SUBMISSION TO HONG KONG LEGISLATIVE COUNCIL
SUBCOMMITTEE ON FOOD AND DRUG (COMPOSITION AND LABELLING) (AMENDMENT)(No.2) REGULATION 2014

ABBOTT LABORATORIES LIMITED

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In November 2012, the Centre for Food Safety, Food and Environmental Hygiene Department issued a Legislative Proposal Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 months in Hong Kong. Abbott Laboratories Limited (Abbott) welcomes the government's initiative to safeguard the wellbeing of infants and young children by regulating both the formula composition and the labeling aspects of formula and foods for children up to 36 months. Abbott also greatly appreciates the opportunities provided over the past two years to participate in the discussion through various trade consultation forums and technical forums. Abbott would like to submit the following comments for consideration.

1 Tolerance Limits

Abbott supports the department's approach in following Codex Alimentarius standards related to both composition and labeling requirements for infant formula and labeling requirements for follow up formulae. In view of the department's intention to introduce tolerance limits on label claims for many nutrients, Abbott proposes to align Hong Kong minimum tolerance limits with those already established within the region, *i.e.*, China and Taiwan, to foster trade and harmonization of formulations in the region. Thus, Abbott proposes the following:

- Minimum tolerance of 80% of the declared label claim value for all macro- and micronutrients.
- No specifically defined maximum tolerance.

Minimum tolerance limit:

Consistent with the regulatory framework for minimum tolerance limits within the region (specifically China and Taiwan), and other global regulatory jurisdictions, Abbott proposes to maintain a minimum tolerance limit as 80% of the declared label claim value. Both **China** and **Taiwan** have established a minimum tolerance limit of 80% of the declared label claim value for all macro and micro nutrients. The majority of the other global regulatory authorities have adopted an average declared label claim value without a specific minimum tolerance. The **Australia** and **New Zealand** food labeling legislation defines declared label claim values as average values, though a specific tolerance limit below label claim has not been defined. The **European Union** legislation defines declared label claim values as average values in EU Regulation 1169/2011, though to date, has not defined a harmonized minimum label claim tolerance for food products which have defined compositional standards nor foodstuffs intended for particular nutritional uses. Because label claims are average values, it is reasonable to conclude that the minimum tolerance limit can fall below 100% of label claim despite lack of a harmonized threshold in Australia/New Zealand and the European Union.

Maximum tolerance limit:

Consistent with **China** regulation for nutrition labeling of prepackaged foods for special dietary use (GB 13432-2013), Abbott proposes to define only the minimum tolerance limit and not define specific maximum tolerance limits. Good Manufacturing Practices (GMPs) are, among other things, intended to assure that consumers receive the amount of nutrients declared on the label throughout shelf life. In addition, GMP regulations assure that maximum tolerance, or overages, are safe, suitable, and within compliance of GMP. Manufacturers bear the burden of designing products and systems to assure compliance with GMPs and thus fortification design and overages are determined based on several factors, including incoming nutrient variability of inherent and fortified raw materials, variability due to multiple sources of addition (either through individual addition or use of nutrient premixes, each with their own variability range), fortification needs based on processing and shelf life stability and degradation of labile nutrients, and

variability due to analytical method. Historical precedent has shown acceptability for not establishing a specific maximum tolerance limit according to other global regulatory authorities. The **Australia** and **New Zealand** legislation does not define a specific maximum tolerance limit. The **European Union** legislation to date, has not defined a harmonized minimum or maximum label claim tolerance for food products which have defined compositional standards nor foodstuffs intended for particular nutritional uses. While the European Union legislation has not yet harmonized either minimum or maximum tolerance limits in these cases, some of the EU member states have established local requirements. The United States Food and Drug Administration has established that tolerance limits should be within GMP (*i.e.*, no defined specific maximum tolerance limit - with the exception of calories, sugar, total fat, saturated fat, trans fat, cholesterol, and sodium, which must not exceed 120% of the label claim). Flexibility on the maximum limits for fortified vitamins, minerals, and other nutrients, allows for formulation modifications as expert nutritional recommendations change with advancing science.

2 Formulas for Special Medical Purpose (FSMP)

Abbott supports the department's intention to exempt FSMP formula from both part IV of Schedule 1 and Schedule 6A. FSMP for infants and young children are specially processed or formulated foods for the dietary management of infants and young children who have a limited or impaired capacity to take, digest, absorb or metabolize ordinary food or nutrients; who have special nutrient requirements that are determined medically; or whose dietary management cannot be achieved only by consumption of other food for special dietary uses or modification of the normal diet; and whom are under medical supervision. The FSMPs Abbott imports into Hong Kong are niche products for specific patient populations and are formulated to meet very special medically determined needs under the supervision of the physician. Examples include Neosure (a formula for pre-term babies) and Glutarex-1 (amino acid modified infant formula for infant with glutaric aciduria type I). The majority of these products are used in the hospital setting. Without the exemptions, these formulas would not be allowed to be sold in Hong Kong because their specialized formulations deviate from standard term infant and follow-on formula requirements to meet the unique needs of the intended populations. The patients' wellbeing, or even survival, could be adversely affected without needed nutritional intervention. Similarly,

specific labeling may be needed to provide information relevant to the health care practitioner and/or caregiver to ensure appropriate understanding and use of the formula. Abbott supports the department's consideration to exempt FSMP from both part IV of Schedule 1 and Schedule 6A.

3 Grace period

During the implementation of the existing nutrition labeling and nutrition claims regulation (*i.e*. 1+7) in 2008, a 24 month grace period was granted for manufacturers to revise their product labels in accordance with the new regulation. As the current amendments could affect formulation, manufacturing process, label development and testing requirement, Abbott proposes a minimum grace period of 24 months to assure time to reformulate product, revise labels, and amend manufacturing and testing requirements accordingly, to comply while also avoiding any supply disruption in the Hong Kong market for consumers and patients of these important formulas. See Appendix for a detailed overview of industry timelines to reformulate and re-label.

ABBOTT NUTRITION INTERNATIONAL

Appendix

Industry Timeline for Proposed Labelling and Composition Regulation

Industry Action	**Timeline**
Reformulation	8 months
Stability Testing	12 months
Packaging Production and Label Development	4 months
Manufacturing and Quality Assurance Release Testing Procedures	1 month
Shipping	1.5 months
Total	**26 months**