FAO/WHO Codex Alimentarius Commission; for animal health, the Office International des Epizooties; and for plant health, the International Plant Protection Convention.

Article 3(2) states that sanitary or phytosanitary measures which conform to international standards, guidelines and recommendations are deemed to be necessary to protect human, animal, or

plant life or health and are presumed to be consistent with the relevant provisions of this Agreement. However, even when developing countries base their standards and legislation on international standards, they frequently do not have the necessary capacities to ensure adherence to these requirements. They may, therefore, be unable to meet the sanitary measures and level of protection required by developed Member countries.

Article 3(3) allows Members to introduce or maintain sanitary or phytosanitary measures which result in a higher level of protection than would be achieved by measures based on relevant international standards, guidelines or recommendations if there is scientific justification, or as a consequence of the level of sanitary or phytosanitary protection that a Member determines to be appropriate in accordance with the relevant provisions of Article 5 (Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection).

The lack of scientific and technical expertise in some developing countries, particularly least developed countries, however sometimes limit their ability to justify their measures based on an assessment of risk and to fully understand or challenge sanitary requirements introduced by other Members.

Article 3.4 instructs Members to play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention.

Again, developing countries may be at a disadvantage in that they often lack the resources and/or expertise necessary to participate effectively in the work of the international organizations. This can result in their limited input into the development of standards and a lack of ownership in the process. It can also inhibit harmonization with and implementation of the adopted standards, guidelines and recommendations in these countries.

#### Article 4 - Equivalence

Article 4(1) directs Members to accept the sanitary and phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.

Article 4(2) directs Members to, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on the recognition of the equivalence of the specified sanitary or phytosanitary measures.

The development of equivalence agreements is facilitated where countries have the technical expertise, technical infrastructure and resources necessary to establish, implement and evaluate sanitary measures. This generally favours developed countries where such conditions exist and may result in less restriction for trade between these countries. Although limited in number, where such agreements have been developed, they can result in a shift of countries' import controls to foods from those developing countries that are unable to demonstrate equivalence. These situations may result in further marginalization of developing countries.

## Article 5 - Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

Article 5 (1) directs Members to ensure that their sanitary and phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

Many developing countries lack the technical expertise and/or resources to carry out an adequate assessment of risks. However, if their sanitary or phytosanitary measures are based on international standards, guidelines or recommendations, a risk assessment may not be necessary (Article 3.2). The inability to conduct risk assessments, however, prevents many developing countries from benefitting from the provisions of Article 3(3) and may impair their ability to challenge measures imposed by other countries or the consistency requirements related to those measures.

It is important that developing countries develop the capacity to assess risks and have access to the information on risk assessments of countries that impose sanitary or phytosanitary measures which are not covered by, or are more stringent than, international standards, guidelines or recommendations.

## Article 7 - Transparency

Article 7 requires that Members notify changes in their sanitary or phytosanitary measures and shall provide information on their sanitary or phytosanitary measures in accordance with the provisions of Annex B to the Agreement.

For transparency, Members are required to notify SPS enquiry points and national notification authorities. However, many Members have still not notified any SPS or TBT measures, and have not identified enquiry points. In addition, Members who notify do not always provide all the information necessary to judge whether the measure in question could affect other Members' exports. Enquiry points need to be able to follow the activities of all the government agencies involved in SPS or TBT measures, and provide information to Members upon request. They can also serve as important sources of information for their domestic industry on changes in the regulations of important export markets.

Developing countries frequently face challenges in meeting their obligations related to the publication of regulations, the establishment of enquiry points, and the notification procedures required. Again, this relates to inadequate infrastructures, resource constraints and the lack of modern information technologies.

## Article 9 - Technical Assistance

Under Article 9 (1), Members have agreed to facilitate the provision of technical assistance to other Members, especially developing country Members, either bilaterally or through the appropriate international organizations. Such assistance may be, *inter alia*, in the areas of processing technologies, research and infrastructure, including in the establishment of regulatory bodies. This assistance may take the form of advice, credits, donations, and grants, including for the purpose of seeking technical expertise, training and equipment to all such countries to adjust to, and comply with sanitary or phytosanitary measures necessary to achieve the appropriate level of sanitary or phytosanitary protection in their export markets.

Article 9(2) states that where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing

Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved.

A number of problems exist with respect to the implementation of technical assistance to developing countries. The first is that many developing countries are not fully aware of the agreement of Members to provide technical assistance under the SPS Agreement and therefore do not request the assistance. The second is that many developed country Members do not take adequate initiatives in providing the necessary technical assistance.

Technical assistance provided to date has in many cases been inadequate to permit developing country Members to meet their obligations and accrue the benefits of the SPS Agreement. Substantial investment and a coordinated and concerted effort among developed country Members and the appropriate international organizations, international banks and other potential partners is needed if the real challenges faced by developing countries are to be addressed.

#### Article 10 - Special and Differential Treatment

As with other agreements from the Uruguay Round, the SPS Agreement contains provisions for special and differential treatment of developing country Members. Article 10(1) directs Members in the preparation and application of sanitary or phytosanitary measures, to take into account the special needs of developing country Members, and in particular of the least-developed country Members.

Article 10(2) provides for phased introduction of new sanitary or phytosanitary measures with longer time-frames for compliance by developing country Members so as to maintain opportunities for their exports.

Article 10(3) enables the SPS Committee upon request to grant developing member countries specified, time-limited exceptions in whole or in part from obligations under the Agreement, taking into account their financial trade and development needs.

Article 10(4) states that Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations. While some support has been provided in the past, substantial financial commitments are necessary if developing country Members are to be able to fully prepare for and participate in the work of the relevant international organizations.

While many developing countries have successfully used international trade as a vehicle for development, many others have been left behind. The WTO Ministerial Declarations of 1996 and 1998 expressed concern over the marginalization of least-developed countries and certain small economies and asked the international community to make a particular effort to help them to take advantage of the opportunities offered by the international trading system.

For a number of countries, food safety considerations continue to be a top public concern to be addressed at the upcoming WTO Ministerial Conference in Doha this November.

#### **VI. Capacity and Technical Assistance Needs**

The food quality and safety systems and institutions of many developing and least developed countries suffer from a number of weaknesses which make them vulnerable in addressing food safety and quality issues. The weaknesses include all the basic elements of an effective national food control system including: basic infrastructure; national food safety and quality strategies and policies; food legislation; food inspection services; food control laboratories; effective participation in the work of international standard setting and trade related organizations; implementing quality and safety assurance

systems throughout the food chain; collaboration and cooperation of national and sub-national agencies; and scientific and technical expertise.

Improving the food safety and quality systems in developing countries requires a well coordinated and integrated set of actions. Capacity building and technical assistance needs include *inter alia* the following:

- ***Basic Infrastructure***

Strengthening food control systems requires considerable development in infrastructure. The setting up, equipping and maintaining of food control services, administration and laboratories requires investment. In many developing and least developed countries, investment in basic infrastructure including sanitation, potable water supplies and power supplies may be a prerequisite for addressing food safety and quality problems. In addition, substantial investment in information technologies is important to improve communication and access to relevant information.

- ***National Food Control Strategy***

Food control is by essence a multi-disciplinary activity that involves a number of government agencies as well as the food industry, consumers and academic/research institutions. It requires a method of close collaboration among all these participants with clearly defined responsibilities for each in order to make effective use of all existing resources. It should have clear objectives with a well designed plan and with operational responsibilities defined for all components of the system. It should have a monitoring provision that enables the evaluation of the effectiveness of the strategy on a continuing basis so that adjustments can be made as necessary.

Quality and safety of food have to be addressed throughout the food production, processing, storage and distribution chain. This is a multi-sectorial activity and its objectives cannot be reached without the active cooperation of producers, traders, industry and government and also the involvement of the scientific community. This can be achieved through a well-conceived national food control strategy developed with the support of the various participants. The strategy clearly lays down the role of governmental agencies, the food industry, and consumers and establishes mechanisms for cooperation and the means of dealing with existing or emerging food safety and quality challenges. It also ensures that available manpower and financial resources are utilized in a co-ordinated manner to achieve optimal results.

Leadership is essential to promote the development of a comprehensive food safety policy. Leaders must be able to convince government, industry at all segments of the food chain, and consumers of the need for support and the benefits that will accrue from improvements to food safety and quality systems.

- ***Food Legislation***

In many developing countries adequate food legislation does not exist. The establishment or updating of food laws and regulations is a necessary first step in establishing an effective food control system. This work should be carried out by a competent team of experts in food legislation and food regulatory requirements and should take into account, in particular, the obligations under the WTO, SPS and TBT Agreements. Attempts should be made, where possible, to base food safety and quality requirements on the standards, guidelines and recommendations adopted by the Codex Alimentarius Commission. There are further, specific needs of consumers and food producers, local sanitary constraints, cultural habits and other considerations, which should also be considered. Legislation

should be flexible enough to allow it to deal with developments in technology, emerging hazards, changing consumer demands, and new requirements for trade.

- ***Food Inspection Services***

Even when adequate food safety and quality legislation exists, the shortage of trained and adequately equipped inspection officials may compromise effective enforcement of the legislation. In order to be effective, food inspection officials should have well planned food inspection programmes, should understand their duties and responsibilities, and should maintain close collaboration with other food control services. This requires adequate management, training and equipment.

- ***Food Control Laboratories***

A sufficient number of adequately equipped food control laboratories, and trained analysts using acceptable analytical methodologies are required to support the monitoring, compliance and enforcement activities of the food inspection services. The overall quality of the work of the laboratory should be addressed by implementation of an analytical quality assurance system that meets international standards.

- ***Participation in the work of international organizations***

In order to input to and benefit from the work of international organizations such as the Codex Alimentarius Commission, many developing countries must strengthen their ability to participate effectively in these organizations. This frequently requires capacity building in the public, private and consumer sectors and may also involve coalitions around issues of mutual regional interest. This can be accomplished by establishing national Codex committees that are able to prepare national positions related to the work of the Commission and that can consult regionally.

- ***Implementing Quality and Safety Assurance Systems in the food industry***

In all countries the food industry bears the responsibility of meeting food quality and safety regulatory requirements and all segments of the food chain have responsibility for establishing food safety and quality controls. The industry needs to be trained on the application of good agricultural, hygienic and manufacturing practices and the use of the Hazard Analysis Critical Control Point System. There is a concurrent need to train official food control inspectors in these approaches and in systems of inspection and audit. Interaction and cooperation between industry and government on food control matters frequently needs to be strengthened to address food safety and quality throughout the food chain.

As a first step in addressing food safety and quality issues, there is a need to develop good agricultural and on farm food safety practices. Establishing controls for production practices, the application of pesticides and veterinary drugs at the production level, and prevention of contamination of crops by contaminated water or environmental contaminants should be included in these practices.

- ***Collaboration and Cooperation of Control Agencies***

Frequently, a number of different agencies have responsibilities for aspects of food safety and quality. It is important that all agencies involved in food safety and quality, including all national and sub-national government agencies, work in an integrated and coordinated manner to ensure adequate control of all aspects of food safety and quality throughout the food chain and to maximize the impact of limited resources.

Food safety systems may differ in focus from that of animal and plant health systems; however, there are important opportunities for cooperation as there are strong linkages among the three systems. First, some animal diseases are zoonotic and can be transmitted to humans, so improving animal health is frequently linked to food safety. In addition, the use of veterinary drugs, if not adequately controlled, can have implications for food safety as the residues may be present in food. Similarly, some plant diseases or inadequate control measures involving the regulation and application of pesticides may result in unacceptable residues in food. Second, similar regulatory approaches may be used to reduce risks in all three areas, so developing food control systems to address all three has some economies of scope. Third, improvement in all three areas may be a prerequisite for entering international trade, and thus need to occur simultaneously. Fourth, all three areas fall under the SPS Agreement and thus are addressed in the same way in terms of the requirements for measures, dispute settlement, notifications, and enquiry points.

Developing an effective strategy to reduce foodborne disease is also facilitated through accurate reporting of foodborne illness, epidemiological surveillance and information related to the potential hazards in the food supply. This frequently requires investment of resources and strengthening of collaboration between health and agriculture ministries at both the national and sub-national levels.

Lack of coherence among different governmental activities concerning agriculture, food, fish, trade, industry and health does not achieve optimal results. Significant opportunities may exist for sharing of expertise, inspection resources, laboratory facilities and administrative support. This is important from the perspective of optimal utilization of limited expertise and resources.

- ***Scientific and Technical Expertise***

There is a need to develop capacity in most developing countries related to scientific and technical expertise. The development of risk analysis capacity is needed to meet the obligations of the SPS Agreement and to identify and prioritize food safety issues within these countries. Food safety measures introduced should be based on an assessment of risk and managed based on priorities both from a human health and economic perspective.

The need for scientific and technical expertise is particularly relevant with respect to the assessment of agricultural products derived through modern biotechnology. All new living modified organisms and their products should be subjected to a rigorous environmental, livestock feed and food safety assessment before they move into the marketplace. In addition, other obligations related to ratification of the Cartagena Biosafety Protocol will need to be addressed.

## **VII. New or Strengthened Approaches to Capacity Building and Technical Assistance**

- ***Building Alliances***

Recognizing the need to assist developing countries in improving their food safety and quality systems, many international organizations, national governments, international and regional banks, and NGOs have undertaken various capacity building and technical assistance activities. While many of these activities have contributed to strengthening specific elements of food safety and quality systems, they frequently have not been coordinated or placed in the context of an overall food safety and quality strategy or development plan. As a result, many of these activities have been ineffective or inadequate in achieving optimal or sustainable results. In addition, many of the specific needs have yet to be addressed.

It is apparent that there is a need to improve the collaboration and coordination among various agencies involved in capacity building and technical assistance activities and where possible to develop alliances among the organizations to provide such assistance.

A number of collaboration and coordination efforts are presently underway at the international level. One such effort is the WTO Integrated Framework for Trade-Related Technical Assistance to Least Developed Countries. This Framework is aimed at improving the overall capacity of least-developed countries to respond to the challenges and opportunities offered by the trading system. The WTO, UNCTAD, ITC IMF, World Bank and UNDP have established an Integrated Framework for the provision of trade-related technical assistance, including human and institutional capacity-building, for supporting trade and trade-related activities of the least-developed countries.

The Framework is intended to enable each agency involved to increase its efficiency and effectiveness in the delivery of trade-related technical assistance activities. The Framework will permit each agency to design and tailor its individual efforts to meet the needs of least-developed countries in the light of full information about the specific needs of each country and about current and projected activities being undertaken by other agencies in the area of trade-related technical assistance. It will allow the trade-related technical assistance activities of all the agencies to be properly coordinated, sequenced and synchronized.

This Framework could serve as a valuable model to consider in building more specific alliances related to capacity building and technical assistance in the area of food safety and quality systems.

The World Bank has a very important role in capacity building and technical assistance as it has expertise and experience in project design and management and thus is an obvious complement to the specific technical assistance expertise and experience of the international community. The Bank already has under way substantial programs to support developing country participation in upcoming WTO negotiations and has initiated a program to build implementation of WTO standards into regular development projects. Bank projects supporting SPS systems have typically placed these measures in a general development context of ensuring food security, increasing agricultural productivity and protecting health, rather than focusing on the narrower objective of meeting stringent requirements in export markets.

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have extensive specific expertise and experience regarding the development of international standards through the Codex Alimentarius Commission and in providing technical assistance related to various food safety and quality measures. They also provide expert advice on food safety and quality matters through the Joint Expert Committee on Food Additives and the Joint Meeting on Pesticide Residues and through expert consultations on other related food safety and quality matters. Both FAO and WHO have also produced manuals on numerous elements of food safety and quality and have developed and delivered associated training programmes. Other international organizations and national governments involved in capacity building and technical assistance activities would benefit through closer cooperation and collaboration with both FAO and WHO in the planning and implementation of these activities.

FAO has recently proposed the establishment of a “Food Safety and Quality Facility for LDCs” to address food safety and quality concerns and to improve the competitiveness of their products in international markets. The Facility will require the establishment of a trust fund to support the rapid and sustainable upgrading of the food safety and quality assurance capabilities of LDCs. The trust fund would support projects to develop, rehabilitate, upgrade and sustain national food safety and quality assurance systems in the 49 LDCs, their compliance with international food safety and quality requirements and their participation in the international standard setting bodies. The resources of the Facility would consist of voluntary contributions from interested bilateral and multilateral donors. It is

estimated that the implementation of projects to achieve the objective of the Facility within three to five years would require, on average US\$ 2 million per country, or US\$ 98 million for the 49 LDCs.

Another interesting approach to capacity building is the Inter-American Institute on the Cooperation on Agriculture (IICA)/Ceres Executive Leadership Seminar in Food Safety: A Programme Designed to Promote Leadership for the Development of Comprehensive Food Safety Policy. This two year seminar program recognizes that leadership is essential to promote development of comprehensive food safety policy. The programme is designed to develop professionals in agriculture, health, and food safety systems (both public and private) into food safety leaders by providing critical information and expertise. The objective is to provide more effective management and improved food safety policies in the countries involved.

Numerous other capacity building and technical assistance initiatives continue to be undertaken by other international and regional organizations and bilaterally by individual countries and NGOs. Unfortunately, very often information available is not shared and activities are not coordinated. It is clearly apparent that improved coordination and collaboration is necessary in order to bring the resources, approaches and collections of expertise together in a way that maximizes the positive impact of the resources applied.

Capacity building and technical assistance related to food safety and quality are costly and therefore would benefit from the coordinated investment and collaboration of all agencies involved. To enable each agency to increase its efficiency and effectiveness in the delivery of technical assistance activities, specific mechanisms should be developed to improve communication, coordination and cooperation among these agencies. These mechanisms are needed to permit each agency to design and tailor its individual efforts to meet the needs of developing countries in the light of full information about the specific needs of each country and about current and projected activities being undertaken by other agencies. This could result in more focused assistance, improved coordination and sequencing, and synergism of activities.

There is a need for a regular review and evaluation of the technical assistance provided to individual developing countries. This review should involve all of the agencies involved and officials of the developing countries concerned. The purpose is to evaluate the effectiveness of the assistance provided in meeting its objectives and, if needed, to make any necessary adjustments in the approach.

- ***Communication and Exchange of Information***

One of the first steps in building alliance is the establishment of clear lines of communication between interested agencies to provide for the regular exchange of information related to technical assistance activities provided or under consideration. This communication would enable the agencies to avoid overlap and duplication and allow them to properly sequence and synchronize technical assistance in specific countries. This communication could take the form of regular meetings of involved agencies, an inventory of technical assistance needed, an inventory of technical assistance provided, a rosters of experts in various subject areas, compilation of resource or reference materials, information on training, workshops, seminars etc. Each agency involved could contribute to the information by establishing and maintaining a database, by country, of the technical assistance activities they undertake.

International organizations such as FAO and WHO would be well placed to coordinate this work and to develop the appropriate data bases to which each agency could input and access. The technical cooperation programs of all organizations involved could benefit from the information provided. The information would also be useful to the SPS Committee in reviewing the technical assistance needs and related activities of Member countries and international organizations.

- ***Needs Assessment and Country Profiles***

Capacity building should start with an assessment to identify the specific needs and to develop an optimal approach to meeting these needs. To enhance ownership and to ensure that the overall process is properly demand-driven, the needs assessment should be carried out by developing countries themselves. However, frequently developing countries may require assistance in completing their needs assessment and this could be provided by the appropriate international organizations. When preparing its needs assessment a developing country should actively involve all appropriate government departments, its private sector and appropriate non-governmental organizations.

The needs assessment process is facilitated by the development of a country profile that includes a review of existing legislation and regulations, food inspection activities and agencies involved, laboratory capacities, public health concerns, priorities for export access etc. The objective of the country profile is to obtain an overall appreciation of the needs for capacity building and technical cooperation broadly defined to include technical assistance and human and institutional capacity building, both in the immediate and longer term.

The results of this needs assessment would provide useful information on which to design a coherent and integrated approach for internal actions and external assistance to meet the specific needs of individual countries. Capacity building and technical assistance activities could then be based on the needs assessment and these activities could be prioritized, designed and sequenced to meet the specific needs most efficiently and effectively. The specific assistance provided should be coordinated by the international agencies and all other parties involved, taking into consideration the agencies' respective mandates, resources and expertise.

- ***Financing***

Each of the agencies involved should finance from its existing resources - or, as necessary, should seek additional finance from the international and regional development banks and donors with the active support of the developing country concerned, to implement the capacity building and technical assistance activities. Where resources additional to those currently available for technical assistance activities are required, they may be mobilized through bilateral and multilateral channels, including from both traditional and non-traditional sources. Where needs are broader in nature than the specific technical assistance activity, these could be submitted collectively for financing to the development banks and donor community.

- ***Technical Cooperation Between Countries***

Specific bilateral technical assistance has been provided by developed countries to developing countries in response to the technical assistance provisions of the SPS Agreement or in response to specific market access or developmental needs. Also many developed countries have specific agencies and programs for capacity building and technical assistance.

There have also been successes where the strength of one developing country has been matched with the needs of another with mutual benefit for both. The UN system has been encouraging this approach of Technical Cooperation among Developing Countries (TCDC). Food control can benefit from this approach, particularly in manpower development and capacity building. Emergence of a number of regional economic groupings, growing food security needs, and trading interests of many developing countries, have improved the scope for TCDC.

Such assistance, however, should be considered in terms of the broader framework of the developing country's overall needs. This assistance would also benefit by interaction and coordination with capacity building and technical assistance activities provided by other organizations.

Opportunities may exist to further develop this type of assistance through institutional cooperation programs between specific agencies, inspection services, laboratory networks, research centers, universities and other appropriate institutions of developed and developing countries. Under this arrangement, the institution of a developed country would be coupled with the institution in a developing country to assist in strengthening their capacities.

- ***Regional Approaches***

Whenever needs common to developing countries in a particular region can be identified, interested agencies should collaborate in providing appropriate technical assistance activities to meet these needs.

Opportunities for regional cooperation could include the establishment of regional training centers and programs, laboratories networks, risk analysis units, regional food safety and quality information repositories etc.

## **VIII. Conclusions**

Many developing countries, especially the least developed, presently have neither the capacity nor the resources to fully face the challenges or take advantage of the opportunities flowing from the Uruguay Round. Strengthening the food safety and quality capacities of these countries is urgently needed in terms of improving food security, public health and international trade opportunities.

A concerted effort is required to meet the capacity building and technical assistance needs of developing countries. Action is required to improve cooperation and collaboration between the various organizations involved and to build alliances so that the available resources are optimally applied. International organizations such as FAO and WHO are well positioned to take leadership in building alliances, establishing frameworks for exchange of information, and coordinating capacity building and technical assistance activities related to food safety and quality.

GF 01/11

## SUPPORT OF THE NETHERLANDS TO CAPACITY BUILDING IN DEVELOPING COUNTRIES

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### 1. Introduction

I would like to put the support of the Netherlands to capacity building in developing countries in the context of globalization and liberalization.

To start with globalization: especially during the last decade of the 20<sup>th</sup> century, consumer preferences have markedly shifted in the direction of higher quality products that are safe, authentic and produced under acceptable health, environmental and social conditions. This shift towards experience and credence attributes not only implies higher product standards, but also more emphasis on process characteristics. Markets have therefore changed from primarily bulk supply to differentiated products for a variety of consumers. Private business has responded quickly and introduced stricter standards in processing and more extensive labelling to communicate non-observable product attributes effectively to consumers. Since the Marrakesh agreement this process of globalization takes place in the context of rules established by the WTO. Although considerable progress has been made since the Second World War through various rounds of GATT negotiations in lowering explicit barriers to trade such as tariffs, only since the WTO trade in agricultural products came for the first time under the discipline of the multilateral trade rules. The most recent Uruguay round in particular resulted in significant commitments to liberalize trade. In particular, significant reductions in tariffs were achieved for tropical agricultural products that are of the greatest interest to developing countries.

Liberalization of agricultural markets has been on the agenda of policy makers and international organizations since the beginning of the 1980's. To a large extent this reflected the growing recognition that widespread government intervention in markets was much less effective than previously expected, while negative side effects resulted in misallocation of resources, reduced economic growth and often adverse impact on equity and environment. Gradually, policies in the industrialized world became increasingly oriented towards less government interference, and were characterized by a simultaneous shift from national to supranational regulations. Developments in Eastern Europe, the former Soviet Union and China took a dramatic change towards more freedom for individual and communal market participants. In much of the developing world, policy reforms under structural adjustment programs led to a redefinition of the government in relation to agricultural markets. As a result of these national and international developments, agricultural markets world-wide entered a long-term process of liberalization. As tariff barriers have declined, however, the emphasis placed on non-tariff barriers has increased, both due to the global proliferation of non-tariff measures and because of wider recognition of the impact non-tariff barriers can have on trade. There is now concern that such technical measures can act, either explicitly or implicitly, as a barrier to trade in a similar manner to tariffs and quantitative restrictions. This is a particular issue for developing countries in view of their lower technical capabilities and the importance of agricultural exports. Attempts have been made to overcome the trade distortive effects of sanitary and phytosanitary measures and technical requirements through the WTO's SPS and TBT Agreements.

It is evident that developing countries are constrained in their ability to export agricultural products to developed countries by SPS requirements. Indeed, a number of developing countries consider SPS requirements to be one of the greatest impediments to trade in agricultural products. This reflects the fact that developed countries typically apply stricter SPS measures than developing countries and that SPS controls in many developing countries are weak and overly fragmented. Furthermore, in

certain circumstances SPS are incompatible with prevailing systems of production and marketing in developing countries. As a consequence, wholesale structural and organizational change may be required in order to comply, and the associated costs can act to restrict trade in a similar manner to tariffs. The problems developing countries have in complying with SPS requirements reflect their wide resource and infrastructure constraints that limit not only their ability to demonstrate compliance. A particularly acute problem is access to appropriate scientific and technical expertise. Indeed, in many developing countries knowledge of SPS issues is poor, both within government and the food supply chain, and the skills required to assess SPS measures applied by developed countries is lacking.

This paper intends to show the efforts of the Netherlands to support capacity building in developing countries in order to overcome these institutional constraints.

## **2. Efforts of international organizations**

Before giving this information I would like to give a short overview of efforts of international organizations to support developing countries to capacity building on food safety in order to put the efforts of the Netherlands in a proper international perspective. The Netherlands supports these efforts of international organizations.

To start with the FAO, the FAO assists efforts to strengthen the physical and institutional trade-related capacities of developing countries. Examples of such support include establishing or adapting legislation, regulations and systems to comply with the WTO agreements relating to agriculture; upgrading domestic SPS/TBT mechanisms to strengthen capacity to meet the standards and norms of the international market place. In particular the FAO assists in:

- the strengthening of national veterinary services to provide them with the capacity and skills to adopt and apply risk analysis techniques effectively;
- the development of national food legislation, taking into account the SPS and TBT Agreements;
- the establishment and strengthening of national food control systems for both imports and exports;
- the updating of national plant and animal quarantine programmes.

WTO, UNCTAD and ITC Secretariats, in collaboration with the staff of the IMF, the World Bank and the UNDP, have an Integrated Framework for trade related technical assistance, including human and institutional capacity-building, to support least developed countries in their trade and trade-related activities. The aim is to assist the least developed countries to enhance their trade opportunities, to respond to market demands, and to integrate into the multilateral trading system. Trade-related technical assistance activities may encompass institution building to handle trade policy issues, including enhancing capacities to make and implement trade policy consistently with WTO obligations.

Also the World Bank seeks to assist developing countries to find solutions to trade-related food safety problems. The World Bank can assist developing countries to formulate the necessary policy, regulatory framework, and establish institutions and national capacities to meet and implement their WTO commitments. The goal is capacity and institution building that will lead to effective action with shared benefits. A public/private collaboration can result in the formulation of interest groups and associations, possibly on a regional basis, that will influence regulators to adopt systems that will facilitate production and trade. A regional approach can be cost-saving solution for countries to cooperate as a region to fund research, laboratories and certification systems.

### 3. Technical assistance of the European Union

As the Netherlands is a Member State of the European Union (EU) I would like to give some information on the technical assistance of the EU to developing countries.

External assistance programmes managed by the European Commission have tripled over the last 10 years to reach 12.3 billion Euro in 2000. The European Commission currently delivers more than 10 per cent of total development assistance world-wide. External aid programmes are managed by it directly and constitute 62 per cent of all its accounts. EC grant aid exceeds concessional loans granted by the World Bank. Examples of this assistance are the following:

- a Pan African Programme for the Control of Animal Diseases for the ACP countries except the Southern African Region. The target group consists of all actors involved in the livestock-farming sector. The aim is to establish lower-cost national and continental epidemiological surveillance networks for the main animal diseases, provide the countries with the capacities needed to organize economically and technically justified control programmes and develop effective and sustainable distribution of veterinary products and services.
- a Special Framework of assistance for traditional ACP suppliers of bananas. The target group consists of certified banana farmers and related people in rural areas, growers associations, public authorities and private sector companies. The aim is to assist in the development of sustainable and viable banana industry, which can withstand competition from other ACP banana producing states and Latin American producers; to assist former banana growers in switching towards other activities.
- a Pesticides Initiative Programme for all ACP-countries. The target group consists of producers and exporters of fruits and vegetables in the ACP countries. The aim is to assist the target group to comply with EU sanitary and phytosanitary rules.
- a Southern Africa Animal Disease Control for the SADC countries. The target group consists of national and regional animal health authorities. The aim is to reinforce the capacities of the countries in the region to control animal diseases, to monitor the circulation of animals and animal products and to exchange epidemiological information at national, regional and international level.
- a Regional Animal Health Programme for Egypt, Israel, Jordan and West Bank Gaza. The target group consists of veterinary services. The aim is to promote a closer co-operation of the national veterinary services in the region in order to improve the animal health situation and make the control of animal diseases more cost efficient.
- Four seminars on SPS and trade related issues organized by FAO and financed by the European Commission for Jamaica, Cameroon, Zambia and Ethiopia.

To illustrate the technical assistance of the EU to developing countries I will elaborate on one example. The example is a project to strengthen the capacity in ACP countries for fishery product health conditions. The specific purpose is to improve the access of ACP fisheries products to the world market, by strengthening the capacity for sustainable export health controls and improving production conditions in an estimated 17 ACP countries, 10 of which are situated in sub-Saharan Africa. Particular attention is to be paid to ensuring that products from small-scale fisheries are not excluded from the global market, and to strengthening regional networks of veterinary and health professionals in the sector. The focal point is the loss of access to international markets for fishery products through a lack

of capacity to respond to requirements for strengthened health controls. Many ACP countries lack the legal, technical, financial and organizational resources to meet the import health conditions required by these developed country markets. In addition to lack of adequate official control, industry itself is often unable to respond to the higher level requirements due to the lack of technical skills, capital for investment in upgraded establishments and weak or non-existent infrastructure in productive regions. The activities of the project will therefore support ACP countries in institutional strengthening of competent authorities through training and technical assistance for improved organizational structure, legislation and financial sustainability. Supporting technical institutes will also be strengthened, as well the inspection and control agencies. The analytical capacity of official testing laboratories will be developed with the supply of new equipment, training and the introduction of suitable systems of quality assurance. Appropriate residue monitoring plans for fishery products will also be introduced.

#### **4. Efforts of the Netherlands: the Center for the Promotion of imports from Developing countries (CBI)**

Firstly I would like to give information on the results of a study on technical non-tariff barriers affecting trade opportunities for developing countries, the case of fresh fruit and vegetables. This study has been prepared by the Center for the Promotion of Imports from developing countries (CBI) in the Netherlands.

Increased demands of European consumers with respect to food quality and safety have resulted in more strict regulations and standards, reflected in the framework of “Good Agricultural Practice”. This framework requires companies to have a good management system in place to deal with quality, hygiene and environmental matters. It puts forward demands on the company’s registration system, stock material used, soil treatment, pesticides and fertilizers used, post-harvest treatment, processing and packaging, waste management, environmental management and workers’ health and safety.

As first impact studies of new European regulations on pesticides have pointed out, the horticultural sector of developing countries is likely to be seriously affected, as responsibility in food safety matters is increasingly weighing heavily on the companies. European buyers ask suppliers for increased guarantees on pesticide levels.

Producers of fresh fruit and vegetables mentioned the following problems:

- not being familiar with the regulations and the interpretation thereof;
- the administrative burden and the lack of technical assistance to identify and implement necessary measures;
- difficulties in complying with environmental and health regulations, such as MRLs. These producers find it hard to avoid using pesticides. In some countries products are still fumigated for decontamination, a treatment not allowed for products entering the EU. Alternative treatments are often not available.
- variations in product definitions and specifications.
- increasingly, labelling requirements for consumer products in the EU are partly passed on to producers and exporters in developing countries. Importers and food manufacturers require thorough product specifications for application, instructions for storage and processing, and information on quality assurance (HACCP or ISO-certification).

As regulations on residues of pesticides and heavy metals are becoming more and more strict, it is crucial for producers and Trade Promotion Organizations in developing countries to have up-to-date information on the regulations and solutions in terms of improved techniques and treatments. Although the Center for the Promotion of Imports from Developing countries and other organizations are

providing assistance in this respect, much more (international) effort is needed to help developing countries to adopt and implement food safety control systems, such as HACCP.

One of the important bottlenecks for the export of organic food by developing countries is the high costs of mandatory certification for producers to enter the international market. When a producer or a group of producers applies for certification, several inspection missions follow in which the production system is judged and recommendations are made for improvement. Since very few developing countries have an accredited local certified, the inspectors often come from Europe or the USA.

Payments have to be made directly after an inspection mission. These initial investments only start to pay back after the first harvests have been sold as organic. After certification, at least one inspection mission is conducted annually. Certification by international certifiers is relatively expensive, since European fees and travel costs have to be paid. For many producers the costs of certification are a major threshold for venturing into the international market. International certification costs a maximum of 5 percent of sales value, but where local certification bodies exist it reduces to 2 percent of sales value.

Conversion from conventional farming to organic farming takes about two to three years. During this period a farmer may not sell his production under the organic label and cannot take advantage of the higher prices normally associated with organic products. The transition is even more difficult for developing country producers as they, generally, do not benefit from specific State aid as is the case for farmers in developed countries.

Developing countries face an additional difficulty. As emphasized by the certification body Ecocert International, the European Union regulation corresponds to the European situation, but the African reality is far different. A clear definition of the production unit is not always easy. It is, for example, sometimes difficult to make developing country operators aware of the differences between traditional farming and organic farming using specific farming techniques. Finally, developing countries' lack of infrastructure results in slowing down organic production because of the limited shelf life of the products.

The Center for the Promotion of Imports from developing countries initiated a new programme, which aims to enhance the fresh fruit and vegetable sector in selected African countries through technical assistance in the field of farm and export management. Aim of the programme is to address some of the critical Technical Non-Tariff Barriers and to build up local institutional capacity. The programme is expected to benefit a great deal from the experience obtained through a similar farm and export management programme for cut flowers that is currently implemented in eastern and southern Africa.

Key elements of the initiative are:

- Identification of national and international organizations (public and private) offering assistance in the field of fresh fruit and vegetables;
- Preliminary assessment of strengths and weaknesses of eligible and qualifying African countries, opportunities and threats, qualifying countries' policies towards the sector, current export markets, analysis of main competitors for the selected countries;
- Comparison of qualifying African countries and interesting product/product mix; interest of European importers, auctions and supermarket chains in the products of these countries based on interviews regarding attitudes, experienced problems and bottlenecks, continuity, requirements and preconditions, business practice and terms of the trade;

- Further elaboration of regional and country-specific strategies for the selected developing countries, on the basis of feasibility studies, identification missions and needs assessments. These strategies entail close consultation with other actors, for integrated approaches are required to overcome bottlenecks and problems related to exports of the selected products: tariffs and quota; certification and labeling; quality and grading standards, health, safety and environmental issues;
- Elaboration of GAP/EurepGap; seeds and propagation material; cultivation; harvest; primary processing; packaging; storage and transport; equipment and technology; personnel and facilities; documentation; education and training ; knowledge/training centres, experimental farms; quality guarantees, testing and laboratories;
- Elaboration of solutions: institutional capacity for exporting fresh fruit and vegetables; assistance by other organizations and possibilities for assistance in farm and export management; opportunities for partnerships and business-to-business arrangements; regulations and assistance for getting access to EU markets, including buying/selling missions and/or trade fairs.

## **5. Efforts of the Netherlands: the EUROPE SADC INITIATIVE**

Secondly I would like to give information on the EUROPE Southern African Development Community (SADC) INITIATIVE. This initiative has been taken within the context of the trade liberalization objectives of SADC Member States. These objectives are enshrined in the Protocol on Trade that entered into application on 1 September 2000. The coming into implementation of the Trade Protocol underscores the urgent need of Member States to harmonize SPS measures required to increase trade in agriculture and agro related products and for development of improved food safety standards. While SADC has made substantial efforts in recent years in setting standards of trade in non-agricultural products, especially manufactured goods and textiles, standards and grades required for trade in agricultural commodities need to be put into place to guide both intra-SADC and/or external trade in agriculture for the economic benefits of a wide range of regional stakeholders, especially smallholders who depend on agriculture for their livelihood.

With globalization and increased trade both within SADC and with the outside world, issues of food safety have also taken on renewed prominence. In many developing countries, a major cause of child mortality is unsafe food caused by poor sanitation and lack of clean water. Food safety issues are not only of importance for the consumers of the developed nations, where SADEC products are sent, but also for exporters of SADC Member States who are required to meet quality and safety standards in a more competitive global market place. Within SADC itself, food safety is now clearly a critical factor in domestic nutrition and health of the citizens of Member States. Given the limited resources and low technology base of some SADC Member States, special efforts must be made to guarantee and certify the safety of export products, in an efficient manner, while ensuring that food products available for the consumption of citizens of the Member States also meet improved safety standards.

The SADC Trade Protocol specifies that Member States shall base SPS measures on science, in accordance with the WTO Agreement. They should also harmonize such measures, so that food safety and SPS concerns are mitigated for the implementation of the Protocol. However, there is little information on the extent to which individual Member States are in compliance with international standards or whether the steps that must be taken to meet these standards have been taken. In many countries these efforts are hampered by technological and capacity constraints, the lack of clear information and data for undertaking such assessments and monitoring their outcomes, and the lack of trained staff and modern laboratories to scientifically confirm compliance with required standards.

The EUROPE/SADC INITIATIVE is a Dutch initiative aimed at achieving further regional co-operation in the area of agriculture between countries in the EU and SADC. This has become necessary

as a result of current agricultural developments. The Netherlands have co-operated with the United Kingdom and Portugal. At this moment also the European Commission, Sweden and Belgium are included in the cooperation.

This initiative also contributes to international agreements on food security and sustainable agriculture made at the World Food Summit in 1996, Agenda 21 and the Maastricht Conference ‘Cultivating our Futures’ (September 1999) and the 8<sup>th</sup> session of the Commission on Sustainable Development (April-May 2000). The emphasis was among others on the following elements: international regional co-operation in the area of agriculture can contribute to the implementation of the “World Food Summit Plan of Action”; regional and international co-operation through private and public partnerships between developed and developing countries must be strengthened. In this way a contribution can be made to the realization of food security at the individual, household, national, regional and international levels. A Dutch NGO helped to get this initiative off the ground and is still acting as a focal point for cooperation with farmer’s organizations and NGOs. In the coming decades the challenge will be to achieve food security for a growing world population. Studies have shown that within the next thirty years food production should be doubled. Key words here are sustainability, production increase and equal access.

In many developing countries agriculture is the driving force for the economy and rural development. In these countries 60 to 70% of the working population is employed in the agricultural sector. Agriculture is therefore of crucial importance for the achievement of food security and the fight against poverty. And it helps to achieve stability in these countries and regions. Food shortage and over-exploitation of natural resources can be a source of conflict. Agricultural developments are closely linked to international nature policy. Thus, for example, the global problem of deforestation can only be resolved when alternatives can be found in agriculture.

The issue of capacity-building and institution-building is in this respect of utmost importance. Capacity-building and institution-building not only have to serve as the base for a strong development of the agricultural sector and rural development, but can also contribute to a strengthening of market-access of products of developing countries.

The regional approach of the initiative is very important: a strengthening of the co-operation in the field of agriculture between developing countries in various regions is essential for further agricultural development and a strong position on the global market. The initiative aims at a political dialogue and institutional co-operation in the field of agriculture between the ministers of agriculture in the Countries of the Southern African Development Community (SADC) and the EU in the field of a number of concrete themes. This means co-operation directed to furthering sustainable agriculture and food security. An integrated approach of governments, farmers’ organizations and non-governmental organizations is used. This co-operation could be realized under the umbrella of annual structural consultations between the ministers of agriculture of the EU and the SADC. The co-operation will in first instance be focused on the political dialogue in the field of agriculture and a work-plan in the field of co-operation and assistance, focused on capacity-building and institution-building.

The following four topics are identified: Food Security; Food Safety; Trade in agricultural products and Sustainable agriculture. Considering the results of the international meetings on sustainable agriculture and food security mentioned above these topics cover most of the ground on which fruitful consultations between ministers of Agriculture from EU- and SADC-member states could take place. However, these are very broad areas and there is a certain risk that the results of the cooperation just do reflect the intentions and commitments agreed upon in the conferences mentioned above. On top of that there is a need to formulate some action-oriented items on which the two regions can cooperate in a concrete manner.

In the framework of the initiative a conference will be organized, hosted by the Government of Namibia and financially assisted by the Netherlands. That conference would take place in Windhoek, Namibia, from October 14<sup>th</sup> till October 17<sup>th</sup>, 2001. Ministers of Agriculture from both regions would participate. Unfortunately this conference has been delayed for different reasons. The four topics mentioned above will be discussed in an general way, but also with a view of identifying the necessary action-oriented items for concrete cooperation. One of that items could be the development of necessary capacity and institutional frameworks in developing countries to comply with the requirements of developed countries and thereby enhancing the market access of developing countries. Interregional cooperation is of the utmost importance in these matters. The goal of the conference is to have an initial exchange of ideas on policy aimed at institutional co-operation which promotes sustainable agriculture and food security and to work these ideas out in some detail. The results of the conference should include apart from the intentions to continue the political dialogue some action-oriented items on which the two regions could cooperate in an concrete manner. This co-operation will involve governments, agricultural organizations and NGOs.

## **6. Efforts of the Netherlands: ASEM seminars on quarantine/SPS**

Thirdly, I would like to give some information on the ASEM seminar on quarantine/SPS in The Hague in September 2000.

The central theme of seminar was the use of Risk Analysis to underpin SPS measures. This seminar covered veterinary matters, phytosanitary matters and food safety. During the last seminar it has been decided that the general exchange of information in the general seminars had been completed and that what was needed subsequently was an analysis in depth which could be done more appropriately in specific workshops. Therefore this workshop in Bangkok is limited only to food safety. Subsequently a workshop on veterinary matters will be held in the Netherlands and a workshop on phytosanitary matters will be held in China. Lastly a wrap up workshop on all three subjects will be held in the Netherlands. All three will be held in 2002. Representatives of seven Asian countries, six countries of the European Union and the European Commission and of four International organizations attended the ASEM seminar in The Hague. Moreover, representatives of the business sector participated in a special session, focused on impediments to trade caused by SPS measures.

The seminar was opened by the Minister of Agriculture, Nature management and Fisheries of the Netherlands, the Chief Administrator of the State Administration of Entry-Exit Inspection and Quarantine of the People's Republic of China and the Director of the Agricultural Regulatory Division from the Ministry of Agriculture and Co-operatives of Thailand. The seminar was divided into 3 parts: the first part consisted of a plenary session, the second part consisted of workshops in the different fields (veterinary matters, phytosanitary matters and food safety) and the third part consisted of a plenary session to draw recommendations.

In the first plenary session representatives of the Codex Alimentarius, IPPC and OIE gave presentations on the use of Risk Analysis in their respective fields of work. An official of the WTO secretariat gave a presentation on the benefits to trade of the WTO/SPS agreement. In the second part of the seminar presentations were given and discussions were held on specific items. This was done in working groups on veterinary matters, phytosanitary matters and food safety. In the Food Safety Working Group, presentations were given by France, China, Thailand, the European Commission and Belgium. France gave a presentation "Specific Risk Analysis case: vibrio in seafood, China on "Risk Analysis and HACCP", Thailand on "Application of Risk Analysis: stevia", the European Commission on the dioxin crisis and Belgium on "CONSUM, the post Belgian dioxin era: a new approach for feed and food control". In addition to the representatives who gave a presentation the meeting of this group has been attended by Denmark, Finland, Italy, the Netherlands, the Philippines, Singapore, South Korea, Spain, the United Kingdom, the European Commission, the Codex Alimentarius and the WTO.

As regards Risk Analysis in general it has been stressed that, although Risk Analysis is a relatively new concept, the principles of Risk Analysis have been used in regulatory processes of several ASEM partners for many years. ASEM partners were of the opinion that the Risk Analysis approach is a very useful tool for the protection of the health of consumers and improving transparency. However, concerns were made on the implementation of the three elements of Risk Analysis.

As regards Risk Assessment, this was considered the most difficult element. Problems in carrying out risk assessments arise from lack of quantified data, lack of relevant research and lack of statistical validity in published research. Also accurate exposure assessment was considered highly difficult. It was suggested that Risk Assessment be carried out by international expert bodies of FAO and WHO such as JECFA and JMPR in order to save resources and acquire overall acceptance.

As regards Risk Management, even though according to the proposed draft Codex working principles for Risk Analysis there should be a functional separation of Risk Assessment and Risk Management in order to ensure the integrity of Risk Assessment and reduce any conflict of interest between Risk Assessment and Risk Management, it was agreed that the Risk Managers should communicate with the Risk Assessors in order to explore management options, as may also be suggested by the Risk Assessors. It was reported by several ASEM partners that the infrastructure of their regulatory system has been restructured towards an integrated management system incorporating all related institutions covering the whole food chain.

As regards Risk Communication, the ASEM partners expressed concerns over the quality and the timing of Risk Communication.

Subsequently the Food Safety Working Group discussed the recommendations of the past two seminars in order to determine progress. It was concluded that the ASEM process has led to closer consultation between ASEM partners in the works of SPS in the WTO. Co-ordination meetings were held prior to the SPS-meetings. Most ASEM partners attended these meetings and considered this exercise useful and worthwhile to continue. It has been useful to build understanding, to exchange information and to have further discussions. Closer consultations have also been held between ASEM partners in the work of the Codex Alimentarius. ASEM partners considered this too to be useful.

Let me just recall shortly the recommendations of the Food Safety working group: The Food Safety Working Group recommends that a workshop to enhance capacity building on practical application of the Risk Analysis concept be held in the coming year. This workshop should concentrate on Risk Assessment (exposure assessment) and Risk Communication. Also a workshop on the principles of equivalence should be conducted. The Food Safety Working Group recommends the ASEM partners to participate actively in the discussions on the Precautionary Principle in the Codex Committee on General Principles, especially in the electronic drafting group. And also to assist Japan in its work on Risk Analysis on foods derived from biotechnology in the Codex ad hoc Task Force on Foods derived from Biotechnology.

What have been the results of these recommendations? I think three conclusions can be drawn:

1. All ASEM partners have been actively involved in the work of the Codex Task Force on Biotechnology in March in Chiba. Thanks to our host Japan, substantial progress has been made. All ASEM partners have been actively involved in the discussions on the Precautionary Principle in the Codex Committee on General Principles in Paris and the Codex Alimentarius Commission in July in Geneva. During the meeting of the Codex Alimentarius Commission in July in Geneva a co-ordination meeting of ASEM partners has been held. Information has been exchanged on items important for the respective partners.
2. A workshop on the principles of equivalence is not yet be planned.

3. Last but not least: thanks to our host Thailand, the first recommendation of the seminar of The Hague has been realized: a workshop on the practical application of the Risk Analysis concept, in particular on Risk Assessment. It has been decided not to include in this workshop Risk Communication. This topic deserves eventually separate attention.

## **7. Lessons and conclusions**

This paper started with analysis of the context of globalization and liberalization. I have worked on the assumption that globalization is a irreversible process and consequently support to capacity building should take account of this fact. This assumption applies equally to liberalization. In 1995, agriculture was included in the international trade agreements for the first time since the signing of the General Agreement on Tariffs and Trade (GATT) after the Second World War. The WTO agreements contain a system on trade in agricultural products. All sorts of quantitative border control measures have been translated into tariffs and subsequently a political decision has been taken to decrease the tariff level globally. There is consensus world-wide that this system is an achievement and should therefore not be abandoned. However, attention will be given to qualitative border measures. And it is precisely here that support to capacity building comes into the picture.

Following the examples of support to capacity building in developing countries by international organizations, the European Union and the Netherlands, we can draw the following lessons and conclusions:

- support should be given for a longer period;
- support should concentrate on regions made up of different countries;
- support of international organizations should be integrated;
- support of the EU should complement the individual programmes of EU Member States;
- support of individual developed countries should continue, as this support is based on the expertise in those countries and special historical relations.

GF 01/12

**CAPACITY BUILDING AND TECHNICAL ASSISTANCE  
– NEW APPROACHES AND BUILDING ALLIANCES**

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The inclusion of Capacity Building as one of the major themes of this Global Forum Meeting reflects both the recognition of the urgent need for Capacity Building in the area of food safety as well as the concern of multilateral institutions and, hopefully, of developed countries, that serious attempts should be put into place for this purpose. Most of the problems and issues were highlighted in the excellent paper presented by Dr. Rios at the Melbourne Conference in October, 1999. Although much progress has been made, the basic problems remain. This paper would, therefore, seek to reiterate many of the things mentioned therein and also try to re-emphasize the context, constraints and the ground realities within which Capacity Building efforts have to be made and thereby try to introduce pragmatic and feasible possibilities in this direction.

An attempt has been made to address three issues separately, although necessarily there will be an overlap: national food safety systems (which is the most important area); Codex matters, and bilateral technical assistance (SPS or otherwise).

**I. Background and Context**

**1. Developed vs. developing countries – Differing scenarios**

In the developed world, the increasing introduction of intensive agriculture and animal husbandry technologies has made food another industrial product. Extensive distribution systems allow for rapid and widespread distribution of potentially contaminated food products. The introduction of preventive techniques such as HACCP is increasing and becomes more and more mandatory. Recall and market reputation become the deterrents rather than legislated punishment. Preference for fresh and minimally processed foods, the increasingly longer interval between processing and consumption of foods, the rising trend of consuming food prepared outside the home, and substantial sourcing of raw materials and products from diverse areas all contribute to the increased prevalence of food borne illnesses ascribed to microbiological organisms. Actual outbreaks in the recent past has led to heightened consumer demand for safer food. In a situation where most critical traditional diseases have been kept under control, it is no surprise that this consumer outcry helps make food safety a political priority. The market compulsions of the private manufacturer and the Government's priority coincide to provide both attention and resources to this area. In totality, therefore, the environment stimulates development of food safety systems.

Contrast this scenario with most developing countries. No doubt, most have pockets, varying in degrees, of similar developing systems, but the much larger picture is totally different. Producers are mostly small, whether in agriculture or processing, and in huge numbers. Distribution and consumption is largely localised though large volumes of fresh food is traded in traditional markets. Food habits largely ensure eating of cooked food, particularly in our part of the world. Food borne illness is a serious but often unnoticed problem. Diarrhoeal diseases are a major cause of morbidity or mortality. For the rural poor the most important question is of food security with malnourishment and micronutrient deficiency being the critical issues. Rapid urbanization has led to more and more people living in slums in conditions of poverty, often substantive, overcrowding, and poor sanitation. Here there is an increasing emphasis on purchase and consumption of food outside the family home through street food vendors and food services premises. Further, development at its initial stages without full ameliorative steps, brings in its wake many industrial and environmental health hazards. And most important of all there is lack of awareness of food safety and hygiene.

## 2. Priority to food safety in developing countries

It has been repeatedly said, with some justification, that food safety has not been a priority for developing countries. But this has to be seen in context. These countries are facing a plethora of problems and fiscal crises. Attention has been largely focussed in the last decade on economic reforms and liberalization. Social sector development has suffered. Education has always been seen as an economic investment and has been relatively high on the agenda of countries. Health has not. WHO has sponsored a Commission to examine health issues and their relationship to economic development under Prof. Jeffrey Sachs of Harvard University whose report will be published in December 2001. The Commission is likely to recommend a minimum of US \$30-40 per capita investment in health. Current expenditure averages US \$4. Most of the increase must come through external assistance, because (a) national incomes cannot provide these amounts and (b) competing critical requirements can allow only limited increases in health investment. While developing countries must raise their public health expenditures to a minimum of 2% of GDP, substantial external assistance to the health sector has also to be committed. Priorities likely to be set out by the Commission for developing countries are communicable diseases, in particular HIV-AIDS, TB and malaria; dealing with problems of anaemia and malnourishment; decreasing infant mortality rates through improved immunization; and improving the quality of water. Where is the priority for food safety? Priority first to health, and then, later to food safety, is thus going to be a long journey in developing countries. We also have to create an environment which stresses the public health importance of food safety. WHO has designated Food Safety as one of its priority areas and this should be reflected in the proportion of funds it spends for food safety vis-à-vis other communicable diseases. This helps in priority setting at national level too.

## 3. Food Safety – A multi-dimensional problem

Unlike many other areas in health, the work related to food safety is multi-dimensional and is simply enormous. Sporadic efforts in different sectors do not create the critical mass. There has been lack of an integrated or holistic approach or a long-term view. Therefore, WHO/FAO assistance over the years has not always yielded sustainable benefits or created the multiplier effect, nor created the institutional network. Clearly governments have also not been able to make the most appropriate use of these resources. International consultants who have been periodically visiting this area have been largely prescriptive after diagnosing the problems. This is easily done. Few have prepared a country based specific plan. This is the hard task.

## 4. Emphasis on export sector

In the economy of a particular country, because of the compulsion necessitated by the demands of the importing countries, most efforts of developing countries in capacity building in the area of food safety, both in public and private sector, tend to get narrowly focussed to the export sector. Multilateral, and particularly bilateral, technical assistance also tends to move in this direction. Therefore, capacity building across the nation has suffered.

## 5. Progress

In terms of Capacity Building, therefore, little appears to have changed over the years. Much has been done but the visible impact is not there notable, there will be inter-country variations. This is reflected in the decade reviews of WHO. A WHO 136 country survey in 1989 had stated that:

*“Few of these countries had adequate legislation, standards or regulations or the capacity to enforce and assess them. Most lacked adequately skilled staff, effective mechanisms for inter-sectoral action and adequate financing and strategies to overcome these limitations. Therefore, while the identification of hazards and risks in food is vital in strategic planning, the capacity to assess and manage those risks is a fundamental lack in many developing countries.”*

The current WHO draft document on Global Food Safety strategy now states that:

*“Many developing countries are poorly equipped to respond to existing and emerging food safety problems. They lack technical and financial resources, an effective institutional*

*framework, trained manpower and sufficient information about the hazards and risks involved. The risks are especially great in countries where low national income coincides with rapid industrial and agricultural development.”*

It is about time, therefore, that the issue of Capacity Building is seriously, separately and comprehensively addressed. The background gives the scenario in which food control systems have to be designed and implemented. Efforts towards capacity building and the nature/extent of technical assistance must also be seen in this context.

## **II. Strategy for Action**

### **1. National Action Plan**

It is now being generally recognized, therefore, that the first necessary step is preparation of a National Action Plan based on an objective needs assessment. This assessment would provide data to be used by member governments, and Capacity Building agencies to set priorities, make decisions about programme activities, and allocate resources. Very varied situations may be found in different countries which require different kinds of responses. This would also provide a census of what exists in a country in terms of institutions, their work and capacity and availability of experts and their expertise. This is also important in view of the need to follow an inter-sectoral approach since many departments would be involved. This will also help in prioritization because, given the magnitude of the food safety agenda, not all activities can either be undertaken or supported. Once the plan is prepared elements of it could be posed for bilateral assistance. But there would be an essential homogeneity in terms of institutions taking this task forward; common pool of trained professionals; commonality in manuals/training materials; avoidance of duplications of funds/activities/target groups etc. It will also ensure collaboration between funding agencies who otherwise proceed independently leading to disparate systems and disjointed end products, and ensure there are no piecemeal or ad-hoc contributions. It will allow various activities to be undertaken by different agencies as per comparative advantage. It will also provide opportunities for support where alliances can be built. This would provide both tangible evidence of the commitment of a member state as well as a road map.

### **2. Strengthening of National Offices**

Preparation of this Plan will be a mammoth exercise, especially for the larger countries. We must recognize that there is a dearth of technical personnel available in the National Secretariats which will be implementing and co-ordinating a plethora of simultaneous activities, many of them difficult and new. At a time when divestment and downsizing is the mantra of the day, it is not going to be easy to strengthen these Secretariats with more staff. Therefore, it is necessary to strengthen the Cell by deputation of a few short-term experts for a suitable length of time, and for sustainability, to identify institutions and to strengthen them. These will provide dedicated attention. Once the hardware and software required is put into place and some cycle of activities completed, these will acquire a momentum of their own. It has been recommended that WHO Regional Offices and FAO Regional Offices should have a strong permanent food safety team. We cannot agree more. This is an absolute minimum and these requirements are immediate.

### **3. Collaborative Projects**

India has asked for World Bank assistance for Capacity Building in this area. The Project will provide some funds. Technical expertise and assistance would, however, still be needed. It is understood that in Vietnam, WHO is involved in a major initiative designed to strengthen the Food Administration (Ministry of Health). WHO will oversee and staff a collaborative project, funded by the Asian Development Bank, involving the finalization of a national plan of action, formalization of food legislation, enhancing laboratory quality assurance, developing standardized food inspection procedures, and establishing a system of food borne disease surveillance. This type of project may serve as a model for future joint projects.

#### 4. Networking

For the preparation and implementation of the National Plan it is necessary to network various institutions and bodies. A proposed National Alliance for Food Safety Promotion in India is given below.

The list is not exhaustive :

Scientific Institutions	Professional Association and their Chapter	Trade Bodies
National Institute of Nutrition (NIN)	Nutrition Society	FICCI/CII
Central Food Technology Research Institute, CFTRI	Association of Food Scientists & Technologists	CIFTI
Indian Toxicology Research Centre, ITRC	Indian Dietetic Association	Hotel Associations
Home Science College Catering Institutions Hotel Management Centres	Association of Catering Professionals	Sectoral Bodies Eg. Halwais Association.

#### 5. Funding Imperatives

There is certainly a much greater recognition now in developing countries of the importance of food safety. The initiation stage appears to have begun, if both individual countries and international agencies commit more funds and proper and systematic planning is done. But it is clear that our discussion in this Global Forum on Capacity Building will become meaningful only if there is an external commitment to pledge sufficient resources. We suggest the setting up of a Global Food Safety Fund which will have a much wider agenda and provide the wherewithal to WHO/FAO to provide that kind of assistance which will make a difference.

#### III. Specific Areas for Action

We now come to some priority specific areas for action based on the WHO draft Global Strategy for Food Safety Document and the ten-point Regional strategy for the South-East Asian Region.

##### 1. Foodborne disease surveillance

The absence of reliable data on the burden of food borne disease impedes understanding about its public health importance and prevents the development of risk-based solutions to its management. Structures and systems must therefore be developed at Sub-national and national (and regional and international) levels to survey food borne disease and at national level to conduct risk assessments and implementation of risk management strategies. This is a new area requiring assistance. WHO should help in the preparation of a project for selected countries on a regional basis and for the setting up of regional sentinel sites. India already has institutions looking into disease surveillance. We are also approaching the World Bank for a Disease Surveillance Project. Therefore, additional assistance in India would be minimal. Countries could be assisted bilaterally too. Successful Projects could be replicated elsewhere.

##### 2. Laboratory infrastructure

For an effective foodborne disease surveillance system and, as a necessary foundation for good regulatory systems, it is essential to have a good laboratory structure. Unfortunately, this is a weak area in most developing countries. The Regional Strategy Document has identified the causes thus;

- Inadequately resourced in terms of funding, equipment and personnel.

- Lack of recurrent expenditure effecting repair of equipment and available replaceable materials such as consumables, columns etc
- Much stronger in chemical analysis – Poor in microbiological
- Inadequate quality assurance procedures.

Over the years, WHO, FAO and other agencies have provided a lot of assistance in this area in India by way of supply of equipment to labs and training public analysts and chemists. In many labs these have been well utilized. In many not.

Here also the problem is multi-dimensional and needs to be accordingly addressed. One view is that there has been un co-ordinated external assistance for selective labs largely in the export sector. However, instruments supplied are too sophisticated, difficult to work and maintain in local conditions and require expensive external help. Therefore, it has been suggested that a needs analysis is required covering the appropriateness of the type of instruments, models, post-purchase maintenance, consumable use pattern etc. One way forward is to strengthen a few laboratories which are of international standard at minimal cost and use them as Regional Resource Centres for upgrading the quality of laboratories within a country or countries of a Region. They would also supply equipment, help in its maintenance, provide reference standards, consumables etc. to a selected network of labs. These centres could be both domestically funded and multilaterally assisted. They could also be used for Analytical Quality Assurance Programmes, as well as training programmes in analytical methods including GLP. A good example of optimum resource utilization through building networks of existing labs in the country, region and international level is the recent initiative of the IAEA, Vienna, (jointly funded by FAO and WHO) for various environmental contaminants.

At a more prosaic level, we are preparing to upgrade infrastructure in our labs through the Capacity Building Project. We are also trying to audit selected labs and prepare a plan for upgrades to lead to accreditation by our National Board. This programme could be assisted by donors and applied in many countries. Further, in times when instrumentation cycles are getting shorter, assistance for replacements must be considered, as well as introducing services for a fee principles.

Finally, special help is required for the upgrade of entire systems of certain labs for microbiological analysis in each country.

Another view is that developed importing countries increasingly require more sophisticated instruments and test methods. Therefore, there is a need to identify test methods which are practical and acceptable and do not require great sophistication in instrumentation. Once this is done, appropriate commodity assistance in kind could be given, apart from required software assistance in calibration, QA systems, SOPs, etc.

### **3. Good Practices**

Traditionally, food safety has been checked through end product testing and culprits punished. This has numerous difficulties as the number of personnel available simply cannot police the market and punishment through complicated and time taking judicial procedures often comes to nothing. Increasingly, therefore, emphasis is on the preventive approach and to adopt HACCP principles and GMP, GHP etc. But for most developing countries these have been new concepts.

WHO/FAO have been generously providing technical assistance for training under HACCP. Both have carried out the training for trainers programme. This conceptually has much more sustainability. Consultants have also held HACCP Seminars during their visits. This appears to be an ad hoc exercise without much lasting benefit. Some countries like US/EU have also supported HACCP training activities, largely addressed to export areas. The EU is currently starting a programme with the Quality Forum of an important Industry Association. This will provide trained quality professionals but work is going to be restricted, to 20-25 SME's. They have built an institutional relationship with a well known HACCP training organization in UK. These partnerships through bilateral means is the kind of 'alliance building' which needs to be encouraged. Many Indian organizations both in private and public

and export sector have also followed through, particularly the dairy, marine products, fruit and vegetable processing sectors. The problem is the huge and dispersed small and medium business sector and the larger unorganized tiny sector.

The approach has been seminar driven. Training has been the basic activity. We really do not know how much we have covered across and within sectors and with what success and depth. Clearly also activities are not integrated. We are convinced, therefore, that a National HACCP Training and Implementation Plan be formulated. This would involve survey of needs of different sectors; identification of the current status of trainers, trained personnel. Sectors of industry/units already having undergone training, evaluation of implementation and an analysis of feedback; preparation of a series of Manuals, Industry wise on HACCP principles; revision of course/training materials etc. Simultaneously, basic GMP GAP and GHP norms need to be prepared for all sectors (big, medium, small and tiny) and they need to be incorporated in some form as guidelines in the National Food legislation. Preparation of these generic, and later more specific, norms are of great priority.

#### **4. Communication and training**

This brings us to the problem of dissemination. One of the ways we are planning to do this is to develop a network of Institutes to adopt street food projects, as well as innovative ways of local dissemination of information through meetings of representatives of retailers and consumers etc. Further, all this should enter the course design of all academic and vocational institutes, teaching/training food service providers. This will immediately make this much more accessible and spread knowledge down stream. A recent analysis concluded that Universities having regular teaching programmes could play an active role in speeding HACCP in the country. On the fisheries side alone there are 8 Agricultural Universities/Fisheries colleges in the country.

Whether it is addressing HACCP or training requirements of regulatory officials, or teachers and students in the network mentioned above, there are huge communication needs as there are thousands of widely varying recipients. To ensure standardization, quality and easy reach, it is time that modern communication technology is utilized. How many Seminars will take place? Therefore, we must organize distance education courses, both through the traditional way and through the Web. This is a promising new area for future work of FAO/WHO. I am sure India can play an important role in helping prepare such courses.

#### **5. Investigational surveys**

A necessary simultaneous activity would be conducting regular investigational surveys to monitor levels and nature of contaminants in food products. These have been largely laboratory based in the past and used for standard formulation. They now need to be more market-based and results utilized for all the activities mentioned above. Further, not only food inspectors but students of the institutions mentioned could be involved in this exercise. We are working on preparation of a plan of action in this direction. This could be easily supported.

#### **6. Institutional strengthening**

In many countries many excellent institutions exist who individually, and together, have a huge store of human, technical and financial resources available. These need to be brought into the system. It is not easy to build an all embracing food agency. Therefore, we have to strengthen these existing institutions so that each can play an important role in an identified sector or nature of activity. The only exercise required when the National Plan is prepared is to identify what strengthening is actually required. Assistance required may not be very substantial. This would also lead to development of intra and inter-country institutional networks. In fact, there is great potential for South-South co-operation in this area, which can obtain much greater value from a given amount of assistance. People in government departments come and go. These institutions as resource centres will remain. Institutional strengthening is crucial for sustainability. They will also then play an important role in Codex matters too.

#### **IV. Codex Issues**

##### **1. Codex standards**

The last decade has seen rapidly increasing global food trade and increased exports from developing countries. SPS measures have enabled many to access exacting markets and helped retain market access when entry requirements have changed. However, perhaps there is cause for concern. Lowering of tariffs and other barriers in developing countries are being accompanied by high standards and stringent requirements for food products in developed countries. So while their exports are threatened, those of developed countries are facilitated.

Since Codex standards are now benchmarks for international food trade, the standard setting process becomes critically important, particularly for developing countries. Most standards are being set based on requirements and information provided by developed countries. Technological developments are leading to detection of progressively lesser amounts of a contaminant. There is pressure to lower standards to those levels. Sometimes, these have no relationship with epidemiological impact and risk. Exposure assessment data is not always fully taken account of. Most importantly, such data from developing countries is rarely considered, yet standards become Global Standards. Doubts arise further when developed countries are seeking 'highest levels of protection' casting away the traditional concept of 'appropriate levels of protection'. This leads to the feeling that they are becoming non-tariff barriers and are adding great costs to developing country exports. The UN Secretary General had publicly referred to the cost to African exports of nuts to Europe because of the totally unrealistic existence of levels of aflatoxin of the EU.

Necessarily then questions arise whether developing countries are having their due say in the setting of standards and how can this be ensured. The other issue which arises is what is required to be done to ensure that these countries are able to meet standards where already set. This becomes the other context in which issues of capacity building and technical assistance have to be seen.

##### **2. Participation of developing countries**

Over the last few years there has been talk of increasing participation of developing countries in the Codex process, but almost wholly restricted to increasing their physical participation in Codex meetings. India has been arguing that while this is important, though largely symbolic, much more important is to address their ability to take part fully in the standard setting process, the greatest constraint to which is lack of effective infrastructure at national levels for evaluation of draft standards. No doubt the extent, manner and quality of developing country participation has greatly increased, but much more needs to be done. A recurring contradiction in the approach of developed countries is that while the problems of effective participation are being recognized, and only partially addressed or remedied, the agenda is growing every day with increased sophistication and simultaneously attempted to push through on fast track basis. This is an important aspect of Capacity Building which requires assistance.

##### **3. Involvement in standard-setting – Data collection and risk assessment**

If countries are to be involved in the standard setting, data from developing countries and different regions has to be collected and incorporated. India has been repeatedly arguing this stand and Codex has accepted this in principle. The World Health Assembly had resolved in its 53<sup>rd</sup> Session in May 2000 that WHO make the largest possible use of information from developing countries in risk assessment for international standard setting. We, therefore, strongly welcome the statement incorporated in the draft WHO Global Food Safety Document which says:

“WHO will improve the methods of risk assessment for chemicals and microbiological hazards in food in order to provide accurate, Globally representative bases for standard setting by Codex. In regard to GEMS/Food databases, it will strive to obtain better data on food intake and on the

level of contamination of food in developing countries to ensure that the risk characterizations provided to Codex are of Global significance.”

This action brooks no delay. FAO/WHO’s ‘call for Data’ or ‘call for Experts’ will not suffice. Data has to be collected if available somewhere in the system or otherwise generated. Assistance would also be required in identifying types of data, collection mechanism and documentation of data bases of both national and international standards formulation. This whole exercise, along with the risk assessment process, would itself be a capacity building exercise apart from generating the data.

We urge WHO/FAO to set up a Working Group of experts and representatives of some developing countries to explore what efforts at Capacity Building and financial assistance for generation of such data are required. The ideal mechanism is to identify Institutions in different regions, which will act as collaborating Institutions and become nodal points. These will be the same which we are proposing to strengthen in relation to domestic food safety systems. And it is experts of these Institutions which should be represented in the Group of Experts such as JECFA/JMPR etc. Transparency of experts lies in their being independent of any manufacturing interest not in involvement with generation of national-level data.

A necessary part of this exercise, as we collect the data, is a good hands on training on both qualitative and quantitative risk assessment covering chemical and microbiological hazards. Risk analysis remains an area of urgent assistance for Capacity Building. More seminars is not the answer. Dr. Rios had mentioned establishment of risk analysis units. We say put these in identified institutions. In addition Universities could be utilized. Training methodologies would need to change too – expert-supported practical applications.

#### **4. Strengthening National Codex Infrastructure**

This becomes an obvious area of action. India is currently implementing an FAO sponsored Project. This has the following elements:

1. Strengthening National Codex point and networking between all points which could be involved in Codex matters.
2. Developing information systems to access information of all Codex matters, Committees and countries views etc.
3. Harmonization of standards,/guidelines made in Rules under our PFA Act with Codex where possible.
4. Exposure to HACCP principles and preparation of training materials.

This project is well designed and is expected to lead to measurable outcomes; strengthen Capacity and capability to respond to Codex issues; identify collaborative institutes; identify and address needs /gaps in this area; and draw up a long-term HACCP education Plan. This Project is expected to give sustainable benefits. It is hoped evaluation of its successes could lead to introduction of more Projects in other countries. In so far as South Asia is concerned, these local experts and expertise gained could be used to help other countries too.

#### **V. SPS Agreement and Technical Assistance**

##### **1. Sensitization to SPS/TBT Agreements**

The SPS and TBT Agreements have completely changed the environment of international food trade. The first requirement is for developing countries to fully understand their provisions and implications. Over the years, WTO has held many seminars and training programmes helping in substantial improvement in this understanding. However, not many know the nuances of how it is operating in practice in different areas, or in what manner advantages can accrue to developing countries. Therefore, there continues to be a case for more detailed dissemination of the Agreements and their working. It is also to be recognized that there is a continuous turnover of personnel dealing with this subject in different countries. Therefore, this training must be institutionalized at National and

Regional levels. Secondly, training methodology needs to change to include hands on exercises based on actual examples and prepared case studies. If developing countries are not taking recourse to this assistance then there seems to be some fundamental lack in communication. Explicit possibilities with some specificity of issues of different kinds need to be developed by some experts. Perhaps a consumer friendly Web based course for these Agreements such as the WIPO Patents course, would be of great use. A large number of people in bureaucracy, in institutions and in the industry and elsewhere can directly access and become familiar with this subject. We recommend action on this immediately.

## **2. Assistance under Clause 8 of SPS Agreement**

Capacity of countries to respond effectively could also improve by collection and dissemination of information of the kind of technical assistance which has or has not been provided by developed countries under Clause 9 of the SPS agreement. There is too little information, or perhaps too little assistance. In this regard, it is a general perception that this Clause has remained at best an endeavor clause without being fully operationalised. India spent about US\$ 25m in adjusting to a country's requirements on marine products without any assistance. The experience of India's Export Inspection Council of trying to incorporate such provisions in Equivalence Agreements has not elicited much positive response. We are also told that there are many cases of rejections even when processing units follow GHP/HACCP and inspections and certifications are done. This area needs to be separately studied and required assistance identified.

## **3. Information on Import requirements**

Data is essential regarding individual import requirements for different products or sectors, or of individual importing countries, or specific international standards which are creating problems for developing countries. Data on standards; methods of sampling, inspections and tests; appeal procedures etc, could be readily made available on computerized databases. Further studies could suggest:

- (a) whether these requirements or standards are justified;
- (b) what would be the cost for developing countries to meet those requirements.
- (c) What assistance SPS agreement would oblige that particular importing country to provide to the developing countries.

There are many experts or Institutions in many developing countries which can do this individually or in collaboration.

## **4. Equivalence Agreements**

Another area is assistance in getting Equivalence Agreements on board. There is a serious difficulty in this area and little progress is being made in the direction of signing Equivalence Agreements. Equivalence determination is of great importance to trade facilitation. Therefore, some detailed attention has to be paid as to who can give what kind of assistance in this area. This is also desirable as it will directly link concerned institutions in both countries.

## **5. Bilateral Assistance**

It is not easy to comment because of absence of information. The US/EU have provided a list of activities supported in different countries. They mostly relate to seminars by experts and some training. The EU has also indicated some activities which seem to go beyond workshops and actually are involved with introduction of SPS measures in different sectors. In both cases it appears that the primary emphasis is on seafood and fisheries and there are fruits and vegetables areas also. Therefore, these efforts perhaps directly relate to import of items of concern to these countries.

## **6. Approach**

Discussions in the SPS Committee have shown that assistance:

- (a) has been dominated by 'Soft infrastructure' like seminars.

- (b) is fragmented rather than there being a holistic approach covering institutional, technical and economic aspects.
- (c) is not co-ordinated.
- (d) must be 'demand driven'.

The first step, therefore, must be diagnosis of the national situation to identify existing capacities and problems thereby identifying the best forms and medium of technical assistance which could be given by different agencies in a co-ordinated manner. This brings us back to the need for a National Action Plan whose part any Aid Project would then necessarily become.

## **VI. Conclusion:**

The discussion in this paper leads us to the following conclusions:

1. While recognizing that ultimately each nation must take action itself to upgrade its food control systems, it must also be recognized that substantial financial assistance apart from technical assistance is required for Capacity Building by developing countries, though the nature and extent may vary with different countries. A Global Food Safety Fund be set up.
2. A national plan of action be prepared. This preparation would itself require assistance. This will be both diagnostic and programmatic and prioritize needs and activities. This will include a National HACCP training and implementation Plan.
3. WHO/FAO should become the coordinator at country level for all assistance and coordinate assistance, bilateral or otherwise, with the recipient country channeling this assistance on the basis of the comparative advantage of the donor.
4. Some continuous technical support in the form of experts is necessary at the national food safety control point to help in the above activities. Regional offices of WHO and FAO must be considerably strengthened by technical capacity in this area.
5. All proposed activities must eventually create Capacity Building by virtue of strengthening of institutions in a country which will provide the sustainability. The nature of strengthening be specified.
6. WHO/FAO facilitate data generation from developing countries for Codex standard setting.
7. Data bases of import requirements of developed countries be prepared.
8. For various areas Web based training and sensitization programmes be prepared.

**SUMMARIES OF CONFERENCE ROOM DOCUMENTS FOR THEME 3*****CAPACITY BUILDING*****▪ CANADA-4**

Officials from Health Canada and the Canadian Food Inspection Agency (CFIA) have participated in and contributed to numerous bilateral or multilateral meetings, workshops and projects in efforts to provide training and capacity building to developing countries. Recent training seminars and workshops were conducted by Health Canada and CFIA officials on procedures in conducting food safety and environmental assessments of foods derived from biotechnology. This led to the development and conducting of a number of hands-on workshops using actual case studies of the assessment of a genetically modified food as the next step in improving the capacity building process. This hands-on approach was used at a number of international workshops sponsored by different international organizations. Future joint sessions are now under consideration and a working group, headed by Canada with the participation of other countries, was established to develop an outline for a pilot training session involving food safety assessment. Canadian lessons which were learned during these recent training initiatives include some of the following aspects: hands-on practical training provides the best opportunity in advancing training on food safety and environmental assessment; attendance at the training sessions will be facilitated with good coordination between the different food control agencies of developing countries; countries or organizations sponsoring the right individuals with the right qualifications will increase the transfer of training skills to their sponsoring countries; standardized train-the-trainer courses will ensure consistency and uniformity in application of training methods and international standards; joint training initiatives involving other developed countries will enhance the coordination and delivery of international training courses and workshops; and capacity building will be enhanced if the recipient countries take ownership in the training activities and invest in long-term infrastructure development.

**▪ CHINA-3**

Over the recent two decades, food safety in China has improved greatly overall. These achievements are the results of capacity building in government control agencies and also industries, including technical assistance from international organizations. This paper describes the implementation of two programmes on street food control by the Ministry of Health, China. FAO sponsored a pilot programme on improving the safety of street food in cities and WHO sponsored a programme on the improvement of street food safety through the application of HACCP principles, as examples to demonstrate the contribution of technical assistance provided by international organizations to the progress of food safety control in developing countries. The implementation of the above two international technical assistance programmes combined the advanced measures of food safety control with Chinese traditional control methods and proved to be very effective in improving the hygienic status of street foods. These two programmes could serve as model examples of successful international technical assistance. The following experiences were learned from the implementation of these two programmes. The programme selected for technical assistance will be the prioritized food safety issue of that country or area. The local government or authority should be aware of the importance of the problems to be solved. This is critical for the success of the programme as only in this case will strong resources and manpower support to the programme be provided by the local government or authority. The implementation of the programme will have a detailed plan and design. The preparation of programme plan and design per se is a process of personnel training and technical support. In the above two programmes, programme experts not only conducted plan preparation, training and guidance, but also carried out field visits and provided assistance in the preparation of summary report. The selected programme should be able to

sustain and fit to the economy and social development of the specific country. The street food programme conducted in China is in line with the plan of hygiene city and hygiene town in China, which is an important prerequisite for the success of these programmes.

#### ▪ HAITI-1

The paper gives a list of recently provided technical assistance by international organisations on food control systems and food quality/safety. In particular, the participation of FAO and UNIDO is highlighted. The paper describes an on-going FAO project on “Strengthening the National Food Control Structure”. This project led to the establishment of the national **Inter-Ministerial Committee** in charge of the implementation of official food control programmes. Future actions are to undertake a communication campaign on education in food safety and social mobilisation to related issues; to continue improvements in prioritised sectors; to organise seminars or courses for food handlers (GHP, GMP and HACCP); to improve the sanitary environment; to create a national Codex Committee as suggested by the inter-ministerial committee; to set up a documentation center (technical and scientific publications, international standards); to develop a support programme to food industries in order to promote or reinforce quality assurance systems and their recognition through officially recognized certification, to support consumer associations in their activities.

#### ▪ MONGOLIA-2

The paper describes the efforts of the Mongolian government over the last ten years to introduce capacity building and HACCP development. However, to date no food industry has introduced HACCP to assure food safety apart from the meat industry. Collaboration with national authorities to promote food safety education in schools and universities should be one of the important strategies to improve food safety in developing countries. It is also essential to strengthen coordination and collaboration between food control agencies and facilitate a multisectoral approach for food safety through the establishment of a national intersectoral coordinating committee. The paper recommends that both government and international agencies seek and support an effective mechanism of cooperation to improve the effectiveness of technical assistance on food safety.

#### ▪ USA-4

The United States supports food safety technical cooperation and assistance to developing countries, directly or coordinated with relevant international organizations, to enhance the safety of foods available to all consumers and to contribute to economic development by strengthening sustainable production systems and export markets. Technical cooperation activities that have been undertaken by the United States include technical training, programs and consultations in such areas as national regulatory and enforcement frameworks, and consumer education. Lessons learned include: a) Consideration should be given to how desired outcomes can be sustained; b) Criteria should be developed to ensure resources are used appropriately and effectively; c) Food safety education strategies should be multi-layered and prioritized; and d) Strengthening food safety systems requires self-assessment, the involvement of donor organizations, and improved coordination of technical assistance activities.

#### ▪ VIETNAM-1

The Vietnam Food Administration is responsible for managing food hygiene, safety, and quality and has made significant progress since its establishment in 1999. Food safety remains a high priority in Vietnam with the growth of export markets and increasing food imports raising the need to rapidly build capacity of the Food Administration in order to reduce threats of foodborne disease. The Food Administration has demonstrated commitment to the food safety challenges it faces, and has embarked on an innovative capacity building activity with technical assistance from the World Health Organization.

## ▪ MOROCCO-2

The document describes food legislation and food control in Morocco and then gives a list of examples of technical assistance/cooperation (bilateral with France, Canada and Germany and with FAO). It proposes the development of tools to facilitate the capacity building and technical assistance effort and through new approaches such as partnerships in the field of food safety and food control. The document recommends a) the creation of an independent scientific body responsible for food safety and risk assessment; b) the development of the food control system throughout the food chain; c) the implementation of a traceability system so as to guarantee the effective retrieval and removal from the market of unsafe food; d) the need for prompt FAO study on the feasibility of establishing a unique Food Inspection and Control Agency; e) the improvement of national laboratory facilities and capabilities; f) capacity building of the food testing laboratories to face evolution in technology and food control requirements (Dioxins, PCBs, GMOs, HAP,...) including training and human resource development programmes; g) the need to set up a national coordinated training programme for food inspectors; h) long-standing education, information and sensitization actions towards consumers regarding food safety concerns; i) the support given to consumer associations; j) the increase of government assistance to small and medium size food industries in their challenge to produce safer food and to ensure quality of Moroccan food products; k) the awareness raising among food retailers about their role and responsibility over the safety of their products; l) the scientific evaluation of sanitary (safety) and nutritional quality of traditional foods and spring, river and well waters used in particular in rural areas and the status of sewage treatment infrastructures and domestic wastes and other waste facilities and economic impacts of pollution from cities; and m) the need for more integrated approach in FAO technical assistance projects.

## ▪ BURUNDI-1

The document explains how food safety has become a new and understood concept since Burundi has been facing a regular decrease of its domestic production in relation to the political troubles that have been rocking the country since 1993, forcing the import of more products and the control of their quality and safety. Prior to 1993, the majority of food was consumed as fresh and/or raw although the food availability had not been satisfactory since 1969. The absence of any sensitization programme for food handlers and consumers is highlighted. Farmers are using intensively chemicals without any specific training and/or control to ensure the application of good agricultural practices and good practice in the use of veterinary drugs in Burundi. It is recommended that technical assistance and capacity in Burundi be focused on laboratory facilities and related human resources and expertise; training and education of official staff (inspectors) involved in food quality control.

## ▪ CI-2

The role consumer organizations can play in strengthening the capacity and effectiveness of food safety and control systems in developing countries cannot be underestimated. From the standards setting process to the monitoring of foods in the marketplace, consumer organisations provide a critical yet neutral voice in supporting government efforts to improve the safety that consumers demand in the market place. Their involvement furthers consumer confidence in government systems and processes. However for them to play their full role, more work is needed to build the capacity of these organizations and also to ensure that their voice is heard within policy making processes. Consumers International has been successful in strengthening consumer organizations ability to contribute to food safety issues. However, these efforts need support directly from the Codex Alimentarius. Consumers International acknowledges the trust fund proposed by both FAO and WHO and are hopeful that some of the proceeds from this fund will be used to address the issues on capacity building of consumer organizations raised by this paper.

### ▪ CÔTE D'IVOIRE-3

New approaches in technical assistance are strongly required due to the entry into force of the WTO Agreement for the Application of SPS Measures (SPS Agreement) which implies binding consequences regarding rights and obligations of every single country willing to put food on the international market in terms quality and safety. The technical fields which would require an immediate technical assistance in Côte d'Ivoire are: a) training needs of personnel involved in food control (only 20 official veterinary inspectors and 200 technicians for the whole country); b) capacity building in infrastructures and equipment (logistics, supplies, computer/IT, and supporting structures) to ensure safety for exported food and domestic produced/consumed food; c) needs for demonstrating the equivalence of Ivorian food inspection and certification systems (by mutual recognition); d) training needs of food handlers (especially in small/medium sized food industry to GHP, GMP and HACCP principles) and consumers (pedagogic educational tools to non visible food contamination). Innovative and specific suggestions are made to donors and to the three international standardization bodies ("three sisters" of the SPS Agreement, i.e., Codex Alimentarius Commission, OIE and IPPC) to take fully into consideration the needs expressed by developing countries, including the least developed ones.

### ▪ ERITREA-1

This document describes Eritrea's attempts to reconstruct their food control infrastructures and their efforts in capacity building in the field of disease prevention and eradication and in upgrading their inspection and laboratory techniques. Rural development is a high priority in Eritrea and one of the main objectives is to achieve greater food security and raise farming incomes. The introduction of technical aid, mechanized farming and proper land use has resulted in economic growth for the country. Eritrea's available resources are limited and depend to a large extent on agreements with external funding sources and donor agencies, (principally the African Development Bank, the National Livestock Development Programme, DANIDA through their Agricultural Sector Support Programme and the EU through the Pan-African Control of Epizootic Diseases Programme) . The Government has undertaken the responsibility for controlling nationally important diseases and is encouraging private veterinary practices and community-based animal health care in order to provide farmers ready access to both animal health and production services. The document stresses Eritrea's need for financial and technical support in order to strengthen their food control systems, especially for export oriented food products. There are currently no systematic food quality control measures as these activities are spread over different ministries, but only basic food control measures and inspections are being practised.

### ▪ TRINIDAD AND TOBAGO-1

According to recent statistics, Trinidad and Tobago is an emerging country which has considerable environmental problems. Like most countries, the Government is concerned about food safety, food security and achieving HACCP standards. The document summarizes the responsibilities assumed by the different units of the Ministries of Health and Agriculture, Land and Marine Resources. In recognition of the number of institutions involved in food control matters, the government realises that a multi-ministerial, multi-disciplinary approach needs to be taken with the full backing of the political leadership. Steps have already been taken in this direction, but much more needs to be done.

### ▪ UGANDA-1

The document gives an overview of the food safety control system in Uganda and highlights some of the urgent issues which require attention, such as foodborne illness resulting from sanitation failures in food production, processing, retailing and handling; basic food hygiene due to lack of necessary sanitation infrastructure; import of processed foods; obsolete food laws and lack of resources which hamper the current food control system. Details are provided on the EU inspection mission to Uganda and the problems that local inspectors are encountering in carrying out their duties due to lack of clear guidelines and standard operating practices and out of date laws and regulations. The document presents

Uganda's achievements in the area of food safety and health, due in part to support from donor agencies, and describes current endeavours towards the development of an effective national food safety control system.

▪ **USA-5**

This document provides a brief summary of new approaches being implemented by US regulatory agencies in capacity building and technical assistance around the world, with emphasis in the Americas. Aims of the work are: protecting public health; enhancing regional/national regulatory systems; and, developing structures and processes. The three projects described (the Caribbean Food Safety Initiative, the University of Puerto Rico Project and the Food Laboratories Network) all seek to capitalize on the unique strengths of participating organizations. The difficulties of participant and donor coordination, financial and technical needs, and sustainability of action are key lessons that have been learned from these projects.

**APPENDIX XI**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakech, Morocco, 28 – 30 January 2002*

**THEME AND TOPIC PAPERS**

**WITH SUMMARIES OF APPLICABLE CONFERENCE ROOM DOCUMENTS FOR**

***COMMUNICATION AND PARTICIPATION***

GF 01/6

**COMMUNICATION AND PARTICIPATION – THE EXPERIENCE IN MEXICO**

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**Introduction**

Food safety is increasingly becoming a more relevant issue. In Mexico, the General Act for Health considers food safety and food hygiene within the concept of sanitary quality and this, in turn, within the concept of general health.

The relevance of food safety lays in that food may cause illness which impairs the individual's ability and his/her possibilities of development; it may affect the community and unbalance the organizations in which individuals participate. From the economy and social point of view, sanitary quality of food –suitable for human consumption as well as safe- is becoming increasingly important for the development of the nation, it has an influence on the expected rise in employment, on the income of capital, and on the resources available for development. The sectors of agriculture and fishery, manufacturing industry, trade, tourism services related to production, processing and provision of food, all contribute significantly to the gross national product and to capital inflow, apart from being the most important employers of the country.

There are several relevant actors involved in the production of safe food: individuals who offer products and services; the consumer; governmental organization which encourage and support individuals in their function or protect or educate the consumer, the challenge here is to get them involved and make them co-responsible for the achievement of food safety.

**Relevance for Public Health**

Foodborne diseases, although difficult to quantify, are considered relevant for the health of the Mexican population. Acute infectious diseases transmitted by bacteria, parasites, and viruses through one of the possible routes, food, are a relevant cause of morbidity. Furthermore, with the increased life expectancy, chronic diseases in which toxins accumulate in the body through prolonged ingestion of contaminated food are a risk factor since, they occur in adulthood affecting the quality of life, the productive performance, and causing death.

One of the most important achievements in the health sector of Mexico is a decrease in the mortality rate. Life expectancy of the Mexican population at birth was 74 years in 1999, partly due to the decreased mortality rate for intestinal infectious diseases. In 1999, these diseases were in the 15<sup>th</sup> place among the main causes of mortality since they only caused 5,622 deaths out of 443,950 deaths that year.

Acute gastrointestinal disease statistics reported by the Single Information System for Epidemiological Surveillance include some potential FBDs such as intestinal amoebiasis, hepatic amoebiasis, cholera, typhoid fever, giardiasis, food poisoning (bacterial), paratyphoid fever and other Salmonellosis, taeniasis –cysticercosis and shigellosis, intestinal infections and wrongly defined infections, and other infections due to protozoans, brucellosis and viral hepatitis. In 1999, total reported cases of potential FBD's were 6,864,686 (See Chart I).

On the other hand, in 1999, malignant tumors, cirrhosis, and other chronic hepatic diseases and kidney failure ranked 2<sup>nd</sup>, 5<sup>th</sup>, and 14<sup>th</sup> among the main causes of death with 53,662, 27,040 and 7,807 casualties, respectively, being toxin-contaminated food a risk factor in these diseases.

### **Relevance for International Trade**

For international food trade, food quality, specifically food safety, is increasingly becoming the key factor for success. The new rules of the game are specified in the Agreement on Sanitary and Phytosanitary Measures (ASPM) and in the Agreement on Technical Barriers for Trade (TBT).

According to these rules, the government of the country establishing them needs resources to show that the sanitary measures applied are legitimate and that national products are compliant, and so they are not biased against foreign products. The importing party or foreign exporting company demands compliance, ensuring also compliance of the suppliers in the previous steps of the productive chain and receiving decisive support from the government to show that the requirements are met and the implementation is equivalent or has a scientific base.

Globally, in the year 2000, exports in Mexico were 7.8 billion dollars and food imports were 7.6 billion dollars. The safety of exported food, particularly fresh fruit and vegetables, fish, crustaceans, and mollusks, among others, is crucial to maintain and increase Mexican exports. If the industry is not able to improve processing and self-controls, and the government does not implement the required measures for the governments of the importing countries to be confident that requirements are met, then exports will encounter difficulties to remain the same or increase, and the impact on the capital inflow, the employment rate, and the possibilities of development will be severely affected.

The safety of imported food requires increased control, free from unnecessary barriers to commodities, as well as the appropriate infrastructure in order to better identify the food which does not meet national requirements, in the same way as Mexico commercial partners monitor Mexican exports. Deficiencies in imported food control, whether actual or not, are identified by national producers as unfair trade which negatively affects the confidence of the society in the Mexican government.

At the same time, the foreign exchange revenues for international tourism in 1998 was 7,987 million dollars. Travellers' diarrhea due to food consumption may represent a barrier for international tourism incomes in Mexico. The endemic characteristic of the disease is caused by inadequate hygiene and the relatively high incidence of asymptomatic carriers, especially among caterers, as well as by the poor conditions of food storage.

### **Socioeconomic Relevance**

The contribution of the sectors involving production, industry, distribution, sales and preparation of food and beverages to the gross national product is really significant. The important agriculture, forestry and fishery sector represented a 6% of GNP in 1998; food products, beverages and tobacco from the manufacturing industry represented 5% of the GNP, and the sector of commerce, restaurants and hotels, accounted for 21%.

Any process which may modify the way in which food producers, food processors and handlers, food vendors, or food service providers, requires to take into account the social extent of the population involved in the food chains as well as consumers, that is, the whole population in Mexico.

An estimated 36% of the total working population was involved in activities related to food productive chains, representing one of the most important employers in Mexico.

The practices for food elaboration and preparation, at any level, require to keep a balance between the changes to improve hygiene and safety control from food providers while preserving the consumers' taste and the dish aspect. For that reason, modification of hygiene practices of food providers should be influenced from the very early stages of their learning in order that the changes bring about solid and complete improvement of food safety in Mexican people's culture.

Consumers spend a high percentage of their income in food, which is one of the most important satisfaction in their life, not only to satisfy a need but as an important part of their individual and community cultural life.

Food is the result of an operational chain which begins in the field, in the farm, in the pond or in the sea, when food is not yet food; the transformation of food continues during the primary stages, sometimes they are subject to industrial transformation, sometimes when sold to the consumers, and it ends when after being prepared at households or at establishments they are finally eaten.

The number of working places where activities related to food are carried out is really big. Analysis of INEGI surveys allowed to determine that the number of food production, processing, distribution or sales units is 5.3 millions of “working places” (Chart II). Possibly due to the easy accessibility to consumers and few requirements of technology and investment in working capital and fixed assets prevailing in Mexico, there are huge numbers of micro-businesses (with 15 employees or less) which represent: 99% of those involved in agricultural activities, forestry, and fishery; 95% of those involved in transformation of food products, beverages, and tobacco; 91% of those involved in wholesale trade of food; 99% of those involved in retail sales of food; 94% of those involved in preparation and sales services of food and beverages in establishments, and, 100% of the ones involved in the preparation and sales of food in the street and at households.

Micro-businesses have the highest limitations, the most important needs, even in hygiene education, they are numerous and the consumers are limited in number. Medium- and big-size companies, i.e. those with more than 51 employees, represent only 0.6% total working places. They generally have the highest number of consumers, they have increased administrative and technical capacity to solve problems to reach and keep their competitive position. They are more aware of the quality and safety of their products. And they generally have better possibilities of exporting their products and they can monitor their quality control systems. Besides, they require certification of their products, processes or systems to meet the requirements of the importing country apart from exerting stronger pressure for the government to assign resources to satisfy their needs and, paradoxically, they are thought to represent a lower risk.

To provide safe food, employees working in the productive food chain need to follow the good sanitary practices in a systematic fashion. Training, development of skills, and generation of a positive attitude to attain this may be acquired in the working place, but the possibilities are reduced for very small companies. So, the possibilities for a worker to receive education on hygienic handling seem to be reduced to primary education. The use of primary education to expose a student to information and training on how to change food selection, preparation and storage habits is a viable way for the country to build sanitary education capable of deeply changing the current situation of food safety in Mexico.

### **Current Sanitary Regulation, Control and Development**

In Mexico, sanitary regulation, control and development of products, establishments and services is a set of preventive actions carried out by the sanitary authority in order to control, based on sanitary regulation, the conditions of the environment of humans, establishments, activities, processes, and products which may represent risks to human health, and, at the same time, to support appropriate attitudes, values, and behavior of the people and companies to encourage their responsible participation for the benefit of individual and public health.

The legal base of the Mexican food regulatory system is the General Act for Health, issued in 1984. From that time, the regulations have allowed to steadily fill in the gaps which made instrumentation of sanitary control difficult. The process of decentralization of public health services terminated in 1999 have allowed to better satisfy local health requirements.

As of 1992 an efficient model of elaboration of official Mexican standards was developed with the active participation of the industry, the commerce, the consumers, the academy, and all the governmental agencies involved. Moreover, the participation of this same actors in the Sub-committees of the Codex Alimentarius has substantially improved resulting in an increasingly proactive performance of the Mexican delegations in the International Codex Committees.

The regulatory system developed since 1991 to implement a consistent, steady, free-from-deviations sanitary control has improved to fight historical deficiencies of sanitary regulations such as lack of administration and improvisation, deficient regulations, dissociation from epidemiological needs, insufficient trained and motivated personnel, absence of adequate and sufficient equipment and few laboratories to support the activity. Pre-market authorizations were abruptly eliminated and the technology for quality management was adapted to the function of the government and to the improvement in information technology to foster permanent progress. Sanitary control was organized to avoid discretionary application of sanitary authority, improved management of resources, and to expand its coverage. Salaries were improved, and a system for learning, training and supervision was implemented.

The system was designed for random surveillance based upon the empiric risk of establishments and products, offering representative information about surveyed establishments and products, concurrently giving attention to sanitary contingencies and emergencies, reports and claims of individuals by means of the guided program. The implementation of the product and service sanitary control system at national level has been gradual.

Up to the present, sanitary control is a governmental exclusive, but not limiting, function of the Secretary of Health (SH). In its operation, federal, state, and jurisdictional actions are coordinated and complemented at their respective levels of competence. Sanitary control and development is performed mainly for the manufacture, import, distribution, commercialization and provision of food, raw material and commodities. Nevertheless, little has been done regarding primary production, specifically for the food consumed fresh or under-processed.

Mexico, as other countries, has not had an integrated program to achieve food safety, which have resulted in some unattended sectors such as the agricultural production, where systems to reduce microbiological, chemical, and physical risk had not been implemented.

### **Historical Participation of other Governmental Agencies**

Additionally, there are other federal government agencies which can legally promote and encourage the development of different sectors of the economy relating to food. The Secretary of Agriculture, Livestock, Rural Development, Fishery and Food (SALRDFF) established in 1951 zoosanitary control of slaughter houses and meat processing establishments by means of Type Federal Inspection system (TFI), especially for the promotion of exports. Since 1988, by agreement with the SH, SALRDFF assumed the responsibility for the control of imported meat and meat products. Later, in 1993, through the Federal Act of Animal Hygiene it was given the authority to carry out the sanitary regulation of other animal products through private monitor agencies accredited by the SALRDFF.

As of 1997, when the United States announced the development of sanitary measures to limit the entry of food not meeting the safety requirements, SALRDFF developed an aggressive development program called Integral Program of Technological Development for Food Quality (IPTDFQ) directed to fostering the importance of food safety and the application of good agricultural-sanitary practices among producers and packaging personnel, especially for fresh fruit and vegetables.

It was also in 1990 that the National Institute of Fishery started a program with the cooperation of the Food and Agriculture Organization (FAO) to train trainers to promote the

establishment of HACCP systems. The Secretary of Economy, previously called Secretary of Commerce and Industrial Development, based upon the Federal Act on Metrology and Normalization issued in 1992, promoted a practical mechanism for the development of mandatory standards (NOM) and voluntary standards (NMX) for the Mexican Accreditation Entities (MAE) and private third parties such as units for the verification of commercial and sanitary labeling, which support fair trade component of sanitary control.

### **Building the National System for Food Safety**

Due to the strategic nature of food safety, the Federal Government agreed on the establishment of an integrated National System for Food Safety, with the joint efforts of the Secretaries of Health and Agriculture, with the aim of assuring sanitary quality of food while enhancing and maintaining national and foreign markets of agricultural, livestock and fishery products to ensure safe food for the national and international population.

On the one hand, only in July 2001, SH set up the Federal Commission for Sanitary Risk Protection in order to integrate all the functions of sanitary control, that is, drugs, medical equipment and other health supplies, environmental and occupational health and food, beverages and cosmetics, in only one organism which should merge and harmonize SH policy to define and have technical, administrative and operative autonomy which allow more efficient and flexible and faster decision making based upon the best technical and scientific evidence available. This change made also possible that other federal government agencies, such as SALRDFF, could participate as sanitary authority in the process of regulation.

On the other hand, the current legislation should be modified, especial the General Act for Health, in order that SALRDFF be identified as the sanitary authority in Mexico through the National Service for Agriculture and Food Health, Safety and Quality. This will allow to establish regulations and control activities in the primary production sectors such as agricultural, livestock and fishery production units as well as in packaging, stores, transport and trade establishments.

Although this agreement exists at the level of the Secretaries of State, modifications to the legislation require to be passed by the Congress which in turn will survey the different sectors involved in production, handling and commercialization of food, the academy and consumers for their opinion on the legislative changes proposed.

Once the legislation has been modified, the respective regulations will be elaborated for the Agencies of the Secretary of Health and the Secretary of Agriculture which will be responsible for food safety; furthermore, to make this cooperation effort between the two Secretaries formal, a Cooperation Agreement for Food Safety will be made.

In Mexico, every modification to the law and regulations, as well as every new legislation, require public comments to attain transparency and the possibility for all the population to give their opinion on the legislation proposed.

The National Service for Agriculture and Food Hygiene, Safety and Quality (NSAFHSQ) is aware that no legislation is completely effective if it is not communicated to the consumers and general public in a simple way. For that reason, a General Office for Consumers' Communication has been established with the aim to inform the general public, especially users of the office's services, about the legislation and regulations in force, for a more effective compliance, and in order that the general public be confident about the work performed by the federal government.

Recently, in February this year a National Forum on Food Safety was carried out with the participation of consumers, industry, academy and farmers, producers, traders, and state governments, in order to hear proposals on the strategy the federal government should develop to attain safety food production. All agreed that food safety should be a priority issue for the federal government and that it was necessary to have an agency exclusively aimed at performing this task

and they also agreed on the need to issue regulations or a specific law to regulate food production from the farm to the table.

This regulating agency has been established as the National System for Food Safety, which will have a Technical Council where the different involved sectors will participate and which will function as a guide to define the policy on this issue and actions taken on this matter will be presented to it.

Currently, a Master Plan on Food Safety is being elaborated including different activities for different sectors, among which the following can be mentioned: promotion of the establishment of Good Agricultural Practices; Good Production Practices; Standard Sanitization Procedures; Risk Analysis and Critical Control Points. This promotion is intended for agricultural, livestock and fishery producers and will be mainly focused to primary production.

Moreover, a promotion program will be carried out to the consumers' sector to direct their preferences towards products having safety quality brands. It is worth mentioning that we presently have a similar system for meat, sausages, and chicken, especially for export products.

It is also deemed necessary to establish a training program for housewives to foster hygiene practices and handling of food at households, since a high percentage of foodborne diseases occur due to inadequate food handling in the household.

Besides, training courses for professionals and producers are being planned for the application of systems to minimize risks and make the process of their establishment in production units easier.

In order to gain the consumers' confidence on the work performed by the federal government in food control, bulletins or reports on the NSAFHSQ activities will be published or issued in order to counteract distorted information, lacking scientific support, disseminated through certain media.

In order to attain effective activities from the Federal Government, cooperation agreements with the States will be signed to delegate some control and follow-up activities of the State Programs for Food Safety.

Also, awareness programs will be established with producers' associations to facilitate the process of establishing risk reduction systems.

This initiative implies several interaction activities with different sectors; nevertheless, we consider that the opinions given at the Global Forum for Food Safety Regulators will allow the establishment of new communication and participation strategies of the different sectors.

### **Conclusion**

Food safety is crucial for Mexico's development because it has an impact on the health of the population, job creation, investments inflow, fair trade of food, and, globally, on the efficiency and productivity of the nation. While contaminated food is a concern involving the functions and responsibilities of different sectors, coordination, an integrating strategy, an explicit definition of responsibilities to achieve food safety from the farm to the table; and the design of models which allow to measure the contribution of food safety to the objectives of the policy of each participating organization are needed.

**Chart I. Reported Cases of Potentially Foodborne Diseases**

Diagnosis	1998	1999
Cholera	71	9
Typhoid Fever	11,546	8,893
Intestinal Amoebiasis	1,613,215	1,516,845
Giardiasis	78,475	63,056
Intestinal and wrongly defined infections	5,023,427	4,862,618
Other protozoan intestinal infections	109,876	124,303
Paratyphoid and other Salmonellosis	215,155	181,239
Bacterial food poisoning	35,081	42,661
Shigellosis	45,372	39,029
Taeniasis	3,061	3,195
Brucellosis	3,550	2,719
Cysticercosis	1,061	920
Viral hepatitis A	18,695	19,199
Total	7,158,585	6,864,686

Source: Single system of information for epidemiological surveillance, 2000, 2001, Secretary of Health

Chart II. Working place by number of employees (thousands)							
Activity	Total	1 person	2 to 5 people	6 to 10 people	11 to 15 people	16 to 50 people	51 or more people
Agricultural activities, forestry, and fishery	3,538	1,625	1,798	83	12	13	7
Transformation of food products, beverages and tobacco	347	201	113	14	3	6	10
Food wholesaler establishment	59	29	17	5	2	3	3
Food retailer establishment	914	606	279	16	3	4	6
Preparation and sale services of food and beverages in establishments.	196	53	107	19	6	7	4
Preparation and sale of food and beverages on the street and in households	273	198	74	1	0	0	0
<b>Total</b>	<b>5,327</b>	<b>2,712</b>	<b>2,388</b>	<b>138</b>	<b>26</b>	<b>33</b>	<b>29</b>

Source: Own elaboration based on INEGI, 2000

Note: Average of each size of working place, according to number of employees, was obtained and then the average by activity was calculated.

GF 01/13

## BRAZIL INSTITUTIONAL EXPERIENCE FOR THE IMPLEMENTATION OF RISK ANALYSIS

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### **I. General Considerations**

The National Agency for Sanitary Surveillance (NASS) of the Ministry of Health (MH) was established in January, 1999. The mission of the Agency is “to protect and promote health ensuring sanitary safety of products and services”, especially for food and their corresponding manufacturing units. It is worth noting that the actions for food sanitary control in Brazil are shared by the health and agriculture sectors.

Both experiences, which will be discussed here, were managed by the NASS.

The initiatives of the food sector of the Agency to set risk analyses in motion have been directed towards the improvement of control and sanitary inspection systems for certain products.

The Risk Analysis process seeks to estimate the risk for human health associated with the presented scenario as well as to select and implement the appropriate measures to control such risks with the aim to ensure safe food for the population. The impact on human health is the main concern of the risk analysis process.

Considering the three components interacting to integrate the risk analysis process, NASS has proceeded as follows:

- Risk evaluation is based upon existing official epidemiological data, upon analytical results of the specific product, and upon the analysis of the food manufacturing process with a view towards identifying the critical stage, which requires systematic control;
- Risk management involves the updating of sanitary norms, technical training for inspectors, and the implementation of national programs for sanitary inspection and monitoring of food sanitary quality;
- Risk communication is achieved by disseminating in the media information on the foodborne risks posed by a given product; by warnings in product labels; and by delivering instructive material to raise public awareness of the risks coming from a certain food.

The risk analysis process is achieved through the participation of the different parties involved –as recommended by the Codex Alimentarius directives- including health and agriculture official institutions, representative entities from the productive sector, teaching and investigation institutions, and consumers’ protection organizations, all of them essential to ensure the transparency of the whole process as well as of decision-making.

Issues to deal with following the risk analysis process have mainly emerged from epidemiological data and food control program outcomes which indicate a risk situation coming from the combination food-agent.

### **II. Institutional Experiences**

#### **Botulism in Canned Palm Heart**

Since the occurrence of three cases of canned palm heart-associated botulism in 1997, 1998 and 1999, risk analysis was started and the Technical Group was established, formed by different interested parties or *stakeholders*, such as the scientific community, e.g., the Food Technology Institute (FTI) and the Adolfo Lutz Institute (ALI); members of representative entities of the

productive sector – Brazilian Association of Food Industries (BAFI), members of the Brazilian Environment Institute (BEI), members of Sanitary Surveillance from the States, the National Agency for Sanitary Surveillance (NASS), Epidemiological Surveillance, and consumers' representatives –Consumers' Protection Institute (CPI).

As described above, the warning label was an emergency measure adopted provisionally, since after the results from the National Program for Sanitary Inspection of Canned Palm Heart Industry, the companies approved were exempted from wearing the warning label in their products. The registration of the products from companies which did not meet the requirements was cancelled, and the authorization to process such products was withdrawn.

Due to the emergency nature of the situation and the remarkable virulence of the toxin *Clostridium botulinum*, a Warning to the Population was published in the most popular newspapers of the country; also, an official release was made to the Sanitary Surveillance Bodies of the States, recalling the brands which have caused the outbreak and it was decided to carry out laboratory analyses to monitor if the pH, considered the Critical Control Point of the product, was within the 4.5 limit in all the batches available in the market.

Following the Warning to the Population, the official press published the resolution that canned palm hearts should be labeled in a clear and readable way for the consumers, with the following warning: "For safety, this product should only be consumed after being boiled either in the can fluid or in freshwater for 15 minutes". This warning was elaborated from scientific studies developed by the Food Technology Institute (FTI).

The Consumers' Protection Institute played a crucial role in communication since it carried out a market research collecting samples from 15 (fifteen) separate brands of canned palm heart. The outcome of this study was made known through an interview about canned palm heart-associated botulism in the most important television network during prime time. Brands were prohibited and their batches released only after an additional laboratory analysis was performed.

As the hazard has been clearly identified and characterized, risk evaluation was based upon the study of the productive process, specifically upon identification of the canned palm heart processing stages considered critical for *Clostridium botulinum* control. As a result of the study, the stages of product acidification and thermal treatment were identified.

Based upon the studies carried out, Resolutions RDC NASS Nbr. 17 and 18/1999 for Canned Palm Heart Standard and Good Manufacturing Practices, respectively, were endorsed. According to the information emerging from the Regulations, the Technical Group elaborated directives for the National Program of Sanitary Inspection for the Canned Palm Heart Industry. The resolutions established a term of 180 (one hundred and eighty) days for the companies to implement Good Manufacturing Practices (GMP) and monitoring of Critical Control Points of the productive process. To meet these requirements, companies should also train a specialist in GMP.

NASS asked the Brazilian Supermarket Association to buy only canned palm hearts having the warning label while this provision was still in effect –29 April, 1999 to 19 February, 2000. After February 2000, the companies could not continue marketing the canned palm heart with the warning label, they should buy and distribute only products with registration and brand authorized by Sanitary Surveillance.

By that time, the population was informed through the media they could consume canned palm heart without the warning label, since the products commercially available had been authorized at the sanitary inspection. NASS offered a site in the Internet including all the brands, industries, and numbers of approved registrations after they have been gazetted (Boletín Oficial de la Unión).

Due to the occurrence of cases of canned palm heart-associated botulism, risk communication showed the need to re-organize the Sanitary and Epidemiological Surveillance Systems in Brazil. To pay better attention to cases, epidemiological surveillance of the major State of the country, São Paulo, established a Reference Center for Botulism. This national-scope center is in operation 24 hours a day, available through a toll-free line (0800) telephone line and has a technical team trained in giving orientation and advice to health professionals regarding diagnosis, treatment, and research on the different signs and symptoms of the disease. The Reference Center for Botulism comprises the Institute Butantan, also located in São Paulo, which has the technical conditions to produce and have the anti-botulinic serum for the whole country and for Latin America.

The setting up of the inspection program within industries was the responsibility of sanitary surveillance bodies of the states, jointly with NASS, and was achieved by sensitizing sanitary inspectors on the importance of product control, and training of 62 (sixty two) inspectors regarding Good Manufacturing Practices for canned palm heart, the productive process safety evaluation, and harmonization of technical-legal procedures.

Only industries (including new industries, in-operation industries, and industries exporting palm heart to Brazil) controlling the critical points of the productive process defined by risk assessors, and meeting other requirements established by the aforementioned Resolutions, were approved during sanitary inspection. There were nearly 519 (five hundred and nineteen) industries when the Program was started; this figure dropped to 120 authorized industries in September 2001. Also, 267 (two hundred and sixty seven) product registrations were cancelled.

Since the implementation of the Program, routine sanitary inspection was established as well as the commitment of the productive sector regarding the product safety.

Although risk communication was, in principle, an experience which had an effect on the productive sector and decreased product consumption in the country, communication was found to be extremely positive, considering the following aspects:

- training of 62 inspectors from NASS and the 27 surveillance agencies from the States regarding GMP for canned palm heart;
- enhancement of sanitary inspection at producing premises and stores;
- organization of the productive sector in associated entities;
- mandatory implementation for industries to have a trained technician in GMP in canned palm heart;
- creation and availability in the internet of a data base on brands, registrations and industries authorized by sanitary surveillance and those whose registrations had been cancelled;
- encouragement for the creation of a Reference Center for Botulism, what allowed for the re-organization of the flow of notification and sanitary, epidemiological, and laboratory investigation of the disease

Since the risk communication as of April 1999, no other case of canned palm heart-associated botulism was observed in Brazil.

### **Iodine Deficiency Disorders in salt for human consumption**

Risk analysis was developed after the establishment of an inter-institutional commission in November, 1999, which gathered all interested parties, *stakeholders*. The commission was formed by the Ministry of Health, represented by the Department of Health Policy, Sanitary Surveillance, Epidemiological Surveillance; the Ministry of Agriculture, the United Nations Children's Fund

(UNICEF) and representative associations and consortiums of the productive sector. This Committee gathered periodically ensuring exchange of information among the involved parties.

The committee decided that the Department of Health Policy would take part in the Thyromobil Project, developed by the *International Council for the Control of Iodine Deficiency Disorders (ICCIDD)*, to evaluate goiter prevalence among 1,977 school children (6-12 years old) from 06 units of the Federation, as well as the level of iodine in the salt consumed in the children's homes. The result of the project showed the prevalence of goiter to be approximately 2%, that is, a value lower than 5%, the normal limit established by the World Health Organization. Regarding iodine content in the salt consumed in the children's homes, the total average obtained was 48.3 ppm, this value being within the limits legally established in the country (40-100 ppm). The outcomes showed a high standard deviation among samples, more precisely, a 29 ppm. average. The analysis of samples of salt intended for human consumption carried out routinely by the sanitary surveillance services confirm the standard deviation obtained by the Thyromobil Project.

Based on the Thyromobil Project results, more specifically, considering iodine high standard deviation in salt samples collected from the children's homes, the inter-institutional commission verified the need to adopt measures to ensure the standard deviation control during the processing of salt for human consumption.

In that sense, the National Agency for Sanitary Surveillance elaborated Technical Regulations, Resolution NASS RDC Nbr. 28/2000, defining Good Manufacturing Practices for salt for human consumption, highlighting which controls should be carried out by each establishment to ensure appropriate iodine levels in the end product. At the same time, with the publication of such technical regulations, NASS established the "National Program for Sanitary Inspection of Establishments Producing Salt for Human Consumption" with the purpose of inspecting 100% of national companies. According to the directives of the Program, salt establishments go through a first inspection step during which salt processing conditions are evaluated. When the Program identifies an establishment which does not meet all the requirements of the technical regulations, it is given a term of 180 days to proceed to adaptation.

After the expiration of this term, establishments will be re-inspected, and only those which fully meet the requirements of the Technical Regulations will be authorized. It was also stated that only establishments approved in the National Program will be authorized for the commercialization of salt for human consumption. With the aim to ensure risk communication to the productive sector, the National Service for Industrial Learning (NSIL) was included in the National Program in order to disseminate in the sector the control measures regulated by NASS, and the reasons for their adoption, and also to provide companies with technical assistance to put these measures into effect.

This National Program is at the end of its initial stage of sanitary inspection, with 122 establishments inspected up to the present.

Apart from the need to establish measures to manage the high deviation of iodine content in salt for human consumption, as revealed by the Thyromobil Project, the inter-institutional commission highlighted the need to inform the consumers about the risks from iodine deficient consumption as well as the importance of iodine salt for the control of Iodine Deficiency Disorders (IDD). Therefore, advertising campaigns were elaborated for television and radio, apart from the informative material delivered to schools, and urban and rural areas.

During the risk communication process, we highlight the importance of the health community agent. This agent is a community member trained by the Ministry of Health in basic health measures, forming a network of 144,000 members all over the Federative Units of Brazil. According to the Control Program of Iodine Deficiency Disorders, these agents took part in the risk communication to the population through house calls explaining the importance of the consumption of iodine salt and the appropriate conditions of product storage.

Among the results obtained through the exchange among involved entities, it is worth mentioning the re-evaluation of analytical methodology used by official laboratories after the account of the productive sector experiences, the recognition of the need to establish an expiration date for iodine salt, and the learning about salt consumption habits in low-income rural populations.

GF 01/14

## ENSURING EFFICIENT COMMUNICATION AND INTERACTION BETWEEN FOOD SAFETY RISK ASSESSORS AND RISK MANAGERS

*Discussion-Paper prepared by Germany*

on the basis of the report of the WHO Expert Consultation  
“*The Interaction between Assessors and Managers of Microbiological Hazards in Food*”,  
21-23 March 2000, Kiel, Germany

### 1. INTRODUCTION

The experts of the WHO Expert Consultation submitted the following principal comments:

- Food Safety Authorities in Member Countries should structure their food safety system(s) on a risk-based approach that includes appropriate communication and interaction between risk assessors, risk managers, and stakeholders.
- The functional separation of risk assessment and risk management is essential to the conduct of risk analysis activities.
- Independence, transparency, and robustness of the scientific analyses and advice are essential determinants of their credibility. Nonetheless, effective dialogue among risk assessors, risk managers, and other stakeholders is essential to maximize the utility of the assessment findings and to ensure that both scientific and societal goals are met.

Concerning the interactions between risk managers and risk assessors, the terminology adopted or under discussion of the FAO/WHO Codex Alimentarius Commission is used. The same applies to the description of risk analysis.

### 2. RISK ANALYSIS

Risk analysis is composed of three components, i.e. risk assessment, risk communication and risk management. The definitions for those three components are described in Codex terminology as follows:

- Risk Assessment is defined in the Codex “Principles and Guidelines for the Conduct of Microbiological Risk Assessment” as a scientifically based process consisting of the following steps: i) hazard identification, ii) hazard characterization, iii) exposure assessment, and iv) risk characterization.
- Risk communication is defined in the Codex as: the interactive exchange of information and opinions throughout the risk analysis process concerning risk-related factors and risk perceptions, among assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

- Risk management is defined in the Codex as: the process, distinct from risk assessment, of weighing policy alternative in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

The following steps of the procedure are within the mandate of risk assessors and risk managers:

Risk assessors:

- hazard identification,
- hazard characterization,
- assessment of the exposure,
- risk characterization
- risk communication with regard to the aforementioned tasks.

Risk managers:

- identification of the problem,
- definition of a risk profile,
- goal description,
- identification and definition of the tolerable risk,
- risk communication with regard to the aforementioned tasks.

### 3. FUNCTIONAL SEPARATION OF RISK ASSESSMENT AND RISK MANAGEMENT

The draft Working Principles of Risk Analysis and the Principles and Guidelines for the Conduct of Microbiological Risk Assessment refer to the functional separation of Risk Assessment and Risk Management. Individual(s) who prepare the risk assessment should not normally be the same individual(s) who are responsible for the management of the risk. The tasks of risk assessment and risk management are best performed by different people or functional groups. However, it is recognized that in many countries an individual may act as both a risk manager and an assessor. In all cases it is paramount that the activities of the risk analysis process are transparent and appropriately documented. This applies to all interactions between risk assessors and risk managers, or to the separation of the activities by an individual.

Functional separation is essential for the conduct of risk analysis activities in order to maintain the scientific integrity of the risk assessment process and to avoid political pressures that would undermine the objectivity and the credibility of the conclusions. Separation of risk management and risk assessment helps to ensure that assessments are not biased by pre-conceived opinions related to management solutions. However, there is a need for frequent interaction between risk managers and risk assessors in order to arrive at effective risk management decisions. Active interaction is necessary to ensure that the assessment will meet the needs and answer the concerns of the risk manager. The assessors must understand the manager's questions and both parties must acknowledge any constraints, which may impact on the risk assessment. The strengths and limitations of the assessment must be properly communicated so that people using the risk assessments can properly understand the results. Interactions between assessors and managers do not end with the completion of the risk assessment. There will often be exchanges of information and input from assessors during subsequent risk management activities, for example, during the option assessment stage and in communication of results to interested parties.

The nature of the interaction between risk assessors and risk managers may differ according to the way national or international organizations are structured. For example, organizational as well as functional separation between risk managers and risk assessors is currently envisaged in the Codex system for microbiological food safety. Nevertheless, interaction and communication are essential for effective risk management, while maintaining the scientific integrity of risk assessment, and should include active steps such as open review.

There are constraints, and inefficiencies in the risk management procedures as carried out by the Codex Committee on Food Hygiene, and improved interaction between risk assessors and risk managers is needed. With this in mind, it is suggested that FAO and WHO give strong consideration on how experts in risk management procedures can feed into the work of the ad hoc FAO/WHO risk assessment consultations, while at all times clearly maintaining risk assessment and risk management as separate functions.

#### **4. INTERACTION BETWEEN RISK ASSESSORS AND RISK MANAGERS**

Risk assessment and risk management interactions may be subject to time constraints, especially in situations where a food safety problem requires rapid deployment of interim or emergency measures. Effective risk management in emergency situations depends on an urgent dialogue between assessors and managers. However, even in such situations managers should strive for open communications in order that the need for transparency is satisfied to the greatest possible extent.

The interaction between managers and assessors depends on the scope of the risk assessment. Often the risk assessment is designed to identify the stage in the food chain where interventions will most effectively reduce the public health burden attributable to the specific food and pathogen in question. A risk assessment may also be initiated to examine the cost effectiveness of current controls or to evaluate a new technology for control. In this case a list of options for consideration will be included in the scope. In an emergency situation with an emerging pathogen where the etiology of disease is not well understood the options comparison will be abbreviated.

#### **5. TRANSPARENCY**

Transparency is a key objective of the risk analysis approach and its importance cannot be overemphasized. This is reflected in the Codex Statement of Principles relating to Food Safety Risk Assessment, the Codex Committee on Food Hygiene (CCFH) Guidelines for Microbiological Risk Assessment, and the CCFH draft Guidelines for Microbiological Risk Management. Transparency in risk assessment means that all assumptions, data, inferences, and conclusions are explicitly documented and made available for open review and discussion. Transparency in risk management means that the process is open and available for scrutiny by interested parties including stakeholders and consumers who may be affected by the outcome of the risk analysis and risk management activity.

#### **6. RECOMMENDATIONS**

The following recommendations of the Expert Consultation held in Kiel 2000 should be discussed:

- Food Safety Authorities in Member Countries should structure their food safety system(s) on a risk-based approach that includes appropriate communication and interaction between risk assessors, risk managers, and stakeholders.
- FAO and WHO should actively seek opportunities to promote collaborative international risk assessment and risk management activities among Member Countries.
- FAO and WHO should encourage the implementation of relevant studies to obtain new and needed information required to support international risk assessment and risk management activities in the area of food safety. This may be best achieved through the FAO and/or WHO collaborative centres, and would involve establishing protocols, providing training, and design of appropriate sampling plans for investigating food-borne risks to human health.
- FAO and WHO should emphasize that communication has to occur frequently and iteratively while striving to ensure scientific integrity and achieve freedom from bias in risk assessments.
- FAO and WHO should invite the CCFH to take account of the output from this consultation in its work to develop “Principles and Guidelines for the Conduct of Microbiological Risk Management”.
- FAO and WHO should give strong consideration to how experts in risk management procedures can interact with risk assessors involved in the ad hoc FAO/WHO Consultation on Microbiological Risk Assessment. This interaction is particularly important when deciding on the scope of a particular risk assessment, developing risk assessment policy appropriate to that risk assessment, and ensuring the results of the risk assessment are of maximum utility for risk management.
- FAO/WHO and national authorities should consider carefully the training needs of risk assessors and managers so that they are able to undertake the full range of their responsibilities efficiently and effectively.
- FAO and WHO should facilitate discussions of the nature and value of food safety objectives especially in the microbiological field. In the light of the report of the Director General of the WHO (EB 105/10 para 10), WHO is requested to expedite consideration of this matter in coordination with FAO.
- National governments should acknowledge the importance of functional separation between risk assessment and risk management while ensuring transparent and appropriate interaction between them.

**SUMMARIES OF CONFERENCE ROOM DOCUMENTS FOR THEME 4*****COMMUNICATION AND PARTICIPATION*****▪ MEXICO-1 (GF 01/6-REV. 1)**

Food safety is becoming increasingly addressed in Mexico, with the General Act for Health considering food safety and food hygiene within the concept of sanitary quality and this, in turn, within the concept of general health. The relevance of food safety lies in the fact that food may cause illness which impairs the individual's ability and possibility of development, as well as affecting the community and imbalancing organizations in which individuals participate. From an economic and social perspective, the sanitary quality of food is becoming increasingly important for the development of the nation, influencing the expected rise in employment, in capital income and in resources available for development. The sectors of agriculture and fisheries; of the manufacturing industry; trade and tourism services; as related to the production, processing and provision of food, all contribute significantly to the gross national product and to capital inflow, while representing the most important national employers. There are several relevant actors involved in the production of safe food: individuals who offer products and services; the consumers; governmental organizations which encourage and support individuals in their function or protect or educate the consumer, the challenge being to establish collective involvement and co-responsibility for the achievement of food safety.

**▪ CANADA-5**

Government, food regulatory agencies and industry stakeholders have a fundamental responsibility to communicate best practices for enhanced food safety as well as potential food safety risks. Clear, concise and timely communication on food safety issues is an essential element of Canada's integrated approach to food safety. The communication objective is to provide individuals and organizations with appropriate information that contributes to improved food safety practices at all levels of the food continuum (i.e.: inputs, production, processing and consumption). Canada has made significant investments in communications to inform, educate and advise consumers and other stakeholders. In addition to more traditional communication tools, increasing use of the Internet by Canadians is providing a new, practical and economic mechanism for governments to reach consumers and other stakeholders. Working with stakeholders, innovative programs such as the Canadian *Fight BAC!*<sup>TM</sup> Campaign are making important contributions to enhancing food safety and minimizing the occurrence of foodborne illness resulting from improper food handling and preparation by the consumer. Implementation of an integrated approach to enhance food safety has resulted in important lessons learned with respect to: food safety communication as an ongoing regulatory responsibility; the need to identify clear communication objectives and to consult with stakeholders as part of ensuring the timely availability of appropriate food safety messages to the right audiences.

**▪ CHINA-4**

The Chinese government is convinced that enabling the consumers, food industry and other stakeholders to learn about the current situation of food safety and to participate in food safety control activities is the most efficient way of strengthening the national food safety control system and of improving the confidence of consumers in the safety of the food supply. Based on this understanding, the Chinese government has adopted various measures to promote the participation of all stakeholders, in particular the consumers. These may include: participation of food industry associations and representatives in food standard and regulation drafting; the increasing of attention by governmental agencies at different levels to consumer complaints and to responding to communications with industry in respect of these complaints; release and dissemination of food safety information through different

mediums; implementing the education programme- "Food Hygiene Law Education Week" annually (since 1996); and establishing close cooperation with the consumer organization. The participation of Chinese consumers in food safety control is still relatively inadequate, particularly regarding consumers from rural areas. Most of the food industries in China are small and medium sized businesses, there being a need to explore better ways to communicate with these food industries. China is a large and diverse country, with significant differences in economic development, education levels, cultural background and dietary habits amongst its different regions and consequently requires an efficient ways in establishing participation and risk communication towards food safety.

### ▪ **CI-3**

Consumers International has participated in Codex work as an observer for three decades, and notes the importance of ongoing efforts by the Codex Commission to improve the participation of consumers in its activities. Sound goals have been established, but the details of implementation have yet to be worked out. Data need to be collected at regular intervals on objective measures to track progress in consumer participation at the national and international level. Some governments are more advanced than others in terms of the extent and mechanisms through which they facilitate consumer participation in their food safety risk analysis. Through fora such as this one and Codex Regional Coordinating Committees, successful experiences can be shared and perhaps, more widely adopted. In order to improve the quality of consumer participation, consumer NGOs should be given opportunities to take part in risk analysis training and similar workshops carried out by international agencies and national governments. The risk assessment process, which has traditionally been closed to observers, should also be more open and transparent, bringing invited consumer participants into that process could both improve the results and add to the credibility of risk assessments.

### ▪ **GERMANY-1**

Presently, the Federal Institute for Risk Assessment advises the Federal Office and its governing body- the Federal Ministry of Consumer Protection, Food and Agriculture (BMVEL), besides cooperating with governmental research departments. With deficits in risk assessment (no central assessment agency, capacity shortages) and risk management (fragmentation of Federal and Ministerial responsibilities, unsatisfactory EU-Federal Government-Laender coordination), Germany aims to consolidate responsibilities of the BMVEL; disunite the administration of risk assessment, risk communication and risk management; establishing an independent scientific agency for the assessment of health risks. The foundations of a new administrative structure for consumer health protection and food safety, require the pooling of resources from various ministerial institutions, permitting an increment in personnel and capital investment.

### ▪ **MOROCCO-3**

A few years ago Morocco initiated the development of a truly integrated approach with all stakeholders of the food chain, to assure a greater understanding and participative process when managing and communicating on food safety and quality related issues. The main objectives of this new approach is to a) increase information circulation among all partners (administration, food chain professionals, and consumers); b) increase the responsible role and behaviour of professionals through voluntary programmes (code of good practices, technical regulations, knowledge of mandatory obligations); c) consumer information and education programmes; d) support to consumers associations. A special food safety inter-ministerial Mission has been established. Food industry operators are organised in branch associations. Six consumers associations are currently active in Morocco. Through different examples, it is shown that communication among the three above components improves the level of reliability of the food safety system. It is suggested that appropriate actions should be taken in the following areas: insufficient coordination among the different ministerial components (on occasion

within a ministry itself); a lack of consumer information and sensitisation policies; a lack of consultation with professionals.

#### ▪ PHILIPPINES-3

Food safety has emerged as the major consumer concern in both developed and developing countries. Foodborne diseases do not only pose tremendous threats to consumer health, but they can also cause serious economic damage. In this regard, risk analysis has become an integral part of ensuring food safety. In the Philippines, the government continues to encourage the involvement and participation of stakeholders and members of the academic, scientific community and consumer groups through the use of effective risk communication and feedback mechanisms. With consideration to factors that serve as an obstacle to risk communication, other popular media channels are utilized in order to gather comments, opinions and suggestions from the stakeholders. The conduct of consultation meetings for the drafting of country position papers regarding food safety concerns is a very good example of effective feedback mechanism as exemplified by the Bureau of Agriculture and Fisheries Product Standards, which operates as a government unit mandated to protect the welfare of the consuming public through the formulation, harmonization and adoption of safety and quality standards for foods. However, given the efficient feedback mechanism to ensure the involvement of stakeholders, more efforts remain to be made in facing new challenges posed by the occurrence of trans-national food safety emergencies. This can only be done if the country continues to strive to strengthen the commitment of the stakeholders because ensuring safe food from farm to plate is a shared responsibility not only of the government and industry sector but also of the consuming public.

#### ▪ SYRIA-1

The paper gives an overview of the food safety programme in Syria with its components: food legislation; quality assurance; prevention and control; compliance and training. In the food legislation field, Syria does not have a single unified food law but several legal texts implemented by various governmental agencies. There are over 440 Syrian food standards issues by the Syrian Standards and Metrology Organization and some 259 decisions issued by the Ministry of supply to enforce these standards and other food regulations. The application of HACCP is limited to a few modern factories and is done on a voluntary basis. The paper describes the case of imported oranges that were found to be contaminated with excessive amounts of carbamate residues. The imported oranges were recalled from the market through a collaborative effort that involved all concerned authorities and stakeholders including the vendors themselves. The paper draws lessons from this contamination case and makes proposals for a risk-based control of all imported foods. The paper gives a tabular overview of the country's national plan in food safety which focuses on 11 priority areas of intervention ranging from the safety of baby foods to training and gives progress made so far and further actions required. It also identifies, for each type of intervention, the agency responsible for follow up.

#### ▪ UNITED KINGDOM-3

The Food Standards Agency recognises the importance and value in involving consumers and other stakeholders effectively in the decision-making process. The involvement of key stakeholders at an early stage has helped the Agency to develop effective policies. The Agency recognises that it can be difficult for consumers to contribute effectively **and** has implemented a number of initiatives targeted specifically at helping consumers. In addition the Agency recognises that being open and accessible has helped build trust in the decision-making process and helped to stimulate a wider debate on food issues.

#### ▪ USA-6

The United States uses the information generated from food safety risk assessments to evaluate options and select strategies for managing identified risks. Risk management strategies often include

new regulatory requirements, but also can include or consist of non-regulatory actions, such as voluntary efforts on the part of industry or consumer education initiatives. The US encourages and facilitates consumer and stakeholder participation in the development of risk management strategies. Further, in the development of new regulations, consumer and stakeholder participation is guaranteed by U.S. law. Food safety risks are communicated to the public through a variety of means, including public meetings, publications in the *Federal Register*, mailings to consumers and other stakeholders, and the Internet. The development of recently proposed regulations concerning the control of *Listeria monocytogenes* in ready-to-eat meat and poultry products provides a good example of how the US Department of Agriculture's Food Safety and Inspection Service facilitates public participation in risk management and rule making.

#### ▪ CANADA-6

Food safety policy in Canada is based on the risk analysis process using risk assessment, risk management and risk communication as its basic tenets. This responsibility is shared by Health Canada and the Canadian Food Inspection Agency (CFIA) and, depending on the issue, other levels of government may be involved. Health Canada's risk analysis process, referred to as a Decision-Making Framework (DMF), provides the basis for a systematic, comprehensive and coordinated approach in the policy development process. Similarly, the CFIA has developed a Risk Analysis Framework to guide its enforcement, compliance and control processes. Both frameworks call for the establishment of separate risk assessment and a risk management teams. It is critical, however, for each team to have a leader who provides direction while maintaining a linkage with the other team. Canada has found that a team approach is necessary for the successful management of risks. In addition, there needs to be an overall risk manager responsible for guiding and integrating the work of the two teams, moving the process forward, and dealing with the various process-related issues. Along with the establishment of the teams, the assignment of roles, responsibilities and accountabilities is critically important. Canada has used the decision making process across a number of food safety files. Health Canada undertook a review of its DMF through a pilot study on prion diseases. The study concluded that the DMF significantly enhanced Health Canada's ability to deal with prion diseases and other potentially hazardous threats to the health of Canadians. Some lessons learned confirmed that the commitment, leadership and involvement of senior management is critical to implementing a systematic approach; that all decisions must be evidenced-based and pulled together in an issue identification document; that barriers must be overcome to ensure that the different teams effectively share information; and that all participants must work through teams. Access to the best available science and the right people for building consensus; developing horizontal relationships through collaboration, partnerships and team work; and documenting all aspects of the decision-making process are some of the key challenges in achieving effective communication and interaction.

#### ▪ DENMARK-1

In Denmark, the concept of risk analysis has been used in the control of *Campylobacter* in chickens. The risk management procedure was initiated by a risk profile on *Campylobacter*, which was elaborated in cooperation with risk managers, risk assessors, and stakeholders representing both the consumers and the industry. Following the preparation of the risk profile the risk managers decided to order a formal risk assessment. The responsibility for the risk assessment was placed in the research institute under the Danish Veterinary and Food Administration, and the work was closely followed by the stakeholders. The results were communicated to the risk managers, who subsequently initiated the process identifying possible management options and their efficiency in reducing the number of human *Campylobacter* cases. This process was carried out in close collaboration with the Consumer Board, the Danish Veterinary Laboratory, the Danish Zoonosis Centre, the broiler industry and the trade organisation. At present (January 2002), the management part of the process is not yet concluded. Throughout the risk analysis procedure there has been a good and intimate collaboration between risk managers, risk

assessors, and involved stakeholders. The procedure has been a very successful and instructive process for all the parts involved.

▪ **USA-7**

The mission of the United States food safety regulatory agencies is to safeguard public health by ensuring the safety of food products in the United States. To accomplish this goal, these agencies are increasingly relying on a risk analysis approach to address complex food safety problems. This document will discuss how US regulatory agencies balance the need to ensure the independence of risk assessors and risk managers, while yet maintaining essential frequent and transparent communication between the two groups. Two illustrative cases of coordinated risk assessment and management are included; these address Salmonella Enteritidis in shell eggs and Listeria monocytogenes in ready-to-eat foods.



**APPENDIX XII**  
**(GF/LIM 2-REV.5)**

**FAO/WHO GLOBAL FORUM OF FOOD SAFETY REGULATORS**

*Marrakesh, Morocco, 28-30 January 2002*

**LIST OF CONFERENCE ROOM DOCUMENTS SUBMITTED BY COUNTRIES**  
*(Sorted by Agenda Item)*

▪ **AGENDA ITEM 4.1**

<b>CRD REFERENCE</b>	<b>ORIGIN</b>	<b>AGENDA ITEM 4.1</b>	<b>AVAILABLE IN</b>
GF/CRD Canada-1	Canada	a	English
GF/CRD EC-1	European Community	a	English
GF/CRD EC-3	European Community	a	English
GF/CRD IACFO-1	International Association of Consumer Food Organizations	a	English
GF/CRD Indonesia-2	Indonesia	a	English
GF/CRD Italy-1	Italy	a	English
GF/CRD Lao-1	Lao's PDR	a	English
GF/CRD Morocco-1	Morocco	a	French
GF/CRD Peru-1	Peru	a	Spanish
GF/CRD Philippines-2	Philippines	a	English
GF/CRD RDCongo-1	Democratic Republic of Congo	a	French
GF/CRD Rep. Congo-1	Republic of Congo-Brazzaville	a	French
GF/CRD Tanzania-1	Tanzania	a	English
GF/CRD USA-8	United States	a	English
GF/CRD WHO-1	World Health Organization	a	English
GF/CRD Côte d'Ivoire-1	Côte d'Ivoire	a and b	French
GF/CRD Nigeria-1	Nigeria	a and b	English
GF/CRD Australia-1	Australia	b	English
GF/CRD Canada-2	Canada	b	English
GF/CRD EC-2	European Community	b	English
GF/CRD Indonesia-1	Indonesia	b	English
GF/CRD Mongolia-1	Mongolia	b	English
GF/CRD New Zealand-2	New Zealand	b	English
GF/CRD Russia-1	Russian Federation	b	Russian, English
GF/CRD Senegal-1	Senegal	b	French
GF/CRD Turkey-1	Turkey	b	English
GF/CRD USA-1	United States	b	English
GF/CRD USA-2	United States	b	English

▪ **AGENDA ITEM 4.2**

<b>CRD REFERENCE</b>	<b>ORIGIN</b>	<b>AGENDA ITEM 4.2</b>	<b>AVAILABLE IN</b>
GF/CRD Argentina-1	Argentina	a	Spanish
GF/CRD BurkinaFaso-1	Burkina Faso	a	French
GF/CRD BurkinaFaso-2	Burkina Faso	a	French
GF/CRD China-1	China	a	English, Chinese
GF/CRD China-2	China	a	English, Chinese
GF/CRD Germany-1	Germany	a	English
GF/CRD Iceland-1	Iceland	a	English
GF/CRD Iran-1	Iran	a	English
GF/CRD Japan-1	Japan	a	English
GF/CRD Japan-2	Japan	a	English
GF/CRD Malaysia-1	Malaysia	a	English
GF/CRD Myanmar-1	Myanmar	a	English
GF/CRD Philippines-1	Philippines	a	English
GF/CRD Rep.Centrafr.-1	République Centrafricaine	a	French
GF/CRD Sweden-1	Sweden	a	English
GF/CRD Switzerland-1	Switzerland	a	French
GF/CRD Tanzania-2	Tanzania	a	English
GF/CRD Thailand-1	Thailand	a	English
GF/CRD United Kingdom-1	United Kingdom	a	English
GF/CRD Vanuatu-1	Vanuatu	a	English
GF/CRD WHO-2	World Health Organization	a	English
GF/CRD Côte d'Ivoire-2	Côte d'Ivoire	a and b	French
GF/CRD Indonesia-3	Indonesia	a and b	English
GF/CRD Liberia-1	Liberia	a and b	English
GF/CRD Mauritania-1	Mauritania	a and b	French
GF/CRD Canada-3	Canada	b	English
GF/CRD CI-1	Consumers International	b	English
GF/CRD Denmark-2	Denmark	b	English
GF/CRD Egypt-1	Egypt	b	English
GF/CRD FAO-1	Food and Agriculture Organization of the United Nations	b	English
GF/CRD IIR-1	International Institute of Refrigeration / Institut International du Froid	b	English, French
GF/CRD Mali-1	Mali	b	French
GF/CRD New Zealand-1	New Zealand	b	English
GF/CRD Senegal-2	Senegal	b	French
GF/CRD Slovak Republic-1	Slovak Republic	b	English
GF/CRD Sweden-2	Sweden	b	English
GF/CRD United Kingdom-2	United Kingdom	b	English
GF/CRD USA-3	United States	b	English
GF/CRD Zimbabwe-1	Zimbabwe	b	English

▪ **AGENDA ITEM 4.3**

<b>CRD REFERENCE</b>	<b>ORIGIN</b>	<b>AGENDA ITEM 4.3</b>	<b>AVAILABLE IN</b>
GF/CRD Canada-4	Canada	a	English
GF/CRD China-3	China	a	English, Chinese
GF/CRD Haïti-1	Haïti	a	French
GF/CRD Mongolia-2	Mongolia	a	French
GF/CRD USA-4	United States	a	English
GF/CRD Vietnam-1	Vietnam	a	English
GF/CRD Morocco-2	Morocco	a and b	French
GF/CRD Burundi-1	Burundi	b	French
GF/CRD CI-2	Consumers International	b	English
GF/CRD Côte d'Ivoire-3	Côte d'Ivoire	b	French
GF/CRD Eritrea-1	Eritrea	b	English
GF/CRD TrinidadTobago-1	Trinidad & Tobago	b	English
GF/CRD Uganda-1	Uganda	b	English
GF/CRD USA-5	United States	b	English

▪ **AGENDA ITEM 4.4**

<b>CRD REFERENCE</b>	<b>ORIGIN</b>	<b>AGENDA ITEM 4.4</b>	<b>AVAILABLE IN</b>
GF/CRD Mexico-1 GF 01/6 - Rev.1	Mexico	a	Spanish
GF/CRD Canada-5	Canada	a	English
GF/CRD China-4	China	a	English, Chinese
GF/CRD CI-3	Consumers International	a	English
GF/CRD Morocco-3	Morocco	a	French
GF/CRD Philippines-3	Philippines	a	English
GF/CRD Syria-1	Syria	a	Arabic
GF/CRD United Kingdom-3	United Kingdom	a	English
GF/CRD USA-6	United States	a	English
GF/CRD Canada-6	Canada	b	English
GF/CRD Denmark-1	Denmark	b	English
GF/CRD USA-7	United States	b	English



**Appendix 9**  
**Canadian Food Safety Agency**  
**Brochure**

加拿大食物安全管理署  
的宣傳小冊子



Canadian Food  
Inspection Agency

Agence canadienne  
d'inspection des aliments

# Protection you can count on



Canada

CFIA·ACIA



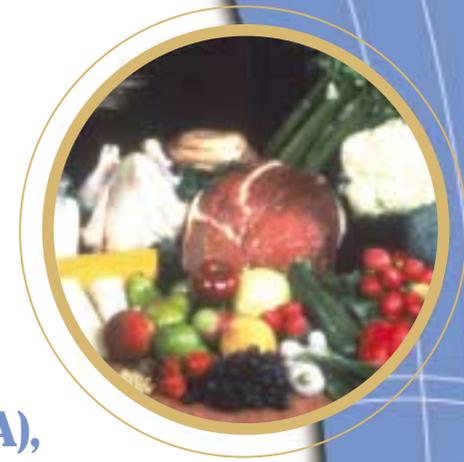
**SAFE FOOD AND HEALTHY PLANTS AND ANIMALS** ARE IMPORTANT TO ALL CANADIANS. THAT'S WHY THE CFIA'S EMPLOYEES — EXPERTS IN NUTRITION, MOLECULAR BIOLOGY, CHEMISTRY, TOXICOLOGY, AGRICULTURE, ENVIRONMENTAL SCIENCE AND FOOD LAW — ARE STATIONED IN HUNDREDS OF FIELD OFFICES, LABORATORIES AND FOOD PROCESSING FACILITIES ACROSS THE COUNTRY. **FOOD SAFETY AND PUBLIC HEALTH ARE THE CFIA'S PRIORITIES.**

**THE CFIA —**  
**THE GOVERNMENT OF CANADA'S REGULATOR FOR**

- **FOOD SAFETY** (ALONG WITH HEALTH CANADA)
- **ANIMAL HEALTH**
- **PLANT PROTECTION**

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**At the Canadian Food Inspection Agency (CFIA),**  
the safety of Canada's food supply  
is central to everything we do

- ▶ CFIA veterinarians and inspectors conduct rigorous inspections in some 1,800 meat and fish processing establishments across Canada.
- ▶ CFIA inspectors check shipments from abroad — examining plants, animals, foods and even packaging materials that can harbour diseases and pests, such as beetles or moths.
- ▶ CFIA agricultural officers inspect potato fields and greenhouses, hatcheries, feed mills and livestock premises.
- ▶ CFIA laboratory scientists analyze food samples for impurities, drug residues or disease-causing agents.
- ▶ CFIA regulators evaluate the safety of the newest kinds of seeds, feeds, fertilizers, and animal health products, such as vaccines, for use in Canada.
- ▶ CFIA officers review food labels for honesty and accuracy, investigate complaints and prosecute offenders.

## Food safety is everyone's business

### Canada's food safety system

In Canada, food safety begins with strong laws. Health Canada establishes standards for the safety and nutritional quality of foods sold in Canada. At the CFIA we enforce those standards rigorously and effectively.

Canada's inspection system is unique because the CFIA works from the ground up: our experts inspect not only foods, but also the seeds, feeds, fertilizers, plants and animals on which a safe food supply depends.

The CFIA does not handle the job alone. Food safety specialists in provinces and municipalities regulate thousands of regional food businesses, such as restaurants and food processors whose markets are local. The CFIA maintains close ties with consumers, distributors, internationally respected food experts, growers and food processors.

Everyone — from the farmer and fisher to the family chef — contributes to the safety of the food we eat.

traditional foods like honey and eggs, and also with foods new to the Canadian marketplace, from specialty frozen dinners to the products of biotechnology. We increase our surveillance on any food or supplier of concern, and we recall suspect products, seize illegal shipments and prosecute law breakers.

CFIA inspectors monitor the safety and quality of agricultural, fish and food products made in Canada, and we oversee the arrival of plants, animals and foods imported from more than 200 countries. Foods imported into Canada, from exotic cheeses to delicate biscuits, are subject to the same strict standards as those made here at home.



CANADA HAS AN  
INTERNATIONALLY RESPECTED  
FOOD SAFETY SYSTEM.  
CONSUMERS AROUND THE  
GLOBE RANK CANADIAN  
FOOD AMONG THE  
SAFEST IN THE WORLD.

## Our job is protection

### The Government of Canada's food safety watchdog

The CFIA works across the food supply. We can be seen inspecting food processing plants and cargos at ports, verifying fertilizers, and inspecting egg hatcheries. We deal with



PASSING INSPECTION FIRST: EVERY YEAR, OVER 1.6 MILLION TONNES OF MEAT AND POULTRY CROSS CANADA'S BORDERS. THE CFIA MONITORS EVERY SHIPMENT, INSPECTING AND SPOT-CHECKING IMPORTS, AND CONDUCTING ON-SITE SAFETY ASSESSMENTS OF FOREIGN FIRMS.

## Giving Canadians the information they need

### Protecting consumers

Canadians must have confidence in the food they buy — and that means providing them with important, factual information on food labels. The CFIA enforces Canada's fair packaging and labelling laws, checking labels for honesty and accuracy.

### Stepping-up emergency alerts

When emergencies occur, it's fast action across the country that counts. Industry is responsible for complying with food safety laws, but when recalls are necessary, the CFIA demands immediate and effective action. On call 24 hours a day, seven days a week, CFIA officials can, through an early warning system, alert emergency teams across the country.

### Allergy alert!

The CFIA manages about 250 food recalls each year. More than half of the recalled foods contain ingredients not mentioned on the labels — ingredients that can cause severe allergic reactions. To receive the CFIA's free food-recall warnings, you can subscribe at [www.inspection.gc.ca](http://www.inspection.gc.ca)



THE CFIA INVESTIGATES  
OVER 3,000 CONSUMER  
COMPLAINTS EACH YEAR.  
VIOLATION OF FOOD SAFETY  
LAWS, ADULTERATION OF  
PRODUCTS, OR IMPROPER  
GRADING ARE JUST SOME  
OF THE OFFENSES THAT  
CAN — AND DO — LEAD  
TO PROSECUTION.



## Safe foods begin with healthy plants and animals

### Safeguarding Canada's plants and animals

The CFIA works with the people who produce Canada's fish, plants and animals, helping to protect these commodities from diseases and pests. Something as small as a foreign beetle or fungus can play havoc with our crops. Animal diseases can wipe out whole herds, with devastating consequences.

Furthermore, the CFIA works to prevent foreign diseases and pests from getting into Canada.

### Be aware, you must declare

In major airports, CFIA inspectors work with detector beagles who sniff out undeclared foods, plants and animals arriving in travellers' baggage. For more information, visit our Web site at [www.inspection.gc.ca](http://www.inspection.gc.ca)

When pests threaten or diseases strike, the CFIA acts quickly to control and eradicate them. To prevent the spread of raccoon rabies, for example, the CFIA developed an improved test that can identify the disease in less than 24 hours.

To keep the food chain healthy, the CFIA regulates animal feeds and veterinary biologics, and conducts regular animal-health detection programs designed to head off serious threats to livestock, such as tuberculosis.

### SAFETY FOR CANADIANS AND CUSTOMERS ABROAD

THE CFIA CERTIFIES THE HEALTH OF CANADA'S ANIMAL EXPORTS, WHETHER THEY BE PIGEONS AND WILD SWINE TO MEXICO, POULTRY TO POLAND OR CATTLE TO LATVIA. ALMOST TWO MILLION LIVE ANIMALS CROSS THE CANADA-UNITED STATES BORDER EACH WEEK..

The CFIA carefully controls small field trials of new plants such as genetically modified crops. These trials help generate research about the potential for a plant to become a pest or to affect other organisms. Individuals involved in the field trial growth of new plants must comply with conditions set out by the CFIA and inspectors ensure that these requirements are met. We put the health of Canada's environment first.

The CFIA also certifies plants and animals that Canadians export around the world. More than 1,500 international agreements include every aspect of safe international trade in plants, animals and foods.



## Raising the bar on safety

### Science and technology contribute to the safety of food, animals and plants

Safety is an ongoing challenge. As a public health agency charged with protecting the health of consumers, plants and animals, the CFIA must keep pace with the newest scientific advances, the best investigative techniques, the most effective regulation and the safest practices worldwide. Our job is never complete and requires day-to-day prevention. The CFIA works with Canadian industries to implement state-of-the-art technology and safety systems capable of pinpointing potential food hazards.

The CFIA is Canada's largest science-based regulatory agency. Our inspectors and investigators depend on sound science and comprehensive laboratory testing to identify chemical, microbiological and physical impurities in our foods, and to diagnose diseases, viruses and pests that can threaten plants and animals. The CFIA's 22 laboratories conduct more than 500,000 tests each year to verify that standards are met.



THE **CANADIAN SCIENCE CENTRE** FOR HUMAN AND ANIMAL HEALTH IN WINNIPEG, JOINTLY OPERATED BY THE CFIA AND HEALTH CANADA, IS THE **FIRST SINGLE-SITE FACILITY** IN THE WORLD DESIGNED TO TACKLE THE MOST SERIOUS **DISEASES** AFFECTING BOTH HUMANS AND ANIMALS.

## Helping Canadians reduce the risks

### Food safety and you

Many food-borne illnesses can be prevented if food is safely handled, cooked, and stored at home. That's why the CFIA helped launch the Canadian Partnership for Consumer Food Safety Education. More than 60 organizations are working to focus attention on food-borne bacteria.

Check out the four basic steps — clean, separate, cook and chill — that consumers can practice to prevent food-borne illness in the home at [www.canfightbac.org](http://www.canfightbac.org)

The CFIA also publishes food safety fact sheets on more than 30 topics — providing tips on how to package school lunches safely or explaining the causes of salmonella. Visit our Web site and follow the links to our food fact sheets at [www.inspection.gc.ca](http://www.inspection.gc.ca)

Food safety is everybody's job.



**To reach us...**

Canadian Food Inspection Agency

59 Camelot Drive

Ottawa ON K1A 0Y9

1-800-442-2342

**[www.inspection.gc.ca](http://www.inspection.gc.ca)**



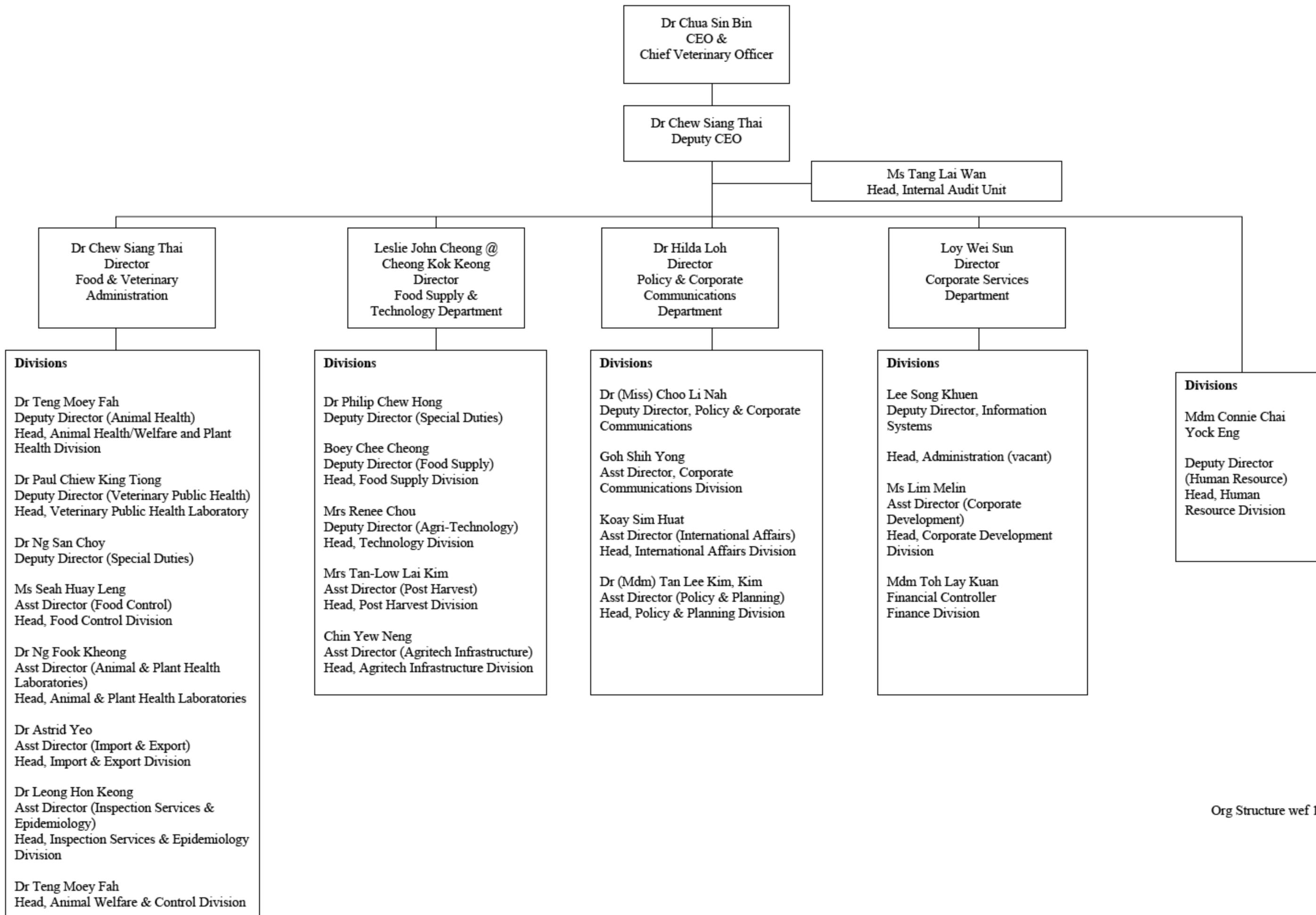
**Appendix 10**  
**Organisational Structure of**  
**Agri-Food and Veterinary**  
**Authority of Singapore**

新加坡

農產食品和獸醫局

的組織架構

# AGRI-FOOD & VETERINARY AUTHORITY



**Appendix 11**  
**Organisational Structure of**  
**Department of Agriculture,**  
**Fisheries and Forestry of**  
**Australia**

澳州

漁農森林署的組織架構



**SECRETARY**  
Joanna Hewitt



**DEPUTY SECRETARY**  
Don Banfield



**DEPUTY SECRETARY**  
Daryl Quinlivan

**GOVERNANCE**  
Craig Penney



**Chief Veterinary Officer/Special Adviser**  
Gardner Murray



**DEPUTY SECRETARY & Executive Director AQIS**  
Peter Yuile

**BIOSECURITY AUSTRALIA**

**CHIEF EXECUTIVE**  
John Cahill

**Principal Scientist (Plant Biosecurity)**  
Bill Roberts

**Plant Biosecurity General Manager**  
Louise van Meurs

**Principal Scientist (Animal Biosecurity)**  
Mike Nunn

**Animal Biosecurity General Manager**  
Robyn Martin

**Biosecurity Development & Communications General Manager**  
Stephen Prothero

RURAL POLICY AND INNOVATION DIVISION	FOOD AND AGRICULTURE DIVISION	INTERNATIONAL DIVISION	NATURAL RESOURCE MANAGEMENT DIVISION	CORPORATE POLICY DIVISION	FISHERIES AND FORESTRY DIVISION	AUSTRALIAN BUREAU OF AGRICULTURAL AND RESOURCE ECONOMICS	BUREAU OF RURAL SCIENCES	MANAGEMENT SERVICES DIVISION	PRODUCT INTEGRITY ANIMAL & PLANT HEALTH DIVISION	AUSTRALIAN QUARANTINE & INSPECTION SERVICE
<b>EXECUTIVE MANAGER</b> Ian Thompson	<b>EXECUTIVE MANAGER</b> David Mortimer	<b>EXECUTIVE MANAGER</b> Paul Morris	<b>EXECUTIVE MANAGER</b> Tom Aldred	<b>EXECUTIVE MANAGER</b> Allen Grant	<b>EXECUTIVE MANAGER</b> Glenn Hurry	<b>EXECUTIVE DIRECTOR</b> Brian Fisher	<b>EXECUTIVE DIRECTOR</b> Cliff Samson	<b>CHIEF OPERATING OFFICER</b> Bill Pahl	<b>EXECUTIVE MANAGER</b> Steve McCutcheon	<b>EXECUTIVE DIRECTOR</b> Peter Yuile
<b>Rural Support &amp; Adjustment General Manager</b> Anne McGovern (A/g)	<b>Crops, Wine and Horticulture General Manager</b> Russell Phillips	<b>Chief International Agricultural Adviser General Manager</b> Dennis Gebbie	<b>Commonwealth Regional NRM Team General Managers</b> Mike Lee Gerry Smith	<b>Parliamentary &amp; Media General Manager</b> Nicola Hinder	<b>Fisheries and Aquaculture General Manager</b> John Kalish (A/g)	<b>Deputy Executive Director</b> Karen Schneider (A/g)	<b>Deputy Executive Director</b> Colin Grant	<b>Finance</b> Chief Financial Officer Allan Gaukroger	<b>Product Safety and Integrity General Manager</b> Bill Magee	<b>QUARANTINE</b> <b>Executive Manager</b> Jenni Gordon
<b>Science &amp; Economic Policy General Manager</b> Simon Murnane	<b>Meat, Wool and Dairy General Manager</b> Sally Standen	<b>Technical Market Access Specialist</b> Sarah Kahn	<b>Landcare and Sustainable Industries General Manager</b> John Cameron (A/g)	<b>Corporate Policy &amp; Governance General Manager</b> Craig Penney	<b>Forest Industries General Manager</b> Tony Bartlett	<b>Research Director</b> Stephen Beare	<b>Deputy Executive Director</b> Kim Ritman (A/g)	<b>Information Services</b> Chief Information Officer Gary Leifheit	<b>Animal and Plant Health Policy General Manager</b> Dean Merrilees	<b>Border</b> General Manager Andy Carroll
<b>Drought Taskforce General Manager</b> Matt Koval	<b>Food Policy and Safety General Manager</b> Richard Souness	<b>International Trade Branch General Manager</b> Nicola Gordon-Smith	<b>Water and Murray Darling Basin General Managers</b> Ross Dalton Simon Smalley	<b>Biosecurity Policy General Manager</b> TBA	<b>Fisheries and Marine Environment General Manager</b> Russell James	<b>General Manager International</b> Don Gunasekera	<b>Chief Scientist</b> Michele Barson	<b>Human Resources General Manager</b> Julie Hicks	<b>National Residue Survey Manager</b> Peter Miller	<b>Cargo Management General Manager</b> Bob Murphy
		<b>International Technical Branch General Manager</b> Melanie O'Flynn	<b>NRM Strategies and Climate Change General Manager</b> Heather Tomlinson	<b>National Biosecurity Strategy Taskforce General Manager</b> Charles Willcocks	<b>Fisheries Adjustment Taskforce General Manager</b> John Talbot (A/g)	<b>General Manager Survey</b> Rhonda Treadwell		<b>Levies Revenue Service General Manager</b> Steve Maxwell	<b>OFFICE OF THE CHIEF VETERINARY OFFICER</b>	<b>EXPORTS</b> <b>Executive Manager</b> Greg Read
		<b>FREE TRADE AGREEMENTS</b> Executive Manager Craig Burns				<b>General Manager Industries</b> Colin Mues (A/g)			<b>Deputy Chief Veterinary Officer</b> Bob Biddle	<b>Animal Programs General Manager</b> Narelle Clegg (A/g)
		<b>OVERSEAS POSTS</b>				<b>General Manager Natural Resource Management</b> Peter Gooday (A/g)			<b>OFFICE OF THE CHIEF PLANT PROTECTION OFFICER</b>	<b>Plant Programs General Manager</b> Peter Lichne
		<b>Brussels</b> Minister-Counsellor, Agriculture Greg Williamson				<b>General Manager Commodity Outlook &amp; Data Management</b> Andrew Dickson (A/g)			<b>Chief Plant Protection Officer</b> Lois Ransom	<b>Food Exports General Manager</b> Tim Carlton
		<b>Paris OECD</b> Minister-Counsellor, Agriculture Roland Pittar							<b>Australian Plague Locust Commission Director</b> Laury McCulloch	<b>Technical Standards General Manager</b> Ann McDonald
		<b>Rome</b> Counsellor, Agriculture Judy Barfield								<b>Business Strategy Group General Manager</b> Cathy Cox
		<b>Tokyo</b> Minister-Counsellor, Agriculture Bill Withers								<b>Compliance &amp; Investigations General Manager</b> Wayne Terpstra
		<b>Washington</b> Minister-Counsellor, Agriculture Fran Freeman								
		<b>Counsellor, Veterinary Services</b> Andrew Cupit								
		<b>Seoul</b> Counsellor, Agriculture Jeremy Cook								
		<b>Beijing</b> Counsellor, Agriculture Mark Schipp								
		<b>Dubai</b> Consul-Agriculture (Middle East) Kiran Johar								