Lawrence Kogan on

Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)

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Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law
(Part 2 of 3)

By

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I. Introduction

Part 1 of this article discussed how the various *food safety*-related provisions of the *Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children*[1] ("the Draft HK Code") violate the WTO Sanitary and Phytosanitary ("SPS") Agreement.[2] In particular, it focused on how the Government of the Hong Kong Special Administrative Region ("the GHK-SAR") had failed to substantiate with scientific evidence, on *food safety* grounds, the Draft HK Code's effective imposition of a 30-month marketing ban on follow-up formula and complementary food products intended for infants and young children up to 36 months of age.

As discussed in Part 1 of this article, the WTO Panel in *EC-Biotech Products*[3] ruled that it is possible to have a consolidated measure part of which qualifies as an "SPS measure" subject to coverage under the WTO SPS Agreement, and part of which qualifies as a "non-SPS measure" potentially subject to coverage under the WTO Technical Barriers to Trade ("TBT") Agreement. It found that TBT "Article 1.5 makes clear that, to the extent the requirement at issue qualifies as an SPS measure, the provisions of the TBT Agreement would 'not apply', even though the requirement at issue is contained in a law which meets the definition of a technical regulation."[4] And, "to the extent the requirement at issue is applied for a purpose not covered by Annex A(1) of the SPS Agreement, it can be viewed as embodying a non-SPS measure."[5] However, since TBT Article 1.5 is not necessarily applicable, by its terms, to non-SPS measures, it must first be demonstrated that the measure qualifies for coverage under the TBT Agreement.

The notification the GHK-SAR submitted in November 2012 to the WTO TBT Committee[6] in accordance with TBT Article 2.9 provides a step in that direction. It indicates that the Draft HK Code also has *non*-food safety-related purposes. While Section 7 of the GHK-SAR's TBT notification provides a statement of purpose that is identical to the statement of purpose contained in Section 7 of the notification it submitted to the SPS Committee,[7] it must be read with an eye towards

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1 *See* Government of the Hong Kong Special Administrative Region, Department of Health, *Public consultation on the HK Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants and Young Children*, Press Release (Oct. 26, 2012), available at: http://www.dh.gov.hk/english/press/2012/121026.html

2 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law*, Part 1 – *The Draft HK Code Violates the SPS Agreement*, LexisNexis (2013), available at: . Part 1 of this article discussed the Draft HK Code's food safety purpose of "protect[ing] human…life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods". *See* SPS Agreement Annex A(1)(b).

3 Panel Report, *EC-Biotech Products*, supra.

4 *Id*., at par. 7.167. TBT Article 1.5 provides that, "[t]he provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures." TBT Art. 1.5.

5 *Id*. In *EC-Biotech Products*, the Panel assumed that the statutory requirement in question was "part of a technical regulation", and consequently, that "it falls to be assessed under the TBT Agreement, to the extent it embodies a non-SPS measure." *See* Panel Report, *EC-Biotech Products* at par. 7.167.

6 *See* Hong Kong, China, *Notification to WTO Committee on Technical Barriers to Trade* G/TBT/N/HKG/43 (Nov. 2, 2012), available at: http://www.tbtvn.org/Lists/Ti%20liu/Attachments/7813/HKG43.doc. Paragraph 7 of said notification provides as follows: **Objective and rationale, including the nature of urgent problems where applicable**: The HK Code aims to contribute to the protection of breastfeeding and provision of safe and adequate nutrition for infants and young children by: (a) protecting breastfeeding and; (b) ensuring the proper use of formula milk, formula milk related products, and food products for infants and young children up to the age of 36 months, on the basis of adequate and unbiased information and through appropriate marketing" (boldface emphasis in original). *Id*. The GHK-SAR filed this notification in compliance with TBT Agreement, Art. 2.9.2.

7 *See* Hong Kong, China, *Notification to WTO Committee on Sanitary and Phytosanitary Measures*, G/SPS/N/HKG/38 (Nov. 2, 2012), available at: http://tbt.testrust.com/image/nsps/803/103803_1.doc.

gleaning the Draft HK Code's *non*-food safety purposes.[8] Both notifications provide that, "[t]he HK Code aims to contribute to the protection of breastfeeding and…provision of safe and *adequate nutrition* for infants and young children *by*: (a) *protecting breastfeeding* and; (b) ensuring the proper use of formula milk, formula milk related products, and food products for infants and young children up to the age of 36 months, *on the basis of adequate and unbiased information and through appropriate marketing*" (emphasis added). The key difference between these two notification documents is to be found in Section 8. Section 8 of the GHK-SAR's TBT notification identifies the WHO *International Code of Marketing of Breastmilk Substitutes* (the "WHO Code") as *the* "Relevant Document", whereas Section 8 of the GHK-SAR's SPS notification identifies eight Codex standards,[9] in addition to, the WHO Code as "Relevant International Standards".[10] The GHK-SAR's TBT notification is important because it "enjoys a rebuttable presumption of truthfulness and good faith consistent with international law."[11]

The Draft HK Code's background description and text support such a reading. They similarly reflect that one such purpose is to promote public health by "protect[ing], promot[ing] and support[ing] breastfeeding" which helps "infants…to achieve optimal growth, development and health and thereafter, to meet their evolving nutritional requirements."[12] The Draft HK Code's background description and text also indicate that another such purpose is to address "the aggressive marketing of formula milk in Hong Kong, which is considered a factor that contributes to the low breastfeeding rates[13]…[i.e., t]o protect breastfeeding from being undermined by inappropriate marketing."[14] The background description states that the intent of this latter purpose is to ensure parental choice in infant feeding decisions free from commercial influence and/or misrepresentations.[15]

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8 The Draft HK Code's food-safety-related purpose can be discerned by juxtaposing the words "safe" and "nutrition" with the phrase "on the basis of adequate and unbiased information and through appropriate marketing." *Id*. at Sec. 7; G/TBT/N/HKG/43, supra at Sec. 7.

9 These Codex standards include *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981); *Standard for Follow-up formula* (CODEX STAN 156-1987), *Standard for Canned Baby Foods* (CODEX STAN 73-1981); *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981); *General Standard for Food Additives* (CODEX STAN 192-1995); *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008); *Guidelines for Formulated Supplementary Foods for Older Infants and Young Children* (CAC/GL 08-1991); and *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CODEX STAN 146-1985). Many of these standards were referenced or discussed in Part 1 of this article.

10 Part 1 of this article concluded that the WHO Code was *not* a relevant international standard for purposes of the SPS Agreement. However, Part 2 of this article concludes that the WHO Code *is* a relevant international standard for purposes of the TBT Agreement. *See* discussion *infra*.

11 *See* Panel Report, *United States - Certain Country of Origin Labeling (COOL) Requirements ("US-COOL")*, WT/DS384/R, WT/DS386/R (Nov. 18, 2011) at pars. 7.605-7.606.

12 Draft HK Code, Background at p. 2. "The Government has all along endeavoured to promote, protect and support optimal feeding of infants and young children." *Id*., p. 3.

13 *Id*.

14 *Id*., p 2. Allegations of inappropriate and/or aggressive marketing of breastmilk substitutes in Hong Kong in violation of the WHO Code appear in a 2006 article authored by a Hong Kong pediatrician calling for Hong Kong's implementation of the WHO Code. *See, e.g.,* PLS Ip, *Health professionals and the International Code of Marketing of Breast-milk Substitutes*, 12 Hong Kong Med J 400-401 (2006), available at: http://www.hkmj.org/article_pdfs/hkm0610p400.pdf. This author apparently approved of Hong Kong' breastfeeding policy of treating *follow-up formula* as a breastmilk *substitute* years before the Draft HK Code was introduced. *Id.*, at p. 400, fn. 6. *See e.g.,* Government of the Hong Kong Special Administrative Region, Department of Health, *Breastfeeding Policy*, available at: http://www.fhs.gov.hk/english/breastfeeding/files/bfpolicy.pdf.

15 "The creation of an environment that protects, promotes and supports breastfeeding requires a systemic approach, which includes enabling parents to make informed decisions on infant feeding free from commercial influence, ensuring policies and practices of maternal-and-child-health facilities are supportive of breastfeeding, and building family-friendly social policies (e.g. maternity legislations) and community services." *Id*.

Although Draft HK Code provisions may qualify (wholly or partly) as non-SPS measures, it cannot be presumed that they fall within the scope and coverage of the TBT Agreement.[16] Part 2 of this article discusses how various such provisions qualify as *de facto* "technical regulations" under the TBT Agreement but nevertheless violate the letter and spirit of the TBT Agreement because they impose unnecessary obstacles to trade.

II. Discussion – The Draft HK Code Violates the TBT Agreement

1. National Non-SPS Measures Must Fall Within the Scope and Coverage of the TBT Agreement

A given measure will be subject to the provisions of the TBT Agreement only if it qualifies either as a "technical regulation" or a "standard," as defined by TBT Annexes 1.1 and 1.2. "[T]echnical regulations [are]…mandatory documents,"[17] [while]…standards [are] voluntary… documents."[18]

a. Ascertaining Whether National Measures are Technical Regulations or Standards

A "technical regulation" is a "[d]ocument which lays down [either] *product* characteristics or *their related processes and production methods*, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method" (emphasis added).[19] A "standard" is a "[d]ocument approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for *products or related processes and production methods*, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method" (emphasis added).[20]

Significantly, the second sentences of Annex 1.1 (technical regulation) and Annex 1.2 (standard) are identical. This means that "the subject matter of a particular measure is therefore not dispositive of whether a measure constitutes a technical regulation or a standard. Instead, 'terminology', 'symbols', 'packaging', 'marking', and 'labelling requirements' may be the subject-matter of either technical regulations or standards."[21] According to the Appellate Body, the "determination of whether a particular measure constitutes a technical regulation must [therefore] be made in the light of the characteristics of the measure at issue and the circumstances of the case."[22] "This

16 SPS Art. 1.4; TBT Art. 1.5.

17 TBT Annex 1.1. A 'technical regulation' is a "[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method." Id.

18 TBT Annex 1.2, Explanatory Note.

19 TBT Annex, 1.1.

20 TBT Annex 1.2.

21 Appellate Body Report, *United States — Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ("US - Tuna II (Mexico)")* WT/DS381/AB/R (May 16, 2012), at par. 187.

22 *Id*., at par. 188; Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products ("EC - Asbestos")*, WT/DS135/AB/R (Mar. 12, 2001) at par. 64; Appellate Body Report, *European Communities - Trade Description of Sardines ("EC - Sardines")* WT/DS231/AB/R (Sept. 26, 2002), at pars. 192-193. "In some cases, this may be a

exercise may involve considering whether the measure consists of a law or a regulation enacted by a WTO Member, whether it prescribes or prohibits particular conduct, whether it sets out specific requirements that constitute the sole means of addressing a particular matter, and the nature of the matter addressed by the measure."[23]

b. The Technical Regulation Three-Part Test

A document must meet three criteria in order to fall within the definition of a technical regulation. "First, the document must apply to an 'identifiable' product or group of products [which]…need not, however, be expressly identified in the document."[24] "Second, the document must lay down one or more characteristics of the product [which]...may be intrinsic or…related to the product [and]…be prescribed or imposed in either a positive or negative form."[25] "Third, compliance with the product characteristics must be mandatory."[26]

The first criterion has been recognized as underlying a WTO Member's core obligation under TBT Article 2.9.2, namely, to notify other members "of the products to be covered" by a proposed technical regulation.[27] However, a document needn't explicitly mention a product for that product to be identifiable. "The identifiable product coverage of a measure can also be determined according to the substance of the measure at issue."[28]

The second criterion has been interpreted as incorporating a rather broad scope of product characteristics. They can include any "definable 'features', 'qualities', 'attributes' or other 'distinguishing mark' of a product."[29] This means that characteristics can relate directly to the "features and qualities intrinsic to the product itself," *as well as indirectly to the means by which products are identified, presented, and made to appear*.[30] In addition, it is also helpful to consider whether the provision that constitutes the essence of the measure addresses a product characteristic, and whether the obligations set out by the measure are closely related to an essential function.[31]

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relatively straightforward exercise. In others, the task…may be more complex. Certain features exhibited by a measure may be common to both technical regulations falling within the scope of Article 2 of the TBT Agreement and, for example, standards falling under Article 4 of that Agreement. Both types of measure could, for instance, contain conditions that must be met in order to use a label. In both cases, those conditions could be 'compulsory' or 'binding' and 'enforceable'. Such characteristics, taken alone, cannot therefore be dispositive of the proper legal characterization of the measure under the TBT Agreement. Instead, it will be necessary to consider additional characteristics of the measure in order to determine the disciplines to which it is subject under that Agreement." *Id*., par. 188; Appellate Body Report, *China – Measures Affecting Imports of Automobile Parts ("China - Auto Parts")* WT/DS339/AB/R, WT/DS340/AB/R, WT/DS342/AB/R, (adopted Jan. 12, 2009) at par. 171.

23 Appellate Body Report, *US - Tuna II (Mexico)* at par. 188.

24 TBT Annex 1.1.

25 *Id*.

26 *Id*., as interpreted in Appellate Body Report, *EC – Sardines* at par. 176; Appellate Body Report, *EC – Asbestos* at pars. 66–70; Panel Report, *US - Tuna II (Mexico)*, at par. 7.58; Panel Report, *US - COOL* at par. 7.147.

27 Appellate Body Report, *EC – Asbestos* at par. 70.

28 Panel Report, *US - COOL* at par. 7.201.

29 Appellate Body Report, *EC - Asbestos* at par. 67.

30 *Id*.

31 Panel Report, *US - COOL* at par. 7.212.

To satisfy the third criterion ("mandatory"), a measure must "lay down . . . set forth, stipulate or provide [the] characteristics," (e.g., qualities or attributes) "of products in a binding or compulsory fashion" or "ha[ve] the effect of prescribing or imposing" them.[32] A measure must be "examined as an integrated whole, taking into account, as appropriate, the prohibitive and the permissive elements that are part of it."[33] The mandatory nature of a given measure may be revealed by the following indicia: 1) whether the measure is composed of classic legal instruments that are legally binding under the law of the home country jurisdiction;[34] 2) whether the measure uses the word "shall" in laying down its requirements;[35] 3) whether the measure is supported by an "enforcement" mechanism that foresees the possibility of imposing a fine/penalty in the event of noncompliance;[36] and 4) whether the measure consistently refers to its core requirement as a "mandatory" requirement.[37]

2. Various Draft HK Code Provisions Satisfy the Technical Regulation Three-Part Test

a. The Products Identified

Draft HK Code Article 2.1(b) identifies, and the GHK-SAR's TBT notification confirms, that three broad categories of products are subject to its provisions: formula milk, infant and young children's foods, and formula milk-related products intended for infants and young children from 0-36 months of age.[38] Draft HK Code Article 3 further breaks down the food categories as follows: formula milk[39] includes "infant formula"[40] and "follow-up formula";[41] infant and young children's foods[42] include any foods (excluding formula milk, but including complementary foods[43]) "intended primarily for use during the normal infant's weaning period and for the progressive adaptation of infants and young children to ordinary food",[44] and any food for special medical purposes, but not formula milk.[45] Non-food formula milk-related products are further broken down into feeding bottles, teats and pacifiers.[46]

Furthermore, Draft HK Code Articles 4 and 5 identify formula milk and formula milk related products (as defined in Article 3) as falling subject to each provision's respective informational/educational materials and promotional activities prescriptions and prohibitions,[47] while Article 8 identifies formula milk, food products for infants and young children, and formula

32 Appellate Body Report, *EC - Asbestos* at pars. 67–69.
33 *Id*., at pars. 64, 75.
34 Panel Report, *US - COOL* at par. 7.157.
35 *Id*. at par. 7.158. The *US - COOL* Panel noted that the use of the word "shall" is indicative of mandatory compliance. *Id*., at par. 7.160; Appellate Body Report, *EC - Sardines* at par. 194.
36 Panel Report, *US - COOL*, at par. 7.159.
37 *Id*. at pars. 7.160–7.16; Appellate Body Report, *EC - Asbestos* at par. 72.
38 Draft HK Code, Art. 2.1(b); G/TBT/N/HKG/43, supra at par. 4.
39 Draft HK Code Art. 3, p. 10.
40 Draft HK Code Art. 3, p. 12.
41 Draft HK Code, Art. 3, p. 9.
42 Draft HK Code, Art. 3, pp. 9-10.
43 Draft HK Code, Art. 3, p. 8.
44 Draft HK Code Art. 3(a), pp. 9-10.
45 Draft HK Code Art. 3(b), p. 10.
46 Draft HK Code Art. 3, p. 10.
47 Draft HK Code Arts. 4.2.1; 4.3.1; 4.4.1(d); 5.1; 5.2(c).

milk-related products (as defined in Article 3) as falling subject to its product container and labeling prescriptions and prohibitions.[48]

Thus, Draft HK Code Articles 3, 4, 5 and 8 satisfy the first criterion of the three-part technical regulation test.

b. The Product Characteristics Described

Draft HK Code Article 3 describes the composition of infant formula and follow-up formula products as a "milk or milk-like product of animal or plant origin formulated industrially",[49] or as "powder[ed]".[50] It describes the use of infant formula as that intended "to satisfy by itself the nutritional requirements of infants during the first months of life up to the introduction of feeding by appropriate complementary food" – i.e., typically, up to the sixth month of life.[51] It describes the use of follow-up formula as that "marketed or otherwise represented as a food suitable for use as a liquid part of the weaning diet for infants from the 6th month on and for young children."[52]

Draft HK Code Article 3 also describes the special medical uses of both "infant formula" and "follow-up formula" – i.e., "any formula for special medical purposes that is specially manufactured to satisfy…the special nutritional requirements of infants […] with specific disorder(s), disease(s) or medical condition(s)."[53] Infant formula used for special medical purposes is described as intended to satisfy "*by itself*" such requirements "during the first months of life *up to the introduction of feeding by appropriate complementary food*",[54] while follow-up formula used for special medical purposes is described as intended to satisfy such requirements "for infants *from the 6th month on* and for young children not as a sole source of nutrition" (emphasis added).[55]

Draft HK Code Article 3, furthermore, describes the composition of "food for infants and young children" as "any food, *except formula milk*…which may be either in ready-to-eat form or in dry form requiring reconstitution with water, milk or other suitable liquids, and includes and includes complementary food" (emphasis added).[56] It describes the use of such foods as that "intended primarily for use *during the normal infant's weaning period* and for the progressive adaptation of infants and young children to ordinary food" (emphasis added).[57] Draft HK Code Article 3 also describes the composition of "complementary food" as "any food except milk or milk-like product",

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48 Draft HK Code Arts. 8.2.1; 8.3.1; 8.4.1.
49 Draft HK Code Arts. 3(a), pp. 9 and 12.
50 Draft HK Code Arts. 3, p. 12, fn. 10; 4.4.1(e)(iii)(G); 8.2.1(c)(viii); 8.2.1(f).
51 Draft HK Code Art. 3(a), p. 12. The WHO has advised that "appropriate complementary feedings should start *from the age of six months* with continued breast feeding up to two years or beyond" (emphasis added). *See* World Health Organization, *Complementary Feeding, Report of the Global Consultation* (2002), at p. 1, available at: http://www.who.int/nutrition/publications/Complementary_Feeding.pdf; World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003), at pp. 11 and 18, available at: http://whqlibdoc.who.int/paho/2003/a85622.pdf; World Health Organization, *Guiding Principles for Feeding Non-Breastfed Children 6-24 Months of Age* (2005), at pp. 7 and 9, available at: http://whqlibdoc.who.int/publications/2005/9241593431.pdf.
52 Draft HK Code Art. 3, p. 9.
53 *Id.*, at pp. 9 and 12.
54 *Id.*, at p. 12.
55 *Id.*, at p. 9.
56 *Id.*, at pp. 9-10.
57 *Id.*

and the use of complementary food as that "suitable as an *addition to breastmilk* or formula milk for infants *of or above the age of 6 month*s and young children *of or below the age of 24 months*" (emphasis added).[58]

Draft HK Code Article 3, moreover, describes the composition of "foods for infants and young children" for "special medical purposes" as "any food, *except formula milk*", and the use of such foods as that "intended for the exclusive or partial feeding of infants and young children with limited or impaired capacity to take, digest, absorb or metabolise ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, or whose dietary management cannot be achieved only by modification of normal diet and/or other food for special dietary uses."[59]

In addition, Draft HK Code Article 4 prescribes how these products can be presented and described to the general public and to healthcare workers in disseminated product information materials and informational/educational materials on breastfeeding and formula milk feeding by manufacturers, distributors, or their third party marketing agents.[60]

Draft HK Code Article 5 proscribes certain conduct – i.e., public promotion, including advertising – in connection with formula milk and formula milk-related products, and restricts other conduct – i.e., public promotion of infant and young children's food products.[61]

Draft HK Code Article 8 prescribes how formula milk, infant and young children's food products and formula milk-related products can be presented and described on product containers and labels via imposition of specific requirements concerning the use of terminology, symbols, packaging, markings, and labeling with respect to such products.[62]

i. Formula Milk and Infant and Young Children's Food Product-Related and Informational/Educational Materials

Draft HK Code Article 4.1.1(b) generally prohibits manufacturers and distributors from directly or indirectly distributing to the general public, pregnant women or mothers of children aged 36 months or below informational/educational materials referring to breastfeeding and formula milk feeding.[63]

While Draft HK Code Article 4.2.1 generally permits manufacturers and distributors to provide product-related information on specific brands of formula milk and formula milk-related products to the public on their websites, at the premises of retailers or at health care facilities,[64] Draft HK Code Article 4.2.1(a) restricts the content of that information to the technical and textual

58 *Id*., at p. 8.
59 *Id*., at p. 10.
60 Draft HK Code Arts. 4.1; 4.1.1 ; 4.2; 4.3; 4.4; 7.2.
61 Draft HK Code Arts. 5.1 (formula milk and formula milk-related products); 5.2 (infant and young children's food products).
62 Draft HK Code Arts. 8.2 (formula milk); 8.3 (food products for infants and young children); 8.4 (formula milk-related products).
63 Draft HK Code Art. 4.1.1(b).
64 Draft HK Code Art. 4.2.1(a).

information that appears on the product container or label.[65] This provision also prescribes the terminology that should be used in product-related materials about breastfeeding,[66] complementary feeding,[67] and formula milk feeding.[68] Draft HK Code Article 4.4.1(e) imposes similar terminology restrictions with respect to information that agents of manufacturers and/or distributors can disseminate to the public on their principals' behalf via the same media and distribution channels.[69] In addition, Draft HK Code Article 4.2.1(b) precludes product-related information on specific brands of formula milk and formula milk-related products from containing specific symbols including "photographs, pictures or any graphic representation other than for illustrating methods of preparation, except for a pack shot of a size not more than one-tenth of the total space occupied by the information".[70]

Furthermore, Draft HK Code Article 4.2.1(d) prohibits the distribution by manufacturers or distributors of product-related information unless the terminology and/or symbols contained in such information satisfy Articles 4.4.1(a)-(c). This means that such information should not: "use any pictures or texts that encourage feeding by formula milk or discourage breastfeeding;[71] or give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or breastfeeding.[72]

Draft HK Code Article 4.3.1(a) prohibits formula milk and formula milk-related product manufacturers from displaying, and thus exercising, economically valuable intellectual property - symbols and marks, including the brand name, logo or trade mark of any formula milk product - on any informational or educational materials they produce, donate or distribute, whether or not such materials are scientifically accurate and truthful.[73]

Draft HK Code Article 4.4.1(d) prohibits third parties other than formula milk and formula milk-related product manufacturers and distributors (e.g., third party marketers, broadcasters or trade associations) from using a formula milk brand name, logo or trade mark or from mentioning the

65 Draft HK Code Art. 4.2.1(a).
66 Such information should "clearly and conspicuously explain": "(A) the benefits and superiority of breastfeeding; (B) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond; (C) how to initiate and maintain exclusive and sustained breastfeeding; (D) why it is difficult to reverse a decision not to breastfeed; (E) the importance of introducing complementary food from the age of six months; and (F) how and why any introduction of bottle feeding or early introduction of complementary food negatively affects breastfeeding." Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(i)(A)-(F).
67 Such information should "clearly and conspicuously explain": "(A) the benefits and superiority of breastfeeding; (B) the importance of introducing complementary food from the age of six months; (C) how and why any introduction of bottle feeding or early introduction of complementary food negatively affects breastfeeding; and (D) that complementary food can easily be prepared at home using ordinary ingredients." Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(ii)(A)-(D).
68 Such information should "clearly and conspicuously explain": (A) the benefits and superiority of breastfeeding; (B) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond; (C) how to initiate and maintain exclusive and sustained breastfeeding; (D) why it is difficult to reverse a decision not to breastfeed;…(F) the health risks of…using a feeding bottle and teat and improper preparation of feeding bottle and teat;…(H) the approximate financial cost of feeding an infant with feeding bottle and teat in the recommended quantities." Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(iii)(A)-(D), (F), (H).
69 Draft HK Code Arts. 4.4.1(e)(i)-(iii).
70 Draft HK Code Art. 4.2.1(b). Part 3 of this article discusses how this restriction violates the WTO TRIPS Agreement.
71 Draft HK Code Art. 4.4.1(a).
72 Draft HK Code Art. 4.4.1(c).
73 Draft HK Code Art. 4.3.1(a). Part 3 of this article discusses in depth how this requirement violates the WTO TRIPS Agreement.

name of any manufacturer or distributor of formula milk on any informational/educational materials they produce or distribute that refer to infant and young child feeding and nutrition, if intended to reach the general public, pregnant women and/or mothers of children aged 36 months or below.[74]

ii. Public Promotion of Formula Milk Products

Draft HK Code Article 5.1 bans manufacturers and distributors from directly or indirectly engaging in any public promotional activities involving formula milk products, including both infant formula and follow-up formula.[75] Draft HK Code Article 5.2 bans manufacturers and distributors from engaging in any promotional activities at healthcare facilities involving food products for infants and young children.[76] In each case, these bans effectively restrict or prohibit the use of certain terminology, symbols, marks, packaging and labeling as part of the promotion of such products via, *inter alia*, advertising, displays, coupons, packaged samples, educational/informational materials[77], etc.[78] Draft HK Code Article 5 effectively bans manufacturers from using their economically valuable intellectual property as part of any promotion of their products to the public.[79]

iii. Formula Milk, Formula Milk-Related, and Infant and Young Children's Food Product Labels and Containers

Draft HK Code Article 8.1.1 bans the use of terminology, symbols, or markings on formula milk, formula milk-related, and infant and young children food product labels that "give an impression or create a belief that the product is equivalent to, comparable with or superior to breastmilk or breastfeeding."[80] Draft HK Code Article 8.2.1(a) prohibits formula milk labels and containers from showing any symbols or marks – i.e., "any photograph, drawing or graphic representation other than for illustrating methods of preparation."[81] Said provision also prohibits the use of a company logo or product trademark on formula milk containers and labels more than once and thereby effectively restricts manufacturers from using economically valuable intellectual property for purposes of identifying and distinguishing their products in the marketplace.[82]

Draft HK Code Articles 8.2.1(d) and (e) prescribe certain terminology that should appear on formula milk (including infant formula and follow-up formula) product containers and labels. First, there should appear an "IMPORTANT NOTICE…'Breastfeeding is the normal means of feeding infants and young children. Breastmilk is the natural food for their healthy growth and development.'"[83]

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74 Draft HK Code Art. 4.4.1(d). Part of this article discusses in depth how this requirement violates the WTO TRIPS Agreement.
75 Draft HK Code Art. 5.1.
76 Draft HK Code Art. 5.2.
77 "Promotional practices include but are not limited to…(d) production and distribution of informational or educational materials on breastfeeding and formula milk feeding or sponsoring such production and distribution, *except as allowed under Articles 4.2.1, 4.2.2, and 4.4.1*" (emphasis added). Draft HK Code Art. 5.4(d). Part 3 of this article discusses in detail how this provision violates the WTO TRIPS Agreement.
78 Draft HK Code Arts. 5.4(a)-(d).
79 Part of this article discusses in detail how this provision violates the WTO TRIPS Agreement.
80 Draft HK Code Arts. 8.1.1; 3, p. 9.
81 Draft HK Code Art. 8.2.1(a).
82 Draft HK Code Art. 8.2.1(a). Part 3 of this article discusses in detail how this provision violates the WTO TRIPS Agreement.
83 Draft HK Code Arts. 8.2.1(d); 8.2.1(e).

Second, there should appear a "'warning' – 'Before deciding to supplement or replace breastfeeding with this product, seek the advice of a health professional as to the necessity of its use.'"[84]

Draft HK Code Article 8.3.1(a) prescribes the type of (non-food safety-related) health and nutrition claims that can appear on the containers and labels of infant and young children's food products, while Draft HK Code Article 8.4.1 prescribes for formula milk-related product containers and labels largely the same type of terminology that should appear on formula milk product containers and labels,[85] plus some additional information.[86]

Finally, Draft HK Code Article 8.6.1 effectively bans the offering for sale and sale of formula milk and infant and children's food products that fail to meet these labeling and container restrictions on the use of terminology, symbols, packaging and marks.[87]

Since Draft HK Code Articles 3, 4, 5 and 8 describe in detail the characteristics of the "covered" products which relate directly to the products' intrinsic features and qualities and indirectly to the means by which products are identified, presented, and made to appear, they satisfy the second criterion of the three-part technical regulation test.

c. *De Facto* Mandatory Compliance With Product Characteristics

As previously discussed in Part 1 of this article,[88] the Draft HK Code is a governmental measure that describes itself as "voluntary in nature". The Code's Preamble states that it "*provide[s] guidelines…*to manufacturers and distributors, health workers and health facilities…on marketing…formula milk, feeding bottles, teats and pacifiers, and food products for infants and young children aged 36 months or below."[89] In addition, the Draft HK Code neither uses the word "shall" in laying down its requirements, nor refers to its core requirement as a "mandatory" requirement. The Draft HK Code is also not the typical classic legal instrument that is legally binding under the law of Hong Kong. To such extent, therefore, it would appear that the Draft HK Code is not "compulsory" or "mandatory", and thus, does not satisfy the third criterion of the three-part technical regulation test.

Nevertheless, the Draft HK Code arguably has *the effect of* mandating compliance with the presentational and content-based prescriptions it imposes with respect to covered ("designated"[90]) products. For example, several Draft HK Code provisions employ the word "requirements" when referring to conditions that must be satisfied in order for a manufacturer or distributor to directly or indirectly promote a formula milk, formula milk-related or complementary food product in Hong Kong.

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84 Draft HK Code Art. 8.2.1(e)(i)-(ii).
85 Draft HK Code Art. 8.4.1(a).
86 Draft HK Code Art. 8.4.1(b)-(c).
87 Draft HK Code Art. 8.6.1.
88 *See* Part 1 of this article at Sec. II.2.b.
89 Draft HK Code, Background at p. 4.
90 Draft HK Code, Art. 3, p. 9.

First, Draft HK Code Article 4.2.1(d) permits manufacturers or distributors to provide information on specific brands of formula milk and formula milk-related products for dissemination on their websites, at retail premises or at healthcare facilities, provided they satisfy the "requirements" of Draft HK Code Article 4.4.1(a) and (c).[91] This means they should not contain pictures or texts encouraging formula milk feeding or discouraging breastfeeding,[92] and should not give an impression or create a belief that a designated product is comparable with or superior to breastmilk or breastfeeding.[93]

Second, Draft HK Code Article 5.2(b) permits manufacturers and distributors to promote infant and young children's food products, provided they satisfy the "requirements" under Articles 4.2.1 (c), 4.4.1(a) and (c) and 4.4.1 (e) (ii). Draft HK Code Article 4.2.1(c) prohibits all product or ingredient health and nutrition claims other than those permitted under Draft HK Code Articles 8.5.1-8.5.3.[94] As noted above, Draft HK Code Articles 4.4.1(a) and (c) prohibits the use of messages that encourage formula milk feeding, discourage breastfeeding, and convey the impression that a designated product is comparable with or superior to breastmilk or breastfeeding.[95] Draft HK Code Article 4.4.1(e)(ii) prescribes that informational/educational materials on complementary food products should explain the benefits and superiority of breastfeeding, the importance of introducing complementary food from the age of six months, the negative effects of early introduction of bottle feeding or complementary food, and that complementary foods can easily be prepared at home.[96]

Third, Draft HK Code Article 8.6.1 provides that manufacturers and/or distributors should not offer for sale or sell in Hong Kong formula milk, formula milk related or infant and young children's food products unless they can ensure that the containers and labels for such products satisfy ALL of Article 8's labeling "requirements".[97] Given the important role that food product labeling plays in identifying and distinguishing products for consumers, and conveying product information, and generating product and brand recognition, the discovery and public reporting of a labeling compliance failure by a company whistleblower or a third party overseer after the product has already entered the Hong Kong marketplace could potentially curtail future product sales and trigger regulatory investigations.

Therefore, although the Draft HK Code generally describes itself as voluntary and Articles 10.1-10.2 impose on industry a form of self-regulation by holding manufacturers and distributors "responsible for implementing the Code themselves",[98] Draft HK Code Articles 10.3-10.4 simultaneously subject such self-regulation to third-party monitoring and follow-up "through a dual surveillance/survey and complaint system, with collaboration from non-governmental organisations, professional

91 Draft HK Code Art. 4.2.1(d).
92 Draft HK Code, Art 4.4.1(a).
93 Draft HK Code, Art. 4.4.1(c).
94 Draft HK Code, Art. 4.2.1(c).
95 Draft HK Code Arts. 4.4.1(a) and (c).
96 Draft HK Code Arts. 4.4.1(e)(ii)(A)-(D).
97 Draft HK Code Art. 8.6.1.
98 Draft HK Code Arts. 10.1-10.2.

bodies, institutions and individuals."[99] This system entails a significant role for the GHK-SAR in ensuring manufacturer and distributor Code compliance which *will* likely result in its interference with the sale of infant-and-young child feeding products,[100] representations to the contrary notwithstanding.[101]

Pursuant to Draft HK Code Annex I, various offices within GHK-SAR Department of Health ("DH")[102] will oversee industry compliance with the HK Draft Code's promotional marketing and labeling requirements by conducting regular public surveys[103] and carrying out studies in collaboration with consumer NGOs and academics.[104] In addition, an Advisory Panel, comprised of Taskforce members including government officials[105] and overseen by a secretariat comprised of DH officials and supported by the Department of Health's Food and Environmental Hygiene Department ("FEDH"),[106] will oversee the monitoring system.[107] It is charged with considering surveillance/survey reports, and responding to and investigating public complaints about manufacturer and distributor formula milk and infant and young children food product promotional activities and product labeling.[108]

Furthermore, where a complaint has been lodged, the GHK-SAR possesses the legal authority to refer suspected manufacturer and distributor violations of existing laws to the relevant GHK-SAR departments for investigation *and follow-up administrative and/or legal action* under at least four different Hong Kong statutes governing food product labeling and advertising.[109] The Draft HK Code,

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99 Draft HK Code Art. 10.3-10.4. "The implementation of the HK Code is monitored through a dual surveillance/survey and complaint system, with collaboration from non-governmental organisations, professional bodies, institutions and individuals concerned." Draft HK Code Background, p. 1.

100 Draft HK Code Annex I.

101 Draft HK Code Background at p. 4 ("The HK Code is voluntary in nature and aims to contribute to the provision of safe and adequate nutrition for infants and young children without interfering with the sale of products for infant-and-young-child feeding.")

102 These include the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD), the FEHD itself, and an Advisory Panel ("AP") comprised of Taskforce members and overseen by a secretariat comprised of DH officials and supported by the FEHD. *See* Part 1 of this article, at Sec. II.1.b.

103 The Department of Health "(DH) *will* conduct regular surveys to monitor the promotional activities of M&Ds [manufacturers and distributors] including advertisements in the media, promotional activities at retail level, sales inducement devices, etc." Draft HK Code Annex I, par. 4. In addition, "the Centre for Food Safety (CFS) of the Food and Environmental Hygiene Department (FEHD)…is responsible for monitoring the labelling requirements and quality standards of formula milk and food products for infants and young children." Draft HK Code I, par. 5. "FEHD will have direct responsibility "for investigating complaints related to labelling and quality of formula milk and food products for infants and young children." Draft HK Code Annex I, par. 9.

104 The "DH may also carry out studies in collaboration with the Consumer Council or Non-governmental Organisations such as the Baby Friendly Hospital Initiative Hong Kong Association, or commission academic units to conduct studies with specific themes." *Id*.

105 "The Taskforce on Hong Kong Code of Marketing of Breastmilk Substitutes ("the Taskforce") was set up in June 2010 under the Department of Health (DH). The Taskforce has a multi-disciplinary membership drawn from representatives of community organizations, professional bodies, academia, *and Government bureau and departments*" (emphasis added). *See* Government of Hong Kong Special Administrative Region, Legislative Council Panel on Panel on Food Safety and Environmental Hygiene and Panel on Health Services (Joint Meeting), *The Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children* (Nov. 20, 2012), at par. 3, available at: http://www.legco.gov.hk/yr12-13/english/panels/hs/papers/fehs1120cb2-192-1-e.pdf.

106 Draft HK Code Annex I, par. 2.

107 *Id*.

108 *Id*; Draft HK Code Annex I, pars. 1-5, 9-11, 13.

109 Draft HK Code Annex I, pars. 12, 14.

however, does not appear to have established an objective evidentiary threshold to serve as the basis for the substantiation of a complaint or for Advisory Panel referrals of suspected violations of law for further investigation and possible administrative or legal action. This strongly suggests that Advisory Panel members possess broad and unfettered discretion to refer unsubstantiated as well as substantiated complaints to GHK-SAR agencies for further investigation and follow-up administrative or legal action based on mere suspicion of legal wrongdoing. In the absence of such an evidentiary threshold, there is little to prevent the use of an implied administrative presumption pursuant to which any Code violation could be treated as giving rise to a justifiable suspicion of legal violation that may then be referred to other government agencies for investigation and possible prosecution.

Moreover, at least two of these sources of law reflect that suspected violations can be quite costly. For example, Regulation 5 of the *Food and Drugs (Composition and Labelling) Regulations (Cap. 132W)*, which is one such source of law,[110] treats food labeling and advertising violations, whether or not intentional, as a level 5 criminal offense punishable by a monetary fine of $50,000 and a mandatory 6-month prison term.[111] Similarly, Sections 61(1) and (2) of the *Public Health and Municipal Services Ordinance*, which is another such source of law,[112] treat false labeling or advertisements of foods, whether or not intentional, as "an offence"[113] punishable by imposition of a level 5 ($50,000) fine and 6 months imprisonment.[114]

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110 Draft HK Code Annex I, par. 14(i).

111 "Any person who advertises for sale, sells or manufactures for sale any food or drug which does not conform to the relevant *requirements as to composition* prescribed in Schedule 1 or which is *not marked and labelled in the manner prescribed* in Schedule 2 commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months" (emphasis added). See *Cap 132W – Food and Drugs (Composition and Labelling) Regulations* (2010), at Regulation 5(1), 5(1)(AA), 5(1)(AB) - Offences and Penalties, available at: http://www.legislation.gov.hk/blis_ind.nsf/CURALLENGDOC/58C03C497F20A036482577520022790 5?OpenDocument. "Any person who advertises for sale, sells or manufactures for sale any prepackaged food which (a) is not marked or labelled in compliance with regulation 4A(1) or 4B(1); or (b) has on its label any nutrition claim that does not conform to regulation 4B(5), *commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months*" (emphasis added). *Id*., at Regulation 5(1)(AA). "If - (a) any person advertises for sale any prepackaged food; and (b) the advertisement contains any nutrition claim that does not conform to regulation 4B(5), the person *commits an offence and is liable to a fine at level 5 and to imprisonment for 6 months*" (emphasis added). *Id*., at Regulation 5(1)(AB). A 'level 5' penalty is equal to $50,000. *See* Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, available at: http://www.legislation.gov.hk/blis_ind.nsf/CURALLENGDOC/CF2DC70EAB6C97C7C82564830029D317?OpenDocument.

112 Draft HK Code Annex I, par. 14(ii).

113 See *Cap 132 - Public Health and Municipal Services Ordinance* (2013), at Section 61(1)-(2) - False Labelling and Advertisement of Food or Drugs, available at: http://www.legislation.gov.hk/blis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/40DC34E06542CFE1482575EE003FE971/$FILE/CAP_132_e_b5.pdf. "If any person gives with any food or drug sold by him, or displays with any food or drug exposed for sale by him, a label, whether or not the same is attached to or printed on the wrapper or container, which- (a) falsely describes the food or drug; or (b) *is calculated to mislead* as to its nature, substance or quality, *he shall be guilty of an offence*, unless he proves that he did not know, and could not with reasonable diligence have ascertained, that the label was of such a character as aforesaid" (emphasis added). *Id*., at Sec. 61(1). "[I]f any person publishes, or is partly to the publication of, an advertisement, other than a label to which the provisions of subsection (1) apply which- (a) falsely describes any food or drug; or (b) *is likely to mislead* as to the nature, substance or quality of any food or drug, *he shall be guilty of an offence*, and, in any proceedings against the manufacturer, producer or importer of the food or drug, it shall rest on the defendant to prove that he did not publish, and was not a party to the publication of, the advertisement" (emphasis added). *Id*., at Sec. 61(2). *See also* Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, *supra*.

114 See *Cap 132 - Public Health and Municipal Services Ordinance* (2013), supra at Section 150 and Schedule 9. "Any person who is guilty of an offence under any of the provisions of this Ordinance specified in the first column of the Ninth Schedule shall be liable on summary conviction to the penalty specified in relation thereto in the second column of that Schedule." *Id*., Sec. 150. A violation of "61(1) or (2)…[will be subject to a penalty of]…level 5 and 6 months imprisonment". *Id*., at Schedule 9. *See*

Therefore, although the Draft HK Code is not mandatory *per se*, it is mandatory *in effect*,[115] and consequently, satisfies the third criterion of the three-part technical regulation test.

Since the Draft HK Code satisfies all three criteria of the three-part technical regulation test, it arguably constitutes a *de facto* technical regulation within the meaning of TBT Annex 1.1.

3. Ascertaining Whether National Measures Are Based On Relevant International Standards

a. Ascertaining Whether a Relevant International Standard Exists

TBT Article 2.4 requires WTO Members to use all or part of "relevant international standards" that exist or the completion of which are imminent *as the basis for* their technical regulations.[116] However, technical regulations need not be based on relevant international standards when such standards, in whole or in part, "would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, [e.g.,] because of fundamental climatic or geographical factors or fundamental technological problems."[117]

In the context of TBT Article 2.4, the complaining Party bears the burden of "demonstrating that a relevant international standard exists and that this standard was not used *as a basis for* the technical regulation" (emphasis added).[118] And, the defending Party bears the burden of "demonstrat[ing] that the international standard is an ineffective or inappropriate means to fulfill the legitimate objectives pursued by the Regulation."[119]

i. Adoption by an International Standardizing Body

In order to constitute an "international standard" for purposes of TBT Article 2.4, a standard must be adopted by an "international standardizing body" rather than by an "international organization".[120] "A 'body' is a 'legal or administrative entity that has specific tasks and

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also Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, supra (A 'level 5' penalty is equal to $50,000.).

115 In *US - Tuna II (Mexico)*, the Appellate Body considered the U.S. government's involvement in enforcing industry compliance with the "dolphin-safe" labeling regime as an important indicator that the labeling measure was mandatory in nature. "[T]he US measure not only sets out certain conditions for the use of a label, but, in addition, it enforces a prohibition against the use of any other label containing the terms 'dolphin-safe', 'dolphins', 'porpoises', or 'marine mammals' on a tuna product that does not comply with the requirements set out in the measure. Moreover, the enforcement of the US measure does not require proving that a given conduct is deceptive under a law against deceptive practices…In effect, the measure at issue establishes a single definition of 'dolphin-safe' and treats any statement on a tuna product regarding 'dolphin-safety' that does not meet the conditions of the measure as a deceptive practice or act." Appellate Body Report, *US - Tuna II (Mexico)*, at par. 195.

116 TBT Art. 2.4.

117 *Id*..

118 Panel Report, *European Communities — Trade Description of Sardines ("EC-Sardines")* WT/DS231/R (May 29, 2002), at par. 7.50.

119 *Id*., at par. 7.52.

120 Appellate Body Report, *US-Tuna II (Mexico)* at par. 356. According to the Appellate Body, this result obtains because "the definitions in Annex 1 to the TBT Agreement prevail over the definitions in the ISO/IEC Guide 2: 1991." *Id*. "Annex 1.2 to the TBT Agreement refers to a 'body', not to an 'organization', and Annex 1.4 defines an 'international body or system', but not an 'international organization'. This suggests that, for the purposes of the TBT Agreement, 'international' standards are adopted by

composition', whereas an 'organization' is a 'body that is based on the membership of other bodies or individuals and has an established constitution and its own administration.'"[121] "[A] body…may, but need not necessarily be [an] organisation."[122] In other words, "for purposes of the TBT Agreement, international standards need to be adopted by 'international standardizing bodies', which may, but need not necessarily, be 'international standardizing organizations'.[123]

In *US-Tuna II (Mexico)*, the Appellate Body ruled that an "international standardizing body" "is a body[124] that has recognized activities in standardization[125] and whose membership is open[126] to the relevant bodies of at least all Members."[127] "[I]n order for a standardizing body to be considered 'international' for the purposes of the TBT Agreement, it is not sufficient for the body to be open, or [to] have been open, at a particular point in time. Rather, the body must be open 'at every stage of standards development'"[128] and "on a non-discriminatory basis".[129]

ii. Identifying a Recognized International Standardizing Body

An international standardizing body will be deemed "recognized" if, at a minimum, WTO Members "are aware, or have reason to expect, that the international body in question is engaged in standardization activities."[130] However, "a 'standardizing body'…with 'recognized activities in standardization', does not need to have standardization as its principal function, or even as one of its principal functions."[131] "In examining whether an international body has 'recognized activities in standardization', evidence of recognition by WTO Members as well as evidence of recognition by national standardizing bodies would be relevant."[132] Such evidence of recognition may be reflected

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'bodies', which may, but need not necessarily, be 'organizations'. This is also supported by the context provided by other provisions of the TBT Agreement. For example, Articles 2.6, 10.1.4, 11.2, 12.5, and 12.6, as well as Annexes 3.G and 3.H to the TBT Agreement envisage that international standards are prepared by 'international standardizing bodies'". *Id*.

121 *Id*., at par. 355, quoting ISO/IEC Guide 2: 1991.

122 *Id*., at par. 356.

123 *Id*., at par. 395.

124 ISO/IEC Guide 2: 1991 provides that a "body" is a "legal or administrative entity that has specific tasks and composition". *Id*., at par. 355. "[F]or the purposes of the TBT Agreement, "international" standards are adopted by "bodies", which may, but need not necessarily, be "organizations". *Id*., at par. 356.

125 According to the Appellate Body, "a body simply has to be 'active' in standardization in order to have 'activities in standardization'." *Id*., at par. 360. This means that it must be actively engaged in "establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context." *Id*. TBT Annex 1.2 defines the term "standards" as a "document … that provides … rules, guidelines or characteristics for products or related processes and production methods" and "may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method". Appellate Body Report, *US-Tuna II (Mexico)* at par. 360.

126 "[A] body will be open if membership to the body is not restricted. It will not be open if membership is a priori limited to the relevant bodies of only some WTO Members. *Id*., at par. 364.

127 *Id*., at par. 359.

128 *Id*., at par. 374.

129 *Id.*, at par. 375. "Thus, provisions for accession that *de jure* or *de facto* disadvantage the relevant bodies of some Members as compared to other Members would tend to indicate that a body is not an 'international' standardizing body for the purposes of the *TBT Agreement*." *Id*.

130 *Id*., at par. 362.

131 *Id*.

132 *Id.*, at par. 363.

by WTO Member or relevant WTO Member bodies' participation in such body's standardization activities.[133]

Furthermore, "evidence of a body's compliance with procedural and substantive safeguards formulated by WTO Members would be relevant for the question of whether its standardizing activities are 'recognized' for the purposes of the TBT Agreement."[134] Thus, the WTO Appellate Body has ruled that, an international standardizing body that has "set[] out principles and procedures that WTO Members have decided 'should be observed' by international standardizing bodies",[135] such as those set forth in the TBT Committee *Decision on Principles for the Development of International Standards, Guides and Recommendations With Relation to Articles 2, 5 and Annex 3 of the Agreement*,[136] will be "recognized" within the meaning of the TBT Agreement.[137] This means that, in addition to elaborating international standards, guides and recommendations, a "recognized" international standardizing body shall adopt principles and procedures that "ensure[138] transparency,[139] openness,[140] impartiality and consensus,[141] effectiveness and relevance,[142] coherence,[143] and…address the concerns of developing countries."[144]

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133 "[W]e note that Articles 2.6, 11.2, and 12.6 of the TBT Agreement contemplate that 'Members' participate in international standardizing activities. Article 12.5, Annex 3.G, and Annex 1.4 to the TBT Agreement, in turn, foresee the involvement of the 'relevant bodies' or 'standardizing bodies' of Members in the development of international standards…In addition, Article 10.1.4 of the TBT Agreement refers to 'membership and participation of the Member, or of relevant central or local government bodies within its territory, in international and regional standardizing bodies'". *Id*., at par. 363 and fn 715.

134 *Id*., at par. 377.

135 *Id*., at par. 378.

136 See Committee on Technical Barriers to Trade, *Second Triennial Review of the Operation and Implementation of the Agreement of Technical Barriers to Trade*, at par. 20, *Annex 4, Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations With Relation to Articles 2, 5 and Annex 3 of the Agreement*, G/TBT/9 (Nov. 13, 2000), available at: http://www.jisc.go.jp/eng/wto-tbt/pdf/g_tbt_9.pdf.

137 *Id*., at par. 378. The Appellate Body took the TBT Committee Decision into account for purposes of interpreting and applying TBT Article 2.4 terms" based on its determinations that "the TBT Committee Decision can be considered as a 'subsequent agreement' within the meaning of Article 31(3)(a) of the Vienna Convention" and that the Decision bore "specifically" and "directly on the interpretation of the term 'open' in Annex 1.4 to the TBT Agreement, as well as on the interpretation and application of the concept of 'recognized activities in standardization'. *Id*., at par. 372.

138 G/TBT/9, Annex 4, supra at par. 1.

139 "All essential information regarding current work programmes, as well as on proposals for standards, guides and recommendations under consideration and on the final results should be made easily accessible to at least all interested parties in the territories of at least all WTO Members. Procedures should be established so that adequate time and opportunities are provided for written comments. The information on these procedures should be effectively disseminated…It is recognized that the publication and communication of notices, notifications, draft standards, comments, adopted standards or work programmes electronically, via the internet, where feasible, can provide a useful means of ensuring the timely provision of information." G/TBT/9, Annex 4, *supra* at pars. B.3 and B.5.

140 "Membership of an international standardizing body should be open on a non-discriminatory basis to relevant bodies of at least all WTO Members. This would include openness without discrimination with respect to the participation at the policy development level and at every stage of standards development… Any interested member of the international standardizing body, including especially developing country members, with an interest in a specific standardization activity should be provided with meaningful opportunities to participate at all stages of standard development." *Id*., at pars. C.6-C.7.

141 "All relevant bodies of WTO Members should be provided with meaningful opportunities to contribute to the elaboration of an international standard so that the standard development process will not give privilege to, or favour the interests of, a particular supplier/s, country/ies or region/s. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments." *Id*., at par. D.8.

142 "[I]nternational standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or

In *US-Tuna II (Mexico)*, the WTO Panel had determined that the parties of the Agreement on the International Dolphin Conservation Program ("AIDCP")[145] "collectively act as a 'standardizing body', that is, a '[b]ody that has recognized activities in *standardization*'…as defined by the ISO/IEC Guide 2 (emphasis in original). It reasoned that "the AIDCP resolutions contain provisions, for common and repeated use, that concern tuna and tuna products and their related processes and production methods and that also deal with marking and labelling requirements", and that "the parties of the AIDCP, within the institutional framework of the IATTC[146], develop and establish, with regard to dolphin mortality and tuna-stock sustainability problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of dolphin protection and rational use of tuna resources in the context of the ETP tuna purse-seine fishery."[147]

The Panel, furthermore, concluded that the AIDCP was "open on a non-discriminatory basis to the relevant bodies of at least all WTO Members in accordance with the principle of openness as described in the TBT Committee Decision".[148] It reasoned that the Agreement was "open" at the time it was signed and has remained "open" for purposes of accession by "any States or regional economic integration organization *that is invited to accede to the Agreement on the basis of the parties' decision*" (emphasis added).[149] Consequently, the Panel found that the AIDCP was "international", and thus, constituted an "international standardization organization" within the meaning of TBT Article 2.4.[150]

The Appellate Body disagreed with this finding. It determined that the AIDCP was not "international" because it was "not open to the relevant bodies of at least all Members".[151] It

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regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics." *Id*., at par. D.10.

143 "[I]t is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential." *Id*., at par. E.12.

144 "Tangible ways of facilitating developing countries participation in international standards development should be sought. The impartiality and openness of any international standardization process requires that developing countries are not excluded de facto from the process." *Id*., at par. E.13.

145 "The AIDCP is an international agreement concluded among States, and it does not as such have an established constitution or its own administration as such. However, the Parties to the convention acting jointly accomplish specific tasks in fulfilment of its objectives." Panel Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products ("US-Tuna II (Mexico)")* at par. 7.682.

146 "The Inter-American Tropical Tuna Commission (IATTC) began in 1976 multilateral endeavours that led to the creation of the International Dolphin Conservation Program (IDCP). These efforts were later reflected in a series of multilateral agreements that were negotiated in response to the evidence that many dolphins were dying in the ETP [Eastern Tropical Pacific] each year. These agreements were the La Jolla Agreement (1992), the Panama Declaration (1995) and the AIDCP (1999). Both Mexico and the United States are signatories to the La Jolla Agreement and the Panama Declaration and parties to the AIDCP." *Id*., at par. 2.35. "The IATTC has an institutional structure composed of a principal body (the Commission), advisory committees, permanent working groups and two other types of committees (the committee for the review of implementation of measures adopted by the Commission and the scientific advisory committee. It also has a constitution, the Antigua Convention as well as its own administration, insofar as it is governed by its own rules of procedures and financial regulations and has a Secretariat." *Id*., at par. 7.683.

147 *Id*., at par. 7.685.

148 *Id*., at par. 7.691.

149 *Id*.

150 *Id*., at pars. 7.692-7.693.

151 Appellate Body Report, *US-Tuna II (Mexico)* at pars. 398-399, 401.

reasoned that Mexico had failed to prove that the parties' rendering of a consensus-based decision to extend an invitation was "a mere formality" – i.e., that "the issuance of an invitation occurs automatically once a WTO Member has expressed interest in joining".[152] Based on this conclusion, the Appellate Body ruled that the AIDCP was "not an '*international* standardizing body' for purposes of the TBT Agreement" (emphasis added),[153] and that, therefore, "the 'AIDCP dolphin-safe definition and certification' [did not] constitute a 'relevant international standard' within the meaning of [said] Agreement".[154]

b. Ascertaining Whether an International Standard is Relevant

In order for an international standard to be "relevant" it must "bear[] upon or relat[e] to the matter in hand; [i.e., it must be] pertinent."[155] In *EC-Sardines*, the Appellate Body found that, "although the [disputed] EC Regulation expressly mention[ed and dealt with] only [preserved] *Sardina pilchardus*, it ha[d] legal consequences for other fish species that could be sold as preserved sardines, including preserved *Sardinops sagax*".[156] It also found that "Codex Stan 94 cover[ed] 20 fish species in addition to *Sardina pilchardus* [which] also are legally affected by the exclusion in the [disputed] EC Regulation."[157] Since Codex Stan 94 and the EC Regulation both referred to preserved *Sardina pilchardus*, the Appellate Body concluded that "Codex Stan 94 bears upon, relates to, or is pertinent to the EC Regulation." [158]

c. Ascertaining Whether a Technical Regulation is Based on a Relevant International Standard

The WTO Appellate Body has ruled that "an international standard is used 'as a basis for' a technical regulation 'when it is used as the principal constituent or fundamental principle for the purpose of enacting the technical regulation'".[159] "[T]here must be a very strong and very close relationship between two things in order to be able to say that one is 'the basis for' the other."[160] Thus, more than a showing of "a rational relationship" between an international standard and a technical regulation will be required "to find that the former is used 'as a basis for' the latter", for purposes of TBT Article 2.4.[161] And, at a minimum, "under Article 2.4, if the technical regulation and the international standard contradict each other, it cannot properly be concluded that the international standard has been used 'as a basis for' the technical regulation."[162]

In *US-Tuna II* (Mexico), the Panel had concluded that "the strong relationship between the US dolphin-safe labelling provisions and the AIDCP resolutions" in question "appear[ed] to be

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152 *Id*., at par. 398.
153 *Id*., at pars. 399 and 401.
154 *Id*., at par. 401. In the absence of a "relevant international standard", the Appellate Body reversed the Panel's findings on these issues and upheld the Panel's finding that "the measure at issue [was] not inconsistent with Article 2.4 of the TBT Agreement." *Id*.
155 Appellate Body Report, *EC-Sardines* at pars. 229-230.
156 *Id*., at par. 232.
157 *Id*.
158 *Id.*, at pars. 231-232.
159 Panel Report, *US-Tuna II (Mexico)*, at par. 7.711; Appellate Body Report, *EC – Sardines*, at pars. 240-245.
160 Appellate Body Report, *EC-Sardines* at par. 245.
161 Panel Report, *US-Tuna II (Mexico)* at par. 7.713; Appellate Body Report, *EC-Sardines* at pars. 247-248.
162 Appellate Body Report, *EC-Sardines* at par 248.

insufficient to infer that the AIDCP standard was used as a basis for the technical regulation."[163] Finding to the contrary that U.S. court rulings, "in particular the *Hogarth* ruling", described the U.S. provisions as having departed from the AIDCP standard, and even contradicting it,[164] the Panel concluded that the U.S. had "failed to base the US dolphin-safe labelling provisions on the relevant international standard of the AIDCP."[165]

4. Various Draft HK Code Non-Food Safety-Related Provisions Are Based On Relevant International Standards

The following discussion confirms that the WHO will likely be deemed a recognized international standardizing body for purposes of Article 2.4 of the TBT Agreement.

a. The WHO is an International Standardizing Body

The WHO is a specialized agency of the United Nations[166] with near universal membership. The WHO Constitution sets forth the organization's objective as "the attainment by all peoples of the highest possible level of health".[167] To achieve this objective, the WHO's core functions have included the *development, establishment and promotion of international standards* with respect to food, biological, pharmaceutical and similar products" (emphasis added).[168] The WHO's 11th "General Programme of Work" clearly reiterates that one of its six core functions is "[s]etting norms and standards, and promoting and monitoring their implementation."[169]

The World Health Assembly ("WHA") is one of three bodies that carry out the work of the WHO,[170] and it is "composed of delegates representing [WHO] Members."[171] The WHA "is the decision-making body of [the] WHO." It meets annually, "is attended by delegations from all WHO Member States", and "focuses on a specific health agenda prepared by the Executive Board."[172] Among its "main functions" is the "determin[ation of] the policies of the Organization."[173] Among its other tasks, the WHA possesses "authority to adopt regulations concerning…*standards* with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in

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163 Panel Report, *US-Tuna II (Mexico)* at par. 7.712.
164 *Id.*, at par. 7.715.
165 *Id*., at par. 7.716.
166 See *Constitution of the World Health Organization* (1946), Final preambular paragraph, available at: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.
167 *Id*., Arts. 1.
168 *Id*., Art. 2(u). "The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends." *See* World Health Organization, *About WHO*, available at: http://www.who.int/about/en/.
169 *See* World Health Organization, *Engaging for Health Eleventh General Programme of Work 2006-2015 A Global Health Agenda* (May 2006), at Executive Summary p. iii, pp. 27-28, available at: http://whqlibdoc.who.int/publications/2006/GPW_eng.pdf.
170 *Id*., Art. 9. The WHO's work is also carried out by the Executive Board and the Secretariat. *Id*.
171 *Id*., Art. 10.
172 *See* World Health Organization, *World Health Assembly*, Media Center, available at: http://www.who.int/mediacentre/events/governance/wha/en/.
173 *Id*. "It is at the [WHA] that [the] WHO's work is reviewed, new goals are set, and new tasks assigned." *See* World Health Organization, *How the World Health Assembly Works*, Media Center, available at: http://www.who.int/mediacentre/events/2013/wha66/how_wha_works/en/index.html.

international commerce [and] advertising and labelling of biological, pharmaceutical and similar products moving in international commerce" (emphasis added).[174]

The WHA consists of "two main committees: (a) Committee A – to deal predominantly with programme and budget matters; (b) Committee B – to deal predominantly with administrative, financial and legal matters…and such other main committees as [the Assembly] may consider necessary."[175] These committees also "approve the text of resolutions which are then submitted to the plenary meeting."[176] "Each delegation shall be entitled to be represented on each main committee by one of its members."[177]

WHA plenary meetings are generally "open to attendance by all delegates, alternates and advisers appointed by Members."[178] "Each Member shall have one vote in the [plenary meetings of the] Health Assembly."[179] "Decisions by the Health Assembly on important questions shall be made by a two thirds majority of the Members present and voting",[180] while "decisions on other questions, including the determination of additional categories of questions to be decided by a two-thirds majority, shall be made by a majority of the Members present and voting."[181]

WHA plenary meetings "shall be held in public unless the Health Assembly decides that exceptional circumstances require that the meeting be held in private."[182] In addition, all Members, Associate Members, and participating intergovernmental and "admitted" non-governmental organizations shall be notified not less than 60 days before WHA regular session meetings and not less than 30 days before special session meetings.[183] Generally, the meetings of the main committees and their sub-committees "shall be held in public."[184]

The WHA shall receive a report from the Director General regarding the technical, administrative and financial implications of all agenda items before the WHA considers them in plenary meetings.[185] Members and Associate Members, participating intergovernmental organizations and "admitted" nongovernmental organizations shall receive from the Director-General, at the same time as the provisional agenda, or in any case not less than 6 weeks prior to a regular session,

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174 See *Constitution of the World Health Organization* (1946), supra Arts. 21(d)-(e).
175 *Id*., Art. 18(e). *See also* World Health Organization, *Rules of Procedure of the World Health Assembly*, Rules 32 and 40, available at: http://www.who.int/governance/rules_of_procedure_of_the_wha_en.pdf.
176 *See* World Health Organization, *How the World Health Assembly Works*, supra. The WHA "meets in plenary [which is the meeting of all WHA delegates] several times in order to listen to reports and adopt the resolutions transmitted by the committees." *Id*. See also World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 51.
177 *See* World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 33.
178 *Id.,* Rule 19.
179 *Id*., Rule 69.
180 See *Constitution of the World Health Organization* (1946), supra at Art. 60(a); World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 70.
181 See *Constitution of the World Health Organization* (1946), supra at Art. 60(b); World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 71.
182 World Health Organization, *Rules of Procedure of the World Health Assembly*, supra Rule 20.
183 *Id.*, Rule 3.
184 *Id*., Rule 37. "Any main committee may set up such sub-committees or other subdivisions as it considers necessary." *Id*., Rule 38. "The Executive Board has recommended that the establishment of working parties in the Health Assembly should be restricted to the following purposes [including]…(3) *to provide a committee with an expert opinion relevant to its discussions*" (emphasis added). *Id*., at footnote 1.
185 *Id*., Rule 13.

copies of all reports and other documents relating to the provisional agenda of any session, which shall also be made available on the Internet.[186]

It is arguable that the WHO is actively engaged in the development of food safety-related standards as well as non-food safety-related public health standards, and thus, constitutes a "standardizing body", within the meaning of TBT Article 2.4. With the assistance of the WHA, the WHO has been able to secure promulgation of its standards, including the WHO Code (addressing both food safety-related and non-food safety-related public health matters), at the international level via procedural means (i.e., the drafting of and voting on resolutions) for purposes of facilitating their adoption at the national level by WHO Member nations in the form of technical regulations or voluntary standards. The WHO Code is one such standard that provides for common and repeated use guidelines and characteristics for products, with which governmental compliance is not mandatory. The WHO Code incorporates terminology, symbols, packaging, marking and labeling requirements that apply to formula milk products, infant and young children's food products, and formula milk-related non-food products.[187] Indeed, recent WHO Director-General and Secretariat reports underscore the identification of "health governance" as one of the WHO's eight leadership priorities, and that its role in future health governance will entail "position[ing] and promot[ing] health in a range of *global, regional and national processes*" (emphasis added), including "the development of norms, *standards*, policies and strategies" (emphasis added).[188]

The WHO also arguably constitutes an "international" standardizing body on non-food safety-related public health matters for purposes of TBT Article 2.4. As WHA rules and procedures reflect, WHO/WHA membership and standards development activities have long been "open" to the relevant designates of at least all United Nations Members, including developing country Members, and at least all WTO Members, on a non-discriminatory basis, at every stage of the standards development process.

b. The WHO is a Recognized International Standardizing Body

Although standardization is not the WHO's principal function, WTO Members are likely aware or have reason to expect that the WHO is engaged in public health-related standardization activities given the current and past involvement of their corresponding government delegations in such activities. And, WTO Member awareness and expectation of WHO standards activities is only likely to grow in the future given the WHO's reform agenda which reflects a broader future "health governance" role for the organization building on the WHO's current constitutionally sanctioned role in global health governance-related standards.[189]

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186 *Id*., Rule 14.

187 TBT Annex 1.2.

188 *Id*., See at pars. 39-61, pp. 9-15. *See also* World Health Organization Executive Board, *WHO's Role in Global Health Governance*, Provisional agenda item EB132/5 Add.5), 132nd Session (Jan. 18, 2013), at pars. 6-7 and 23, available at: http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_5Add5-en.pdf.

189 *See* World Health Organization Executive Board, *WHO Governance Reform* – Report by the Secretariat, Provisional agenda item 5 (EB133/16), 133rd Session (May 17, 2013) at par. 34, available at: http://apps.who.int/gb/ebwha/pdf_files/EB133/B133_16-en.pdf. The WHO Constitution states that the WHO's first objective is to "act as the directing and co-ordinating authority on international health work". *See* WHO Constitution, Art. 2(a).

Nevertheless, the WHO has not formally embraced the WTO TBT Committee *Decision on Principles for the Development of International Standards, Guides and Recommendations*.[190] And, while it is arguable that the WHO's primary governance documents already contain several of these requirements, such instruments and the mechanisms underlying them arguably do not adequately fulfill them or even address them.

For example, WHA rules and procedures provide generally for openness and inclusiveness[191] to the extent all WHO Member States (and their designees) are eligible to participate in WHA committee and plenary meetings and to vote on agenda and work program matters which may include standards development efforts. However, WHO openness and inclusiveness with respect to organizational voting and decision-making does not appear to extend to the national standardizing bodies of WHO/WTO Members that are non-State actors.[192] Unfortunately, there is also no assurance that the WHO regional committees representing regional organizations established by the WHA will adopt WHA's rules and procedures,[193] let alone, the principles contained in the TBT Committee Decision.

WHA rules and procedures appear to ensure transparency (notification and disclosure) to WHO/WTO Member States as well as non-State actors.[194] However, additional organizational efforts to improve the WHO's engagement with non-State actors and to facilitate further transparency[195] could potentially produce outcomes adverse to international trade if the majority of non-State actors with which the WHO decides to engage are biased against international trade, commercial enterprises and intellectual property, and are permitted to unduly influence WHO standards development activities.

WHA rules and procedures do not seem to provide safeguards to preserve the principle of consensus to the extent WHA supermajority and majority voting rules may apply to resolutions pertaining to standards development activities. Such rules and procedures also do not seem to preserve the principle of impartiality to the extent that WHA committees involved in standards development initiatives can create subcommittees to perform supporting substantive work that are staffed by appointment rather than by membership to secure the propagation of certain views and positions.[196]

Both the WHO Constitution and WHA rules and procedures appear to ensure the principle of coherence by enabling WHO institutional outreach efforts aimed at avoiding the development of conflicting or duplicating international public health standards. For example, the WHA can invite any national or international organization to attend, without the right of vote, its meetings or the meetings of committees and conferences convened under its authority.[197] In addition, the WHO

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190 *See* G/TBT/9, supra.
191 *See* WHA Rules of Procedure, supra at Rules 19, 33, 69-71.
192 The "WHO is an intergovernmental body in which Member States have the exclusive right of decision-making." *See* World Health Organization Executive Board, *WHO Governance Reform* (EB133/16), supra at par. 2.
193 See *Constitution of the World Health Organization* (1946), supra at Arts. 44-47, 49.
194 *Id*., at Rules 3, 13-14, 20.
195 *See* World Health Organization Executive Board, *WHO Governance Reform* (EB133/16), supra at pars. 18-19, 26-29.
196 *See* World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 39.
197 See *Constitution of the World Health Organization* (1946), supra at Art. 18(h).

"shall establish effective relations and co-operate closely with such other inter-governmental organizations as may be desirable", subject to the WHA's approval by two-thirds vote.[198] Also, the WHO "may take over from any other international organization or agency whose purpose and activities lie within the field of [WHO] competence such functions, resources and obligations conferred upon" it by mutual international agreement.[199] Furthermore, the WHO Director-General shall consult with the United Nations and its specialized agencies about new WHO activities of direct concern to such organizations and shall report to the WHA about how such activities may be pursued using the coordinated resources of the respective organizations.[200] In this vein, the WHO and WTO have attempted to reconcile what appear to be conflicting standards with different objectives – standards that promote international trade vs. standards that restrain trade for public health reasons.[201]

It remains questionable, therefore, whether WHO/WHA governance rules can satisfy the principle of effectiveness and relevance which endeavors to ensure that international standards can facilitate trade by responding to regulatory and market needs and scientific and technological developments, without creating unnecessary trade barriers. For example, this principle expresses a preference for performance-based rather than design or characteristics-based international standards. However, public health standards are often focused on the latter rather than the former – i.e., the way products are made or sold - rather than on the end-products themselves, even where science cannot demonstrate a cause-and-effect relationship between a product's design and characteristics and the genuine risks it poses to public health and safety. The WHO Secretariat has emphasized that the "WHO is a science and evidence-based Organization espousing a public health approach", that "[t]he development of norms, standards, policies and strategies must continue to be based in all circumstances on the systematic use of evidence, and [that] the process by which they are derived must be protected from influence by any form of bias or vested interest, commercial or otherwise."[202] But, the diet-related NCD food safety risks alleged to arise from consumption of follow-up formula and complementary food products and the non-food safety-related general health benefits alleged to derive from exclusive breastfeeding beyond the first 6-12 months of life, which appear to serve as the 'scientific' basis for a growing number of national initiatives that exploit the WHO Code and subsequent WHA resolutions in order to effectively impose 30-month breastmilk *supplement* marketing bans, have yet to be causally substantiated.[203]

Lastly, it is arguable, that the applicable WHO/WHA governance rules discussed above adequately ensure that developing country WHO/WTO Members, like developed country WHO/WTO Members, can effectively participate in the standards development process. Yet, as in the case of developed country WHO/WTO Members, there is no assurance that all developing country governments will be able to participate in subcommittee work related to standards development where

198 *Id.*, Art. 70.
199 *Id.*, Art. 72.
200 *See* World Health Organization, *Rules of Procedure of the World Health Assembly*, supra, Rule 8.
201 *See* World Health Organization and World Trade Organization, *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* (2002) at par. 5, p. 11, available at: http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf. "The endorsement by the international community of the Doha Declaration on the TRIPS Agreement and Public Health is a very visible expression of governments' commitment to ensuring that the rules-based trading system is compatible with public health interests." *Id.*, Foreword at p. 1.
202 *See* World Health Organization Executive Board, *WHO Governance Reform* (EB133/16), supra at par. 19.
203 *See* discussion, Part 1 of this article.

subcommittees are composed of smaller groups of individuals selected by appointment rather than voting. Similarly, there is no assurance that regional committees will adopt WHA rules and procedures that approximate TBT Committee Decision principles.

In sum, WTO Members are likely aware or have reason to expect that the WHO is engaged in public health-related standardization activities, and the WHO's governance mechanisms adhere to most of the TBT Committee Decision principles for the development of international standards, guides and recommendations. However, these governance mechanisms fail to ensure full strict adherence to all of the principles. If a strict interpretation of the Appellate Body's holding on this issue in *US-Tuna II (Mexico)* were applied, the WHO would *not* constitute a "recognized" international standardizing body within the meaning of TBT Article 2.4. As a result, the WHO Code arguably would *not* constitute a "relevant international standard" for purposes of TBT Article 2.4. If, however, TBT Article 2.4 is not interpreted strictly, it is arguable that the WHO *does* constitute a recognized international standardizing body within the meaning of TBT Article 2.4. In that case, the WHO Code *would* arguably constitute a "relevant international standard" under TBT Article 2.4.

c. The WHO Code is a Relevant International Standard

To recall, a relevant international standard is one that "bears upon, relates to, or is pertinent to…the matters at hand."[204] The WHO Code, which is generally regarded as an international "minimum requirement",[205] recommends the prohibition and restriction of manufacturer and distributor advertising and promotion/marketing efforts specifically relating to "breastmilk *substitutes*", including "infant formula" and "*bottlefed* complementary food" products (emphasis added).[206] WHO Code Article 3 defines "infant formula" as a Codex Alimentarius Commission-compliant industrially formulated breastmilk substitute satisfying "the normal nutritional requirements of infants up to *between four and six months of age*" (emphasis added).[207] WHO Code Article 3 defines "complementary food" as "any food…suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant,"[208] but does not define the term "infant".

The Draft HK Code similarly prohibits and restricts the promotion/marketing, including advertising, of formula milk and infant and young children's food products. Draft HK Code Article 3 defines the term "infant" as "a person not more than 12 months of age,"[209] and the term "young child" as "a person from the age of more than 12 months up to the age of three years (36 months)."[210] Draft HK Code Article 3 uses terminology similar to that employed by WHO Code Article 3, and covers products similar to those falling within the scope of WHO Code Article 3, and to such extent, addresses subject matter falling within the scope of the WHO Code.

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204 Appellate Body Report, *EC-Sardines* at pars. 229-230.
205 The WHA has referred to national government "adoption of and adherence to" the WHO Code as "a minimum requirement and only one of several important actions required in order to protect healthy practices in respect of infant and young child feeding." *See* WHA Resolution 34.22 at p. 2.
206 WHO Code Art. 2.
207 WHO Code Art. 3, p. 9.
208 WHO Code Art. 3, p. 8.
209 Draft HK Code, Art. 3, p. 11.
210 Draft HK Code, Art. 3, p. 15.

More specifically, WHO Code Article 4.2 imposes prohibitions and restrictions on the dissemination of informational/educational materials intended to reach pregnant women and mothers of infants and young children that are related to infant feeding and concern the use of infant formula. Materials concerning the use of infant formula may not "use any pictures or text which may idealize the use of breast-milk substitutes".[211] Materials related to infant feeding must contain language discussing the following non-food safety-related points: "(a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; [and] (d) the difficulty of reversing the decision not to breast-feed."[212] WHO Code Article 4.3 prohibits the donation of informational/educational materials to the public unless requested, and then, only upon government authority approval or if consistent with government guidelines. It recommends that such materials "should be distributed only through the health care system."[213] Such materials "may bear the donating company's name or logo, but should not refer to a proprietary product" within the scope of the Code.[214] Draft HK Code Articles 4.2.1(b) and 4.4.1(a) and (c) impose restrictions similar to those covered by WHO Code Articles 4.2 and 4.3, and to such extent, address subject matter falling within the scope of the WHO Code. Although the prohibitions imposed by Draft HK Code Articles 4.3.1(a) and 4.4.1(d) go beyond the WHO Code which does not impose such restrictions, and are consequently trade-disruptive, it could nevertheless be argued that they address similar subject matter.

WHO Code Article 5 prohibits manufacturers and distributors from: 1) providing product samples to pregnant women, mothers or members of their families;[215] 2) distributing to pregnant women or mothers or infants and young children gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding;[216] and 3) point-of-sale advertising, sampling, or any other promotion device to induce product sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.[217] In addition, the WHO Code Article 5 prohibits third-party marketing agents employed by formula milk product manufacturers and distributors from seeking direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.[218] Draft HK Code Articles 5.1-5.4 prohibit similar activities with respect to similar products covered by WHO Code Articles 5.2-5.5. Although these Draft HK Code provisions go beyond their WHO Code counterparts and consequently disrupt international trade, they can nevertheless be considered to address subject matter falling within the scope of the WHO Code.

WHO Code Articles 6.2-6.3 prohibits the display or other promotion of infant formula or other products at healthcare system facilities.[219] And, WHO Code Article 7.3 prohibits healthcare workers

211 *Id.*, Art. 4.2.
212 *Id.*
213 *Id.*, Art. 4.3.
214 *Id.*
215 *Id.*, Art. 5.2.
216 *Id.*, Art. 5.4.
217 *Id.*, Art. 5.3.
218 WHO Code, Art. 5.5.
219 *Id.*, Arts. 6.2-6.3.

from promoting infant formula or other products.[220] Draft HK Code Articles 7.2.1 and 7.2.2 limit all commercial communications between formula milk manufacturers/distributors and healthcare workers to the submission of products for purposes of clinical evaluation,[221] scientific, technical and use-related product information,[222] and peer-reviewed scientific studies substantiating product health, growth and/or developmental claims.[223] Draft HK Code Articles 7.2.1-7.2.2 prohibit similar activities with respect to similar products covered by WHO Code Articles 6.2-6.3 and 7.3, and to such extent, address similar subject matter falling within the scope of the WHO Code.

WHO Code Article 9.2 imposes non-food safety-related labeling restrictions to ensure that breastmilk substitute product labels are designed so as "not to discourage breast-feeding."[224] Formula milk product containers and labels must contain "(b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;…and (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation."[225] It prohibits formula milk product containers and labels from having any "pictures of infants [or]…other pictures or text which may idealize the use of infant formula."[226] Graphics are permitted only "for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation."[227] Containers and labels may not use the terms "humanized", "materialized" or similar terms.[228] Draft HK Code Articles 8.1., 8.2.1(a), (d), (e), (h) and (i) impose similar restrictions and requirements to those imposed by WHO Code Article 9.2. While such Draft HK Code provisions go beyond their WHO Code counterparts and consequently disrupt international trade in such products, they nevertheless can be considered to address similar subject matter falling within the scope of the WHO Code.

Hence, to the extent that Draft HK Code Articles 3, 4.2.1(b), 4.3.1(a) and 4.4.1(a), (c), and (d), 5.1-5.4, 7.2.1-7.2.2, and 8.1, 8.2.1(a), (d), (e), (h) and (i) cover subject matter that falls within the scope of WHO Code Articles 3, 5.2-5.5, 6.2-6.3, 7.3 and 9.2, it is arguable that the WHO Code "bears upon, relates to, or is pertinent to" the Draft HK Code, and is thus, a relevant international standard for purposes of the TBT Agreement.

d. The Draft HK Code is Based on the WHO Code

To recall, "an international standard is used 'as a basis for' a [de jure or de facto] technical regulation 'when it is used as the principal constituent or fundamental principle for the purpose of enacting" it.[229] The Draft HK Code's Introduction indicates that, "[f]or the purpose of developing the

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220 *Id*., Art. 7.3. World Health Assembly Resolution WHA47.5 (1994) subsequently banned distribution of "'free or low cost supplies' to all parts of the health care system", effectively superseding the provisions of Art.6.6 of the [WHO] Code." WHA 47.5 (1994), par. 2(2), available at: http://www.who.int/nutrition/topics/WHA47.5_iycn_en.pdf.
221 Draft HK Code Art. 7.2.1.
222 Draft HK Code Art. 7.2.2(a).
223 Draft HK Code Art. 7.2.2(b).
224 *Id*., Art. 9.1.
225 *Id*., Art. 9.2.
226 *Id.*
227 *Id*.
228 *Id*.
229 Panel Report, *US-Tuna II (Mexico)*, at par. 7.711; Appellate Body Report, *EC – Sardines*, at pars. 240-245.

code of marketing of breastmilk substitutes, the Taskforce on Hong Kong Code of Marketing of Breastmilk Substitutes ("the Taskforce") was set up in June 2010 by the Department of Health. In drafting the code for Hong Kong, the Taskforce has referred to the International [WHO] Code and the relevant subsequent WHA resolutions, which prescribe the current international standards on the matters covered."[230] The Draft HK Code also notes that "[t]he aims of the International Code are to empower mothers to make fully informed decisions on infant feeding free from commercial influences, restrict marketing practices of breastmilk substitutes so that breastfeeding can thrive and minimise risks for infants who are fed formula milk."[231] It is therefore arguable that the Draft HK Code and the WHO Code have very similar principal objectives. Since the Draft HK Code provisions discussed above address subject matter that is similar to that covered by various WHO Code provisions in order to achieve those objectives, it is arguable that such Draft HK Code provisions were based on the provisions of the WHO Code, for purposes of the TBT Agreement.

5. Ascertaining Whether National Measures Create Unnecessary Obstacles to Trade Within the Meaning of TBT Article 2.2[232]

In *US-Clove Cigarettes*,[233] the WTO Appellate Body ruled that "the object and purpose of the TBT Agreement is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members' right to regulate."[234] One of the TBT Agreement's primary objectives is to prevent WTO Members from using regulations as unnecessary barriers to trade while ensuring that they retain their sovereign right to regulate "for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels [they] consider appropriate."[235] Thus, where national measures go beyond and are more stringent than relevant international standards and may affect international trade, a complaining WTO Member must present a *prima facie* case showing that they are more trade-restrictive than necessary to fulfill the measure's legitimate policy objectives considering the risks nonfulfillment of those objectives would create.

TBT Article 2.2 sets forth the framework[236] to discern whether a disputed measure imposes an unnecessary obstacle to trade. The first sentence of Article 2.2 reflects the general principle set

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230 Draft HK Code Introduction, p. 3.

231 Draft HK Code Introduction, p. 2.

232 "Three WTO Panels and the Appellate Body have reaffirmed that the TBT Agreement recognizes the sovereign right of WTO Members to regulate for the protection of human health and the environment at their chosen level of protection, provided that right is not exercised to employ such regulations in a discriminatory manner or as unnecessary obstacles to trade." *See* Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure Has Matured into an Actionable Non-Tariff Trade Barrier*, 28 American University International Law Review 101-280 (2012) at p. 275, available at: http://www.koganlawgroup.com/uploads/REACH_Revisited___A_Framework_For_Evaluating_Whether_a_Non-Tariff-_Measure_Has_Matured_Into_a_Non-Tariff_Barrier.pdf. Part 2 of this article does not discuss whether the Draft HK Code is employed in a discriminatory manner, in contravention of TBT Article 2.1, by failing to accord most favored nation or national treatment to the formula milk products, infant and young children's food products and/or formula milk non-food products exported from a specific WTO Member to Hong Kong.

233 Appellate Body Report, *United States - Measures Affecting the Production and Sale of Clove Cigarettes ("US-Clove Cigarettes")* WT/DS406/AB/R (Apr. 4, 2012).

234 *Id*., at par. 174.

235 TBT Agreement Preamble, Sixth Recital.

236 "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate

forth within both the TBT Agreement Preamble's fifth recital and TBT Article 2.5, namely the "desire" that technical regulations "not create unnecessary obstacles to trade."[237] The second sentence of Article 2.2 sets forth an "obligation" to fulfill the general principle contained in the first sentence of Article 2.2.[238] This entails a multi-step inquiry.[239]

a. Whether the Measure Is Trade-Restrictive

A measure will be deemed "trade restrictive" within the meaning of TBT Article 2.2 if it affects "the competitive opportunities available to imported products".[240] Such a finding requires neither "the demonstration of any actual trade effects" nor a showing of the "level" of trade-restrictiveness.[241] In other words, a measure will be considered trade-restrictive if it has some "limiting effect on trade."[242]

b. Whether the Measure Pursues a Legitimate Objective

Recent WTO jurisprudence reflects that the objective of a technical regulation is distinguishable from the technical regulation itself, "including the alleged intent behind the enactment of the particular technical regulation," since "it is the objective that leads to a Member's determination to adopt a technical regulation" and it is typically the objective that precedes the establishment of the regulation to be adopted or maintained.[243] TBT Article 2.3[244] and the TBT Agreement Preamble's sixth recital confirm this distinction.[245]

TBT Article 2.2 requires that complaining Members identify the objective pursued by the government sponsor of a disputed technical regulation on the basis of information they obtain prior to or during the dispute settlement proceeding.[246] Typically, the objective of a disputed technical regulation can be identified in the "notification" that a Member submitted to the WTO TBT

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objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology, or intended end-uses of products" (first emphasis added). TBT Art. 2.2.

237 Panel Report, *US-COOL* at par. 7.551.

238 *Id*., at par. 7.552.

239 Id., at pars. 7.554–7.557.

240 Id., at par. 7.572.

241 Id at pars. 7.572 and 7.575.

242 Appellate Body Report, *US-Tuna II (Mexico)* at par. 319; Appellate Body Report, *US-COOL* at par. 375. The Appellate Body also found "that the reference in Article 2.2 to 'unnecessary obstacles' implies that 'some' trade-restrictiveness is allowed . . . ." *Id*.

243 Panel Report, *US-COOL* at pars. 7.597–7.599, 7.602, 7.609, 7.615, 7.617.

244 TBT Article 2.3 confirms this distinction by providing that "[t]echnical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade restrictive manner." TBT Art. 2.3.

245 The TBT Agreement Preamble's sixth recital explicitly recognizes every Member's "right to regulate in order to pursue certain legitimate objectives." *See* Appellate Body Report, *Clove Cigarettes* at pars. 94–95. It also "acknowledges the right of every WTO Member to establish for itself the objectives of its technical regulations." Panel Report, *US-COOL* at par. 7.584.

246 Panel Report, *US-COOL* at par. 7.592. The Appellate Body has noted that the "TBT Agreement affords a complainant adequate opportunities to obtain information about the objectives of technical regulations or the specific considerations that may be relevant to the assessment of their appropriateness." *Id*., at par. 7.593 (quoting Appellate Body Report, *EC-Sardines* at par. 277.

Committee pursuant to TBT Article 2.9, which enjoys a rebuttable presumption of truthfulness and good faith consistent with international law.[247]

i. Whether the Identified Objective Is Indeed the Objective of the Measure

To discern whether a technical regulation's stated objective is, indeed, the regulation's actual objective, it is necessary to evaluate the measure's text as well as its design, architecture, and structure. This same rule of thumb applies where a technical regulation has failed to expressly state its objective.[248] The significance of statements made by various legislators during the legislative process surrounding a disputed measure can also be considered, but they may not be very revealing.[249]

ii. Whether the Identified Objective is Legitimate

Recent WTO jurisprudence reflects that "the legitimacy of a given objective must be found in the 'genuine nature' of the objective, which is 'justifiable' and 'supported by relevant public policies or other social norms.'"[250] A complaining WTO Member bears the burden of establishing that the objective of a disputed regulation is not legitimate within the meaning of Article 2.2.[251]

TBT Article 2.2 sets forth a non-exclusive open list of legitimate objectives, which include, *inter alia*, national security requirements; the prevention of deceptive practices; protection of human health or safety; animal or plant life or health; or the environment.[252] Thus, a wide range of objectives could potentially fall within the scope of legitimate objectives under Article 2.2 and that "a policy objective pursued by a technical regulation [need not] be specifically linked in nature to those objectives explicitly listed in Article 2.2."[253] For example, although "consumer information" is not expressly listed as a "legitimate objective" in the text of Article 2.2, the Panel in *US-COOL* determined that "consumers generally are interested in having information on the origin of the products they purchase" and that, consequently, "providing consumer information on origin is a legitimate objective within the meaning of Article 2.2."[254]

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247 TBT Arts. 2.91-2.92; Panel Report, *US-COOL* at par. 7.605–7.606.

248 Although the Panel in *US—COOL* found that the COOL measure did not expressly state its objective, the Panel nevertheless concluded that said measure's objective was to provide consumer information on origin, as the United States had declared, because it was "devoted exclusively to the labelling requirements on origin." Panel Report, *US-COOL* at pars. 7.680, 7.685.

249 The Appellate Body has deemed such an inquiry unnecessary and unadvisable given the difficulties of ascertaining and second-guessing the intent behind a measure that has multiple objectives. *See* Panel Report, *US-COOL* at par. 7.686-7.691 (citing Appellate Body Report, *Japan — Taxes on Alcoholic Beverages*, WT/DS8/AB/R (Oct. 4, 1996)) at pars. 27–28; *See also* Appellate Body Report, *Chile — Taxes on Alcoholic Beverages*, WT/DS87/AB/R (Dec. 13, 1999), at par 62.

250 Panel Report, *US-COOL* at par. 7.632.

251 *Id.*, at pars. 7.629–7.631 (highlighting that, under the ordinary meaning of the term "legitimate," a measure's objective will generally be deemed legitimate if it is "conformable to law or principle," "justifiable and proper," or "conformable to a recognized standard type").

252 *Id.*, at pars. 7.632–7.634; TBT Art. 2.2.

253 Panel Report, *US-COOL* at pars. 7.634, 7.637.

254 *Id.*, at pars. 7.650–7.651. The Panel in *US-COOL* found that many WTO Members, including the complainants and third-party amici, had "maintain[ed] some form of mandatory country of origin labelling for food and other products intended for human consumption" that "apply to food products at the retail level." *Id.*, at par. 7.637. This "suggest[ed] that consumer information on country of origin [was] considered by a considerable proportion of the WTO Membership to be a legitimate objective under the TBT Agreement." *Id.*, at par. 7.638.

c. Whether the Measure Fulfills the Identified Objective(s)

Recent WTO jurisprudence reflects that a measure will be deemed to have "fulfilled" an identified objective if it "*makes a contribution to* the objective pursued", which means that "there is a genuine relationship of ends and means between the objective pursued and the measure at issue" (emphasis added).[255] The determination of whether a measure "fulfills" its objective under TBT Article 2.2 does not necessitate a finding that the measure "must meet some minimum threshold of fulfillment."[256] Such a determination "is concerned with *the degree of contribution* that the technical regulation makes towards the achievement of the legitimate objective," which "may be discerned from the design, structure, and operation of the technical regulation, as well as from evidence relating to the application of the measure" (emphasis added).[257] In other words, the fulfillment of an objective by a technical regulation depends on how much that regulation helps to actually achieve that objective, taking into account the regulation's overall contribution[258] – i.e., the extent to which the contribution is capable of achieving the objective pursued.[259]

d. Whether the Measure Is More Trade-Restrictive than Necessary to Fulfill the Objective(s) Concerned

Three factors must be evaluated to determine whether a technical regulation is "more trade-restrictive than necessary" within the meaning of Article 2.2. First, "the degree of contribution made by the measure to the legitimate objective at issue" must be ascertained.[260] Second, "the trade-restrictiveness of the measure" must be determined.[261] And, third, "the nature of the risks at issue as well as the gravity of consequences that would arise from non-fulfillment of the objective pursued by the Member through the measure" must be considered.[262] In other words, "the assessment of "necessity" involves a relational analysis of the trade-restrictiveness of the technical regulation, the degree of contribution that it makes to the achievement of a legitimate objective, and the risks non-fulfilment would create."[263]

According to the Appellate Body, it must be discerned "whether such trade-restrictiveness is required to fulfill the legitimate objectives pursued by the Member at its chosen level of protection"[264] – i.e., "whether the restrictions on international trade…exceed what is necessary to achieve the degree of contribution that a technical regulation makes to the achievement of a legitimate objective."[265]

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255 Panel Report, *US-COOL* at par. 7.693.
256 Appellate Body Report, *US-COOL* at par. 461.
257 *Id*.
258 Appellate Body Report, *US-Tuna II (Mexico)* at pars. 315–17; Appellate Body Report, *US-COOL* at pars. 461–66.
259 Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres* WT/DS332AB/R (Dec. 3, 2007) at par. 149.
260 Appellate Body Report, *US-Tuna II (Mexico)* at par. 322; Appellate Body Report, *US-COOL* at par. 471.
261 *Id*.
262 *Id*.
263 Appellate Body Report, *US-Tuna II (Mexico)* at par. 318. *See also* Panel Report, *US-Tuna II (Mexico)* at par. 7.460 ("[T]he aspect of the measure to be justified as 'necessary' [in the context of TBT Article 2.2] is its trade restrictiveness rather than the necessity of the measure [itself] for the achievement of the objective.").
264 Appellate Body Report, *US-Tuna II (Mexico)* at par. 318.
265 *Id*., at par. 319.

i. Whether a Less Trade-Restrictive Alternative is Reasonably Available

Recent WTO jurisprudence reflects that, "[t]o the extent that a measure is capable of contributing to its objective, it would be more trade-restrictive than necessary if an alternative measure that is less trade-restrictive is reasonably available, that would achieve the challenged measure's objective *at the same level*" (emphasis added).[266] Consequently, a comparison of the trade-restrictiveness of the disputed measure with other reasonably available alternatives is required.[267] The complaining party bears the burden of identifying a reasonably available alternative that is capable of achieving the objective pursued by the disputed measure at the same level of protection, taking into account the risks non-fulfillment would create.[268]

ii. The Risks Engendered if the Available Less Trade-Restrictive Alternative Cannot Fulfill the Identified Objective(s)

To determine "the risks that non-fulfillment would create", panels must consider "the likelihood and the gravity of potential risks (and any associated adverse consequences) that might arise in the event the legitimate objective being pursued would not be fulfilled."[269] And, in assessing such risks, panels may use "relevant…available scientific and technical information, related processing technology, or intended end-uses of products," among other tools.[270] Therefore, "an alternative means of achieving the objective that would entail greater 'risks of non-fulfilment' would not be a valid alternative, even if it were less trade-restrictive."[271]

6. Various Draft HK Code Provisions Impose an Unnecessary Obstacle to Trade That Is More Trade-Restrictive Than Necessary to Fulfill a Legitimate Objective Considering the Risks Non-Fulfillment Would Create

a. Draft HK Code Articles 2, 3, 4, 5 and 8 are Trade-Restrictive

"[M]ost formula products and foods intended for infants and young children under the age of 36 months in the local [Hong Kong] market are imported from overseas".[272] Consequently, various Draft HK Code provisions will very likely affect the competitive opportunities available to, and thus, international trade in, such products in Hong Kong. These provisions include: Articles 2 and 3, because of their broader than WHO Code/Feeding Strategy product scope and coverage; Article 4, because of its more stringent than WHO Code prohibitions and restrictions relating to manufacturer, distributor and third party product informational and breastfeeding and formula feeding informational/educational materials disseminated "to the general public, pregnant women or mothers of children aged 36 months or below"; Article 5, because of its more extensive than

266 Panel Report, *US-Tuna II (Mexico)* at par. 7.465.
267 Appellate Body Report, *US-Tuna II (Mexico)* at par. 322.
268 Panel Report, *US-Tuna II (Mexico)*, at par. 7.468.
269 *Id*., at pars. 7.466-7.467.
270 *Id*., at par. 7.466.
271 *Id.*, at par. 7.467. This conclusion is consistent "with the fact that each Member is entitled, as expressed in the preamble of the TBT Agreement…to define its own level of protection." *Id*.
272 See *LegCo Panel Paper - March 2013*, supra at par. 5, pp. 2-3. "At present, there are more than 120 products of infant formula and follow-up formula available in Hong Kong imported from various places including the United States, Europe, Australia and Japan." See *GHK Food Safety Consultation Document*, supra at par. 3.5, p. 12.

WHO Code resolution ban on promotional and advertising activities relating to follow-up formula and complementary food products suitable by infants less than 12 months of age and by young children more than 12 months up to the age of 36 months; Article 8, because of more stringent than WHO Code resolution restrictions on the labeling of formula milk products and food products for infants and young children; and Article 4, 5 and 8's more expansive than WHO Code resolution prohibition of or restrictions on the use of proprietary company intellectual property in informational/educational materials, on formula milk product containers and labels, and in such product-related advertising.[273]

Significantly, these Draft HK Code provisions, unlike the corresponding provisions of the WHO Code or relevant subsequent WHA resolutions, impose prohibitions and restrictions on promotion, advertising and dissemination of other information relating to two types of food products that are *not* intended or marketed as breastmilk *substitutes*.[274] First, they apply to follow-up formula "marketed or otherwise represented as a food suitable for use as a liquid part of the weaning diet *for infants from the 6th month on* and for young children" (emphasis added), defined as a "person from the age of more than 12 months up to the age of three years (36 months)."[275] Second, they apply to "food products for infants and young children" (infant and young children's food products) "intended primarily for use during the normal infant's weaning period and for the progressive adaptation of infants and young children to ordinary food", which includes complementary food. Complementary foods are "non-milk or milk-like product[s] suitable or represented as suitable as *an addition to breastmilk* or formula milk for *infants of or above the age of 6 months and young children of or below the age of 24 months*" (emphasis added).[276] The WHO has made patently clear that "appropriate complementary feedings should start *from the age of six months* with continued [partial] breast feeding up to two years or beyond" (emphasis added). [277]

Indeed, the WHO Code recommends that infant formula products intended for infants up to 4-6 months of age and complementary food products intended for infants older than 6 months of age and young children not be marketed *to replace* breastfeeding at all *as the sole food source* (i.e., as a breastmilk *substitute*) *during the first 6 months* of an infant's life.[278] WHA 55/25[279]endorses the WHO *Global Strategy on Infant and Young Child Feeding* ("WHO Feeding Strategy")[280] which recommends that such products not be marketed to displace breastfeeding's role as a *partial food source* (i.e., as a breastmilk substitute) *after the first six months* of an infant's life, up to two years

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273 Part 3 of this article will discuss in detail how these prohibitions and restrictions violate the WTO TRIPS Agreement.

274 It is herein acknowledged that it would be much more difficult to distinguish on such grounds the Draft HK Code's treatment of formula milk-related products such as bottles, teats, pacifiers which can just as easily be used with follow-up formula products as with infant formula products.

275 Draft HK Code Article 3, pp. 9 and 15.

276 Draft HK Code Article 3, p. 8.

277 *See* World Health Organization, *Complementary Feeding, Report of the Global Consultation* (2002), at p. 1, available at: available at: http://www.who.int/nutrition/publications/Complementary_Feeding.pdf; World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003), at pp. 11 and 18, available at: http://whqlibdoc.who.int/paho/2003/a85622.pdf; World Health Organization, *Guiding Principles for Feeding Non-Breastfed Children 6-24 Months of Age* (2005), at pp. 7 and 9, available at: http://whqlibdoc.who.int/publications/2005/9241593431.pdf.

278 WHO Code Articles 2 and 3, p. 9.

279 *See* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition*, Resolution WHA55.25 (May 18, 2002), at par. 1, available at: http://www.who.int/nutrition/topics/WHA55.25_iycn_en.pdf.

280 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), available at: http://whqlibdoc.who.int/publications/2003/9241562218.pdf.

or beyond.[281] Therefore it is clear that the Draft HK Code's prohibitions and restrictions, unlike the WHO Code and WHO Feeding Strategy, effectively apply to such products even if they are exclusively marketed and suitable for use as *supplements to partial breastfeeding*. Consequently, these Draft HK Code provisions, which effectively impose a 30-month marketing ban on such products, will likely be considered "trade-restrictive" in nature within the meaning of TBT Article 2.2.

b. Draft HK Code Articles 2, 3, 4, 5 and 8 Pursue Legitimate Policy Objectives

The GHK-SAR filed a TBT Committee notification describing the Draft HK Code as having two plausible non-food safety-related public policy objectives which enjoy a rebuttable presumption of truthfulness and good faith consistent with international law. It states that the "HK Code aims to contribute to the *protection of breastfeeding* and [the] *provision of…adequate nutrition for infants and young children*" (emphasis added).[282] It seeks to achieve this objective "by…protecting breastfeeding and…ensuring proper use of formula milk, formula milk-related and food products for infants and young children up to the age of 36 months, *on the basis of adequate and unbiased information and through appropriate marketing*" (emphasis added).[283]

Indeed, an in-camera review of the Draft HK Code's preamble and Articles 4, 5 and 8 confirm that the Code's primary non-food safety-related objective is to "creat[e] an environment that protects, promotes and supports breastfeeding".[284] In particular, it is to protect exclusive breastfeeding during the first 6 months of an infant's life[285] the superiority of which has been recognized by the WHO,[286] *as well as*, partial breastfeeding "for up to two years of age or beyond".[287] Arguably, the text, structure and design of the marketing bans and restrictions imposed by Draft HK Code Articles 4, 5 and 8 substantiate that the policy objective identified by the GHK-SAR (i.e., "the protection of breastfeeding") is the Code's actual and primary non-food safety-related objective.

The "protection of breastfeeding", however, is not expressly among the nonexclusive list of TBT Article 2.2 "legitimate objectives". In light of the widely recognized benefits of exclusive breastfeeding for the first 6 months of life - i.e., "the physical and psychosocial health of mother and child"[288] - it is arguable that such objectives are related to "the protection of human health" - which *is* among the nonexclusive list of legitimate objectives.[289]

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281 *Id*., at pars. 10, 28 and 30.
282 G/TBT/N/HKG/43, *supra* at par. 7. Part 1 of this article discussed the Draft HK Code's food safety-related policy objectives which fall under the scope and coverage of the WTO SPS Agreement.
283 *Id*.
284 Draft HK Code, Preamble, p. 1.
285 "The World Health Organisation (WHO) has made a global public health recommendation that infants should be *exclusively breastfed for the first six months of life* to achieve optimal growth, development and health" (emphasis added). Draft HK Code, Preamble, p. 1. *See also* Arts. 4.4.1(e)(i)(A)-(B); 4.4.1(e)(iii)(A)-(B).
286 "The superiority of breastfeeding in ensuring physical and psychosocial health and well-being of mother and child as well as the important impacts of early nutrition on long-term health are widely recognized." *Id*.
287 "The World Health Organisation (WHO) has made a global public health recommendation that infants should receive nutritionally adequate and safe complementary foods *while breastfeeding continues for up to two years of age or beyond…*" (emphasis added). *Id*.
288 *Id*., p. 1.
289 TBT Art. 2.2.

A likely but unstated second non-food safety-related objective of the Draft HK Code is to prevent the aggressive marketing and advertising of formula milk products, infant and young children's food products and formula milk-related non-food products from confusing mothers of infants and young children from 0-to-36 months of age, such that they are dissuaded from continuing breastfeeding, and/or persuaded to use those products in lieu of breastfeeding. Paragraph 7 of the GHK-SAR's TBT notification identifies a need to ensure the proper use of such products "on the basis of adequate and unbiased information and through appropriate marketing."[290] The Draft HK Code's preamble confirms this secondary objective, noting that "the proper use of formula milk, formula milk related products, and food products for infants and young children up to the age of 36 months" can be ensured only "*on the basis of adequate and unbiased information and through appropriate marketing*" (emphasis added).[291] The Draft HK Code's preamble also expressly refers to the WHO's *International Code of Marketing of Breastmilk Substitutes*, the aims of which include "empower[ing] mothers to make fully informed decisions on infant feeding *free from commercial influences* [and] restrict[ing] marketing practices of breastmilk substitutes so that breastfeeding can thrive" (emphasis added).[292] The Draft HK Code's preamble similarly emphasizes the importance of "protect[ing] breastfeeding *from being undermined by inappropriate marketing*"[293], particularly, "the *aggressive marketing* of formula milk in Hong Kong, which is considered a factor *that contributes to the low breastfeeding rates*" (emphasis added).[294]

The prevention of aggressive breastmilk substitute product marketing and advertising is not expressly among the nonexclusive list of TBT Article 2.2 "legitimate objectives". However, it is arguable that this unstated objective is partly intended to prevent consumers from being misled by breastmilk substitute marketing and advertising activities that are deemed other than truthful,[295] which are believed to influence and shape consumer behavior away from breastfeeding. Thus, to such extent, the objective of preventing aggressive breastmilk substitute product marketing and advertising activities is related to "the prevention of deceptive practices", which *is* among the nonexclusive list of TBT Article 2.2 legitimate objectives.

Therefore, it is arguable that the Draft HK Code's actual non-food safety-related objectives are to protect general human health by protecting breastfeeding, and to prevent deceptive marketing and advertising practices by manufacturers, distributors and marketers of formula milk, infant and young children's food products and formula milk-related products intended for infants and young children up to 36-months of age, both of which are "legitimate" objectives within the meaning of TBT Article 2.2.

c. The Degree to Which Draft HK Code Articles 2, 3, 4, 5 and 8 Are Capable of Fulfilling the Code's Legitimate Objectives is Uncertain

As previously discussed, recent WTO jurisprudence indicates that a disputed measure will be considered to have fulfilled its identified objectives depending on the degree of contribution that

290 G/TBT/N/HKG/43, supra at par. 4.
291 G/TBT/N/HKG/43, *supra* at par. 7.
292 *Id*.
293 *Id*.
294 *Id*., p. 3.
295 Draft HK Code, Annex I, pars. 14(ii) and (iv).

the measure is capable of making or actually makes towards the achievement of the legitimate objective. The degree of contribution may be discerned from the design, structure, and operation of the technical regulation, as well as from evidence relating to the application of the measure.

In order to protect/promote breastfeeding and to prevent deceptive or otherwise misleading marketing/advertising of formula milk, infant and young children's food products, and formula milk-related products in Hong Kong, Draft HK Code Articles 4, 5 and 8 effectively impose a 30-month *de facto* marketing ban that severely limits the opportunity to offer for sale and sell such products in Hong Kong. The intended effect of this *de facto* marketing ban is to mostly remove such products and their images from public view and, ultimately, from the Hong Kong public's consciousness.

i. The Broad Reach and Goals of Draft HK Code Articles 2 and 3

The Draft HK Code covers "designated products", which include formula milk, formula milk-related products, *and* food products for infants and young children.[296] Formula milk is defined to include infant formula and follow-up formula.[297] Infant formula is suitable for infants - "person[s] not more than 12 months of age", while follow-up formula is suitable "for infants from the 6th month on and for young children".[298] Young children are "person[s] from the age of more than 12 months up to the age of three years (36 months)."[299] Food for infants and young children includes non-formula food "intended primarily for use during the normal infant's weaning period and for the progressive adaptation of infants and young children to ordinary food."[300]

While the general physical and mental health benefits of exclusive breastfeeding for an infant's first 6 months of life are generally well recognized, this WHO recommendation has not been entirely free from scientific challenge.[301] Furthermore, evidence of the benefits conferred by exclusive breastfeeding beyond the first 6 months of life is limited, suggestive, circumstantial and dependent on various factors, such as "age, education, smoking, family income, family structure, life stress events and depression."[302] The lack of conclusive evidence of long-term breastfeeding, or the

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296 Draft HK Code, Arts. 2.2; 3, p. 9.
297 Draft HK Code, Art. 3, p. 9.
298 Draft HK Code, Art. 3, pp. 11-12.
299 Draft HK Code, Art. 3, p. 15.
300 Draft HK Code, Art. 3, pp. 9-10.
301 *See e.g.*, Mary Fewtrell, David C Wilson, Ian Booth, Alan Lucas, *Six Months of Exclusive Breast Feeding: How Good is the Evidence?*, 342 British Medical Journal (2011), available at: http://www.bmj.com/content/342/bmj.c5955?hwoasp=authn%3A1368774369%3A5531153%3A1534235762%3A0%3A0%3A1uNZzgftfk7ch5ka3GQXKg%3D%3D. ("In the West, exclusive breast feeding for six months is linked to reduced risk of infection. Nevertheless, the studies are observational and some evidence suggests that introducing solids (rather than formula) before six months may not significantly affect risk of infection. By contrast, exclusive breast feeding to six months raises concerns.") *Id*; UCL Institute of Child Health News, *Six Months of Exclusive Breast Feeding: How Good is the Evidence?* (Jan. 20, 2011), available at: http://www.ucl.ac.uk/ich/ich-news/Article13; Science Daily, *Is 'Breast Only' for First Six Months Best?* Press Release (Jan. 14, 2011), available at: http://www.sciencedaily.com/releases/2011/01/110113213100.htm; Sarah Boseley, *Six Months of Breastmilk Alone is Too Long and Could Harm Babies, Scientists Now Say*, The Guardian (Jan. 13, 2011), available at: http://www.guardian.co.uk/lifeandstyle/2011/jan/14/six-months-breastfeeding-babies-scientists; Mary S Fewtrell, Jane B Morgan, Christopher Duggan, Geir Gunnlaugsson, Patricia L Hibberd, Alan Lucas, and Ronald E Kleinman, *Optimal Duration of Exclusive Breastfeeding: What is the Evidence to Support Current Recommendations?*, 85(2) American Journal of Clinical Nutrition (Feb. 2007), available at: http://ajcn.nutrition.org/content/85/2/635S.long.
302 *See e.g.*, Wendy H. Oddy, Garth E. Kendall, Jianghong Li, Peter Jacoby, Monique Robinson, Nicholas H. de Klerk, Sven R. Silburn, Stephen R. Zubrick, Louis I. Landau, and Fiona J. Stanley, *The Long-Term Effects of Breastfeeding on Child and*

longer-term benefits of exclusive breastfeeding,[303] or even partial breastfeeding, is likely to reduce the ability of Draft HK Code Articles 2 and 3 to achieve their objective of protecting breastfeeding, and thus, human health.

In addition to these studies, one 2007 WHO-commissioned study found that while "[b]reastfeeding presents clear short-term benefits for child health, mainly protection against morbidity and mortality from infectious diseases…there is some controversy on the long-term consequences of breastfeeding…Whereas some studies reported that breastfed subjects present a higher level of school achievement and performance in intelligence tests, as well as lower blood pressure, lower total cholesterol and a lower prevalence of overweight and obesity, others have failed to detect such associations."[304] Consequently, "[t]he available evidence suggests [only] that breastfeeding *may* have long-term benefits" (emphasis added).[305]

A 2013 update of this WHO-commissioned study strongly suggests that the anticipated long-term benefits associated with exclusive breast-feeding are overstated, and remain largely questionable and uncertain. It concluded that: 1) "breastfeeding does not seem to protect against total cholesterol levels"; 2) "the protective effect of breastfeeding [on incidents of high blood pressure], if any, is too small to be of public health significance"; 3) there were "conflicting results (one showing an increase and another a reduction among breastfed subjects)" with respect to breastfeeding's effect on diabetes; 4) "breastfeeding may provide some protection against overweight or obesity, but residual confounding cannot be ruled out"; and 5) "there is strong

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Adolescent Mental Health: A Pregnancy Cohort Study Followed for 14 Years, 156(4) The Journal of Pediatrics (April 2010), available at: http://www.bpni.org/Article/Oddy.pdf. "[C]onsistent with our findings, infants who are breastfed for at least 6 months have a distinct developmental advantage over non-breastfed infants and infants breastfed for a short period of time." *Id.*, at p. 4. "Following adjustment of the associated socioeconomic, psychological and birth exposures in early life, breastfeeding for 6 months or longer was positively associated with the mental health and well-being of children and adolescents." *Id*., at p. 6. "Potential confounders were: maternal age at child's birth…maternal education…maternal smoking…family structure…and life stress events." *Id*., at p. 2. *See also* UNICEF UK, The Baby Friendly Initiative, *Breastfeeding May Have Protective Effect on Child and Adolescent Mental Health*, available at: http://www.unicef.org.uk/BabyFriendly/News-and-Research/Research/Mental-development/Breastfeeding-may-have-protective-effect-on-mental-health/.

303 *See, e.g.*, C. Flohr1, G. Nagel, G. Weinmayr, A. Kleiner, D.P. Strachan, and H.C. Williams, *Lack of Evidence For a Protective Effect of Prolonged Breastfeeding on Childhood Eczema: Lessons From the International Study of Asthma and Allergies in Childhood (ISAAC) Phase Two*, 165 (6) British Journal of Dermatology 1280-1289 (Dec. 2011), available at: http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2133.2011.10588.x/full. "Although there was a protective effect of ever having been breastfed on more severe disease, we found no evidence that exclusive breastfeeding for 4 months or longer protects against eczema. Our results are consistent with findings from a recent systematic review of prospective studies. The U.K. breastfeeding guidelines with regard to eczema should be reviewed. Intervention studies are now required to explore how and when solids should be introduced alongside breastfeeding to aid protection against eczema and other allergic diseases." *Id*. *See also* Pat Hoddinott, Leone C A Craig2, Jane Britten, Rhona M McInnes, *A Serial Qualitative Interview Study of Infant Feeding Experiences: Idealism Meets Realism*, 2 British Medical Journal Open (March 14, 2012), available at: http://bmjopen.bmj.com/content/2/2/e000504.full.pdf+html. "Adopting idealistic global policy goals like exclusive breast feeding until 6 months as individual goals for women is unhelpful. More achievable incremental goals are recommended. Using a proactive family-centred narrative approach to feeding care might enable pivotal points to be anticipated and resolved." *Id*., at p. 1. *See also* KJ Dell'Antonia, *Study Urges Revision of Six-Month Breast-Feeding Recommendations*, New York Times (March 15, 2012), available at: http://parenting.blogs.nytimes.com/2012/03/15/study-urges-revision-of-six-month-breast-feeding-recommendations/?_r=0.

304 *See* Bernardo L. Horta, Rajiv Bahl, José C. Martines and Cesar G. Victora, *Evidence on the Long-term Effects of Breastfeeding: Systematic Reviews and Meta-Analyses*, World Health Organization (2007) at pp. 2-3, available at: http://whqlibdoc.who.int/publications/2007/9789241595230_eng.pdf.

305 *Id.*

evidence of a causal effect of breastfeeding on IQ, although the magnitude of this effect seems to be modest."[306]

In light of all this evidence, it is uncertain whether the broader scope and duration of Draft HK Code Articles 2 and 3, which endeavor to protect exclusive breastfeeding for infants through the first 6 or even 12 months of life, as well as partial breastfeeding for infants and young children *up to 36 months of age*, well beyond WHO and United Nations recommendations,[307] will be capable of achieving said objective in Hong Kong. Efforts undertaken by the WHO's Pan American Health Organization affiliate to exaggerate such health benefits are unlikely to improve this capability.[308]

ii. The Broad Reach and Goals of Draft HK Code Article 4

Draft HK Code Article 4 restricts the type of information that can appear in formula milk product-and-feeding-related and breastfeeding-related informational/educational materials distributed by manufacturers and distributors to the public online, at retail establishments, and at healthcare

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306 *See* Bernardo L. Horta and Cesar G. Victora, *Long-term Effects of Breastfeeding: A Systematic Review*, World Health Organization (2013) at p. 68, *supra*. *Cf.* Mandy B. Belfort, Sheryl L. Rifas-Shiman, Ken P. Kleinman, Lauren B. Guthrie, David C. Bellinger, Elsie M. Taveras, MD, Matthew W. Gillman and Emily Oken, *Infant Feeding and Childhood Cognition at Ages 3 and 7 Years Effects of Breastfeeding Duration and Exclusivity*, JAMA Pediatr (2013), Abstract available at: http://archpedi.jamanetwork.com/article.aspx?articleid=1720224. This study "examined [the] relationships of breastfeeding duration and exclusivity with child cognition at ages 3 and 7 years and…evaluate[d] the extent to which maternal fish intake during lactation modifies associations of infant feeding with later cognition." *Id*. The study found that, "[a]djusting for sociodemographics, maternal intelligence, and home environment…longer breastfeeding duration…*to age 12 months*…was associated with higher Peabody Picture Vocabulary Test score at age 3 years…and with higher intelligence on the Kaufman Brief Intelligence Test at age 7 years…Beneficial effects of breastfeeding on the Wide Range Assessment of Visual Motor Abilities at age 3 years seemed greater for women who consumed 2 or more servings of fish per week" (emphasis added). *Id*. *See also* Nicole Ostrow, *Breastfeeding Boosts Smarts as Babies Grow, Study Finds*, Bloomberg (July 29, 2013), available at: http://www.bloomberg.com/news/2013-07-29/breastfeeding-boosts-smarts-as-babies-grow-study-finds.html. "After controlling for maternal intelligence, they found that IQ scores for 7 year olds increased by about one-third of a point for every month of breastfeeding. That means a 7-year-old child who was breastfed as a baby for 12 months would score four points higher on intelligence tests than a child who was never breastfed…*The findings also hinted that children's intelligence benefited when their moms ate more fish while breastfeeding* then those who ate less fish, but the results weren't statistically significant" (emphasis added). *Id*.

307 The WHO and the United Nations Secretary General have continued to promote "exclusive breastfeeding for 6 months" and "nutritionally adequate and safe complementary feeding starting from the age of 6 months with continued [partial] breastfeeding up to 2 years of age or beyond" as the recommended infant and toddler health regimen throughout the world. *See* World Health Organization, *Package of Essential Noncommunicable (PEN) Disease Interventions for Primary Health Care in Low-Resource Settings* (2010) at p. 18, available at: http://whqlibdoc.who.int/publications/2010/9789241598996_eng.pdf. *See also* United Nations General Assembly, Sixty-Sixth Session, Prevention and Control of Non-communicable Diseases, Report of the Secretary-General A/66/83 (May 19, 2011), at par. 42, p. 13, available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/66/83&Lang=E ("[T]here are many other cost-effective and low-cost population-wide interventions that can reduce risk factors for non-communicable diseases. They include…promotion of adequate breastfeeding and complementary feeding…"). *Id*. However, the GHK-SAR endeavors to promote partial breastfeeding for a period of up to 36 months of age, and Draft HK Code Articles 4, 5 and 8 arguably go beyond the WHO Code to achieve this objective, as discussed *infra*.

308 WHO's Pan American Health Organization affiliate has arguably ignore the evidence and exaggerated the health benefits of breastfeeding. "The simple act of breastfeeding has numerous health advantages to both mothers and their babies: in terms of NCD prevention, breastfeeding has long-term benefits in the form of reduced risk of chronic illness…breastfed infants have lower blood pressure, serum cholesterol, and type-2 diabetes…[m]any – though not all – studies show a reduced risk of overweight and obesity in adults who were breastfed as infants." *See* Pan American Health Organization, *Breastfeeding and Non-Communicable Diseases (NCDs): What Are the Health Advantages of Breastfeeding?*, available at: http://new.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=17750&Itemid=.

facilities. Only the types of technical and textual information contained on such products' labels may be included.[309] Although this provision could possibly contribute to the prevention of deceptive (misrepresentative) marketing of such products in egregious cases, there is no assurance that such information will avoid confusing or misleading some consumers. It also remains questionable whether such provision will promote breastfeeding if cultural, lifestyle, or other factors are driving formula milk product demand.

Article 4 prohibits such materials from containing photographs, pictures or graphic representations other than for illustrating methods of preparation, except for a pack shot of limited size.[310] The GHK-SAR apparently believes that consumers will find such information too appealing, deceiving or misleading if it contains any images other than product preparation illustrations, and will thereby be encouraged to purchase formula milk products and discouraged from breastfeeding. While the absence of images and illustrations other than for product preparation may make such materials less attractive to the eye, it is uncertain whether it could contribute to the protection of breastfeeding if cultural, lifestyle or other factors are driving product demand. In addition, a less than perfect illustration of product preparation can just as easily confuse and mislead consumers as other images and illustrations can. Therefore, it is uncertain whether the absence of images and illustrations other than for product preparation will be capable of contributing to the prevention of deceptive or misleading product marketing/advertising. The determination of whether a given image or illustration is deceptive or misleading is often a subjective and circumstantial one, and depends on the particular image and/or illustration, reviewer, and context.

Article 4 also prohibits the display in formula milk feeding-related informational/educational materials of the formula milk brand name, logo or trade mark,[311] in an apparent effort to reduce direct communications between formula milk manufacturers and distributors and the consuming public. This measure is also arguably intended to diminish the image and reputation of all formula milk brands in the minds and eyes of mothers, caregivers and healthcare workers, relative to that of the GHK-SAR and/or NGOs. In other words, such measure indirectly endeavors to increase public reliance upon and confidence and trust in government (the GHK-SAR) and civil society (breastfeeding-focused NGOs) concerning infant and young children's food and nutrition issues. The GHK-SAR apparently believes that if consumers are unable to associate formula milk feeding and/or breastfeeding information with a particular formula milk brand or company, they will be less likely encouraged to discontinue breastfeeding, purchase formula milk products, and to ignore GHK-SAR breastfeeding recommendations. However, the extent to which this measure is capable of contributing to the protection of breastfeeding and to the prevention of deceptive or misleading breastmilk substitute product marketing is, at best, uncertain.

In addition, Article 4 prescribes the use of terminology in disseminated formula milk product-related information materials and in informational/educational materials on breastfeeding, formula milk feeding and complementary food feeding in an effort to protect breastfeeding. This includes language highlighting the benefits of breastfeeding, the health and financial costs of formula milk and complementary foods, and why the early introduction of bottle feeding or complementary

309 Draft HK Code Art. 4.2.1(a).
310 Draft HK Code Art. 4.2.1(b).
311 Draft HK Code Art. 4.3.1(a).

foods "negatively affects breastfeeding.[312] However, since the research results of a recently released study strongly suggest that this last point reflects outdated science,[313] the capability of these provisions to protect breastfeeding in Hong Kong is uncertain.

Furthermore, Article 4 prohibits third parties (e.g., advertisers, broadcasters, marketers, etc.) employed by formula milk and infant and young children's food manufacturers and distributors from producing or distributing infant and young child feeding and nutrition-related written, audio and/or visual informational/educational materials that "give an impression or create a belief that a designated product is equivalent to, comparable with or superior to breastmilk or breastfeeding."[314] This general effort to preclude the use of such media to engage the public in an open, objective, and candid public dialogue that explores how formula milk products can serve as a viable and/or medically necessary alternative to breastfeeding for some infants younger than 6 months of age, or how follow-up formula and/or complementary foods can be used to advantage to supplement breastfeeding for infants and young children older than 6 months of age, is actually a disservice to the people of Hong Kong. It deprives the public of freedom of speech and much needed access to non-government generated information, which is quite a sore subject in Hong Kong given popular suspicions over government motives[315] in light of China's growing influence.[316]

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312 Such information should "clearly and conspicuously explain": "(A) the benefits and superiority of breastfeeding; (B) the value of exclusive breastfeeding for six months followed by sustained breastfeeding for two years or beyond; (C) how to initiate and maintain exclusive and sustained breastfeeding; (D) why it is difficult to reverse a decision not to breastfeed; (E) the importance of introducing complementary food from the age of six months; and (F) how and why any introduction of bottle feeding or early introduction of complementary food negatively affects breastfeeding." Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(i)(A)-(F). *See also* Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(ii)(A)-(D); Draft HK Code Arts. 4.2.1(a); 4.4.1(e)(iii)(A)-(D), (F), and (H).

313 *See* Catharine Paddock*, Giving Babies Formula In Early Days May Help Prolong Breastfeeding For Some*, Medical News Today (May 14, 2013), available at: http://www.medicalnewstoday.com/articles/260441.php ("In a bid to promote breastfeeding, hospitals push to reduce formula feeding in infants in the days following their birth. But in a new study, the first to carry out a randomized trial, researchers show that giving small amounts of formula to newborns who lose a lot of weight in their first few days of life, can actually help prolong breastfeeding in the long term."). *Id*. *See also* Lauren McMullen, *Health Buzz: Breast-feeding and Formula May Benefit Newborns*, US News & World Reports (May 14, 2013), available at: http://health.usnews.com/health-news/articles/2013/05/14/study-breast-feeding-and-formula-benefit-newborns ("Babies with early weight loss may benefit from receiving limited intakes of formula in addition to breast milk, suggests a study published Monday in Pediatrics. In fact, the randomized trial suggests that these early formula feedings may even help the infants transition later to breast milk only."). *Id*.

314 Draft HK Code Art. 4.4.1(c).

315 *See, e.g.*, Terry Wing, *Hong Kong Protest Targets Propaganda in Schools*, Voice of America News Asia (July 30, 2012), available at: http://www.voanews.com/content/hong_kong_protest_school-based_chinese_propaganda/1449312.html; Sisi Tang, *Hong Kong Protesters Oppose 'Propaganda' Education Plan*, Reuters (July 29, 2013), available at: http://www.reuters.com/article/2012/07/29/us-hongkong-china-protest-idUSBRE86S07820120729.

316 *See* William Pesek, *China's Slowdown Could Slam Hong Kong*, Bloomberg (July 1, 2013), available at: http://www.bloomberg.com/news/2013-07-01/china-s-slowdown-could-slam-hong-kong.html ("In the run-up to Hong Kong's return to China in 1997, the world wondered what officials in Beijing would do with the place. Would Hong Kong's dynamism and openness catalyze change in China, or would the Communist Party try to remake the freewheeling city-state in its image? Sixteen years on, we know it's more the latter than the former. Beijing has shackled Hong Kong with one bad, handpicked leader after another. China's commissars and their local lackeys continue to push anti-sedition laws, patriotic education and Mandarin on 7 million people who seek democracy and prefer Cantonese…Since 1997, Hong Kong's leader has been a glorified mayor beholden to the Communist Party, and Leung is barely more popular than the city's last three. He miscalculated as soon as he took office in July 2012, when he tried to force-feed the mainland's "patriotic education" program to Hong Kong's students. Leung also got terrible headlines from efforts to block personal data on company directors, a step that could enable mainland bigwigs to hide ill-gotten gains in Hong Kong. Leung bowed to public pressure and shelved both plans, but Hong Kong's ability to resist China's influence is weakening. Already pressure from Beijing has had a chilling effect on the Hong Kong media, which increasingly exercise self-censorship on controversial issues."). *See also* Kahon Chan, *British Influence Still Shapes*

As a permissible form of commercial speech,[317] such information can, and should, be subject to the legal requirements of truthfulness and accuracy, as set forth in Section 61 of Hong Kong's *Public Health and Municipal Services Ordinance* ("Cap 132")[318] and the *Generic Code of Practice on Television Advertising Standards*, implementing Section 3 of the Hong Kong *Broadcasting Ordinance* ("Cap 562"),[319] both of which are referenced in Draft HK Code Annex 1.[320] For example, Cap 132 Section 61(2) treats false "advertisements" of foods, whether or not intentional, as "an offence"[321] punishable by imposition of a level 5 ($50,000) fine and 6 months imprisonment.[322] Since Hong Kong is known for its adherence to freedom of speech, including free commercial speech, it is highly uncertain whether this provision is capable of contributing to the objectives of protecting/promoting breastfeeding and preventing deceptive and/or misleading marketing/advertising.

SAR: Veteran, China Daily Asia (April 24, 2013), available at: http://www.chinadailyasia.com/news/2013-04/24/content_15073248.html; James Pomfret and Tan Ee Lyn, Hong Kong to Vote Amid Discontent Over China Influence, Reuters (Sept. 7, 2012), available at: http://www.reuters.com/article/2012/09/07/hongkong-china-idUSL4E8K70OO20120907; Rosa Trieu, *Hongkongers' Press Freedom Threatened By China's Creeping Influence*, Forbes (June 25, 2012), available at: http://www.forbes.com/sites/rosatrieu/2012/06/25/hongkongers-press-freedom-threatened-by-chinas-creeping-influence/; Vaudine England, *Hong Kong Suffers Identity Crisis as China's Influence Grows*, The Guardian (March 23, 2012), available at: http://www.guardian.co.uk/world/2012/mar/23/china-hong-kong-identity-crisis.

317 See National People's Congress, *The Basic Law of the Hong Kong Special Administrative Region of the People's Republic of China* (1997), available at: http://www.basiclaw.gov.hk/en/basiclawtext/images/basiclaw_full_text_en.pdf. Article 27 of the Basic Law provides that, "Hong Kong residents shall have freedom of speech, of the press and of publication". *Id*., at Art. 27. Article 30 of the Basic Law provides that, "The freedom and privacy of communication of Hong Kong residents shall be protected by law. No department or individual may, on any grounds, infringe upon the freedom and privacy of communication of residents except that the relevant authorities may inspect communication in accordance with legal procedures to meet the needs of public security or of investigation into criminal offences." *Id*., at Art. 30.

318 See *Cap 132 - Public Health and Municipal Services Ordinance* (2013), at Sections 61(1)-(2) - *False Labelling and Advertisement of Food or Drugs*, supra.

319 *See* Hong Kong Communications Authority, *Generic Code of Practice on Television Advertising Standards* (Jan. 2013), available at: http://www.coms-auth.hk/filemanager/common/policies_regulations/cop/code_tvad_e.pdf.

"All materials included in a television programme service licensed under the Broadcasting Ordinance (Cap.562) must comply with this Code. The CA has the power to impose sanctions on licensees who do not comply with the Code." *Id*., at Preamble, par. 1. "It is the responsibility of the licensees to ascertain the applicable and up-to-date legal and regulatory requirements. As a matter of principle, the CA will not try to interpret or enforce the law under the purview of other enforcement agencies. When there is an alleged breach of the law, the CA will generally refer the case to the proper enforcement agency for action." *Id*., at Preamble par. 13. Paragraph 9 of Chapter 3 of the Generic Code provides that, "[n]o advertisements may contain any descriptions, claims or illustrations which expressly or by implication depart from truth or mislead about the product or service advertised or about its suitability for the purpose recommended." *Id*., p. 9. Paragraph 5 of Chapter 4 of the Generic Code provides that, "[n]o advertisement may misleadingly claim or imply that the product or service advertised, or any ingredient of it, has some special features or compositions which are incapable of being established." *Id*., p. 11. Paragraph 7 of Chapter 4 of the Generic Code provides that, "[i]nformation conveyed must be accurate and not misleading by concealing or failing to make clear significant facts." *Id*., p. 12.

320 Draft HK Code Annex I, pars. 14(ii) and (iv).

321 See *Cap 132 - Public Health and Municipal Services Ordinance* (2013), at Section 61(2) (dealing with product advertisements other than labels). *See also* Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, *supra*.

322 See *Cap 132 - Public Health and Municipal Services Ordinance* (2013), supra at Section 150 and Schedule 9. "Any person who is guilty of an offence under any of the provisions of this Ordinance specified in the first column of the Ninth Schedule shall be liable on summary conviction to the penalty specified in relation thereto in the second column of that Schedule." *Id*., Sec. 150. A violation of "61(1) or (2)…[will be subject to a penalty of]…level 5 and 6 months imprisonment". *Id*., at Schedule 9. *See also* Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, supra (A 'level 5' penalty is equal to $50,000.).

In sum, there are multiple cultural, lifestyle and other factors that drive product demand in Hong Kong for foreign formula milk and infant and young children's food products, and the global reputations of the global foreign brands are largely well established in terms of quality and identification, especially as compared to competing Chinese mainland brands.

iii. The Broad Reach and Goals of Draft HK Code Article 8

Draft HK Code Article 8 bans the use of terminology, symbols, or markings on formula milk and infant and young children food product containers and labels that "give an impression or create a belief that the product is equivalent to, comparable with or superior to breastmilk or breastfeeding."[323] Article 8 specifically prohibits the use of any photograph, drawing or graphic representation on formula milk product containers and labels other than for illustrating preparation, and also prohibits the use of a company logo or product trademark on product labels and containers *more than once*.[324] Apparently, these prohibitions and restrictions are intended make such products less distinctive and attractive in the eyes of the consuming public, in order to diminish the likelihood that mothers, caregivers and other healthcare workers will purchase them.

The GHK-SAR's general effort in Article 8 to preclude any illustrative comparison between breastfeeding and breastmilk substitutes on product containers or labels suffers from the same infirmities as does the analogue provision in Article 4 discussed above. It is difficult to conceive of how the more limited available space on formula milk product containers and, especially labels, could convey an impression or belief that such product is superior to breastmilk or breastfeeding. Thus, it is highly uncertain whether this provision is capable of contributing to the protection of breastfeeding. As discussed above, Section 61 of Hong Kong's *Public Health and Municipal Services Ordinance* ("Cap 132") provides ample legal means to address the risk of deceptive or misleading labeling of formula milk and infant and young children's food products,[325] including with respect to nutritional matters.[326] Therefore, it is also highly uncertain whether this provision is capable of contributing to the prevention of deceptive and/or misleading marketing/advertising of such products.

Given the multiple factors that drive product demand in Hong Kong for foreign formula milk and infant and young children's food products, and the various ways in which Hong Kong consumers can obtain formula milk product information from overseas sources, the extent to which such measures can and/or will contribute to protecting/promoting breastfeeding and preventing deceptive or misleading formula milk product marketing/advertising *in Hong Kong* is currently uncertain.

iv. The Broad Reach and Goals of Draft HK Code Article 5

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323 Draft HK Code Art. 8.1.1.
324 Draft HK Code Art. 8.2.1(a).
325 *See* Cap 132 - *Public Health and Municipal Services Ordinance* (2013), supra at Section 61(1) (dealing with product displays and labels). *See also* Chap. 221 – Criminal Procedure Ordinance, Schedule 8 – Level of Fines for Offence, *supra*.
326 As previously discussed in Part II.2.c, *supra*, proposed amendments to the *Food and Drugs (Composition and Labelling) Regulations* (Cap. 132W) implementing Section 54 of the Hong Kong *Public Health and Municipal Services Ordinance* (Cap 132) are intended to extend the coverage of the Cap 132W nutritional composition and nutrition labeling requirements to "formula products and foods intended for infants and young children under the age of 36 months". *GHK Food Safety Consultation Document*, supra at pars. 1.2-1.5. The violation of these requirements would arguably then also be addressed by Sections 61(1) of the Cap 132.

Draft HK Code Article 5.1 bans, without any evidence of intentional legal wrongdoing, all public promotional activities, including advertising, concerning formula milk and formula milk-related products intended for infants and young children from *0-36 months of age*.[327] In addition, Draft HK Code 5.2 bans the promotion/advertising, of infant and young children's food products, including complementary foods, intended for older infants from *6-12 months of age* and for young children from *12-36 months of age*, at Hong Kong healthcare facilities.[328] Draft HK Code 5.2, nevertheless, permits the promotion/advertising, of infant and young children's food products to the Hong Kong public, provided the information to be disseminated satisfies the requirements of Article 4,[329] and such activities do not also include the promotion of formula milk or formula milk-related products.[330]

The bans against product-related promotional activities at Hong Kong healthcare facilities have the potential to significantly impact international trade in such products because "[e]ach year, over 90% of the local newborns whose parents are Hong Kong residents receive services from the [Maternal and Child Health Centres] MCHCs."[331] "Healthcare facilities are defined broadly as "any institution or organisation or practice engaged directly or indirectly in the provision of health care or in health care education", including hospitals, non-hospital maternity wards, day-care centers, nurseries, and/or other infant care facilities.[332]

The Draft HK Code Article 5-imposed marketing bans substantially eliminate the ability of foreign manufacturers and distributors of follow-up formula and complementary food products to actively sell their products into the Hong Kong market. Article 5 effectively relegates these economic actors to a largely passive product fulfillment role driven by consumer demand shaped mostly by the GHK-SAR. Contrary to GHK-SAR representations the Draft HK Code reflects that the Government will most certainly intervene in the Hong Kong marketplace in a manner that will significantly and adversely interfere with the sale of products for infant-and-young-child feeding.[333]

Moreover, the GHK-SAR arguably endeavors to censor, if not, eliminate virtually all commercial communications between formula milk manufacturers/distributors and the Hong Kong public and to substantially restrict communications with Hong Kong healthcare facilities regarding formula milk and formula milk-related products, whether they are in written, audio, verbal, digital or other

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327 Draft HK Code Art. 5.1. Draft HK Code Art. 5.4(d) provides that banned promotional activities do not include the preparation and distribution of informational/educational materials allowed under Articles 4.2.1, 4.2.2, and 4.4.1.

328 Draft HK Code Art. 5.2(a).

329 Draft HK Code Art. 5.2(b). For example, Draft HK Code Article 4.2.1(c) precludes such materials from containing health or nutrition claims not otherwise permitted by Draft HK Code Articles 8.5.1-8.5.3. Draft HK Code Article 4.4.1(a) precludes such information from containing pictures or texts encouraging formula milk feeding or discouraging breastfeeding, while Draft HK Code Article 4.4.1(c) precludes such information from giving an impression or creating a belief that a designated product is comparable or superior to breastmilk or breastfeeding. Draft HK Code Article 4.4.1(e)(ii), meanwhile, prescribes added terminology for materials discussing complementary feeding which explains the benefits and superiority of breastfeeding and the importance of introducing complementary foods from the age of 6 months.

330 Draft HK Code Art. 5.2(c).

331 *See* Joanna Leung, *Current Role of Maternal and Child Health Service*, The Hong Kong Medical Diary Vol. 14 No. 3 (2009), at p. 17, available at: http://www.fmshk.org/database/articles/03mb04_3.pdf. *See also* Shirley Leung, Cynthia Leung and Wai-yin Luk, *Survey of Infant and Young Child Feeding in Hong Kong: Parental Perceptions and Practices*, supra at p. 6.

332 Draft HK Code Art. 3, p. 10.

333 Draft HK Code Preamble, p. 4.

physical form.[334] No commercial communications above and beyond those sanctioned in Draft HK Code Articles 4[335] and 8 are permitted between such parties. And, very limited communications of a noncommercial nature are permitted between formula milk manufacturers/distributors and healthcare workers which consist only of the submission of products for clinical evaluation,[336] scientific, technical and use-related product information,[337] and peer-reviewed scientific studies substantiating product health, growth and/or developmental claims.[338]

Arguably, despite the absence of practically all active product promotional activities, including advertising, that could convey a positive image of foreign branded infant formula, follow-up formula and complementary food products to the Hong Kong general public, to Hong healthcare facilities and to Hong Kong healthcare workers, the degree to which Article 5 is capable of contributing to the protection of breastfeeding remains questionable. As discussed below, the decision to engage in prolonged breastfeeding and/or to purchase a breastmilk substitute or supplement in Hong Kong is often determined by multiple cultural, social and economic factors that are simply beyond the control of the GHK-SAR in a liberally democratic Hong Kong. That being said, it is difficult not to acknowledge that there is some other rationale underlying the GHK-SAR's claim that the Draft HK Code aims to prevent deceptive marketing practices by ensuring "adequate and unbiased information and through appropriate marketing." Arguably, by eliminating virtually all public marketing/advertising associated with such products, except as provided for in Articles 4 and 8, especially considering the criminal penalties that may already be imposed for false and misleading advertising,[339] Article 5 may, perhaps, be capable of contributing to something far greater than the prevention of deceptive or misleading breastmilk *substitute* and *supplement* product marketing/advertising practices – i.e., to the suppression of commercial speech, and hence, individual free speech, via the curtailment of freedom of choice in Hong Kong.[340]

v. Multiple Factors Driving Breastfeeding Rates and Formula Milk and Complementary Food Product Demand in Hong Kong Diminish the Draft HK Code's Ability to Achieve its Policy Objectives

Clearly, Draft HK Code Articles 4, 5 and 8 are intended to increase the breastfeeding rate (protect breastfeeding) in Hong Kong among infants and young children up to 36 months of age. The extent to which each of these measures may be capable of contributing to the achievement of this objective, however, will largely depend on other factors that largely influence maternal decision-making.

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334 *See* Draft HK Code Art. 3, p. 8 (broadly defining the term "advertisement"); Draft HK Code Art. 5.4 (broadly defining the term "promotional activities" as including distribution of physical premiums and samples; Art. 5.4(b) and (d).
335 Draft HK Code Arts. 5.2(b); 5.4(d).
336 Draft HK Code Art. 7.2.1.
337 Draft HK Code Art. 7.2.2(a).
338 Draft HK Code Art. 7.2.2(b).
339 Hong Kong's *Public Health and Municipal Services Ordinance* and *Generic Code of Practice on Television Advertising Standards* impose some rather significant criminal penalties and prison terms for commission of false or misleading advertising "offenses". *See* discussion *supra*.
340 *See, e.g.*, Milton Friedman, *The Economics of Free Speech* (1979), Presentation made at the University of San Diego Law School, San Diego, California (Nov. 7, 1977) available at: http://0055d26.netsolhost.com/friedman/pdfs/other_academia/Ordo.1979.pdf (discussing how the disparate treatment of commercial and individual free speech in free societies overlooks the illusory dividing line between political and economic freedom.)

As previously discussed in Part 1 of this article,[341] the GHK-SAR has performed extensive research[342] which estimates a pre-Code exclusive breastfeeding rate for newborns in Hong Kong of 73.7%.[343] One GHK-SAR-administered consumer survey[344] found exclusive breastfeeding and partial breastfeeding rates for infants up to 6 months of age of less than 10% and 15%, respectively.[345] This less than scientific survey also found that a majority of infants up to 6 months of age, older infants up to 12 months of age, and young children up to 48 months of age consumed formula milk and complementary food products.[346] However, GHK-SAR research reveals that other factors having little or nothing to do with inappropriate or aggressive breastmilk substitute and supplement product marketing are likely responsible for Hong Kong's recent perceptively low post-hospital discharge breastfeeding rates. These factors will likely reduce the capability of Draft HK Code Articles 4, 5 and 8 to fulfill this objective.

For example, a second less than scientific GHK-SAR administered consumer survey focused on the child feeding perceptions and practices of Chinese parents of 6- to-48 month old Hong Kong children. It found that "parental over-concern about their children being under-weight and not eating enough was associated with various controlling feeding practices (i.e., pressure to eat) which might result in a negative eating atmosphere and avoidant eating behaviours, or over-eating and over-weight."[347]

And, a third GHK-SAR-administered consumer survey focusing on milk consumption found that Hong Kong mothers commonly promoted night feeding and sleeping with bottles which gave rise to extensive infant and toddler milk (predominantly infant formula and follow-up formula)

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341 See Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law*, Part 1 – *The Draft HK Code Violates the SPS Agreement*, LexisNexis (2013), at Sec. II.5.b.i.

342 *See* Department of Health, Hong Kong Special Administrative Region of China, *Action Plan to Promote Healthy Diet and Physical Activity Participation in Hong Kong* (May 2010), available at: http://www.change4health.gov.hk/filemanager/common/image/strategic_framework/action_plan/action_plan_e.pdf.

343 *Id*., at par. 2.34. "It was estimated that the percentages of newborns ever breastfed on discharge from hospitals rose from about 10% in 1981 to around 76.9% in 2009. The ever breastfeeding rate increased from 50% for babies born in 1997 to 73.7% for those born in 2008. The exclusive breastfeeding rate for over 4-6 months increased from 6% for babies born in 1997 to 12.7% for those born in 2008." *Id*., at par. 2.2.

344 *See* Jean Woo, Ruth Chan, Liz Li, and WY Luk, *A Survey of Infant and Young Child Feeding in Hong Kong: Diet and Nutrient Intake* (2012), at p. ix, available at: http://www.fhs.gov.hk/english/reports/files/Survey_IYCF_Dietnutrient%20intake.pdf. "Among 2,849 parents sampled, 1,893 were contactable and 1,581 consented to participate. The participation and response rate were 55.5% and 83.5% respectively. A total of 1,272 children (50.8% boys and 49.2% girls) with complete data were included in the final analysis." *See also*, Executive Summary at 6, available at: http://www.fhs.gov.hk/english/reports/files/Diet_nutrientintake_executive%20summary_2504.pdf.

345 *Id*., at x. "Among the 6-month group, 6.8% consumed breastmilk as the sole source of milk; 13% consumed both breastmilk and formula milk and 80.2% took formula milk only. Among the 12- to 24-month groups, over 90% drank formula only. For the 48-month group, 77% still drank formula milk." *Id*.

346 *Id*.

347 *See* Shirley Leung, Cynthia Leung and Wai-yin Luk, *Survey of Infant and Young Child Feeding in Hong Kong: Parental Perceptions and Practices* (2012), at p. 57, available at: http://www.fhs.gov.hk/english/archive/files/reports/Survey_IYCF_parents%20perception.pdf; *See also* Executive Summary at p. 8, available at: http://www.fhs.gov.hk/english/reports/files/Survey_IYCF_parents_perception_executive%20summary_0304.pdf.

consumption.[348] This same survey attributed the higher consumption of follow-up formula milk to parents' beliefs that follow-up formula was more suitable and nutritious for 1-4 year-olds than cow milk.[349] This last survey, however, did not address, let alone, consider whether mothers were also concerned about the safety and healthfulness of local cow's milk relative to imported formula products, given the food safety issues associated with mainland China-made dairy products, including formula, which have created a huge demand for and shortage of foreign formula in Hong Kong.[350]

These surveys and reports as well as recent WHO pronouncements collectively suggest that the GHK-SAR is well aware that more could be done locally in Hong Kong to promote initiatives that support breastfeeding in the health system, the workplace and the community, consistent with the WHO and UNICEF *Global Strategy for Infant and Young Child Feeding*.[351] For example, the WHO recently emphasized that, in addition to effectively implementing the WHO Code and WHA resolutions, "[n]ecessary actions…to ensure breastfeeding is adequately promoted, protected and supported…include revitalizing the *Baby-Friendly Hospital Initiative*…extending maternity leave…[and helping w]omen before, during and after pregnancy…to correct inappropriate nutrition that leads to low birth weight and stunting, as well as the growing problems of overweight and diabetes."[352] Thus, consistent with the 1990 WHO/UNICEF *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding*,[353] the GHK-SAR, should be undertaking local initiatives to "[e]nsure that every facility providing maternity services fully practices all Ten Steps to Successful Breastfeeding set out in the Joint WHO/UNICEF Statement - *Protecting, Promoting and Supporting Breastfeeding: the Special Role of Maternity Services*".[354] The GHK-SAR, therefore, should also have "[e]nacted imaginative legislation protecting the breastfeeding rights of working women and

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348 *See* Wai-yin Luk, Shirley Leung, and Cynthia Leung, *A Survey of Infant and Young Child Feeding in Hong Kong: Milk Consumption* (2012) at p. 21, available at: http://www.fhs.gov.hk/english/reports/files/Survey_IYCF_milkconsumption_1904.pdf/.

349 *Id*., at pp. 18, 20.

350*See, e.g.,* Li Yao, *Hong Kong Sets Baby Formula Limits*, China Daily (3/4/13), available at: http://www.chinadaily.com.cn/china/2013-03/04/content_16271673.htm; Associated Press, *China: Baby Formula Safety Affects Nation's Future* (May 31, 2013), available at: http://abcnews.go.com/International/wireStory/china-baby-formula-safety-affects-nations-future-19295485#.Ua0TZEDCaSo.

351 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding*, supra at pars. 28 and 30. ("Mothers should also be able to continue breastfeeding and caring for their children after they return to paid employment. This can be accomplished by implementing maternity protection legislation… A first step to achieving the objectives of this strategy is to reaffirm the relevance – indeed the urgency – of the four operational targets of the *Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding*:…enacting imaginative legislation protecting the breastfeeding rights of working women and establishing means for its enforcement.") *Id*., at p. 30.

352 *See* World Health Organization, Regional Office for the Western Pacific 63rd Session, Regional Committee, Provisional Agenda Item 15 - *Nutrition*, WPR/RC63/10 (June 29, 2012), at p. 4, available at: http://www.wpro.who.int/about/regional_committee/63/documents/RC63_10_Item_15_Nutrition_FINAL.pdf.

353 The Innocenti Declaration was "[a]dopted by participants at a WHO/UNICEF meeting at the Spedale degli Innocenti, Florence, Italy, from 30 July to 1 August 1990." *See* WHA 43.33, World Summit for Children: Follow-up Action (May 15, 1991) at fn. 2, available at: http://www.who.int/nutrition/topics/WHA44.33_nut_en.pdf.

354 World Health Organization Regional Office for Europe, *Comparative Analysis of Implementation of the Innocenti Declaration in WHO European Member States: Monitoring Innocenti Targets on the Protection, Promotion and Support of Breastfeeding*, supra, at p. 6, citing World Health Organization, *Joint WHO/UNICEF Statement - Protecting, Promoting and Supporting Breastfeeding: the Special Role of Maternity Services* (1989) at p. iv, available at: http://whqlibdoc.who.int/publications/9241561300.pdf.

established means for its enforcement."[355] Furthermore, consistent with the 1991 WHO/UNICEF *Baby-friendly Hospital Initiative (BFHI)*, the GHK-SAR should be "ensur[ing] that all maternities, whether free standing or in a hospital, become centers of breastfeeding support", which "include pledging to ensure that women and newborns can remain together all the time and that women must be free to begin breastfeeding promptly after birth and to continue exclusive breastfeeding on demand during their hospital stay." [356]

Moreover, there are "other" factors that may dissuade mothers from continuing exclusive breastfeeding for longer than the WHO-recommended 6-month period. The WHO Code and the Draft HK Code both acknowledge that there may be special medical reasons why exclusive or partial breastfeeding would not be appropriate and formula milk and follow-up formula required instead. For example, the WHO has noted that breastmilk or any other milk should not be fed to infants with classic galactosemia, maple syrup urine disease, or phenylketonuria,[357] and breastfeeding should be avoided if the mother is HIV-infected and replacement feeding is acceptable, feasible, affordable, sustainable and safe.[358] The WHO also recommends that breastmilk substitutes be used to supplement breastfeeding where infants are born with a very low birth weight (less than 1500 g), at a very early term (less than 32 weeks of gestational age), or are "at risk of hypoglycaemia by virtue of impaired metabolic adaptation or increased glucose demand...if their blood sugar fails to respond to optimal breastfeeding or breast-milk feeding."[359] The WHO has also pointed out that the medical conditions of the mother could justify temporary avoidance of breastfeeding,[360] or engender health or safety risks to the infant were breastfeeding is continued.[361]

In light of this evidence, the degree to which the prohibitions, restrictions and prescriptions imposed by Draft HK Code Articles 2, 3, 4, 5 and 8, will be capable of protecting exclusive breastfeeding for the first 6 months and partial breastfeeding for older infants and young children

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355 *Id*., at p. 6. The Innocenti Declaration was updated in 2005 to incorporate an additional five operational targets. For example, Member States should: 1) "[e]nsure that the health and other relevant sectors protect, promote and support exclusive breastfeeding for six months and continued [partial] breastfeeding up to two years of age or beyond, while providing women access to the support they require…to achieve this goal" (emphasis added); 2) "[p]romote timely, adequate, safe and appropriate complementary feeding with continued breastfeeding"; 3) "[p]rovide guidance on feeding infants and young children in exceptionally difficult circumstances"; and 4) consider enacting legislation that "give[s] effect to the principles and aim of the International Code of Marketing of Breast-milk Substitutes and to subsequent relevant Health Assembly resolutions". *See* WHO/UNICEF, *INNOCENTI DECLARATION 2005 On Infant and Young Child Feeding*, available at: http://innocenti15.net/declaration.pdf.pdf; http://www.unicef.org/nutrition/files/innocenti2005m_FINAL_ARTWORK_3_MAR.pdf.

356 World Health Organization Regional Office for Europe, *Comparative Analysis of Implementation of the Innocenti Declaration in WHO European Member States: Monitoring Innocenti Targets on the Protection, Promotion and Support of Breastfeeding*, supra at p. 9.

357 World Health Organization and Unicef, *Acceptable Medical Reasons for Use of Breast-milk Substitutes* (2009), at p. 7, available at: http://whqlibdoc.who.int/hq/2009/WHO_FCH_CAH_09.01_eng.pdf.

358 *Id*., p. 8.

359 *Id*. These include newborns "who are preterm, small for gestational age or who have experienced significant intrapartum hypoxic/ischaemic stress, those who are ill and those whose mothers are diabetic." *Id*.

360 These include a "[s]evere illness that prevents a mother from caring for her infant" (e.g., sepsis), Herpes simplex virus type 1, and maternal medications" (e.g., "sedating psychotherapeutic drugs, anti-epileptic drugs and opioids"; "radioactive iodine-131"; "excessive use of topical iodine or iodophors (e.g., povidone-iodine), especially on open wounds or mucous membranes"; "cytotoxic chemotherapy." *Id*., at p. 8.

361 These include a maternal breast abscess, Hepatitis B or C, mastitis, tuberculosis, or substance use (nicotine, alcohol, ecstasy, amphetamines, cocaine and related stimulants). *Id*., at p. 9.

for up to 36 months, and of preventing deceptive breastmilk substitute and supplement marketing in Hong Kong remains highly uncertain.

d. Draft HK Code Articles 2, 3, 4, 5 and 8 Are Arguably More Trade-Restrictive than Necessary to Fulfill the Code's Legitimate Objectives

Assuming arguendo that the Draft HK Code provisions discussed above are capable of contributing, at least somewhat, to the achievement of the two legitimate policy objectives discerned – protecting breastfeeding and preventing deceptive breastmilk substitute *and* supplement marketing activities, they nevertheless violate TBT Article 2.2 because they are more trade restrictive than necessary to achieve those objectives.

i. Comparing the Draft HK Code to the WHO Code and the WHO Feeding Strategy Endorsed via WHO Resolution 55/25

Although the Draft HK Code is allegedly "based on" the WHO Code and on the WHO *Global Strategy for Infant and Young Child Feeding*[362] ("WHO Feeding Strategy") endorsed via WHA Resolution 55/25,[363] it departs from these instruments in three important ways. First, the Draft HK Code's product scope (coverage), and thus, its marketing ban, is broader and deeper than that recommended by these initiatives. Second, the Draft HK Code imposes more prohibitions and restrictions on manufacturer, distributor or third party-marketers' publicly disseminated informational/educational materials than does either the WHO Code or WHA 55/25. Third, the Draft HK Code imposes more prohibitions and restrictions on the use of economically valuable company intellectual property rights - brand names, logos and trademarks than does the WHO Code or WHA 55/25. Such excesses strongly suggest that the Draft HK Code is more trade restrictive than necessary to achieve its legitimate objectives.

A. The Draft HK Code's Broader Than WHO Code/Feeding Strategy Product Scope and Coverage

The WHO Code covers "breast-milk substitutes, including infant formula" and "other milk products, foods and beverages, including *bottlefed* complementary foods, *when marketed*…for use as a partial or total *replacement* of breast milk" (emphasis added).[364] Infant formula is defined as a partial or total "breastmilk substitute" for "infants up to between four and six months of age".[365] A complementary food is defined as a food that is "suitable as a *complement* to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant", which is also called a "breastmilk *supplement*" (emphasis added). Complementary foods arguably include follow-up formula products unless they are marketed, represented or intended for use as a breastmilk substitute. Codex STAN 156-1987, which defines "follow-up formula" as "a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for

362 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), supra.
363 *See* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition*, Resolution WHA55.25 (May 18, 2002), at par. 1, available at: http://www.who.int/nutrition/topics/WHA55.25_iycn_en.pdf.
364 WHO Code, Art. 2.
365 WHO Code, Art. 3, pp. 8- 9.

young children,"[366] reinforces the notion that follow-up formula is generally considered a breastmilk *supplement*. It specifies that "such products…are not breast-milk substitutes and shall not be presented as such."[367] The WHO has confirmed that the WHO Code does *not* cover "follow-up formula [that] is not marketed or otherwise represented to be suitable as a breast-milk substitute."[368] WHO Code Annex 3 indicates that any product marketed to replace breastmilk *during the first 4-6 months of life* will be treated as a breastmilk *substitute* falling within the scope of the Code, and that any liquid or solid food product intended for infants and given *after this initial 4-6 month period* will *not* be treated as a *breastmilk replacement/substitute* falling within the scope of the Code, but rather as a breastmilk *supplement*.[369]

Consistent with the WHO Code,[370] the WHO Feeding Strategy recommends that: 1) "infants should be exclusively breastfed for the first six months of life"; and 2) "*[t]hereafter*, to meet their evolving nutritional requirements, *infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues* for up to two years of age or beyond" (emphasis added).[371] Several other WHO documents focused on complementary feeding clarify that "appropriate complementary feedings should start *from the age of six months* with continued [partial] breast feeding up to two years or beyond" (emphasis added).[372]

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366 Codex Alimentarius Commission, *Codex Standard for Follow-up Formula* ("CODEX STAN 156-1987"), available at: http://www.codexalimentarius.org/download/standards/293/CXS_156e.pdf

367 *Id*., at Sec. 9.6.

368 *See* World Health Organization, Nutrition for Health and Development, *Follow-up Formula in the Context of the International Code of Marketing of Breastmilk Substitutes* (June 2001), available at: http://www.who.int/nutrition/follow-up_formula_eng.pdf citing as support WHA95/1992/REC/1, Annex 9, paragraphs 45–51.

369 "During the first four to six months of life, breast milk alone is usually adequate to sustain the normal infant's nutritional requirements. Breast milk may be replaced (substituted for) during this period by bona fide breast-milk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semisolid food intended for infants and given after this initial period, can no longer be considered as a replacement for breast milk (or as its bona fide substitute). Such foods only complement breast milk or breast-milk substitutes, and are thus referred to in the draft code as complementary foods. They are also commonly called weaning foods or breast-milk supplements. Products other than bona fide breast-milk substitutes, including infant formula, are covered by the code only when they are 'marketed or otherwise represented to be suitable…for use as a partial or total replacement of breastmilk'. Thus the code's references to products used as partial or total replacements for breast milk are not intended to apply to complementary foods unless these foods are actually marketed - as breast-milk substitutes, including infant formula, are marketed - as being suitable for the partial or total replacement of breast milk. So long as the manufacturers and distributors of the products do not promote them as being suitable for use as partial or total replacements for breast milk, the code's provisions concerning limitations on advertising and other promotional activities do not apply to these products" (italicized emphasis in original) WHO Code, Annex 3, *Excerpts from the Introductory Statement by the Representative of the Executive Board to the Thirty-fourth World Health Assembly on the Subject of the Draft International Code of Marketing of Breast-milk Substitutes*, at p. 23.

370 "The Member States of the World Health Organization…Convinced that it is important for infants to receive appropriate complementary foods, usually when they reach four to six months of age…" WHO Code, at Introduction, p. 6.

371 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), supra at par. 10. *See also* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition - Global Strategy on Infant and Young Child Feeding*, Report by the Secretariat, A55/15 (April 16, 2002), Annex – Draft Global Strategy for Infant and Young Child Feeding, at par. 10, available at: http://apps.who.int/gb/archive/pdf_files/WHA55/ea5515.pdf.

372 *See* World Health Organization, *Report of the Expert Consultation on the Optimal Duration of Exclusive Breastfeeding*, March 28-31, 2001 (2002) at Sec. 3, p. 2, available at: http://whqlibdoc.who.int/hq/2001/WHO_NHD_01.09.pdf; World Health Organization, *Complementary Feeding, Report of the Global Consultation* (2002), supra at p. 1; World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003), supra at pp. 11 and 18; World Health Organization, *Guiding Principles for Feeding Non-Breastfed Children 6-24 Months of Age* (2005), supra at pp. 7 and 9.

In light of the WHO Feeding Strategy and other related WHO documents, the WHO Code is best understood as applying to infant formula, follow-up formula and complementary food products marketed, represented or intended to *replace/substitute* breastfeeding as an exclusive food source during the first 6 months of life. In addition, the WHO Code is best understood as applying to follow-up formula and other liquid and solid food (e.g., complementary food) products marketed, represented or intended to *displace/substitute* breastfeeding as a partial food source after the first six months of life, and potentially up to two years of age or beyond, depending on the needs of the child and preference of the mother. Thus, the WHO Code is best understood as *not* covering liquid and solid infant and young children's food products, including follow-up formula and complementary foods, that are marketed, represented or intended to *supplement* partial breastfeeding for infants older than 6 months of age. Since the upcoming Codex review of Codex STAN 156-1987 is unlikely to change this,[373] activists have seized upon World Breastfeeding Week 2013 to pursue a controversial agenda.

Recent activist efforts to whimsically reinterpret the WHO Code based on dated scientific grounds, beliefs, and subjective unsubstantiated anecdotal observations[374] are morally irresponsible and unnecessarily provocative, and are likely to lead to an international trade war. They seek to

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373 Activists have long endeavored to exploit the "divergence in approaches between member countries as to whether follow-up formula is defined as a breast-milk substitute". *See* Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirty sixth Session (July 1-5, 2013), *Report of the Thirty-Fourth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, REP13/NFSDU, at Appendix VIII – *Proposal to Review the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)* Project Document, at Sec. 3, p. 62, available at: https://www.ccnfsdu.de/fileadmin/user_upload/Download/2012/REP13_NFSDUe.pdf. The Codex Committee on Nutrition and Foods for Special Dietary Uses ("CCNFSDU") is well aware of how the resulting "diversification of national regulation for follow-up formula products across member countries may present significant issues for the international trade of these products." *Id*. at Sec. 4.1, p. 63. It has very recently responded, at the 36th Session of the Codex, by initiating a process to review CODEX STAN 156-1987, led by the Government of New Zealand. *See* Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirty sixth Session (July 1-5, 2013), *Report of the Thirty-Fourth Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, REP13/NFSDU, *supra* at pars. 136-138; 147-148. Such review is intended to foster greater harmonization of international standards in follow-up/follow-on formula products intended "for older infants and young children aged 6-36 months", "tak[ing] into account technological developments." *Id*., at par. 137.

374 *See* World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), available at: http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf. "In 1986, the World Health Assembly stated that "the practice being introduced in some countries of providing infants with specially formulated milks (so-called 'follow-up milks') is not necessary". *Id.*, at p. 1*, citing* World Health Assembly Resolution 39.28 (May 16, 1986), available at: http://www.ibfan.org/issue-international_code-full-3928.html. "The Organization further maintains that as well as being unnecessary, follow-up formula is unsuitable when used as a breast-milk replacement *from six months of age onwards*. *Current formulations lead to higher protein intake and lower intake of essential fatty acids, iron, zinc and B vitamins than those recommended by WHO* for adequate growth and development of infants and young children" (emphasis added). *Id*., at p. 1. As support for this proposition, this WHO document cites dated studies that are inconsistent with more recent scientific evidence which has been discussed in Part 2 of this article. Furthermore, this July 2013 WHO document which is merely hortatory and has NO LEGAL SIGNIFICANCE, states that "[a] number of studies strongly *suggest a direct correlation* between marketing strategies for follow-up formulae, and perception and subsequent use of these products as breast-milk substitutes. In many instances, the packaging, branding and labelling of follow-up formula closely resembles that of infant formula. This leads to confusion as to the purpose of the product, i.e. a perception that follow-up formula is a breast-milk substitute. *This may result* in its early introduction, *thereby undermining* exclusive breastfeeding up to six months of age and *sustained breastfeeding up to two years or beyond*" (emphasis added). *Id.*, at p. 2. However, the support cited for this proposition is also contradictory and highly questionable. *See, e.g.*, Scientific Advisory Committee on Nutrition, United Kingdom*, Infant Feeding Survey 2005: A commentary on Infant Feeding Practices in the UK*, Position Statement by the Scientific Advisory Committee on Nutrition (2008), at pars. 101-102, available at: http://www.sacn.gov.uk/pdfs/sacn_ifs_paper_2008.pdf.

preclude all marketing of follow-up formulas by *presuming* them to be breastmilk substitutes.[375] The WHO Code cannot be triggered simply because an infant or young child's mother following WHO recommendations for exclusive breastfeeding subsequently decides to exercise her freedom of choice to cease exclusive breastfeeding *after 6 months*. Similarly, the WHO Code cannot be triggered simply because an infant or young child's mother following WHO recommendations for partial breastfeeding subsequently decides to cease partial breastfeeding *after 12 months*, which she has the freedom of choice to do. **WHO** Code **implementation should be based primarily** objective facts and circumstances and not on activist dictates or national government predilections. Whether or not the WHO Code (or national implementing legislation/regulation) will apply to follow-up formula in a particular situation should depend on how a specific follow-up formula product(s) is marketed, represented or intended for use, , as reflected by objective evidence. Such a determination should not be based on how follow-up formula product marketing is subjectively perceived, and it certainly should not be based on an administratively created presumption. In other words, substantial objective evidence of violation must first be presented before the WHO Code's application can be triggered.

Contrary to activist assertions, national governments cannot rely on such a WHO Code reinterpretation to create a legal presumption of violation[376] that contravenes due process of law. Due process of law requires that governments and civil society first present objective evidence able to demonstrate that the decision to cease exclusive breastfeeding in a particular case was caused by (was the proximate result of) specific infant formula products being marketed, represented or intended for use by infants or young children younger than 6 months of age. Likewise, due process of law requires that governments and civil society first present objective evidence able to demonstrate that the decision to cease partial breastfeeding in a particular case was caused by (was the proximate result of) specific follow-up formula or complementary food products being marketed, represented or intended for use by infants and young children younger than 6-12 months of age.

The WHO is skating on perilously thin ice by embracing activist demands to encourage national governments to "take the position" (presume) that follow-up formula is a "*de facto* breast-milk substitute".[377] The evidence thus far proffered amounts to nothing more than unsubstantiated activist/advocate conjecture and propaganda that company follow-up product packaging, branding

375 "[W]hile follow-up formula may not be explicitly promoted as a breast-milk substitute, documented marketing strategies, such as packaging, branding and labelling may induce mothers to use follow-up formula in the first six months of life and/or to stop breastfeeding after this period." *See* World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), supra at p. 3. *See also* World Health Organization, Nutrition for Health and Development, *Follow-up Formula in the Context of the International Code of Marketing of Breastmilk Substitutes* (June 2001) *supra* at p. 1.

376 "As WHO has already observed, *on the assumption that follow-up formula is not marketed or otherwise represented to be suitable as a breast-milk substitute*, strictly speaking it does not fall within the scope of the International Code. However, WHO has also made clear that, taking into account the intent and spirit of the Code, there would appear to be grounds for the competent authorities in countries to conclude otherwise in the light of the way follow-up formula is perceived and used in individual circumstances" (emphasis added). *Id*., at p. 1.

377 "In addition – and notwithstanding the statement in the Codex standard for follow-up formula that this product is not a breast-milk substitute – *the competent national authorities may wish to take the position that follow-up formula should be considered a de facto breast-milk substitute*. WHO recommends that infants be breastfed exclusively for the first 6 months of life and that, once complementary feeding has begun, breastfeeding should continue up to the age of two years or beyond. Seen in this context, it could be argued that breast milk is the most appropriate liquid part of a progressively diversified diet once complementary feeding has begun" (emphasis added) *Id*.

and labeling strategies generally aim to create such a perception by promoting consumer confusion to secure greater product sales.[378] The WHO must recognize that its adoption of this policy will incite WTO challenges of national, regional or local legislation, regulations and codes that employ such a presumption. Consequently, if the GHK-SAR adopts the Draft HK Code in its current form, which incorporates a *de facto* presumption of violation within Draft HK Code Articles 2 and 3, it should prepare for WTO litigation.

The Draft HK Code Articles 2 and 3, cover formula milk which includes follow-up formula *and* food products for infants and young children, which includes complementary foods, marketed, represented or intended *for infants and young children up to the age of 36 months*.[379] As previously discussed, formula milk is defined to include infant formula and follow-up formula.[380] Infant formula is suitable for infants - "person[s] not more than 12 months of age, while follow-up formula is suitable "for infants from the 6th month on and for young children".[381] Young children are "person[s] from the age of more than 12 months up to the age of three years (36 months)."[382] Food for infants and young children includes non-formula food "intended primarily for use during the normal infant's weaning period and for the progressive adaptation of infants and young children to ordinary food…and includes complementary food"[383] The effect of these Draft HK Code provisions is to expand the WHO Code's product scope and coverage from only infant formula products suitable for newborn infants up to 6 months of age, to follow-up formula and infant and complementary foods intended for older infants of more than 6 months of age to young children up to 36 months of age. In other words, the Draft HK Code effectively extends the duration of the ban the WHO Code imposes on the marketing of breastmilk substitutes from the end of the 6th month of exclusive breastfeeding to the end of the 36th month of a child's life – i.e., for an additional 30-months. In doing so, the Draft HK Code also contravenes the WHO Feeding Strategy and other WHO documents.

B. The Draft HK Code's Broader Than WHO Code Prohibitions and Restrictions on Informational/Educational Materials

The WHO Code Article 4.3 directs manufacturer and distributor donations of informational/educational materials on *infant feeding* intended to reach pregnant women and mothers of infants and young children through the healthcare system, and subjects them to governmental request and approval, or compliance with governmental guidelines.[384] WHO Code Article 4.2 precludes such materials from containing pictures or text that may idealize the use of

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378 *See* World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), *supra* at p. 2.

379 Draft HK Code, Arts. 2.1(b); 2.2. "The Taskforce therefore developed and promulgated the Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children ("the HK Code") to provide guidelines on marketing and quality of formula milk, feeding bottles, teats and pacifiers, and food products *for infants and young children aged 36 months or below* to manufacturers and distributors, health workers and health facilities" (emphasis added). *Id*., at Introduction, pp. 3-4.

380 Draft HK Code, Art. 3, p. 9.

381 Draft HK Code, Art. 3, pp. 11-12.

382 Draft HK Code, Art. 3, p. 15.

383 Draft HK Code, Art. 3, pp. 9-10.

384 WHO Code, Art. 4.3.

breast-milk substitutes, and otherwise prescribes that such materials include certain language.[385] WHO Code Article 3 also excludes from the definition of "healthcare system" "pharmacies or other established sales outlets."[386] These WHO Code restrictions apply only to information about infant and young children's food products intended or marketed as breastmilk *substitutes*, and not to information about infant and young children's food products intended or marketed exclusively as breastmilk *supplements*.

Draft HK Code Article 4.2.1, unlike the WHO Code, restricts manufacturer and distributor-produced informational materials on specific brands of infant formula *and follow-up formula* (and formula milk-related) products disseminated on company websites, in retail premises and at healthcare facilities to technical and textual information and health and nutrition claims approved for use on a product label, and prescribes certain additional terminology to be used.[387] It precludes all images other than small pack shots.[388] Draft HK Code Article 3 defines "healthcare facilities" more broadly than the WHO Code for such purposes.[389] Draft HK Code 4.3.1, unlike the WHO Code, prohibits manufacturer or distributor public dissemination of informational/educational materials on breastfeeding and infant formula and *follow-up formula* feeding,[390] and restricts manufacturer and distributor dissemination of informational/educational materials on infant and *young child* (*complementary food*-related) feeding.[391] Draft HK Code Article 4.4.1 subjects third party public dissemination via various media of informational/educational materials concerning infant and *young child feeding* to numerous conditions that are more extensive than those imposed by the WHO Code.[392]

By restricting or precluding information about follow-up formula and complementary food products intended or marketed as breastmilk *supplements* for use by infants *6 months or older*, such provisions clearly exceed WHO Code standards and conflict with WHO recommendations for complementary feeding. What's worse, these Draft HK Code provisions go well beyond the support offered by the dated research contained within the WHO's most recent July 2013 breastfeeding report.[393] That report cites only one dated (2000) study indicating that women with uncertain breastfeeding goals were more likely to cease breastfeeding during the first two weeks following childbirth if exposed to formula promotion materials. However, the study also demonstrated that exposure to such materials did *not* affect the initiation of breast-feeding or its continuation/duration once such 2-week period had elapsed.[394] This new WHO report also cites a

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385 WHO Code, Art. 4.2.
386 WHO Code, Art. 3.
387 Draft HK Code Art. 4.2.1(a)-(d).
388 Draft HK Code, Art. 4.2.1.
389 Draft HK Code Article 3 defines the term "healthcare facilities" as "any institution or organisation or practice engaged directly or indirectly in the provision of health care or in health care education, including day-care centre, nursery, or other infant care facility."
390 Draft HK Code Art. 4.3.1.
391 Draft HK Code Art. 4.3.1(a)-(b).
392 Draft HK Code Art. 4.4.1.
393 *See* World Health Organization, *Country Implementation of the International Code of Marketing of Breast-milk Substitutes: Status report 2011* (2013), available at: http://apps.who.int/iris/bitstream/10665/85621/1/9789241505987_eng.pdf.
394 *See* Cynthia Howard, Fred Howard, Ruth Lawrence, Elena Andresen, Elisabeth DeBlieck, and Michael Weitzman, *Office Prenatal Formula Advertising and Its Effect on Breastfeeding Patterns* , 95(2) Obstetrics & Gynecology (2000) at 296-303, available at: http://journals.lww.com/greenjournal/Fulltext/2000/02000/Office_Prenatal_Formula_Advertising_and_Its_Effect.24.aspx#.

2005 pamphlet prepared by the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention ("CDC")[395] which references a second dated (2000) study which has since been withdrawn from publication.[396] It suggested that the distribution of hospital discharge packs consisting of free formula samples and information had a negative effect on the duration and exclusivity of breastfeeding.[397]

The apparent excess of these Draft HK Code provisions reflects that they are more trade restrictive than necessary to achieve the Code's legitimate objectives.

C. The Draft HK Code's Broader Than WHO Code Prohibitions/Restrictions on Use of Proprietary Intellectual Property[398]

The WHO Code prohibits any reference to a "proprietary product" falling within the WHO Code's scope and coverage, in manufacturer or distributor-donated informational/educational materials on *infant feeding* that are intended to reach pregnant women and mothers of infants and young children, which could potentially entail economically significant product names, logos or marks.[399] This prohibition applies to breast-milk *substitutes*, including infant formula, and other *milk* products, foods and beverages, including *bottlefed* complementary foods.[400] This WHO Code prohibition does not apply to follow-up formula or solid and liquid complementary foods intended or marketed exclusively as breastmilk *supplements*. The WHO Code does not impose any restriction or prohibition on the use of proprietary IP in connection with covered product labeling, unless such IP contains pictures or text which may idealize the use of infant formula.[401]

The Draft HK Code, however, applies to breastmilk supplements *as well as* to breastmilk substitutes. For example, Draft HK Code Article 4.2.1(b) precludes product-related information on specific brands of infant formula, follow-up formula and formula milk-related products from containing

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395 See Katherine R. Shealy, Ruowei Li, Sandra Benton-Davis and Laurence M. Grummer-Strawn, *The CDC Guide to Breastfeeding Interventions*, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (2005) at p. 36, available at: http://www.cdc.gov/breastfeeding/pdf/breastfeeding_interventions.pdf.

396 *See* Angela A Donnelly, Helen HM Snowden, Mary J Renfrew, and Mike Woolridge, *Commercial Hospital Discharge Packs for Breastfeeding Women*, John Wiley & Sons, Ltd., (Publ. online on July 25, 2005; Assessed as up-to-date: 20 FEB 2000), available at: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD002075.pub2/abstract. "The 'Commercial hospital discharge packs for breastfeeding women' was withdrawn from Issue 2, 2005 of The Cochrane Library because it is out-of-date, and this review team cannot update it." *Id.*

397 *Id.* A subsequent 2006 report prepared by the U.S. General Accounting Office was also unable to draw a definitive connection between post-hospital discharge breastfeeding rates and formula milk company marketing efforts *unrelated to* the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") administered by the United States Department of Agriculture. *See* United States Government Accountability Office (GAO), *Breastfeeding: Some Strategies Used to Market Infant Formula May Discourage Breastfeeding; State Contracts Should Better Protect Against Misuse of WIC Name*, Report to Congressional Addresses. GAO-06–282, (Feb. 2006), at p. 33, available at: http://www.gao.gov/new.items/d06282.pdf. Apparently, the GAO "[could] not assess the impact of other types of [non-WIC program] formula marketing on breastfeeding rates because [it] found no rigorous studies of mass media advertisements, direct mail coupons, marketing through health care providers, or other advertising activities." *Id*.

398 Part 3 of this article will address how the Draft HK Code's prohibitions and restrictions on the use of trademarks (word marks and non-word marks) constitute "special requirements" under TRIPS Article 20 that are more trademark-encumbering and trade-restrictive than necessary to achieve the Code's public policy objectives.

399 WHO Code, Arts. 4.3; 6.8.

400 WHO Code Art. 2.

401 WHO Code Art. 9.2.

specific symbols including "photographs, pictures or any graphic representation other than for illustrating methods of preparation, except for a pack shot of a size not more than one-tenth of the total space occupied by the information".[402] Draft HK Code Article 4.3.1(a) prohibits the use of economically valuable company brand names, logos or trademarks on informational/educational materials produced or disseminated by manufacturers or distributors to the public which discuss matters related to infants *and young children*, even when the subject matter does not concern breastfeeding or formula milk feeding.[403] Draft HK Code Article 4.4.1(d) prohibits the use of such economically valuable IP in third party-produced and/or disseminated informational/educational materials discussing infant formula and *follow-up formula* milk feeding, if such materials are intended to reach the general public, pregnant women and/or mothers of children aged 36 months or below.[404] Unlike the WHO Code, these provisions apply to restrict or preclude information about follow-up formula and complementary food products intended or marketed as breastmilk *supplements* for use by infants 6 months or older, consistent with WHO complementary feeding recommendations.

Draft HK Code Article 5-imposed marketing bans substantially eliminate the ability of foreign manufacturers of infant and young children's food products, especially formula milk products, to actively use proprietary IP tied to their company brand and to the company's follow-up formula and complementary food products into the Hong Kong market,[405] even if such products are intended and marketed exclusively as breastmilk *supplements* for use by infants 6 months or older, consistent with WHO complementary feeding recommendations. In effect, the Article 5 marketing ban substantially impairs the ability of local distributors of such products to exploit in the Hong Kong market the economically valuable brand names and reputations (goodwill) of foreign follow-up formula and complementary food product manufacturers to which they are legally entitled pursuant to the terms of economically valuable (exclusive or nonexclusive) and legally valid Hong Kong distributorship or licensing agreements into which they may have entered.

Draft HK Code Article 8.2.1(a) prohibits the use of a company logo or product trademark on infant formula and *follow-up formula* product labels and containers *more than once*,[406] even if such follow-up formula products are intended or marketed exclusively as breastmilk *supplements* for use by infants 6 months or older, consistent with WHO complementary feeding recommendations.

These excessive IP use-impairing provisions strongly suggest that the Draft HK Code is more trade restrictive than necessary to achieve its legitimate objectives.

ii. Comparing the Draft HK Code to Available Less Trade-Restrictive Alternatives

A comparison of the Draft HK Code with WHO Code-implementing measures enacted/adopted by other developed countries in the Asia region having not-too dissimilar demographics and hygienic

402 Draft HK Code Art. 4.2.1(b).
403 Draft HK Code Art. 4.3.1(a).
404 Draft HK Code Art. 4.4.1(d).
405 Draft HK Code Arts. 5.1-5.2.
406 Draft HK Code Art. 8.2.1(a).

living conditions,[407] furthermore, reflects that the Draft HK Code is more trade-restrictive than necessary to achieve its policy objectives. Australia and New Zealand, each of which are common law jurisdictions, are two such countries that have comparable GDP and GDP per capita to Hong Kong.[408] In addition, UNICEF data show that Australia and New Zealand are similarly characterized as 2 of 11 governments that have "adopted all or nearly all provisions of the [WHO] Code through non-binding [voluntary] measures."[409] Hong Kong is currently included in the group of 8 countries that have "adopted some, but not all provisions of the [WHO] Code through non-binding measures,"[410] but this designation should change if and when the Draft HK Code is finally adopted.[411] According to the WHO's and UNICEF's latest official tally, "only 37 nations out of 199 countries reporting (19%)"[412] "have enacted legislation or other legal measures encompassing *all or substantially all* provisions of the International [WHO] Code".[413] As a result, commentators have

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407 Given Hong Kong's much improved hygienic living conditions it is comparable to developed rather than developing countries. *See* Government of Hong Kong Special Administrative Region, *Final Report on Measures to Improve Environmental Hygiene in Hong Kong* (Aug. 2003), at Legislative Brief for Council, available at: http://www.legco.gov.hk/yr02-03/english/panels/fseh/papers/fe0815tc_rpt.pdf; at Foreword, available at: http://www.legco.gov.hk/yr02-03/english/panels/fseh/papers/tc_rpt/fore.pdf; Executive Summary, available at: http://www.legco.gov.hk/yr02-03/english/panels/fseh/papers/tc_rpt/exec.pdf. *See also* Government of Hong Kong Special Administrative Region, *LCQ12: Enhance Environmental Hygiene*, Press Release (March 20, 2013), available at: http://www.info.gov.hk/gia/general/201303/20/P201303200309.htm; Government of Hong Kong Special Administration Region, Food and Environmental Hygiene Department (FEHD), *Hong Kong: The Facts - Food and Environmental Hygiene* (Feb. 2013), available at: http://www.gov.hk/en/about/abouthk/factsheets/docs/f&e_hygiene.pdf; Government of Hong Kong Special Administrative Region, Food and Health Bureau (FHB), *LegCo Panel on Food Safety and Environmental Hygiene 2013 Policy Address - Policy Initiatives of Food and Health Bureau* (Jan. 2013), available at: http://www.fhb.gov.hk/download/panel_papers/2013/2013_Policy_Address_Policy_Initiatives_of_Food_and_Health_Bureau_(Food_Portfoilo)_Eng.pdf. Hong Kong's improved hygienic living conditions are far from developing country levels and do not pose nearly the risk of bacterial infection. *See* UNICEF Progress for Children, *Nutrition Indicators – Exclusive Breastfeeding*, available at: http://www.unicef.org/progressforchildren/2006n4/index_breastfeeding.html.

408 The CIA World Factbook ranks Hong Kong, Australia and New Zealand, respectively, 36th, 19th and 65th in terms of GDP, and respectively, 13th, 22nd, and 50th in terms of GDP per capita. *See* Central Intelligence Agency, *The World Factbook*, Country Comparison: GDP (Purchasing Power Parity), available at: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html; Central Intelligence Agency, *The World Factbook*, Country Comparison: GDP Per Capita (PPP), available at: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2004rank.html. Other developed Asia economies considered for these purposes include Singapore, South Korea, Taiwan and Japan. They rank, respectively, 41st, 13th, 20th, and 5th in terms of GDP, and respectively, 7th, 43rd, 30th, and 39th in terms of GDP per capita. *Id*.

409 *See* UNICEF, *National Implementation of the International Code of Marketing of Breastmilk Substitutes* (April 2011), available at: http://www.unicef.org/nutrition/files/State_of_the_Code_by_Country_April2011.pdf. Singapore and South Korea are also included in this grouping.

410 *Id*.

411 Upon adoption of the Draft HK Code, Hong Kong would likely be included in the grouping of governments adopting "all or nearly all provisions of the International Code through non-binding measures", but should arguably be included within the grouping of governments which "have enacted legislation or other legal measures encompassing many of the provisions of the International Code".

412 *See* World Health Organization, *Country Implementation of the International Code of Marketing of Breast-milk Substitutes: Status report 2011* (2013), supra at Executive Summary p. vii. "This report summarizes the progress countries have made in implementing the Code. It is based on data received from WHO Member States between 2008 and 2010 and on information for 2011 from UNICEF…Sixty-nine countries (35%) fully prohibit advertising of breast-milk substitutes; 62 (31%) completely prohibit free samples or low-cost supplies; 64 (32%) completely prohibit gifts of any kind from relevant manufacturers to health workers; and 83 (42%) require a message about the superiority of breastfeeding on breastmilk substitute labels. Only 45 countries (23%) report having a functioning implementation and monitoring system." *Id*.

413 *See* UNICEF, *National Implementation of the International Code of Marketing of Breastmilk Substitutes*, supra. 47 nations, including Japan, "have enacted legislation or other legal measures encompassing many of the provisions of the International Code", and 19 countries have "enacted legislation or other legal measures encompassing a *few* provisions of the International Code" (emphasis added). Although Taiwan is nowhere mentioned in these listings, the Taiwanese Government enacted in 2010 the Public Breastfeeding Act. See *Public Breastfeeding Act*, Hua-Tsung (1)-Yi-Tzu No.09900317131 (Nov. 24, 2010), available at:

acknowledged that national governments' implementation of the WHO Code is, at best, spotty, varied and inconsistent.[414]

A comparison between the Australia and New Zealand initiatives and the Draft HK Code reveals: 1) how the Draft HK Code reflects a combination of typically distinct voluntary and mandatory measures into one *de facto* mandatory instrument; 2) how the governments of Australia and New Zealand have developed more extensive efforts to promote breastfeeding through means other than imposition of product marketing bans and infringement of private intellectual property rights; and 3) how the Draft HK Code unnecessarily exceeds the letter and spirit of the WHO Code which the Australia and New Zealand Codes frameworks more closely embrace.

A. Comparing the Draft HK Code to Australia's Implementation of the WHO Code

The Government of Australia implements the WHO Code primarily through the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* ("MAIF Agreement").[415] The MAIF Agreement is a voluntary self-regulatory code of conduct between the manufacturers and importers of infant formula in Australia, intended as a response to and implementation of the WHO Code. It applies to Australian manufacturers and importers of infant formula who are signatories to said Agreement.[416] Although the MAIF Agreement's Preamble states that it "sets out the obligations of manufacturers in and importers to Australia of infant formulas", it, like the Draft HK Code, actually applies more broadly to promoters, distributors, salespersons, advertisers, public relations personnel, and information service providers that market infant formula products.[417]

The MAIF Agreement is overseen and monitored by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF), currently managed by the Healthy Living and Chronic Disease

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https://www.bhp.doh.gov.tw/BHPNet/English/file/ContentFile/201103090939463800/Public%20Breastfeeding%20Act(2010.11.24).pdf; http://www.bhp.doh.gov.tw/BHPnet/English/ClassShow.aspx?No=201103090002."In addition to protecting the right to breastfeed in public, the Act Governing Breastfeeding in Public Places also requires lactation rooms to be set up with clear directions in certain public-owned locations with wide open spaces, train stations, airports, metro transfer stations, department stores and merchandise stores. The purpose of this arrangement is to provide an alternative to mothers; it should not be interpreted as, since there are lactation rooms set up in public, mothers should only breastfeed in lactation rooms, not in public." *See* Taipei City Government Department of Health, *Bureau of Health Promotion's Reaffirmation to Protect Mothers' Right to Breastfeed in Public*, News (8/10/12), available at: http://english.doh.taipei.gov.tw/ct.asp?xItem=30247711&ctNode=15405&mp=109002.

414 "States are free to choose the type of measure a voluntary code, a law, a decree, a regulation, et cetera) through which they will implement the Code, which has led to a high variability of the types of measures adopted at the domestic level by States. This high variability is a direct consequence of the Code as an informal mechanism." *See* Ina Verzivolli, *The Domestic Effectiveness of the International Code of Marketing of Breastmilk Substitutes*, Chap. 12, at pp. 445-446, in Informal International Lawmaking: Case Studies, Future Law Series, (Torkel Opsahl Academic EPublisher The Hague2012) (A. Berman, S. Duquet, J. Pauwelyn, R. Wessel and J. Wouters (Eds.), available at: http://www.fichl.org/fileadmin/fichl/documents/LOTFS/LOTFS_3_Web.pdf.

415 *See* Australian Government Department of Health and Ageing, *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* ("MAIF Agreement") (1992), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/7DB73D6678B4EEEACA256F190003F748/$File/maif-agreement.pdf.

416 *See* Australian Government Department of Health and Ageing, Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF), *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement - The MAIF Agreement* , available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-publicat-document-brfeed-maif_agreement.htm.

417 See *MAIF Agreement*, Cl. 3.

Programs Branch of the Department of Health and Ageing."[418] The APMAIF is "a non-statutory advisory panel appointed by the Australian Government".[419] The APMAIF is charged with: 1) "receiv[ing] and investigat[ing] complaints regarding the marketing in Australia of infant formulas;" 2) "act[ing] as a liaison point for issues relating to the marketing in Australia of infant formulas;" 3) "develop[ing] guidelines on the interpretation and application of the MAIF Agreement; and" 4) "provid[ing] advice to the Australian Government Minister for Health and Ageing, on the operation of the Agreement."[420]

In addition to the MAIF Agreement, Australia employs other separate measures to implement the WHO Code. One such measure is the *Infant Feeding Guidelines for Health Workers*.[421] Another such measure is Standard 2.9.1 of the *Australia New Zealand Food Standards Code* which contains mandatory labeling and composition provisions for infant formula.[422] Standard 2.9.1, addresses food safety-related matters that are beyond the scope of this TBT Agreement inquiry, except for one provision concerning non-food safety-related matters that tracks WHO Code Article 9.2.[423] The Draft HK Code, by comparison, combines all of these measures into one.

Like the Draft HK Code and WHO Code Article 1, the MAIF Agreement's objectives are "to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding *and* by ensuring the proper use of breast milk *substitutes*, *when they are necessary*, on the basis of adequate information through appropriate marketing and distribution" (emphasis added).[424] Unlike the Draft HK Code which contributes to its objectives by

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418 *See* Australian Government Department of Health and Ageing, *Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)*, available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pubhlth-strateg-foodpolicy-apmaif.htm.

419 *Id*.

420 *Id*.

421 *See* Australian Government, National Health and Medical Research Council, *Eat for Health Infant Feeding Guidelines: Information for Health Workers* (2012), available at: http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n56_infant_feeding_guidelines.pdf. "The Infant Feeding Guidelines are aimed at health workers to assist them in providing consistent advice to the general public about breastfeeding and infant feeding. They support optimum infant nutrition by providing a review of the evidence, and clear evidence-based recommendations on infant feeding for health workers." *See* Australian Government, National Health and Medical Research Council, Infant Feeding Guidelines: Information for Health Workers (2012), available at: http://www.nhmrc.gov.au/guidelines/publications/n56.

422 *See* Australian Government ComLaw, *Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products* - F2013C00302 (2000), as amended, available at: http://www.comlaw.gov.au/Details/F2013C00302. "This Standard provides for the compositional, and labelling requirements for foods intended or represented for use as a substitute for breast milk, herein referred to as 'infant formula products'. This Standard applies to all infant formula products whether in powder, liquid concentrate or 'ready to drink' forms. This Standard also provides for infant formula products intended for infants with special nutritional requirements." *Id*., at Purpose. Interestingly, Standard 2.9.1 defines "infant formula product" to include "infant formula" and "follow-on formula". "[I]nfant formula means an infant formula product represented as a *breast milk substitute* for infants and which satisfies the nutritional requirements of infants aged up to four to six months…[F]ollow-on formula means an infant formula product represented as either a *breast-milk substitute or replacement for infant formula* and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months." *Id*., Cl. 1(2). In other words, the Standard apparently does NOT cover follow-on formula intended as a breastmilk or infant formula *supplement*.

423 *Id*., at Cl. 20(1)(a)-(d) "Prohibited representations (1) The label on a package of infant formula product must not contain – (a) a picture of an infant; or (b) a picture that idealises the use of infant formula product; or (c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or (d) words claiming that the formula is suitable for all infants."

424 *Id.*

directing mothers of infants how to proceed, the MAIF Agreement pursues its objectives while giving deference to the right and capability of mothers to "make an informed choice [concerning whether or not] to use breast milk substitutes."[425] Although the MAIF Agreement and the Draft HK Code have both food safety-related and non-food safety-related objectives, the comparison that follows will focus only on the non-food safety-related purpose(s).

The scope of the MAIF Agreement more closely resembles the WHO Code than does the Draft HK Code. Like WHO Code Article 2, it prohibits and/or restricts the marketing in Australia of only "infant formulas".[426] The MAIF Agreement defines "infant formula" as "any food described or sold *as an alternative for human milk* for the feeding of infants *up to the age of twelve months*" (emphasis added), which strongly suggests that it covers infant formulas marketed or represented as suitable for use as a partial or total *replacement* of breast milk by older infants up to 12 months of age.[427] The APMAIF recently confirmed that the MAIF Agreement covers both "infant formula that is suitable for babies from birth" and "[f]ollow-on formula i.e. formula that is suitable for babies from six months."[428] The APMAIF also confirmed that the MAIF Agreement does not apply to "[t]oddler milk drinks suitable from 12 months (sometimes called Growing Up milks), [c]omplementary foods (i.e. baby cereal and packaged baby foods) [or] [f]eeding bottles and teats."[429] The APMAIF's position therefore suggests, consistent with the WHO,[430] that the MAIF Agreement does not apply to infant formulas marketed or represented as suitable for use as a *supplement* to breast milk.[431]

The Draft HK Code, by comparison, covers formula milk (including infant formula and follow-up formula) suitable as either breast milk replacements *or* supplements.[432] Indeed, it has been the GHK-SAR's breastfeeding policy to treat as "breastmilk substitutes" all "infant formula, follow-up formula, feeding bottles, teats, baby food and beverages etc."[433] In addition, the Draft HK Code also covers food products for infants and young children (including ready-to-eat, powdered and complementary foods). In other words, the Draft HK Code covers liquid and non-liquid foods suitable as a replacement *or supplement* of breast milk for older infants and toddlers up to 36 months of age.[434]

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425 *Id*., Cl. 1, footnote 2.
426 *Id*., Cl. 2.
427 *Id*., Clauses 2 and 3.
428 *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2011-2012* (2013), at p1, available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/63979A562D3850ABCA257B180002E3BF/$File/APMAIF%20AR%202011-12.pdf.
429 *Id*., at p. 2.
430 *See* World Health Organization, Nutrition for Health and Development, *Follow-up Formula in the Context of the International Code of Marketing of Breast-milk Substitutes*, supra (noting the WHO's observation that where "follow-up formula is not marketed or otherwise represented to be suitable as a breast-milk substitute, strictly speaking it does not fall within the scope of the International Code.").
431 *Id*., Cl. 3.
432 Draft HK Code Art. 8.2.1(e)(i)-(ii).
433 *See* Government of the Hong Kong Special Administrative Region Department of Health, *Breastfeeding Policy*, available at: http://www.fhs.gov.hk/english/breastfeeding/policy_detail.html.
434 Although Draft HK Code refers to neither infant formula nor follow-up formula in terms of replacing or supplementing breast milk, it defines "follow-up formula" more broadly as being "marketed or otherwise represented as a food suitable for use as a liquid part of the weaning diet for infants from the 6th month on and for young children." *Id*., Art. 3., p. 9.

The significantly narrower product coverage of the MAIF Agreement relates directly to the narrower scope and shorter duration of the ban it imposes on the marketing and promotion of "infant formulas" (12 months), which closely follows WHO Code Articles 5.1-5.2 and 5.4-5.5.[435] Whereas the Draft HK Code appears to be stretching the scope of the WHO *Global Strategy for Infant and Young Child Feeding* to cover more infant and young children's food products for longer periods of time, the more limited product coverage of the MAIF Agreement, however, which closely tracks the WHO Code, does not appear to undermine it.[436]

In addition to placing responsibility primarily upon manufacturers and distributors of covered products to ensure that dissemination of informational/educational materials and marketing to the general public satisfies applicable respective Code requirements,[437] the MAIF Agreement, like the Draft HK Code, also places direct compliance responsibilities upon marketers of such products.[438] However, the MAIF Agreement, unlike the Draft HK Code, does not prohibit the dissemination to the public of informational/educational materials relating to infant or formula feeding, but subjects such materials to the same conditions imposed by WHO Code Article 4.2.[439] Unlike the Draft HK Code, the MAIF Agreement also does not restrict informational/educational materials about infant formula products disseminated via company website, in retail premises or at healthcare facilities to strictly textual information, and does not forbid images other than small pack shots or health and nutrition claims.[440] The MAIF Agreement Guidelines, however, recommend certain self-regulatory restraints in connection with informational/educational materials disseminations via electronic means.[441]

Consistent with WHO Code Article 4.3, the MAIF Agreement restricts donations of such materials to the healthcare system and subjects them to governmental request or approval if they are not otherwise consistent with governmental guidelines.[442] And, consistent with WHO Code Article 3, the MAIF Agreement defines the term "healthcare system" to exclude "pharmacies or other established sales outlets".[443] By contrast, the Draft HK Code defines the term "healthcare system" quite broadly, which significantly limits marketing opportunities for such products in Hong Kong.

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435 *See* MAIF Agreement, Clauses 5(a)-(d).

436 Said strategy recommends that, in addition to being "exclusively breastfed for the first six months of life to achieve optimal growth, development and health…infants should receive nutritionally adequate and safe complementary foods [intended to supplement] while [partial] breastfeeding continues for up to two years of age or beyond…to meet their evolving nutritional requirements." *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003) at Background, p. 2, available at: http://whqlibdoc.who.int/publications/2003/9241562218.pdf.

437 *See* MAIF Agreement, Clauses 4(a) and 4(c), 5(a)-(c), 6(a)-(b) and (d)-(f), 7(a)-(e); Draft HK Code, Articles 4.1.1, 4.2.1, 4.3.1, 5.1-5.3, 6.1, 7.2-7.3.

438 *See* MAIF Agreement, Cl. 5(d); Draft HK Code, Art. 4.4.1, 6.1, 7.3.1, 7.3.2.

439 *See* MAIF Agreement, Cl. 4(a) and 4(b) (indicating that such "materials should not use any pictures or text which may idealise the use of infant formulas.").

440 Draft HK Code, Art. 4.2.1.

441 *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2011-2012*, supra at pp. 33-35. "The purpose of these guidelines is to support the interpretation of the MAIF Agreement. This guidance does not replace the responsibility of the APMAIF to apply the MAIF Agreement objectively, using commonsense in light of the context of the website, on a case by case basis." *Id*., par. 1, p. 33.

442 *Id*., Cl. 4(c).

443 *Id*., Clauses 3 and 4(c).

Moreover, the MAIF Agreement, like the WHO Code, does not prohibit manufacturer or distributor-produced informational/educational materials "dealing with the feeding of infants" that are disseminated to the public or to a healthcare system from bearing a company's name or logo. The MAIF Agreement, consistent with the WHO Code Articles 4.3 and 6.8, however, does prohibit donations of such materials to the public and to healthcare facilities from containing any reference to a "proprietary product",[444] which could potentially entail an economically valuable product name, logo or mark. This notion is reinforced in the corresponding clauses of the *Infant Feeding Guidelines for Health Workers*.[445]

The MAIF Agreement, unlike the Draft HK Code, however, does not restrict the use of company logos or trademarks on infant formula product containers or labels. And, because it does not ban the marketing and promotion of more than infant formulas, including follow-on formulas, the MAIF Agreement, unlike the Draft HK Code, does not restrict manufacturers' or distributors' exploitation of economically valuable company intellectual property rights as well as intellectual property rights, including licensing rights, relating to other infant and young children's non-formula complementary food products.

The MAIF Agreement is also self-regulated, unlike the Draft HK Code which imposes extensive obligations on the GHK-SAR to monitor and oversee (with some assistance from stakeholders) industry product marketing practices, and provides for a complaint process and an enforcement mechanism replete with potentially severe criminal fines, penalties and terms of imprisonment, even for unintentional Code violations. MAIF parties are generally subject to an obligation of self-monitoring, pursuant to which "each manufacturer and importer of infant formulas…regard[s] itself as responsible for monitoring…at every level…its marketing practices according to the principles and aim of" the Agreement.[446] This results in what would appear to be a less than robust MAIF Agreement enforcement mechanism to ensure manufacturer and importer compliance. However, perceptions are deceiving.

While the APMAIF Secretariat investigates consumer complaints it receives pursuant to defined procedures,[447] the "APMAIF has no statutory or formal regulatory powers either to obtain information from industry participants or other parties or to enforce the MAIF Agreement"[448] via imposition of sanctions,[449] but must instead rely upon Agreement parties' cooperation. If the APMAIF determines that manufacturer or importer marketing practices should change, industry participants' voluntary adherence to such determination is required.[450] However, although MAIF Agreement breaches do not result in the imposition of financial or legal sanctions, they do engender

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444 *Id.*, Clauses 4(c) and 6(g).
445 *See* Australian Government, National Health and Medical Research Council, *Eat for Health Infant Feeding Guidelines: Information for Health Workers*, supra at Clauses 4(c) and 6(g).
446 *See* MAIF Agreement, Cl. 10(a).
447 *See* Australian Government Department of Health and Ageing, *Complaints Handling Process for the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF)* (April 2012), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/EBAA003A5377E490CA2574D300076D50/$File/120411%20APMAIF%20Complaints%20Handling%20Process%20(FINAL).pdf.
448 *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2011-2012*, supra at p. 2.
449 "There are no financial or legal sanctions associated with breaches of the MAIF Agreement." *Id*.
450 *Id*.

a form of "naming and shaming" that can result in "a level of public reporting which can receive global publicity and brand damage [and corporate goodwill] for the infant formula manufacturer involved."[451] APMAIF-determined breaches are brought to the attention of the Minister for Health (or Parliamentary Secretary) and published in the APMAIF's annual report, which is normally tabled in Parliament, made available upon request, and posted online.[452] Human rights organizations have shown how effective public "naming and shaming" campaigns can be, and it appears that such campaigns have already begun to be applied to alleged violations of the WHO Code in the UK.[453]

B. Comparing the Draft HK Code to New Zealand's Implementation of the WHO Code

The Government of New Zealand implements the WHO Code through three voluntary and self-regulatory Codes and a fourth legislated food standards regulation. The voluntary Codes include: 1) the *Code of Practice for Health Workers (Health Workers' Code)*;[454] 2) the *New Zealand Infant Formula Marketers' Association (Infant Nutrition Council) Code of Practice for the Marketing of Infant Formula (the NZIFMA (INC) Code of Practice)*;[455] and 3) the *Advertising Standards Authority*

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451 *Id.*

452 *Id*.

453 *See* Baby Feeding Law Group, *STOPPED: Boots, the Retailer, Advertises 'Essential' Formula to 'New Mums'* (Feb. 2, 2013), available at: http://www.babyfeedinglawgroup.org.uk/reports/retailers020213. ("On 9th January 2013 an advertisement by Boots appearing on Facebook (left), was reported…Advertising of infant formula is illegal under the Infant Formula and Follow-on Formula Regulations (2007) (see the 'Law' section). In an attempt to exploit a loophole in the law, the actual packshot shown is SMA 2, which is a follow-on milk, although it is the SMA brand, used across the range, which is prominent. The International Code of Marketing of Breastmilk Substitutes, which companies should also abide by in the UK, is clear that no breastmilk substitutes (infant formula and follow-on formula) should be advertised or promoted. The law in the UK is very clear in that there must be no risk of confusion between infant formula and follow-on formula…Baby Milk Action has contacted Boots, the Advertising Standards Authority and (via Citizens Advice) Trading Standards…The ASA indicated that information about this decision would appear on the ASA website on 27 February 2013.") *Id*. The ASA also has a chapter in New Zealand. *See* discussion *infra*. *See also* James Meernik, Rosa Aloisi, Marsha Sowell, and Angela Nichols, *The Impact of Human Rights Organizations on Naming and Shaming Campaigns*, 56 (2) Journal of Conflict Resolution, pp. 233-256 (2012), available at: http://www.polisci.wisc.edu/Uploads/Documents/IRC/Meernik%20et%20al.pdf. "*The principal weapon of choice* among many international organizations and governments to improve states' human rights *is the naming and shaming campaign*. United Nations–affiliated organizations, such as the Human Rights Council and High Commissioner for Human Rights; nongovernmental organizations (NGOs), such as Amnesty International (AI) and Human Rights Watch; and individual governments target some nations for particular attention and condemnation in the hope that through such publicity, these governments will be pressured into changing their abusive practices." Id., at pp. 233-234. "[Our analyses show that the number of human rights organizations operating in a nation is a critical determinant of its likelihood of being targeted in naming and shaming campaigns by AI [Amnesty International]…[W]e have shown in our analysis how such groups influence the behavior of larger international organizations. Further, we have provided evidence and demonstrated how one vital element of *the boomerang model* (Keck and Sikkink 1998) works in operation. Human rights organizations, working locally, act as the conduit of information that is transmitted to international organizations that then utilize this information to place pressure on the local governments to change their behavior" (emphasis added). *Id*., at p. 252.

454 *See* Government of New Zealand, Ministry of Health, *Code of Practice for Health Workers*, available at: http://www.health.govt.nz/our-work/who-code-nz/code-practice-health-workers. Among other goals, "the Health Workers' Code wants health workers to: protect, promote and support breastfeeding, giving clear, consistent and accurate information about the importance of breastfeeding and the health consequences of not breastfeeding encourage mothers and families before the birth of their infant to make an informed decision on the feeding method they will use help mothers and families to prevent and resolve the most common problems that cause mothers to stop breastfeeding." *Id*.

455 *See* Infant Nutrition Council, *The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand* (Nov. 2012), available at: http://www.infantnutritioncouncil.com/wp-content/uploads/2013/05/48511-INC-A5-booklet_FA-web.pdf. "The Infant Nutrition Council (INC) was established in 2009 and is an amalgamation of the Infant Formula Manufacturers' Association of Australia (IFMAA) and the New Zealand Infant Formula Marketers' Association (NZIFMA). The Infant Nutrition Council represents the significant majority of companies marketing and manufacturing infant formula in

Code for Advertising of Food ("ASA Code").[456] The legislated food standards regulation is Standard 2.9.1 of the *Australia New Zealand Food Standards Code (Food Standards Code) (Standard 2.9.1)* established under the Food Standards Australia New Zealand Act 1991[457] (which deals mostly with food safety-related matters).[458]

Unlike the Draft HK Code which directs mothers how to proceed, Health Workers' Code Article 2 provides that "[h]ealth workers should enable mothers to make an informed decision about infant feeding."[459] Similarly, the objective of the INC Code of Practice is to "ensure the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information",[460] which tracks the language of Clause 1 of Australia's MAIF Agreement. New Zealand's Health Workers' Code thus recognizes that "[w]hen breast milk is not available infants *must be given* an appropriate infant formula until they are one year old. Infant formula can be used *for up to 12 months of age*" (emphasis added).[461]

In effect, the Health Workers' Code covers both infant formula *and* follow-on formula because they may be used as a breast milk *substitute (replacement)* until 12 months of age. As previously noted, the Australia New Zealand Food Standards Code Standard 2.9.1 also covers both infant formula and follow-on formula, for food safety-related purposes, without regard to how they are marketed.[462] These instruments are thus broader than the INC Code of Practice which covers infant formula only, considering that "[*f*]*ollow-on formula is not marketed as a breast milk substitute in New Zealand*" (emphasis added).[463]

Apparently, in New Zealand, only infant formula has been marketed and defined as a breast milk *substitute/replacement*[464] that is suitable for infants up to 6 months of age, even though it may also

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Australia and New Zealand." *See* Infant Feeding Association of New Zealand, *The Code*, available at: http://www.ifanz.org.nz/The-code.aspx.

456 *See* Advertising Standards Authority New Zealand, *Code for Advertising of Food*, available at: http://www.asa.co.nz/code_food.php. "The purpose of the Code is to ensure that advertising of food will be conducted in a manner that is socially responsible and does not mislead or deceive the consumer…[It] applies to food advertising to persons 14 years and over." *Id*.

457 *See* Government of New Zealand, Ministry of Primary Industries, *Food Standards Australia New Zealand (FSANZ)*, available at: http://www.foodsafety.govt.nz/policy-law/food-regulation/australia-nz-cooperation/FSANZ/.

458 *See* discussion, *supra*.

459 *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra at p. 14; Government of New Zealand, Ministry of Health, *Code of Practice for Health Workers*, supra.

460 INC Code of Practice, Art. 1.

461 *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra at p. 13; Government of New Zealand, Ministry of Health, *Code of Practice for Health Workers*, supra.

462 *See* Australian Government ComLaw, *Australia New Zealand Food Standards Code - Standard 2.9.1 - Infant Formula Products* - F2013C00302, supra.

463 *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra *at* p. 14; Government of New Zealand, Ministry of Health, *Code of Practice for Health Workers*, supra.

464 "This Code applies to the marketing in New Zealand of infant formula as suitable to provide the sole source of nourishment for an infant or replace part of a breastfeed." INC Code of Practice, Art. 2. A breastmilk substitute is "[a]ny food marketed or otherwise represented as a partial or total *replacement* for breast milk, whether or not suitable for that purpose" (emphasis added). INC Code of Practice, Art. 3.

be marketed and is suitable as such for older infants up to 12 months of age.[465] Meanwhile, follow-on formula has been marketed as a breast milk or infant formula *supplement* that "is *not* suitable for infants under six months of age" (emphasis added).[466] This has resulted in the INC Code of Practice's express exclusion of follow-on formula from its coverage: "[f]ollow-on formula for infants over six months of age *is excluded* from the provisions of the INC Code of Practice" (emphasis added).[467] Consequently, the INC Code of Practice Article 5 arguably imposes a marketing ban on fewer products and for a shorter period of time than do either the Australian MAIF Agreement (which covers both infant and follow-on formulas suitable for infants up to 12 months of age), or the Draft HK Code (which covers infant and follow-on formulas and liquid ready-to-eat, powdered and complementary foods suitable for infants and young children up to 36 months of age).

The INC Code of Practice, as adopted, unlike the MAIF Agreement or the Draft HK Code, appears to more evenly divide responsibility for ensuring compliance with applicable Code prohibitions and restrictions relating to dissemination of informational/educational materials and general promotional/advertising activities, between "marketers", which include distributors,[468] and manufacturers and importers (including their marketing personnel).[469] The former appear to be held more responsible for dissemination of informational/educational materials,[470] while the latter appear to be held more responsible for general promotion/advertising activities and product labeling.[471] This, however, does not suggest that manufacturers will not be held *indirectly* responsible for marketer INC Code of Practice violations.[472]

Like the MAIF Agreement and its implementing guidelines, but unlike the Draft HK Code, the INC Code of Practice does not restrict informational/educational materials about infant formula products disseminated via company website or other electronic means,[473] in retail premises or at healthcare facilities to strictly textual information, and does not forbid images other than small pack shots or health and nutrition claims.[474] Furthermore, the INC Code of Practice appears more

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465 The INC Code of Practice defines an infant as a "person under the age of 12 months", and "infant formula" as a product represented as a breast milk substitute for…infants aged from birth up to four to six months." INC Code of Practice, Art. 3.
466 INC Code of Practice, Introduction, at p. 3.
467 INC Code of Practice, Art. 2. The INC has made a conscious effort to differentiate infant formula from follow-up formula for marketing purposes. It has adopted certain *Follow-on Formula Guidelines* that distinguish "infant formula, which is a breast milk substitute suitable for infants under six months of age", from follow-on formula. These guidelines recommend that INC "companies should position [follow-on formula] product[s] as being suitable for (1) infants already on infant formula when they reach the age of at least six months, and (2) infants of six months of age or over, who are receiving complementary foods, in preference to cows' milk. In addition these guidelines recommend that "[f]ollow-on formula is marketed in New Zealand as an alternative to cows' milk, not as an alternative to breast milk", and as "not suitable for infants under six months of age." *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra, at p. 20.
468 "Marketers" are defined, for these purposes, as any "person, corporation or any other entity engaged in the business of *distributing* and marketing infant formula to wholesale or retail level, whether directly or through an agent". INC Code of Practice, Art. 3. While distributors are included in this definition, manufacturers generally are not.
469 It is likely assumed that manufacturers will be treated as "marketers" only if they are also *engaged in the business of* distributing and marketing infant formula. Therefore, if they are merely engaged in ancillary marketing activities through "marketing personnel", they will not fall within the definition of "marketers". *Id*.
470 INC Code of Practice, Articles 4.1, 4.2, 6.1, 6.3, 7.1, 8.1.
471 *Id*., Articles 5.1-5.3, 5.6, 9.1-9.5, 10.1, 11.1
472 *Id*., Art. 11.1.
473 INC Code of Practice, Art. 5.6.
474 *Id*.

progressive than the MAIF Agreement in interpreting WHO Code Article 6.3 to permit the display of infant formula informational/educational materials in healthcare facilities, as opposed to infant formula products,[475] which the Draft HK Code Article 6.1(c) prohibits altogether.[476] And, the INC Code of Practice, unlike both the MAIF Agreement and the Draft HK Code, provides extra safeguards to ensure appropriately directed donations of infant formula specifically in emergency relief situations that comply with "national emergency preparedness plans and supporting documents."[477]

Moreover, like the MAIF Agreement and the WHO Code, but unlike the Draft HK Code, the INC Code of Practice does not prohibit manufacturer or distributor-produced informational/educational materials "dealing with the feeding of infants" that are disseminated to the public or to a healthcare system from bearing a company's name or logo. The INC Code of Practice, consistent with the WHO Code Articles 4.3 and 6.8, however, does prohibit materials donated to the public and to healthcare facilities from containing any reference to a "proprietary product",[478] which is reinforced in the Health Workers' Code,[479] even though such prohibition could potentially prevent the exercise of an economically valuable product name, logo or mark.

Moreover, the INC Code of Practice, like the MAIF Agreement, but unlike the Draft HK Code, does not restrict the use of company logos or trademarks on infant formula product containers or labels, consistent with Australia New Zealand Food Standards Code Standard 2.9.1.[480] And, because it does not ban the marketing and promotion of more than infant formulas, the INC Code of Practice, unlike both the MAIF Agreement and the Draft HK Code, does not restrict manufacturers' or distributors' use/exploitation of economically valuable company IP, including licensing rights associated with follow-on formula or other infant and young children's food products.

The New Zealand Breast-milk Substitutes Complaints Procedure, which is applicable only to the Health Workers' Code and the INC Code of Practice, is overseen by the New Zealand Ministry of Health.[481] *This procedure reflects the distinction between how infant formulas and follow-on formulas are marketed in New Zealand*. Complaints about objectionable healthcare worker practices and those that relate to the marketing of infant formula for infants from birth to six months of age are to be filed with the Ministry of Health's Population Health Directorate,[482] whereas, complaints relating to the advertising of formula for infants aged over six months are to be filed with the Advertising Standards Authority ("ASA").[483] The ASA is a private independent body established by the advertising industry "to administer the rules laid down in advertising codes."[484]

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475 *Cf*. INC Code of Practice, Article 6.3 with MAIF Agreement Clause 6(b).
476 Draft HK Code, Art. 6.1(c).
477 INC Code of Practice, Art. 6.6.
478 *Id*., Art. 6.7.
479 *See* Government of New Zealand, Ministry of Health, *Code of Practice for Health Workers*, supra at Art. 9.3.
480 INC Code of Practice, Articles 9.1 and 9.3.
481 *See* Matt Burgess and Neil Quigley, *Effectiveness, Implementation and Monitoring of the International Code of Breast-Milk Substitutes in New Zealand: A Literature and Interview-Based Review* (2011), at Executive Summary, p. vii, available at: http://www.health.govt.nz/system/files/documents/pages/code-of-breastmilk-substitutes-review-july2011.pdf.
482 *See* Government of New Zealand, Ministry of Health, *Breast-milk Substitutes Complaints Procedure*, available at: http://www.health.govt.nz/our-work/who-code-nz/breast-milk-substitutes-complaints-procedure.
483 *Id*.
484 *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of*

The ASA addresses complaints filed for alleged violations of the ASA Code through its Advertising Standards Complaints Board[485] and Advertising Standards Complaints Appeals Board.[486] Finally, complaints about the labeling, composition or quality of infant formula falling under the Food Standards Code are to be filed with the New Zealand Food Safety Authority.[487]

The New Zealand governmental monitoring and oversight of the complaints process relating to the marketing of infant formula for infants from birth to six months of age may be as extensive as the governmental oversight called for by the Draft HK Code. However, the New Zealand complaint process, unlike the Draft HK Code, does not provide for an enforcement mechanism replete with potentially severe criminal fines, penalties and terms of imprisonment, even for unintentional Code violations. Nevertheless, the New Zealand process is more "final" and "resolute" than the purely self-regulated process prescribed by the MAIF Agreement which does not contain any compulsory or binding enforcement mechanism to ensure manufacturer and importer compliance.

Once a complaint is filed with the Ministry of Health it is forwarded to the infant formula company or other party that is the subject of the complaint, which is provided 20 working days to respond. If the complainant is dissatisfied with the response, the Ministry forwards the complaint for review to the Compliance Panel which may seek additional information for purposes of rendering its decision.[488] The Compliance Panel was established by the Ministry of Health to make decisions on unresolved complaints relating to, and to provide advice on appropriate action to remedy a breach of, the Health Workers' Code or the INC Code of Practice.[489] "The CP can declare a complaint upheld or not upheld", and [i]n the event it is upheld, the CP may issue a recommendation to remedy the breach."[490]

The Compliance Panel consists of four members (consisting of a community/consumer representative, the INC Executive Director, a health practitioner, and an academic in a field related to infant and maternal nutrition), an independent Chair who works closely with the Secretariat on administration of complaints, and an Adjudicator who addresses appeals from Commission Panel decisions, *all of whom are Ministry-appointed*.[491] The Compliance Panel's diversity is designed to ensure a range of skills and expertise. Compliance Panel members are bound by conflict-of-interest

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Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand (2007), available at: http://www.health.govt.nz/publication/implementing-and-monitoring-international-code-marketing-breast-milk-substitutes-nz-code-nz.

485 *See* Advertising Standards Authority, *Advertising Standards Complaints Board*, available at: http://www.asa.co.nz/ascb.php.

486 *See* Advertising Standards Authority, *Advertising Standards Complaints Appeals Board*, available at: http://www.asa.co.nz/ascab.php.

487 *See* Government of New Zealand, Ministry of Health, *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra at 22.

488 *See* Government of New Zealand, Ministry of Health, *Breast-milk Substitutes Complaints Procedure*, supra. "If an issue is not resolved to the complainant's satisfaction through a natural justice process, it will be submitted to a Compliance Panel for a decision." *See* Government of New Zealand, Ministry of Health, *Breast-milk Substitute Questions and Answers*, at Q&A #6, available at: http://www.health.govt.nz/our-work/who-code-nz/breast-milk-substitute-questions-and-answers.

489 *See* Government of New Zealand, Ministry of Health, *Terms of Reference - Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, available at: http://www.health.govt.nz/our-work/who-code-nz/compliance-panel/terms-reference.

490 *See* Matt Burgess and Neil Quigley, *Effectiveness, Implementation and Monitoring of the International Code of Breast-Milk Substitutes in New Zealand: A Literature and Interview-Based Review*, supra at p. 7.

491 *See* Government of New Zealand, Ministry of Health, *Compliance Panel*, available at: http://www.health.govt.nz/our-work/who-code-nz/compliance-panel.

and information confidentiality obligations and the Compliance Panel is subject to performance metrics.[492]

Given the self-regulatory nature of the Codes it is overseeing, the Compliance Panel "has no power to compel sanctions on subjects."[493] The Compliance Panel does, however, have the power of public reporting (i.e., effectively "naming and shaming"), since it is required to keep minutes of all CP meetings including a clear record of any decisions or recommendations made about any complaint which the Secretariat will include in its annual report.[494] In addition, if an affected party is dissatisfied with the Compliance Panel's decision when rendered, it may file an appeal with the Ministry of Health within 20 working days. Where the parties are satisfied and an appeal has not been filed within the required 20 day period, the Compliance Secretariat will initiate any action the Compliance Panel has recommended.[495]

When an appeal is filed, all affected parties are notified, and all documentation received by the Compliance Panel is sent to the Adjudicator.[496] The Adjudicator first determines if what is alleged constitutes a legitimate ground for appeal. If it identifies a legitimate ground for appeal, the Adjudicator then proceeds to review and decide the merits of the appeal, considering only the material that the Compliance Panel had considered (i.e., no new evidence). The Adjudicator is provided 30 working days to consider the grounds for the appeal, make a decision, and provide written reasons for the decision.[497] In deciding the case, the Adjudicator can take only four actions: It may uphold the complaint, amend the Compliance Panel decision, quash the Compliance Panel decision, or refer the complaint back to the Compliance Panel for re-determination; it does not possess the authority to issue sanctions. Whatever the Adjudicator decides *it is final and unappealable*.[498]

A breach of the INC Code of Practice does not result in the imposition of financial or legal sanctions. However, the INC Code, like the MAIF Agreement, provides for a level of national, regional and global publicity and potential "naming and shaming" capable of significantly impairing the economic value of the breaching party's brand reputation and company goodwill, which can potentially be greater than any fine or penalty levied.[499]

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492 *See* Government of New Zealand, Ministry of Health, *Terms of Reference - Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra.

493 *See* Matt Burgess and Neil Quigley, *Effectiveness, Implementation and Monitoring of the International Code of Breast-Milk Substitutes in New Zealand: A Literature and Interview-Based Review*, supra at p. 7.

494 *See* Government of New Zealand, Ministry of Health, *Terms of Reference - Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra.

495 *Id.*

496 *See* Government of New Zealand, Ministry of Health, *Breast-milk Substitutes Complaints Procedure*, supra.

497 Legitimate grounds for appeal will be found to exist where the Compliance Panel: "1) did not follow a fair process based on the principles of natural justice; 2) failed to take a relevant fact into consideration or took an irrelevant fact into account, or gave a relevant fact insufficient weight; or 3) did not properly apply the relevant codes in its decision." *See* Government of New Zealand, Ministry of Health, *Terms of Reference - Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand*, supra.

498 *Id.* "The [Compliance Panel] CP secretariat has 20 working days from receipt of the Adjudicator's written decision to inform affected parties and initiate any action recommended by the Adjudicator." *Id*.

499 *See* Quigley and Watts Ltd, *Key Stakeholder Consultation to Complete the Evaluation of the Effectiveness of the WHO International Code of Marketing of Breast-Milk Substitutes in New Zealand*, Report prepared for the Ministry of Health (Sept. 2012) at pp. 12 and 21, available at: http://www.health.govt.nz/system/files/documents/pages/keystakeholde-consultation-evaluation-effectiveness-who-code-marketing-breast-milk-substitutes.pdf. (Discussing opposing stakeholder views concerning

iii. Assessing the Risks that Non-Fulfillment of Draft HK Code Legitimate Objectives by Reasonably Available Less Trade-Restrictive Alternatives Would Create

To recall, in determining "the risks that non-fulfillment would create", it is necessary to consider the likelihood and the gravity of potential risks (and any associated adverse consequences) that might arise in the event the Draft HK Code's legitimate objectives would not be fulfilled. In assessing such risks, reference can be made to "relevant…available scientific and technical information, related processing technology, or intended end-uses of products," among other tools.

The evidence reflects that the adoption of a combined New Zealand-Australia self-regulatory framework would present a reasonably available less trade-restrictive alternative capable of achieving the Draft HK Code's legitimate objectives with minimal, if any, risk of nonfulfillment. The combined framework would feature New Zealand's several codes, positive initiatives and multilevel government-monitored complaint process bearing a final adjudicatory resolution that is enforced via use of a public reporting-based naming and shaming publicity mechanism. Said framework would be extended to include the broader product scope of the Australian self-regulatory framework which covers both infant formulas and follow-up formulas marketed as breastmilk substitutes/replacements, but would exclude from coverage the marketing of follow-up formula and complementary food products as breastmilk supplements. This would ensure that the GHK-SAR could impose a marketing ban on products intended for infants and young children up to 12 months of age without creating unnecessary obstacles to trade.

No evidence has been proffered to-date to demonstrate that the failure of the Australia and New Zealand WHO-implementing frameworks to impose more stringent enforcement mechanisms on Code violations has either encouraged deceptive marketing practices or resulted in diminished rates of breastfeeding in either of these WTO jurisdictions. Indeed, the Annual Reports that Australia's Advisory Panel on the Marketing in Australia of Infant Formula publicly filed for the last five reporting periods show a diminishing number of potential Code violation complaints from year-to-year,[500] as well as a significant drop in Code breaches since the Code was first instituted.[501] The five

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whether fines and penalties should be imposed on companies violating the INC Code of Practice, and recommending further discussion of "possible penalties/sanctions for complaints that are upheld to ensure sanctions are meaningful to both complainants and the industry and are sufficient to deter re-offending.").

500 *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2011-2012* (2013), supra at p. 9 (discussing the receipt of thirteen new complaints, nine of which were assessed as falling outside the scope of the MAIF Agreement); *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2010-2011* (2011), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/8429754539FC9428CA25799D0019F576/$File/APMAIF_Annual%20ReportFINAL%20%5B20_12%5D.pdf (discussing the receipt of thirteen new complaints, eleven of which were assessed as falling outside the scope of the MAIF Agreement); *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2009-2010* (2011), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/98FCF0F10D646F6ACA257842000376C3/$File/2009-10%20APMAIF%20Annual%20Report.pdf (discussing the receipt of thirty-six new complaints, twenty-nine of which were assessed as falling outside the scope of the MAIF Agreement); *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2008-2009* (2010), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/290339127D750BC2CA257749007D035D/$File/2008-09%20Annual%20Report.pdf (discussing the receipt of forty-four new complaints, thirty-seven of which were assessed as falling outside the scope of the MAIF Agreement; of the remaining seven complaints one was found to be "in-breach"); *See* Australian

Annual Reports publicly filed by New Zealand's WHO Compliance Panel reflect the logging of even fewer complaints – under ten potential Code violation complaints per year.[502]

In this regard, it is not suspected that the request made by the New Zealand Food Safety Minister to the New Zealand Ministry for Primary Industries ("MPI") "to undertake an audit of the verification, compliance and testing regimes in place for infant formula" will engender adoption of the kind of legislation imposing criminal fines, penalties and prison terms that is currently in force in Hong Kong which the Draft HK Code would extend to substantiated Code violations. The New Zealand Minister's request, rather, had been prompted by *industry* warnings about potential food safety issues arising from inexperienced (and perhaps, unscrupulous[503]) Chinese-owned export-market-

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Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2007-2008* (2009), available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/49409F02A00490B3CA25767E007C8019/$File/2007-08%20APMAIF%20Annual%20Report.pdf (discussing the receipt of one hundred fifty-nine complaints, one hundred forty of which were assessed as falling outside the scope of the MAIF Agreement).

501 "The annual number of breaches of the MAIF Agreement has decreased over the fourteen years of the APMAIF's history, reflecting compliance with the MAIF Agreement by participating companies. In 2007–08 there were no breaches of the MAIF Agreement." *See* Australian Government Department of Health and Ageing, *Annual Report of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) 2007-2008* (2009), supra at p. 10.

502 *See* New Zealand Ministry of Health *WHO Compliance Panel, Summary for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand, (July 1, 2011 to June 30, 2012)*, available at: http://www.health.govt.nz/system/files/documents/pages/compliance-panel-summary2011-12.pdf (discussing the receipt of one formal complaint); New Zealand Ministry of Health *WHO Compliance Panel, Summary for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand, (July 1, 2010 to June 30, 2011)*, available at: http://www.health.govt.nz/system/files/documents/pages/who-code-meeting-summary-2010-11.pdf (discussing the receipt of six formal complaints); *See* New Zealand Ministry of Health *WHO Compliance Panel, Summary for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand, (July 1, 2009 to June 30, 2010)*, available at: http://www.health.govt.nz/system/files/documents/pages/compliance-panel-summary-2009-10.pdf (discussing the receipt of three complaints); *See* New Zealand Ministry of Health *WHO Compliance Panel, Summary for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand, (July 1, 2008 to June 30, 2009)*, available at: http://www.health.govt.nz/system/files/documents/pages/compliance-panel-summary-2008-09.pdf (discussing the receipt of five complaints); *See* New Zealand Ministry of Health *WHO Compliance Panel, Summary for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand, (July 1, 2007 to June 30, 2008)*, available at: http://www.health.govt.nz/system/files/documents/pages/compliance-panel-summary-2007-08.pdf (discussing the receipt of nine complaints).

503 It is more than possible that a number of such companies are Chinese-owned export-only companies operating unscrupulously below the New Zealand regulatory authorities' radar. Apparently, cost-cutting, which is firmly embedded in the Chinese business culture, has raised the fears of Chinese consumers concerning the safety of infant formula and many other Chinese-manufactured products. It is significant that Chinese entrepreneurs would relocate their infant formula manufacturing to New Zealand and continue their cost-cutting ways in order to take advantage of Chinese consumer fears and New Zealand's booming dairy product export trade with China. "Chinese parents want to ensure that the formula they are feeding their babies has never been touched by a Chinese company…The reason is obvious. In 2008, six babies died and some 300,000 became ill after their mothers fed them baby milk products that were tainted with the chemical melamine. Ever since, Chinese mothers haven't trusted domestically made baby milk products — starting with formula. In fact…*Chinese consumers don't trust a lot of Chinese-made goods*…In recent years, there have been food scandals surrounding cooking oil, eggs and meat, for starters. A few months ago, according to Time magazine, three people were caught processing pigs that had died of infectious diseases. A few years ago, contamination of Chinese-produced heparin, the blood-thinner, was linked to 81 deaths. Chinese consumers don't even favor Chinese cars…So problem No. 1:...*there is a sense among consumers that no matter what the industry, too many Chinese businesspeople are willing to scam their own customers to make a buck. With corner-cutting deeply ingrained as a Chinese business practice*, it's really up to the government to change that ethos through regulation and enforcement" (emphasis added). *See* Joe Nocera, *The Baby Formula Barometer*, New York Times Op-Ed (July 26, 2013), available at: http://www.nytimes.com/2013/07/27/opinion/nocera-the-baby-formula-barometer.html?_r=0.

only New Zealand-based companies[504] lacking basic supply chain integrity,[505] and is more likely to be directed at Standard Australia-New Zealand Food Safety Standard 2.9.1. In response, since September 2012, the New Zealand MPI and the New Zealand Customs Service have taken prompt action to mitigate potential formula product safety and marketing risks. They have not only prosecuted exporters which have failed to comply with New Zealand's agricultural (dairy) product export laws,[506] but have also developing a public registry of all New Zealand infant formula exporters.[507]

While the GHK-SAR possesses the discretion to select its own level of protection to achieve its objectives, TBT Article 2.2 requires that the GHK-SAR justify the necessity of the trade restrictiveness of Draft HK Code Articles 2, 3, 4, 5, 6, 8 and 10 for such purposes. Thus far, the GHK-SAR has failed to make the case for the intrusive *negative* governmental market intervention it has selected. As discussed above, it remains uncertain whether these Draft HK Code Articles would be capable of contributing significantly to the achievement of the measure's legitimate objectives of protecting/promoting breastfeeding and preventing deceptive marketing/advertising of breastmilk substitute products in Hong Kong, a modern and developed common law jurisdiction.

The Draft HK Code's imposes what amounts to a broad 30-month public marketing ban on infant formula, follow-up formula, and other liquid, ready-to-eat and complementary food products suitable as either breastmilk substitutes *or* supplements for infants and children from 0-36 months

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504 *See* Zhou Wenting, *Complaints Spike Over Subpar Baby Formula Imports*, People's Daily Online/China Daily (July 29, 2013), available at: http://english.peopledaily.com.cn/90778/8343660.html; http://usa.chinadaily.com.cn/business/2013-07/29/content_16848364.htm. "Industry experts said that one reason for the rise in complaints against imported brands is that *some Chinese businesspeople* have been taking advantage of consumers' blind trust in such brands. Heitiki, a milk powder brand which its distributor in Shenzhen claims is 'a top brand' in New Zealand, was discovered in 2011 to be *registered by Chinese businesspeople* and *unknown to New Zealanders*" (emphasis added) *Id*. *See also* Christopher Adams, *New China Heat on NZ Baby Formula*, New Zealand Herald (July 31, 2013), available at: http://www.nzherald.co.nz/business/news/article.cfm?c_id=3&objectid=10905697. "Kiaora New Zealand International [had been] claiming in the Chinese marketplace that the company was 'dedicated to sourcing and providing Kiwi mums with the best and healthiest infant formula available' and that its 'Heitiki' formula had 'become the new standard in New Zealand.' But as the New Zealand Food and Grocery Council point[ed] out, *the brand is export-only formula*. The Council released a perplexed statement: 'It's hard to fathom how Heitiki is the 'new standard' when scan data shows New Zealand and Australian supermarkets do not sell the product at all.' The Council called for a full investigation. Kiaora New Zealand International, which had only been producing formula since March and clearly [wasn't] aware of the WHO's global standards on infant formula marketing…" *See* Abe Sauer, *Infant Formula Marketing Scam Unravels in New Zealand*, Brandchannel (June 3, 2011), available at: http://www.brandchannel.com/home/post/2011/06/03/Intl-Infant-Formula-Marketing-Scam-Unravels-in-New-Zealand.aspx.

505 *See* Xinhua, Interview: *New Zealand, Australia Baby Formula Makers to Push Integrity at China Expo* (July 15, 2013), available at: http://news.xinhuanet.com/english/indepth/2013-07/15/c_132542294.htm; Xinhua, *Infant Formula Firms Welcome New Zealand Food Safety Review Over China Concerns* (June 27, 2013), available at: http://english.peopledaily.com.cn/90777/8302615.html.

506 *See* Xinhua, *New Zealand Moves to Stop Illegal Infant Formula Exports*, Global Times (9/28/12), available at: http://www.globaltimes.cn/content/735978.shtml. ("MPI and Customs' investigations had revealed substantial growth in the amount of unlawfully exported infant formula in the past year, primarily to China, with the unlawful trade valued at more than 150 million NZ dollars ($125.18 million) and growing.") *Id*.

507 *See* Xinhua, *NZ to Publish Registered Infant Formula Products for China: Report*, Global Times (7/22/13), available at: http://www.globaltimes.cn/content/798087.shtml#.UflXBWLCaSo. "MPI introduced the new infant formula brand register, which requires companies exporting to China to have the specific brand name included on the export certificate [this past June]…MPI said 30 exporters had registered their brands last month, and they were required to provide more detailed information by July 6, including copies of actual labels approved by Chinese regulators with translations and associated formulation information, said the report." *Id*.

of age in Hong Kong. Such a marketing ban, however, would not necessarily prevent manufacturing, distributing and/or marketing companies from seeking to generate confusion between infant formula and follow-up formula in the minds of consumers, any more than criminal fines and penalties for false or misleading advertising already do. And, such a ban would not necessarily stem a perceived decline in the breastfeeding rate in liberal democratic Hong Kong which is driven by multiple cultural, economic and social factors beyond the control of the GHK-SAR, which are not attributable to such practices. In addition, such a ban would also significantly and unnecessarily impede international trade in what has become a vibrant market for mostly foreign breastmilk substitute *and supplement* food products due to strong consumer demand triggered as the result of infant formula and children's food safety scares on the Chinese mainland. Moreover, it is also arguable that the imposition of criminal sanctions on both intentional and unintentional marketing/advertising and labeling violations rather than stepped civil fines goes far beyond what is necessary to address false and misrepresentative marketing/advertising which is essentially a question of fact dependent on the particular circumstances and context at issue.

Indeed, the GHK-SAR is aware that it must do much more, as a governmental entity, to support private breastfeeding initiatives, especially educational initiatives, which can be accomplished through *positive* governmental market interventions. At least one recent study[508] concluded, for example, that "breastfeeding promotion interventions" consisting of formal or structured breastfeeding education[509] "increased exclusive and any breastfeeding rates at 4-6 weeks and at 6 months. A relatively greater impact of these interventions was seen in developing countries with 1.89 and 6 folds increase in [exclusive breastfeeding] EBF rates at 4-6 weeks and at 6 months respectively."[510] Significantly, while this study cited the WHO Code as among "[o]ther strategies to *protect* breastfeeding", and the Baby-Friendly Hospital Initiative as a primary strategy "to *promote* EBF [exclusive breastfeeding]" (emphasis added), it highlighted that "[c]omprehensive and culturally appropriate breastfeeding education through counselors…during the prenatal period, in the hospital during first week postpartum, *and* repeated, continual support in the mother's home *may be critical* for facilitating breastfeeding among mothers, especially those belonging to the low-income groups" (emphasis added).[511] As the study noted, "*[b]oth prenatal and postnatal* education [are] important as the incidence of breastfeeding is affected primarily by prenatal education, whereas the duration and exclusivity of breastfeeding is affected by both prenatal and postpartum management" (emphasis added).[512]

Furthermore, the British Dietetic Association ("BDA"), the professional association and trade union for British dietitians, recently issued a Policy Statement written in conjunction with the BDA

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508 *See* Aamer Imdad, Mohammad Yawar Yakoob, and Zulfiqar A Bhutta, *Effect of Breastfeeding Promotion Interventions on Breastfeeding Rates, With Special Focus on Developing Countries*, BMC Public Health 2011, 11(Suppl 3):S24, available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3231898/pdf/1471-2458-11-S3-S24.pdf.

509 "Formal or structured breastfeeding education [is] defined as: 1) one-to-one or group education sessions or classes (e.g., curriculum or standard agenda) directed at mothers or other family members; 2) professional support divided into system level support (PS-SL) involving interventions at mass level like implementing policies of baby-friendly hospital initiative (BFHI) or training of health professionals; and individual level (PS-IL) where support was provided individually to mothers during hospital stay or outpatient clinics; social support (e.g., home visits or telephone support) from health professionals]; and 3) lay support (LS) in which there was social support (e.g., home visits or telephone support) from peers." *Id*., at p. 3.

510 *Id*., at p. 1.

511 *Id*., at p. 2.

512 *Id*.

Paediatric Specialist Group concerning complementary feeding.[513] This policy statement bears upon the Draft HK Code's coverage of both formula milk and infant and young children's food products. The BDA Policy Statement made several recommendations that support WHA54.2 (which declared "exclusive breastfeeding for six months as a global public health recommendation"),[514] the WHO Expert Consultation on the Optimal Duration of Exclusive Breastfeeding (which recommended exclusive breastfeeding for six months, with introduction of complementary foods and continued breastfeeding thereafter),"[515] and relevant UK Department of Health policies (which implement them). According to the BDA, exclusive breastfeeding should begin at birth and continue "until the introduction of solid foods", and partial "breastfeeding should continue throughout complementary feeding."[516] In addition, the BDA recommends that solid food should be introduced "'at around six months of age' in line with DH guidance"[517] and WHO guidance.[518] In other words, "[t]he introduction of solid food should commence no later than six months (26 weeks) of age, but not before four months (17 weeks)."[519] Furthermore, BDA recommends that dieticians should consider "[d]evelopmental signs of readiness for solid food, together with parental opinion… when advising on the ideal age to begin complementary feeding."[520] It found that "[t]here is little evidence that complementary feeding before 6 months is harmful and [that] there is some emerging evidence to support the introduction of solid food before 6 months [while] breastfeeding, which may be beneficial for some infants."[521]

The GHK-SAR would be wise to closely evaluate the scientific data underlying these two studies prior to finalizing the Draft HK Code. The Draft HK Code is an aggressive experiment in negative governmental market intervention and societal behavior modification the adverse trade consequences of which are already apparent, but the potential benefits of which (i.e., the protection of breastfeeding and prevention of deceptive practices) are highly illusory. A combined New Zealand-Australia framework which more closely hues to the WHO Code would have a track record with useful lessons learned. Consequently, should Hong Kong become enlightened and

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513 *See* British Dietetics Association, *Complementary Feeding: Introduction of Solid Food to an Infants Diet*, Policy Statement (April 2013), available at: http://www.bda.uk.com/policies/WeaningPolicyStatement.pdf.

514 *See* World Health Assembly, 54th Session, *Infant and Young Child Nutrition*, WHA54.2 (May 18, 2001) at pars. 2(4); 3(3), available at: http://apps.who.int/gb/archive/pdf_files/WHA54/ea54r2.pdf. This recommendation took into account "the findings of the WHO expert consultation on optimal duration of exclusive breastfeeding…[and] the provision of safe and appropriate complementary foods, with continued breastfeeding up to two years of age or beyond…" *Id*.

515 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003) at par. 10, p. 8, available at: http://whqlibdoc.who.int/publications/2003/9241562218.pdf, citing World Health Organization, *Global Strategy for Infant and Young Child Feeding: The Optimal Duration of Exclusive Breastfeeding*, EXPERT CONSULTATION ON THE OPTIMAL DURATION OF EXCLUSIVE BREASTFEEDING, A54/INF.DOC./4 (May 1, 2001), at par. 11, p. 3, available at: http://apps.who.int/gb/archive/pdf_files/WHA54/ea54id4.pdf ("The expert consultation recommends exclusive breastfeeding for six months, with introduction of complementary foods and continued breastfeeding thereafter."). *Id*. *See also* World Health Assembly, *Infant and Young Child Nutrition Global Strategy on Infant and Young Child Feeding, Report by the Secretariat, Annex Draft Global Strategy for Infant and Young Child Feeding* at par. 10, p. 5, A55/15 (April 16, 2002) available at: http://apps.who.int/gb/archive/pdf_files/WHA55/ea5515.pdf; WHA Resolution 57.17 - *Global Strategy on Diet, Physical Activity and Health* (May 22, 2004) at pars. 11, 28-29, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf.

516 *See* British Dietetics Association, *Complementary Feeding: Introduction of Solid Food to an Infants Diet*, Policy Statement, supra at Sec. 2, par. 1.

517 *Id*., at par. 2.

518 See discussion supra.

519 *Id*.

520 *Id*., at par. 4.

521 *Id*.

adopt a hybrid New Zealand-Australia framework, as suggested, the risks nonfulfillment would create would be minimal, if any, especially if the GHK-SAR were to simultaneously pursue prenatal and postnatal education initiatives.

III. Conclusion – The Draft HK Code's Non-Food Safety-Related Provisions Violate TBT Article 2.2

The Draft HK Code is a complex instrument that has both food safety-related and non-food safety-related purposes. To the extent that Draft HK Code Articles 2, 3, 4, 5, 8, 10 and Annex I concern non-food safety-related matters, they qualify as *de facto* technical regulations under the TBT Agreement. These provisions meet the three-part technical regulation test articulated by TBT jurisprudence because they adequately identify three broad product categories covered by the Code, describe the characteristics of such products and their treatment in sufficient detail, and are mandatory in effect despite being represented as voluntary *per se*.

Draft HK Code Articles 2, 3, 4, 5 and 8 are modeled after and aim to implement the WHO *International Code of Marketing of Breast-milk Substitutes* (the "WHO Code"). The WHO may be considered a recognized international standardizing body, within the meaning of TBT Article 2.4, because it is actively engaged in the development of non-food safety-related public health standards, and since WTO Members are likely aware or have reason to expect that the WHO is engaged in public health-related standardization activities. Although WHO governance mechanisms do not fully adhere to the WTO TBT Committee *Decision on Principles for the Development of International Standards, Guides and Recommendations*, the WHO may, nevertheless, qualify as a recognized international standardizing body if TBT Article 2.4 is not interpreted strictly. In such case, the WHO Code may be viewed as a relevant international standard because Draft HK Code Articles 2, 3, 4, 5 and 8 bear upon, relate to, or are pertinent to the matters the WHO Code addresses.

Draft HK Code's two stated non-food-safety related policy objectives will likely be considered legitimate within the meaning of TBT Article 2.2. These provisions endeavor to: 1) protect breastfeeding via provision of adequate nutrition for infants and young children; and 2) prevent aggressive marketing and advertising of formula milk products, infant and young children's food products, and formula milk-related non-food products intended for infants and young children from 0-to-36 months of age. Although neither of these objectives is explicitly included among TBT Article 2.2's nonexclusive list of presumptively valid policy objectives, they relate closely to the protection of public health and the prevention of deceptive practices which do fall within that list.

A growing number of scientific studies have questioned the benefits of long-term breastfeeding and the long-term benefits of exclusive breastfeeding for the first 6 months of an infant's life. Thus, the degree to which the broader scope and duration of Draft HK Code Articles 2 and 3, which endeavor to protect exclusive breastfeeding in Hong Kong for infants through the first 6 months of life and partial breastfeeding for infants and young children until 36 months of age, will be capable of achieving said objective is uncertain.

Furthermore, the degree to which the prohibitions and restrictions imposed by Draft HK Code Articles 4, 5 and 8 on manufacturer, distributor and/or third party-disseminated product information and other informational/educational materials, advertising, and product container and

labeling information will be capable of protecting breastfeeding and preventing deceptive marketing practices in Hong Kong is uncertain. Criminal fines and penalties are already imposed under Hong Kong Law for the false or misleading advertisement, marketing and labeling of food products. In addition, Hong Kong residents have proven highly sensitive to the GHK-SAR's recent effort to indirectly modify consumer behavior and curtail commercial and individual speech. Also, there are multiple cultural, lifestyle and other factors that have driven formula milk and complementary food product demand and affected breastfeeding rates in Hong Kong which are beyond the control of the GHK-SAR and which are not attributable to aggressive marketing practices.

Although the Draft HK Code is allegedly "based on" the WHO Code and on the *WHO Global Strategy for Infant and Young Child Feeding*, it goes well beyond these WHO initiatives. The WHO initiatives focus on protecting public health via exclusive breastfeeding only for the first 6 months of an infant's life, and on preventing deceptive marketing/advertising practices relating to infant formula, follow-up formula and complementary food products intended as breastmilk *substitutes* during such period, and potentially up to the first year of an infant's life. The Draft HK Code, by contrast, pursues these objectives with respect to any such product intended as either breastmilk substitutes *or* breastmilk *supplements* for infants and young children up to *36 months* of age. Thus, the Draft HK Code creates unnecessary obstacles to trade by ignoring the WHO's recommendation that complementary feeding be commenced from an infant's 6 month of life and continued along with partial breastfeeding thereafter until two years or beyond.

Draft HK Code Articles 2, 3, 4, 5 and 8 are more trade-restrictive than necessary to achieve the Draft HK Code's policy objectives, especially when compared with reasonably available less trade-restrictive alternatives. The WHO Code-implementing frameworks adopted by Australia and New Zealand, two developed common law jurisdictions located in the Asia region having not-too dissimilar socioeconomic demographics and hygienic living conditions, present two such examples.

Similar to the WHO Code, Australia's MAIF Agreement and accompanying framework do not apply to infant formulas and complementary foods marketed or represented as suitable for use from 12 months as a *supplement* to breast milk, or to feeding bottles and teats. As a result, the MAIF Agreement does not impose as extensive prohibitions and restrictions on manufacturer and distributor disseminated product information and other informational/educational materials, or as extensive curtailments of the use of manufacturer company or brand logos or trademarks in such materials and on infant formula product containers or labels, as does the Draft HK Code. The MAIF Agreement, like the Draft HK Code, largely places self-regulatory responsibility upon industry (manufacturers, distributors and third-party marketers) to ensure their Code compliance. Similar to the Draft HK Code, the MAIF Agreement largely provides for third-party oversight of industry compliance via a government-appointed Advisory Panel, but unlike the Draft HK Code, there is no legal enforcement mechanism. Instead, the MAIF Agreement relies on the popular technique of public "naming and shaming" which is achieved through public registration of the names of those companies found to be noncompliant with the MAIF Agreement. Naming and shaming has been shown to severely diminish a company's economic value by impairing the reputation of its brands as well as its corporate goodwill.

The New Zealand INC Code of Practice covers infant formula only, because follow-on formula intended for infants over 6 months of age is not marketed as a breast milk substitute in New Zealand; it is marketed only as a breastmilk *supplement* which is expressly excluded from the Code. Other elements of the New Zealand framework (the New Zealand Health Workers' Code and the Australia-New Zealand Food Standards Code) cover both infant formula and follow-on formula marketed as breastmilk substitutes, and thus effectively extend the duration of coverage of marketed products from 6 to 12 months, similar to the MAIF Agreement. Unlike the Draft HK Code, the INC Code of Practice does not: 1) restrict informational/educational materials about infant formula products disseminated via company website or other electronic means, in retail premises or at healthcare facilities to strictly textual information; 2) prohibit images other than small pack shots or health and nutrition claims; 3) prohibit manufacturer or distributor-produced informational/educational materials dealing with the feeding of infants that are disseminated to the public or to a healthcare system from bearing a company's name or logo; or 4) restrict the use of company logos or trademarks on infant formula product containers or labels, or manufacturers' or distributors' use/exploitation of economically valuable company IP assets, including licensing rights associated with follow-on formula or complementary food products.

The New Zealand framework, however, like the Draft HK Code, provides for largely governmental oversight of an extensive breastmilk substitutes complaint procedure with several levels of appeal. Although the New Zealand complaint process does not provide for an enforcement mechanism replete with financial and legal sanctions even for unintentional Code violations, as does the Draft HK Code, it does ensure a final administrative result. A final determination of Code noncompliance is reinforced by a "naming and shaming" global reporting mechanism capable of significantly impairing the economic value of the breaching company's brand reputation and goodwill.

While the degree to which the broader and longer 30-month Draft HK Code marketing ban imposed on follow-up formula and complementary food products intended as breastmilk substitutes or supplements can contribute to the achievement of the Code's policy objectives is uncertain, its trade-restrictiveness is well recognized. A combined New Zealand-Australia self-regulatory framework that covers infant formulas and follow-on formulas marketed only as breastmilk substitutes/replacements suitable for use by infants and young children up to 12 months of age would offer a reasonably available less trade-restrictive alternative that would be capable of achieving the Draft HK Code's legitimate objectives with minimal risk of nonfulfillment. The GHK-SAR should seriously consider this realistic option before finalizing the Draft HK Code in its current form so that it may avoid a potential TBT Agreement challenge.

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