

*Lawrence Kogan on*  
**Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 1 of 3)**  
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***Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 1 of 3)***

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I. Introduction

During October 2012, the Government of the Hong Kong Special Administrative Region ("GHK-SAR") issued in draft form the *Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children*<sup>2</sup> ("the Draft HK Code"). The GHK-SAR encouraged (effectively required) all formula milk manufacturers and distributors, health workers and health facilities to follow these guidelines.<sup>3</sup> The Draft HK Code's stated objective is to provide "safe and adequate nutrition to infants<sup>4</sup> and young children<sup>5</sup>...by protecting breastfeeding and...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

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2 See Department of Health, The Government of the Hong Kong Special Administrative Region, *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>

3 Draft HK Code, Background, p. 4.

4 An "infant" is "a person not more than 12 months of age." Draft HK Code, Art. 3, p. 11.

5 A "young child" is "a person from the age of more than 12 months up to the age of three years (36 months)." *Id.*, Art. 3, p. 15.

information and through appropriate marketing...by...enabling parents to make informed decisions on infant feeding free from commercial influence” (emphasis added).<sup>6</sup>

The Draft HK Code is modeled after and aims to implement for Hong Kong the World Health Organization’s (“WHO”)’s *International Code of Marketing of Breast-milk Substitutes*,<sup>7</sup> the WHO/UNICEF *Global Strategy for Infant and Young Child Feeding*,<sup>8</sup> and subsequent World Health Assembly resolutions. These international initiatives focus partly on ensuring food safety,<sup>9</sup> partly on promoting general public health by protecting breastfeeding, and partly on preventing deceptive marketing practices alleged to influence consumer decisions not to breastfeed.

The Draft HK Code, in its current form, however, is quite objectionable. It employs onerous means to achieve its policy objectives that go far beyond relevant international standards developed by recognized international standards bodies, including the Codex Alimentarius Commission and the WHO. The Draft HK Code effectively imposes, without substantiating scientific evidence, a 30-month marketing ban on all follow-up formula and nonformula complementary food products intended for Hong Kong-based infants and young children 6-36 months of age, even if such products are marketed for use as breastmilk *supplements*.

The Draft HK Code’s follow-up formula and complementary food marketing ban is arguably 30 months longer than what the WHO Code and accompany World Health Assembly resolutions recommend, and consequently, certainly more trade-disruptive than reasonably available less trade-restrictive alternatives enacted by other WTO Members. Generally speaking, while the WHO Code focuses on liquid and solid infant food products marketed only as breastmilk *substitutes* for infants up to 4-6 months of age,<sup>10</sup> the Draft HK Code focuses instead primarily on liquid and solid

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6 Draft HK Code, Art. 2.1; Background, p. 2.

7 See World Health Organization, *International Code of Marketing of Breast-milk Substitutes* (1981), available at: [http://www.who.int/nutrition/publications/code\\_english.pdf](http://www.who.int/nutrition/publications/code_english.pdf); [http://www.unicef.org/nutrition/files/nutrition\\_code\\_english.pdf](http://www.unicef.org/nutrition/files/nutrition_code_english.pdf).

8 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>.

9 “[T]he important impacts of early nutrition on long-term health are widely recognised. 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 and thereafter, 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.” *Id.*, Background at p. 2.

10 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*. WHO Code, Annex 3, p. 23. Subsequently enacted World Health Assembly Resolution A55/15, however, arguably confounds this interpretation to the extent it calls for partial breastfeeding “for up to two years of age or beyond” together with “nutritionally adequate and safe complimentary foods[,] to meet [infants] evolving nutritional requirements”. See A55/15 at par. 10, p. 5; *Global Strategy for Infant and Young Child Feeding* (2003) at par. 10, p. 8. If WHA Resolution A55/15 is interpreted as superseding the WHO Code, confusion may be avoided only if liquid and solid food products are not marketed to displace breastfeeding as a partial food source (i.e., marketed as a breastmilk substitute) after the first six months of a child’s life for up to two years of age or beyond, which should effectively leave parents and healthcare providers unlimited time to decide whether to continue breastfeeding. This means that liquid and solid infant and young children’s food products marketed as supplements to partial breastfeeding suitable for infants 6 months of age or older would *not* be treated as “covered” products and thus subject to WHO Code brand name restrictions.

food products intended for infants and young children from 6-36 months of age and targets both breastmilk substitutes *and* supplements.<sup>11</sup>

Furthermore, unlike the WHO Code, the Draft HK Code also prohibits and/or severely restricts, during such 30-month period, the use in Hong Kong of economically valuable intellectual property (“IP”) assets (i.e., trademarks, logos, symbols, and names consisting of word marks and non-word marks) on formula milk *supplement* product containers and labels, informational/educational materials and in all forms of product or company advertising.<sup>12</sup> Granted, the Draft HK Code does not contain the more intrusive and trade-restrictive ‘plain packaging’ requirement incorporated in Australia’s controversial tobacco legislation which mandates the use of unbranded, standardized containers for products, that has triggered international consternation and World Trade Organization (“WTO”) litigation.<sup>13</sup> Nevertheless, given the Draft HK Code’s broad product scope, its word mark and non-work mark prohibitions and restrictions similarly deny formula manufacturers, distributors and licensees the ability to distinguish and differentiate their products in the Hong Kong marketplace.

The Draft HK Code is certainly a complex instrument containing both food safety-related and non-food safety-related features, and for this reason, warrants analysis under several WTO Agreements. This article examines in-depth how the Draft HK Code prohibitions and restrictions outlined above create unnecessary obstacles to international trade that violate the provisions of the Sanitary and Phytosanitary (“SPS”) Agreement,<sup>14</sup> the Technical Barriers to Trade (“TBT”) Agreement,<sup>15</sup> and the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Agreement.<sup>16</sup> As the analysis will reveal, these objectionable prohibitions and restrictions are not substantiated by scientific or other evidence and are more trade-restrictive than necessary to achieve the Draft HK Code’s legitimate

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11 Draft HK Code Art. 2.

12 See Mimi Lau, *China to Step Up Monitoring of Foreign Baby Formula Sold Online*, supra. See also Li Likui, *Baby Formula Regulations Applauded*, ChinaDaily.com (11/21/12), available at: [http://www.chinadaily.com.cn/business/2012-11/21/content\\_15946701.htm](http://www.chinadaily.com.cn/business/2012-11/21/content_15946701.htm) (“A government proposal to ban all forms of advertising on baby formula for infants under three years old has won the backing of some stakeholders on Tuesday during a joint meeting of a Legislative Council panel...The proposal - The Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children - is currently under public consultation until the end of the year. The code's mandate is to contribute to the protection of breast-feeding and provision of safe and adequate nutrition for infants aged 36 months or below.”).

13 See *Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Request for the Establishment of a Panel by the Ukraine, WT/DS434/11 (Aug. 17, 2012). The WTO Dispute Settlement Body established a panel at its September 28, 2012 meeting. See also *Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Request for the Establishment of a Panel by Honduras WT/DS435/16 (Oct. 17, 2012); *Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Request for the Establishment of a Panel by Dominican Republic WT/DS441/15 (Nov. 14, 2012); *Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Request for the Establishment of a Panel by Cuba WT/DS458/1 (May 7, 2013).

14 See *Agreement on Sanitary and Phytosanitary Measures*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 33 I.L.M. 1125 [hereinafter SPS Agreement] (covering technical regulations and standards addressing food product safety issues), available at: [http://www.wto.org/english/docs\\_e/legal\\_e/15-sps.pdf](http://www.wto.org/english/docs_e/legal_e/15-sps.pdf).

15 See *Agreement on Technical Barriers to Trade*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120 (covering technical and standards addressing other than food product-related safety issues) [hereinafter TBT Agreement], available at: [http://www.wto.org/english/docs\\_e/legal\\_e/17-tbt.pdf](http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf).

16 See *Agreement on Trade-Related Aspects of Intellectual Property Rights*, (Apr. 15, 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

policy objectives considering the risks of nonfulfillment. This article will be divided into three parts. The first part will analyze these restrictions under the terms of the SPS Agreement. The second part will analyze these restrictions under the terms of the TBT Agreement. The third part will analyze these restrictions under the terms of the TRIPS Agreement.

The GHK-SAR would be well advised to carefully review these agreements and this analysis prior to finalizing the Draft HK Code for adoption, lest it may find itself before a WTO tribunal. Although Hong Kong is a Special Administrative Region of China, it has retained the status of a separate customs territory that continues to decide its own economic and trade policies,<sup>17</sup> and has remained a full member of the WTO.<sup>18</sup> Consequently, any WTO Member grievance relating to the Draft HK Code may be lodged directly with the competent authority of the GHK-SAR, rather than with the competent authority of the Peoples' Republic of China.<sup>19</sup> Hopefully, this article's analyses will diminish the likelihood of such an outcome, and promote further constructive dialogue among GHK-SAR's many agencies and interested public stakeholders regarding less IP and trade-restrictive ways to address food safety, public health and commercial practice concerns.

## II. Applicable SPS Agreement Provisions

### 1. Determining the Character of Disputed Measures

#### a. Identifying an SPS Measure

A national measure will fall within the scope and coverage of the WTO Sanitary and Phytosanitary ("SPS") Agreement if it qualifies as an "SPS measure". An SPS measure is one that both meets the definition of an "SPS measure" in SPS Annex A(1), including A(1)(a)-(d), *and* directly or indirectly affects international trade.<sup>20</sup>

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17 "The Basic Law (mini-constitution) provides a constitutional framework for the Hong Kong Special Administrative Region (SAR). It institutionalizes the concept of "one country, two systems". The Basic Law clearly prescribes that the social, economic and political systems in Hong Kong will be different from those in the mainland of China. It protects the rights, freedoms and life-style of Hong Kong people until the year 2047. The Basic Law guarantees the independence of Hong Kong's judiciary and, apart from foreign affairs and defense, gives Hong Kong people full responsibility to manage their own affairs. It allows Hong Kong complete financial autonomy, and the independence of its monetary system. Perhaps *most importantly, it establishes Hong Kong as a separate international customs territory, enabling it to work directly with the international community to control trade in strategic commodities, drugs, illegal transshipments, and to protect intellectual property rights.* Hong Kong remains a free port, maintaining free trade practices" (emphasis added). See Caroline Yuen, *Hong Kong - Food and Agricultural Import Regulations and Standards – Narrative*, GAIN Report Number: HK1233, U.S. Foreign Agricultural Service (12/6/12), at p. 4, available at: <http://www.usfoods-hongkong.net/res/mns/00191/HK1233.pdf>.

18 See World Trade Organization, *WTO Successfully Concludes Negotiations on China's Entry*, Press Release Press/243 (Sept. 17, 2001), available at: [http://www.wto.org/english/news\\_e/pres01\\_e/pr243\\_e.htm](http://www.wto.org/english/news_e/pres01_e/pr243_e.htm). By virtue of Article XI of the Marrakesh Agreement Establishing the World Trade Organization, Hong Kong became an original Member of the WTO and has since continued to be a WTO Member using the name of "Hong Kong, China".

19 To date, Hong Kong has been involved in only one dispute at the WTO, which it initiated and in which it prevailed. See Appellate Body Report, *Turkey – Restrictions on Imports of Textile and Clothing Products*, WT/DS34/AB/R (Oct. 22, 1999).

20 See Panel Report, *United States-Certain Measures Affecting Imports of Poultry From China ("US-Poultry (China))*, WT/DS392/R (Sept. 29, 2010), at par. 7.82.

Annex A(1)(b) defines an SPS measure as including one “applied to protect human or animal life or health within the territory of the Member from risks arising from [that ‘occur as a result of’<sup>21</sup>] additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs”.<sup>22</sup> This has been referred to as one example of the “purpose” of a measure.<sup>23</sup> In addition, SPS “measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures;...provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.”<sup>24</sup> These criteria are said to relate to the “form” of the measure. How these measures are then applied to achieve their stated or intended purpose relates to the “nature” of the measure.<sup>25</sup>

#### b. Identifying a Consolidated SPS and non-SPS Measure

In *EC-Biotech Products*,<sup>26</sup> the WTO Panel ruled that it is possible to have a consolidated measure part of which qualifies as an SPS measure, and part of which qualifies as a non-SPS measure. This will depend on the character of the measure’s different purposes, their respective independent bases, and the extent to they are each applied for that purpose(s).<sup>27</sup> The *EC-Biotech Products* Panel recognized that, although “formally, the requirement at issue [may] constitute[] one single requirement...neither the WTO Agreement nor WTO jurisprudence establishes that a requirement meeting the condition referred to in the previous paragraph may not be deemed to embody two, if not more, distinct measures which fall to be assessed under different WTO agreements.”<sup>28</sup> Since SPS Annex A(1) refers to “any measure” in its definition of an SPS measure, it is possible that a requirement may “be considered to embody an SPS measure as well as a non-SPS measure.”<sup>29</sup>

If a portion of a consolidated requirement is applied for one of the purposes enumerated in Annex A(1), and thus, can be viewed as an SPS measure, it must be determined whether that portion of such measure may affect international trade, within the meaning of SPS Article 1.5. “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

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21 Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (“*EC-Biotech Products*”), WT/DS291/R, WT/DS292/R and WT/DS293/R (Sept. 29, 2006) at par. 7.224.

22 SPS Annex A(1)(b).

23 Panel Report, *US-Poultry (China)* at par. 7.85; Panel Report, *EC-Biotech Products* at par. 7.149.

24 SPS Annex A(1).

25 Panel Report, *US-Poultry (China)* at par. 7.85; Panel Report, *EC-Biotech Products* at par. 7.149.

26 Panel Report, *EC-Biotech Products*, supra. The *EC-Biotech Products* Panel found that, “[since]...the EC approval legislation which sets out the relevant [EC moratorium] approval procedures is applied in part for purposes which are identified in Annex A(1) of the SPS Agreement and in part for other purposes...[-] it may conceivably be warranted to view each of the relevant EC approval procedures as incorporating an SPS measure as well as a non-SPS measure.” *Id.*, at par. 7.172.

27 “[T]o the extent the requirement in [a] consolidated law is applied for one of the purposes enumerated in [SPS] Annex A(1), it may be properly viewed as a measure which falls to be assessed under the SPS Agreement; to the extent it is applied for a purpose which is not covered by Annex A(1), it may be viewed as a separate measure which falls to be assessed under a WTO agreement other than the SPS Agreement. It is important to stress, however, that our view is premised on the circumstance that the requirement at issue could be split up into two separate requirements which would be identical to the requirement at issue, and which would have an autonomous *raison d’être*, i.e., a different purpose which would provide an independent basis for imposing the requirement.” *Id.*, at par. 7.165.

28 *Id.*, at par. 7.166.

29 *Id.*

which meets the definition of a technical regulation.”<sup>30</sup> However, “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.”<sup>31</sup> According to the Panel,<sup>32</sup> the SPS Agreement contains no directive “which says that a requirement can never be deemed to embody two or more distinct measures which fall to be assessed under different WTO agreements.”<sup>33</sup>

The *EC-Biotech Products* Panel, furthermore, provided a rule-of-thumb to be followed in distinguishing between a measure’s food-safety and non-food safety-related purposes. It noted that, to the extent a measure is applied to ensure that a food item is “not nutritionally disadvantageous for the consumer...it *cannot* be considered a measure applied to protect the life or health of consumers from risks arising from, e.g., additives or contaminants that is...covered by Annex A(1)” (emphasis added).<sup>34</sup>

## 2. The Draft HK Code, in Part, is an “SPS Measure”

### a. Various Draft HK Code Provisions Have a Food Safety Purpose Which Qualifies Them as SPS Measures Within the Meaning of SPS Annex A(1)(b)

During November 2012, the GHK-SAR filed a notification with the WTO SPS Committee in compliance with SPS Article 7 identifying a purpose of the Draft HK Code as “food safety”-related. Consistent with Draft HK Code Article 2, the notification states that the Code “aims to contribute to the protection of breastfeeding *and provision of safe and adequate nutrition for infants and young children, by...(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).<sup>35</sup>

This notification indicates that certain Draft HK Code provisions are partly concerned with food safety, and particularly, with mitigating the “direct” short-term and “indirect” long-term risks of food-related illness/disease arising from consumption of breastmilk substitute and supplement products. Clearly Draft HK Code Article 3 defines the term “food” for purposes of SPS Annex A(1)(b) as: “formula milk”, which includes “infant formula” and “follow-up formula” (inclusive of formula for special medical purposes for infants from the 6th month on and for young children); and (nonformula milk) “food products for infants and young children”, including “complementary foods” (inclusive of “any [nonformula milk] food products for special medical purposes for infants and young children”).<sup>36</sup> The common definition of “[f]ood” is “a substance taken into the body to

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30 *Id.*, at par. 7.167.

31 *Id.* Since SPS Article 1.5 is not applicable, by its terms, to non-SPS measures, “the requirement is assumed to be part of a technical regulation [that] falls to be assessed under the TBT Agreement to the extent it embodies a non-SPS measure.” *Id.* That “a requirement may in certain cases incorporate more than one measure is consistent with, and gives meaning and effect to, the provisions of Article 1.5.” *Id.*

32 *Id.*

33 *Id.*, at par. 7.170.

34 Panel Report, *EC-Biotech Products*, at pars. 7.413-7.414.

35 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](http://tbt.testrust.com/image/nsps/803/103803_1.doc).

36 Draft HK Code, Art. 3, at pp. 9, 10, 12.

maintain life and growth,” including “a substance which a human being or an animal consumes for nutritional reasons”.<sup>37</sup>

Direct short-term food safety-related risks have been found to arise from “disease-causing organisms”<sup>38</sup> (bacteria) naturally occurring in formula milk, especially “powdered formula milk”, including “infant formula” and “follow-up formula”, which can cause diarrhea, dehydration and other illness in infants and young children<sup>39</sup>. Direct short-term risks also arise from certain “additives”,<sup>40</sup> like sugar, contained in “sweetened liquids, including formula milk” which, through “extended contact...may cause severe tooth decay”.<sup>41</sup> Indirect long-term risks are believed to arise from the ongoing consumption of certain “additives”<sup>42</sup> contained in infant and follow-up formula and infant and young children’s food products (including complementary foods), such as sugar, non-iodized salt,<sup>43</sup> and transfat<sup>44</sup>, which are alleged to contribute to non-communicable diseases

37 Panel Report, *EC-Biotech Products*, at par. 7.291. Similarly, the U.S. FDA defines infant formula as “a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk”. (FFDCA 201(z)). See U.S. Food and Drug Administration, *Frequently Asked Questions about FDA’s Regulation of Infant Formula – Guidance for Industry* (March 1, 2006), available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/InfantFormula/ucm056524.htm#q1>.

38 See Panel Report, *Australia-Measures Affecting Importation of Salmon (“Australia-Salmon”)*, WT/DS18/R (June 12, 1998) at par. 8.34.

39 Draft HK Code Arts. 4.1.1(a)-(b) (“formula milk feeding”);

40 “Additives” are commonly defined as “a substance added to another so as to give it specific qualities”. See Panel Report, *EC-Biotech Products*, at par. 7.297. The Codex defines “food additives” as “any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities” (emphasis added). See Codex Alimentarius Commission Procedural Manual (21st Ed.) (FAO/WHO 2013) at pp. 22, available at: [ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual\\_21e.pdf](ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_21e.pdf). See also Codex Alimentarius Commission, *Codex General Standard for Food Additives* (CODEX STAN 192-1995), at Sec. 2(a), available at: [http://www.codexalimentarius.net/gsaonline/docs/CXS\\_192e.pdf](http://www.codexalimentarius.net/gsaonline/docs/CXS_192e.pdf). “Salt, sugar, and corn syrup are by far the most widely used additives in food in [the United States]”. See United States Department of Agriculture Food Safety and Inspection Service, *Food Labeling - Additives in Meat and Poultry Products*, available at: [http://www.fsis.usda.gov/factsheets/Additives\\_in\\_Meat\\_&\\_Poultry\\_Products/index.asp](http://www.fsis.usda.gov/factsheets/Additives_in_Meat_&_Poultry_Products/index.asp); CODEX STAN 192-1995, supra (addressing inter alia salt and sugar); Codex Alimentarius Commission, *Codex Standard for Sugars*, (CODEX STAN 212-1999 (Amended 2001)), available at: [http://famis.comesa.int/pdf/Sugar\\_FDHS\\_6\\_CXS\\_212.pdf](http://famis.comesa.int/pdf/Sugar_FDHS_6_CXS_212.pdf); Codex Alimentarius Commission, *Codex Standard for Food Grade Salt*, (CODEX STAN 150-1985), available at: [http://www.codexalimentarius.org/input/download/standards/3/CXS\\_150e.pdf](http://www.codexalimentarius.org/input/download/standards/3/CXS_150e.pdf);

41 Draft HK Code Art. 8.4.1(b)(iv). Short-term non-food safety-related risks include those arising from improperly prepared and/or sterilized formula milk-related feeding bottles and teats harboring bacteria. See Draft HK Code, Art. 4.4.1(e)(iii)(F) and (G); Art. 8.2.1(d), 8.4.1(b)(i) and (iii).

42 “The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable.” See CODEX STAN 192-1995, supra at Sec. 3.2.

43 Draft HK Code, Art. 8.5.3(a). The GHK-SAR is likely aware of the WHO recommendation to “limit salt (sodium) consumption from all sources and ensure that salt is iodized.” See World Health Organization, *Global Strategy on Diet, Physical Activity and Health* (2004) at p.1, available at: [http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy\\_english\\_web.pdf](http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf).

44 Draft HK Code, Arts. 3, p. 13; 8.5.3(a) and (d). On July 8, 2013, it was reported that “[t]hree popular [China] mainland milk powder brands contain trans-fat that experts say could lead to heart disease and should be avoided by infants.” See Emily Tsang, Lo Wei and Celine Sun, *Trans-fat Found in Mainland China Milk Formula Brands*, South China Morning Post (July 8, 2013), available at: <http://www.scmp.com/news/hong-kong/article/1277600/trans-fat-found-mainland-china-baby-milk-formula-brands>. Although the “levels of trans-fat in the formula [tested] fall within mainland and international safety standards”,

(“NCDs”) later in life. Indeed, infant formula and complementary foods are two food categories in which the use of “additives” is carefully monitored,<sup>45</sup> and in which sodium, sugar and transfat are also known to occur naturally.

“The WHO defines “disease” as “[a] pathological condition of the body that presents a group of clinical signs, symptoms, and laboratory findings peculiar to it and setting the condition apart as an abnormal entity differing from other normal or pathological conditions (CMD 1997)”.<sup>46</sup> The WHO defines a...disease-causing organism [within the meaning of Annex A(1)(a) and A(1)(b)] as a ‘pathogen’”.<sup>47</sup> According to the WHO, “[t]he four main types of non-communicable diseases are cardiovascular diseases (like heart attacks and stroke), cancers, chronic respiratory diseases (such as chronic obstructed pulmonary disease and asthma) and diabetes.”<sup>48</sup>

Certain subsections of Draft HK Code Articles 4 (imposing restrictions on disseminated informational/educational materials relating to formula milk and infant and young children’s food products) and 8 (imposing restrictions on formula milk and infant and young children’s food product containers and labels)<sup>49</sup> reflect a direct short-term and/or indirect long-term food safety-related “purpose”/objective. Therefore, they arguably fall within the scope of SPS Annex A(1)(b) – “to protect human or animal life or health within the territory of the Member from risks arising from additives...or disease-causing organisms in foods.”\*<sup>50</sup> The Draft HK Code’s preamble reaffirms that its policy purpose, in part, is to address the indirect long-term risks to human life or health associated with NCDs.<sup>51</sup> In other words, the Code is, in part, a national implementation of the *WHO*

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paediatricians noted that parents “should avoid feeding their infants the substance.” It was also found that although the sodium content of one of the brands falls within mainland and international safety standards, it is twice that indicated on the package. *Id.* See also Phila Siu, *SCMP Defends Report on Trans-fat Levels in Baby Milk Formula*, South China Morning Post (July 10, 2013), available at: <http://www.scmp.com/comment/insight-opinion/article/1279042/scmps-statement-its-july-8-milk-formula-report> (wherein the SCMP responded to allegations made in an article published on Xinhuanet, a news portal affiliated with Xinhua, that the SCMP “was spreading fear among mainland parents by saying that mainland brands of infant milk formula contain trans-fat.”).

45 For example, the “[c]arry-over of a food additive from a raw material or ingredient [used to produce the food] is unacceptable for foods...belonging to the food category [of] Infant formulae, follow-up formulae, and formulae for special medical purposes for infants [and] [c]omplementary foods for infants and young children.” See CODEX STAN 192-1995, *supra* at Sec. 4.3(a)-(b).

46 Panel Report, *EC-Biotech Products*, at par. 7.277.

47 *Id.* See also World Health Organization, *Emerging Issues in Water and Infectious Disease* (2003), at p. 5, available at: [http://www.who.int/water\\_sanitation\\_health/emerging/en/emerging.pdf](http://www.who.int/water_sanitation_health/emerging/en/emerging.pdf) (referring to “Pathogenic (disease-causing) microorganisms”); World Health Organization, *Five Keys to Safer Food Manual* (2006), at p. 27, available at: [http://www.who.int/foodsafety/publications/consumer/manual\\_keys.pdf](http://www.who.int/foodsafety/publications/consumer/manual_keys.pdf) (defining “Pathogen” as “[a]ny disease-causing microorganism such as a bacterium, virus or parasite. Often referred to as a ‘germ’ or ‘bug’.”).

48 See World Health Organization, *Noncommunicable Diseases – Fact Sheet* (Updated March 2013), available at: <http://www.who.int/mediacentre/factsheets/fs355/en/>. “Children, adults and the elderly are all vulnerable to the risk factors that contribute to non-communicable diseases, whether from unhealthy diets, physical inactivity, exposure to tobacco smoke or the effects of the harmful use of alcohol. These diseases are driven by forces that include ageing, rapid unplanned urbanization, and the globalization of *unhealthy lifestyles*. For example, globalization of *unhealthy lifestyles like unhealthy diets may show up in individuals as raised blood pressure, increased blood glucose, elevated blood lipids, overweight and obesity*. These are called ‘intermediate risk factors’ which can lead to cardiovascular disease, a NCD” (emphasis added). *Id.*

49 Certain subsections of Article 9 (concerning product quality of infant formula, follow-up formula and food products for infants and young children) also constitute food safety-related measures, but they are not the subject of dispute.

50 \*See Appendix I.

51 “[T]he “Steering Committee on Prevention & Control of Non-Communicable Diseases, chaired by the Secretary for Food and Health, endorsed the proposal of developing and implementing a code of marketing of breastmilk substitutes as part of an

*Global Strategy on Diet, Physical Activity and Health*, which “addresses two of the main risk factors for non-communicable diseases, namely, diet and physical activity.”<sup>52</sup> Consequently, to the extent of the food safety-related purpose of such provisions, the Draft HK Code qualifies as an “SPS measure”.

Applying the *EC-Biotech Products Panel’s* rule-of-thumb, those Draft HK Code provisions concerned about direct, short-term human life or health risks posed to infants from the consumption of improperly prepared or inappropriately used formula milk products, could arguably be viewed as “food safety”-related, and thus, constitute “SPS measures”. And, Draft HK Code provisions concerned about permissible formula milk product nutrition or health claims that can be placed on informational/educational materials and formula milk product containers and labels to ensure that a formula milk product is “not nutritionally disadvantageous” would arguably be non-food safety-related, and thus, constitute “non-SPS measures”, because they are not concerned about and would not be applied to protect against risks human life or health. However, if the latter provisions are also concerned about and applied to address indirect long-term human life or health risks (or even hazards) potentially posed by the presence of certain core nutrients (e.g., sodium, sugar and transfat), naturally or as additives beyond a certain compositional level, these provisions, to such extent, would arguably be “food safety”-related, and thus, constitute “SPS measures”.

#### i. Food Safety-Related Aspects of Draft HK Code Articles Concerned About Direct Short-Term Risks to Human Life or Health

Draft HK Code Article 4.4.1(e)(iii)(F) concerns the direct short-term “health risks of feeding by [powdered] formula milk”, including infant formula and follow-up formula,<sup>53</sup> arising from naturally occurring “disease-causing organisms” (bacteria)<sup>54</sup>. Draft HK Code Article 4.4.1(e)(iii)(G) concerns the direct short-term health risks arising from improperly prepared and/or consumed [powdered] formula milk products.<sup>55</sup>

Draft HK Code Article 8.2.1(c)(i) concerns direct short-term health risks associated with formula milk consumption and preparation. It requires formula milk labels and/or containers to include “instructions for appropriate preparation and use”, is concerned about the risk to human life or

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action plan recommended by the Working Group on Diet and Physical Activities under the Steering Committee to promote healthy diet and physical activity in Hong Kong” (emphasis added). Draft HK Code, Preamble at p. 3.

52 See World Health Organization, *Global Strategy on Diet, Physical Activity and Health* (2004) at p.1, available at: [http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy\\_english\\_web.pdf](http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy_english_web.pdf).

53 Draft HK Code Article 3 defines “formula milk” as including “infant formula and follow-up formula.” Draft HK Code Art. 3, p. 10.

54 Draft HK Code 4.4.1(e)(iii)(F) provides that permissible informational/educational materials discussing “feeding by formula milk” should explain “the *health risks* of feeding by formula milk” (emphasis added).

55 Draft HK Code Article 4.4.1(e)(iii)(G) provides that permissible informational/educational materials discussing “feeding by formula milk” should explain that “powdered formula milk is not a sterile product”, and consequently, “that to minimize the risks of serious illness, formula should be prepared one feed at a time using boiled water cooled to no less than 70°C\* and that the reconstituted formula milk should be consumed within 2 hours after preparation and any unused milk must be discarded...To achieve this temperature, the water should be left for no more than 30 minutes after boiling.” This is consistent with the applicable Codex standard. See Codex Alimentarius Commission, *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (“CAC/RCP 66 – 2008”), at Sec. IX, pp. 16-17, available at: [http://www.codexalimentarius.org/input/download/standards/11026/CXP\\_066e.pdf](http://www.codexalimentarius.org/input/download/standards/11026/CXP_066e.pdf).

health arising from “disease-causing organisms” naturally occurring in formula milk products.<sup>56</sup> Draft HK Code Articles 8.2.1(c)(ii),(iii) and (v) require labels and/or containers to include “the age for which the product is recommended [which] should not be less than 6 months in the case of follow-up formula”,<sup>57</sup> a “warning about the health risks of improper preparation and of introducing the product prior to the recommended age”,<sup>58</sup> and a statement describing “the required storage conditions both before and after opening...the product, taking into account climatic conditions”.<sup>59</sup> These related provisions, as well, are concerned about the direct short-term risk to human life or health arising from “disease-causing organisms” naturally occurring in follow-up formula. Similarly, to the extent Draft HK Code Article 8.2.1(d), which requires formula milk product labels and/or containers to include an “IMPORTANT NOTICE...[that u]se of breastmilk substitutes may put infants and children at risk of diarrhea and other illnesses”, it also is concerned about the direct short-term risk to human life or health posed by “disease-causing organisms.”<sup>60</sup>

Draft HK Code Article 8.2.1(c)(ix) requires infant formula product labels and containers to include “a declaration that the product is made in accordance with the applicable Codex standard.”<sup>61</sup> This provision is apparently concerned with both food safety and non-food safety matters because the Codex standard it references addresses, “the normal nutritional requirements of infants”, as well as, the “compositional, quality and *safety* requirements for infant formula.”<sup>62</sup> These food safety requirements address both direct short-term and indirect long-term risks to human life or health.<sup>63</sup>

Draft HK Code Articles 8.2.1(f)(i)-(iii) require powdered formula milk product labels and/or containers to include “preparation and use” statements alerting consumers that powdered formula is “not a sterile product and may become contaminated during preparation”,<sup>64</sup> must “be prepared one feed at a time using boiled water allowed to cool to no less than 70C”,<sup>65</sup> and must be discard if it “has not been consumed more than two hours after reconstitution.”<sup>66</sup> These provisions highlight the food safety-related life and health risks arising from “disease-causing organisms” naturally occurring in powdered formula.

Draft HK Code Article 8.3.1(b)(i)-(ii) require labels and/or containers of “food products for infants and young children” to include “the age for which the product is recommended [which] should not be less than 6 months”,<sup>67</sup> preparation and use instructions,<sup>68</sup> a “warning about the health risks of

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56 Draft HK Code Article 8.2.1(c)(i).

57 Draft HK Code Art. 8.2.1(c)(ii).

58 Draft HK Code Art. 8.2.1(c)(iii).

59 Draft HK Code Art. 8.2.1(c)(v).

60 Draft HK Code Article 8.2.1(d).

61 Draft HK Code Art. 8.2.1(c)(ix), referencing Codex Alimentarius Commission, *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (“CODEX STAN 72-1981”), as amended, available at: [http://www.codexalimentarius.org/input/download/standards/288/CXS\\_072e.pdf](http://www.codexalimentarius.org/input/download/standards/288/CXS_072e.pdf).

62 See CODEX STAN 72-1981, *supra*, at Sections 1.1-1.2.

63 This standard addresses food safety issues in Sections 4 (“Food Additives”), 5 (“Contaminants”), 6 (“Hygiene”), 7 (“Packaging”), 9.4 (“Date Marking and Storage Instructions”) and 9.5 (“Information for Use”).

64 Draft HK Code Art. 8.2.1(f)(i).

65 Draft HK Code Art. 8.2.1(f)(ii).

66 Draft HK Code Art. 8.2.1(f)(iii).

67 Draft HK Code Art. 8.3.1(b)(i).

68 Draft HK Code Arts. 8.3.1(b)(ii); 8.2.1(c)(i).

improper preparation and of introducing the product prior to the recommended age”,<sup>69</sup> and a statement describing “the required storage conditions both before and after opening...the product, taking into account climatic conditions”.<sup>70</sup> These provisions are concerned with the direct short-term food safety-related risks arising from “disease-causing organisms” naturally occurring in such products, due to improper preparation, storage and use, especially follow-up formula products inappropriately consumed by underage infants.

ii. Food Safety-Related Aspects of Draft HK Code Articles Concerned About Both Direct Short-Term and Indirect Long-Term Risks to Human Life or Health

Draft HK Code Articles 8.2.1(c)(iv)(A)-(B) require that labels and containers for formula milk products include a “declaration of the nutritive value” that is consistent with applicable Codex standard for infant formula and infant special medical purposes,<sup>71</sup> and for follow-up formula.<sup>72</sup> HK Code Article 8.2.1(c)(x) requires follow-up formula product labels and containers to include “a declaration that the nutritional composition standard(s) adopted are those of the Codex or other recognised international/national authorities.”<sup>73</sup> Each of these provisions are apparently concerned with both direct short-term life or health risks posed by improper preparation and use of infant formulas and by indirect long-term food safety-related risks posed to human life or health by the possible presence of excessive amounts of certain “nutrients” – i.e., of sodium, sugar and/or trans-fats which may give rise to NCDs. However, they may also be considered non-food-safety related to the extent the nutritional composition rules are applied solely for promoting better health consistent with the non-food safety-related sections within the referenced Codex standards.

Draft HK Code Article 8.2.1(c)(ix) requires infant formula product labels and containers to include “a declaration that the product is made in accordance with the applicable Codex standard.”<sup>74</sup> This provision is similarly concerned with both food safety and non-food safety matters because the Codex standard it references addresses, “the normal nutritional requirements of infants”, as well as, the “compositional, quality and *safety* requirements for infant formula.”<sup>75</sup> These food safety requirements address both direct short-term and indirect long-term risks to human life or health.<sup>76</sup> However, this provision, like HK Draft Code Article 8.2.1(c)(x) may also be considered non-food-safety related to the extent the nutritional composition rules are applied solely for informational purposes consistent with the non-food safety-related sections within the referenced Codex standards.

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69 Draft HK Code Arts. 8.3.1(b)(ii); 8.2.1(c)(iii).

70 Draft HK Code Arts. 8.3.1(b)(ii); 8.2.1(c)(v).

71 Draft HK Code Art. 8.2.1(c)(iv)(A), referencing CODEX STAN 72-1981, as amended *supra*.

72 Draft HK Code Art. 8.2.1(c)(iv)(B), referencing 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](http://www.codexalimentarius.org/download/standards/293/CXS_156e.pdf). This standard addresses food safety issues in Sections 4 (“Food Additives”), 5 (“Contaminants”), 6 (“Hygiene”), 7 (“Packaging”), 9.4 (“Date Marking and Storage Instructions”) and 9.5 (“Information for Use”).

73 Draft HK Code Art. 8.2.1(c)(x).

74 Draft HK Code Art. 8.2.1(c)(ix), referencing CODEX STAN 72-1981, *supra*.

75 See CODEX STAN 72-1981, *supra*, at Sections 1.1-1.2.

76 This standard addresses food safety issues in Sections 4 (“Food Additives”), 5 (“Contaminants”), 6 (“Hygiene”), 7 (“Packaging”), 9.4 (“Date Marking and Storage Instructions”) and 9.5 (“Information for Use”).

Draft HK Code Article 8.2.1(b), applicable only to formula milk products, prohibits the use on formula milk product labels and containers “of any representation that states or suggests any health claim or nutrition claim, except those health claims and representations provided in Articles 8.5.2 to 8.5.3” (emphasis added).<sup>77</sup> Draft HK Code Article 8.5.2 (which applies for purposes of Article 8.2.1(b) only to formula milk product labeling<sup>78</sup>) provides that permitted “health claims” must: 1) be “permitted by [a] recognised international/national authority;” 2) “be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of the effect claimed and the *relationship with health* as recognised by generally accepted scientific review of the data” (emphasis added); 3) must “compl[y] with...the relevant claim condition(s) and the exact claim statement set by the concerned recognised international/national authority;” and 4) “*the absolute amount of the nutrient* claimed either on the labels or in the advertisement of the designated product must be declared on the container or label” (emphasis added).<sup>79</sup> Draft HK Code Article 8.5.3 provides examples of “representations [that] are allowed on the container or label of formula milk or food products for infants and young children”.<sup>80</sup> They include descriptions such as “low iodized salt”,<sup>81</sup> “no added salt” and “no added sugar”,<sup>82</sup> which relate, as discussed above, to the use of sodium and sugars as both “nutrients” and “additives”. To the extent that Draft HK Code Article 8.2.1(b) and Article 8.5.2 health claims are dependent on review of scientific data and the absolute amount of the nutrient claimed, it is arguable that they are concerned with the potential indirect long-term risks to human life or health. The illustrations contained in Draft HK Code Article 8.5.3(a) and (c) appear to confirm this reading.

Draft HK Code Articles 8.3.1(a), applicable only to infant and young children’s food products (other than formula milk) similarly prohibits the use on labels and containers for “food products for infants and young children” “of any representation that states or suggests any health claim or nutrition claim, except those health or nutrition claims and representations provided in Articles 8.5.1 to 8.5.3.”<sup>83</sup> Draft HK Code Articles 8.5.1 precludes “nutrition claims” from appearing on the labels and containers of “foods for infants and young children”, unless they are legally permissible, as previously discussed in subsection (i) above, with respect to restrictions imposed on the public distribution of formula milk product informational/educational materials that make health and nutrition claims.<sup>84</sup> Draft HK Code Article 8.5.2, as discussed above, describes the legal (domestic and international) requirements and scientific evidence required for including “health claims” on the labels and containers of follow-up formula and food products for infants and young children.<sup>85</sup> Draft HK Code Article 8.5.3(a) and (c), as discussed above, provides examples of “representations [that] are allowed on the container or label of formula milk or food products for infants and young children”.<sup>86</sup> To the extent that Draft HK Code Article 8.3.1(b) and Article 8.5.2 health claims are dependent on review of scientific data and the absolute amount of the nutrient claimed, it is

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77 Draft HK Code Art. 8.2.1(b).

78 Draft HK Code Article 8.5.2 applies ordinarily to health claims relating to follow-up formula and food products for infants and young children.

79 Draft HK Code 8.5.2(a)-(d).

80 Draft HK Code Art. 8.5.3.

81 Draft HK Code Art. 8.5.3(a).

82 Draft HK Code Art. 8.5.3(c).

83 Draft HK Code Art. 8.3.1(a).

84 Draft HK Code Arts. 8.5.1(a)-(d).

85 Draft HK Code 8.5.2(a)-(d).

86 Draft HK Code Art. 8.5.3(a) and (c).

arguable that they are concerned with the potential indirect long-term risks to human life or health. The illustrations contained in Draft HK Code Article 8.5.3(a) and (c) appear to confirm this reading.

Draft HK Code Article 8.3.1(b)(iii)(A)-(C) require that labels and containers for “food products for infants and young children” include a “declaration of the nutritive value” that is consistent with that required by applicable Codex standards for canned baby foods,<sup>87</sup> cereal-based foods, for general prepackaged foods for special dietary uses.<sup>88</sup> To the extent that the Codex standards referenced in Draft Articles 8.3.1(b)(iii)(A)-(C), in part, are focused on identifying the presence of excessive amounts of nutrients, such as sodium, sugar and trans-fats, contained in such products (either naturally or as additives), it is arguable that such provisions are concerned with indirect long-term food-safety-related risks to human life or health.

Lastly, HK Code Article 8.6.1 precludes the offering for sale and selling of any “designated products”, including formula milk and food products for infants and young children, if manufacturer’s and/or distributors fail to satisfy the Article 8 container and labeling requirements applicable to such products, as discussed above.<sup>89</sup> To the extent that food safety-related health or nutrition claims do not comply with Draft HK Code Article 8’s container and labeling requirements, Draft HK Code Article 8.6.1, as applied to those provisions, would also be considered an “SPS measure.”

In sum, these Draft HK Code provisions endeavor to address direct short-term and/or indirect long-term food safety-related risks to human life or health by curtailing the promotion of formula milk and infant and young children’s food product via distribution of informational/educational materials and on product containers and labels. Therefore, they qualify as “SPS measures” within the meaning of SPS Annex A(1).

b. The Draft HK Code’s “Form” Qualifies it as an “SPS Measure” Within the Meaning of SPS Annex A(1)

The SPS Agreement generally, and the text of SPS Annex A(1), specifically, covers “any” and “all” types of governmental measures,<sup>90</sup> whether they are mandatory or non-mandatory in nature.<sup>91</sup>

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87 Draft HK Code Art. 8.3.1(b)(iii)(A), referencing Codex Alimentarius Commission, *Standard for Canned Baby Foods* (CODEX STAN 73-1981), available at: [http://www.codexalimentarius.org/download/standards/289/CXS\\_073e\\_u.pdf](http://www.codexalimentarius.org/download/standards/289/CXS_073e_u.pdf). This standard addresses food safety issues in Sections 4 (“Food Additives”), 5 (“Contaminants”), 6 (“Hygiene”), 7 (“Packaging”), 9.4 (“Date Marking and Storage Instructions”) and 9.5 (“Information for Use”).

88 Draft HK Code Art. 8.3.1(b)(iii)(B), referencing Codex Alimentarius Commission, *Codex Standard for Processes Cereal-Based Foods for Infants and Young Children*, (“CODEX STAN 074-1981, REV. 1-2006”), available at: [http://www.codexalimentarius.org/input/download/standards/290/cxs\\_074e.pdf](http://www.codexalimentarius.org/input/download/standards/290/cxs_074e.pdf). This standard addresses food safety issues in Sections 4 (“Food Additives”), 5 (“Contaminants”), 6 (“Hygiene”), and 7 (“Packaging”).

89 Draft HK Code Art. 8.6.1.

90 See Part II.1, *supra*.

91 See Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R (Oct. 27, 1998) at par. 8.111. “The footnote to paragraph 1 of Annex B refers in general terms to ‘phytosanitary measures such as laws, decrees or ordinances’. Nowhere does the wording of this paragraph require such measures to be mandatory or legally enforceable. Moreover, Paragraph 1 of Annex A to the SPS Agreement makes clear that ‘phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures’. *It does not, in turn, require that such measures be mandatory or legally enforceable. The interpretation that measures need not be mandatory to be subject to WTO disciplines is confirmed by the context of the relevant SPS provisions*, a context which includes provisions of other WTO agreements and the way these provisions define ‘measure’.

Even if a measure is a non-mandatory guideline, it will be considered an “SPS” measure “in the event compliance with [it] is necessary to obtain an advantage from the government or, in other words, if sufficient incentives or disincentives exist for that measure to be abided by.”<sup>92</sup>

The Draft HK Code is a governmental measure that describes itself as “voluntary in nature”<sup>93</sup> and as designed “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” (emphasis added).<sup>94</sup> 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.”<sup>95</sup> The Draft HK Code also describes itself as holding manufacturers and distributors “responsible for implementing the Code themselves – thus imposing on industry a form of ‘self-regulation’<sup>96</sup> - subject to third-party monitoring “through a dual surveillance/survey and complaint system, with collaboration from non-governmental organisations, professional bodies, institutions and individuals concerned.”<sup>97</sup>

This self-description aside, various Draft HK Code provisions operate to preclude the offering for sale or sale of any “designated product [that] does not satisfy the labelling requirements provided under Article 8.”<sup>98</sup> In addition, Draft HK Code Article 10 and Annex I reveal that the government will play a quite extensive role in overseeing the monitoring and surveillance of industry Code compliance, which provides sufficient incentives and/or disincentives for formula milk and infant and young children’s food product manufacturers and distributors to ensure their Code compliance. In other words, at the very least, Draft HK Code operates as a voluntary measure compliance with which is necessary to obtain an advantage from the GHK-SAR, namely, market access and freedom to operate. And, and at most, the Draft HK Code qualifies as a *de facto* mandatory measure for purposes of being challengeable under the SPS Agreement.<sup>99</sup>

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‘requirement’ or ‘restriction’, as interpreted in GATT and WTO jurisprudence. *This context indicates that a non-mandatory government measure is also subject to WTO provisions in the event compliance with this measure is necessary to obtain an advantage from the government or, in other words, if sufficient incentives or disincentives exist for that measure to be abided by*” (emphasis added). *Id.* “We consider that in this case the varietal testing requirement, as set out in the ‘*Experimental Guide for Cultivar Comparison Test on Insect Mortality – Fumigation*’ (hereafter referred to as ‘*the guidelines*’), does provide sufficient incentives for it to take effect. Indeed, if an exporting country abides by the guidelines, its request for entry of a certain variety of a product will be granted. If an exporting country accepts the varietal testing requirement and follows the guidelines, it will do so in order to obtain an advantage from the government. We thus consider that the varietal testing requirement is a phytosanitary regulation in the sense of paragraph 1 of Annex B” (emphasis added). *Id.*, at par. 8.112.

<sup>92</sup> *Id.*, at par. 8.111.

<sup>93</sup> “*The HK Code provides voluntary guidelines to manufacturers and distributors of formula milk; feeding bottle, teats and pacifiers; and, food products for infants and young children aged 36 months or below*” (emphasis added). See Family Health Service Department of Health, Government of Hong Kong Special Administrative Region, *Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children* (*The HK Code*), available at: <http://www.fhs.gov.hk/english/news/hkcode/hkcode.html>.

<sup>94</sup> Draft HK Code, Background at p. 4.

<sup>95</sup> Draft HK Code, Background at p. 4.

<sup>96</sup> “[T]he trade is...[held] responsible for monitoring its own marketing practices.” *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> Draft HK Code, Art. 8.6.1.

<sup>99</sup> Panel Report, *EC-Biotech* supra at pars. 7.1294-7.1295. “We recall, however, the Appellate Body’s statement in *US - Carbon Steel* [United States - Sunset Review of Anti-Dumping Duties on Corrosion-Resistant Carbon Steel Flat Products From Japan, WT/DS244/AB/R (Dec. 15, 2003) at par. 81] that a measure of a Member can only be challenged if the measure is attributable to that Member. Thus, for the general *de facto* moratorium on approvals to qualify as a challengeable EC measure, it must be attributable to the European Communities. We note that both the Commission and the individual member States which are

For example, the Department of Health (DH) will “conduct regular surveys to monitor the promotional activities of M&Ds including advertisements in the media, promotional activities at retail level, sales inducement devices, etc.”<sup>100</sup> In addition, 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.”<sup>101</sup> And, “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”,<sup>102</sup> with FEHD having direct responsibility “for investigating complaints related to labelling and quality of formula milk and food products for infants and young children.”<sup>103</sup>

Furthermore, an Advisory Panel (“AP”) comprised of Taskforce members and overseen by a secretariat comprised of DH officials and supported by the FEHD will “oversee the monitoring system”.<sup>104</sup> The AP will “be responsible for considering surveillance/survey reports from DH and FEHD and complaints from the public.”<sup>105</sup> This means that, aside from being authorized to take action in response to public complaints, the AP possesses the authority to refer suspected manufacturer and distributor violations of existing laws (presumably including noncompliance with the Draft HK Code when finalized into legislation), “to the relevant Government departments for investigation and follow-up actions including legal actions under the existing laws.”<sup>106</sup>

These features of the ostensibly ‘voluntary’ Draft HK Code strongly suggest that it will operate as a *de facto* mandatory governmental measure. Although currently voluntary in nature, the Draft HK Code, which is to be implemented sometime during 2013, “is seen as an interim measure prior to related legislation.”<sup>107</sup> Consequently, the Draft HK Code constitutes an “SPS measure”, both in its current voluntary guidelines ‘form’ and its anticipated mandatory legislation ‘form’.

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part of the Group of Five from the perspective of public international law are organs of the European Communities. Accordingly, there can be no doubt that the general moratorium, which is the result of the application of separate decisions by these different EC organs, is attributable to the European Communities...In the light of the foregoing considerations, *we conclude that the general de facto moratorium on approvals constitutes a challengeable EC measure*” (emphasis added). *Id.* The *EC-Biotech* Panel, however, subsequently concluded that the EC’s *de facto* moratorium did not qualify as an “SPS measure within the meaning of Annex A(1) and Article 5.1”, because it did not qualify as “a substantive SPS ‘requirement’” (i.e., it did not establish “a substantive decision to ban biotech products”), a “‘procedure’” (i.e., it did not establish “a procedure for approving or not approving [biotech product] applications...and...did not effectively amend the existing EC approval procedures either”) or “a measure of a different nature” (i.e., “it did not provide for ‘requirements [or] procedures’”) “within the meaning of Annex A(1).” *Id.*, at pars. 7.1338, 7.1358, 7.1358, 7.1360, 7.1362, 7.1371, 7.1378, 7.1380, 7.1383.

100 Draft HK Code, Annex I, par. 4.

101 *Id.*

102 *Id.*, par. 5.

103 *Id.*, par. 9.

104 *Id.*, par. 2.

105 *Id.*

106 *Id.*, pars. 12 and 14.

107 See also Li Likui, *Baby Formula Regulations Applauded*, *supra*. “[T]he Hong Kong government is planning to introduce and enact a labeling and nutrition regulation on formula and food products for infants and young children under 36 months of age. The implementation date has yet to be determined. As an interim measure, the HKG will introduce voluntary guidelines which are to be implemented in 2013 regulating the marketing, labeling and nutrition requirements for formula and food products for infants and young children under 36 months of age” (emphasis added). See Caroline Yuen, *Hong Kong - Food and Agricultural Import Regulations and Standards – Narrative*, GAIN Report Number: HK1233, *supra* at pp. 1-2. “The Hong Kong government (HKG) plans to introduce and enact a legislative regulation in 2013 on the labeling and nutrition requirements for formula and

c. The “Nature” of Certain Draft HK Code Provisions is to Effectively Create a Substantive 30-Month Marketing Ban on Formula Milk and Complementary Food Products for Food Safety Purposes, Which Qualifies Them as “SPS Measures” Within the Meaning of SPS Annex A(1)

The Draft HK Code creates, on food safety grounds, new prohibitions and restrictions collectively establishing a framework of substantive requirements that “impose an effective marketing ban”<sup>108</sup> on formula milk and complementary food products intended for infants and young children up to 36 months of age.

The Draft HK Code imposes three types of 30-month marketing “bans” for food safety-related purposes which will severely curtail the ability of manufacturers, distributors and product licensees to promote, offer for sale and sell such products in the Hong Kong marketplace:

i. Article 4 Prohibits/Restricts Formula Milk Product Informational/Educational Materials From Making Health and Nutrition Claims Relating to Direct Short-term and Indirect Long-term Food Safety Risks

Draft HK Code Article 4.1.1(b) prohibits formula milk manufacturers and distributors from producing and distributing informational/educational materials referring to breastfeeding and formula milk feeding to the general public, pregnant women or mothers of children aged 36 months or below. Draft HK Code Article 4.2.1(a) provides an exception from this prohibition for informational/educational materials *on specific brands of formula milk*, which may be disseminated to the public online at company websites, at retail premises, or at healthcare facilities, provided certain conditions are satisfied. For example, such information must discuss only technical and textual information appearing on the label of the product and contain only information relating to breastfeeding and formula milk feeding in Article 4.4.1(e), including discussion of the food safety-related matters identified in Draft HK Code Article 4.4.1(e)(iii)(F)-(G) discussed above. In other words, these provisions impose restrictions on informational/educational materials intended for the general public, pregnant women or mothers of children aged 36 months or below that require discussion of the direct short-term (bacterial) risks to human life or health that are posed by formula milk products.

Draft HK Code Article 4.2.1(c) and (e) prohibit these same parties from disseminating such informational/educational materials at such locations if intended for the general public, pregnant women or mothers of children aged 36 months or below, *unless* additional conditions are satisfied. Such information must consist of “health claims or nutrition claims regarding the product or its ingredient or constituent” that may be placed legally<sup>109</sup> on product labels and containers<sup>110</sup>, and can

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food products for infants and young children under 36 months of age. (The current nutrition labeling regulation does not cover infant formula and food for children under 36 months of age.) The regulation will not have any provisions regulating manufacturers’ claims. The HKG indicated that the proposed regulation is based on Codex principles and international practices in order not to impede trade, as most formula products and foods intended for infants and young children in Hong Kong are imported from overseas.” *Id.*, at p. 21.

<sup>108</sup> See Panel Report, *EC-Biotech Products*, at pars. 7.1380-7.1381.

<sup>109</sup> Draft HK Code Arts. 4.2.1(c); 8.5.1-8.5.3.

be provided only after such information has been requested.<sup>111</sup> Legally sanctioned health and nutrition claims are those which: 1) “relate[] to sodium, sugars [apparent NCD concerns], vitamins and minerals”;<sup>112</sup> 2) are permitted to be made by a recognized international/national authority;<sup>113</sup> 3) comply with the relevant conditions set by that authority;<sup>114</sup> and 4) whose product labels and containers declare the absolute amount of any nutrient claimed on labels or in advertisements.<sup>115</sup>

The relevant international authority to which Article 4 (by virtue of Article 8.5.1(b)) refers is the Codex Alimentarius Commission (“Codex”). Updated Codex *Guidelines for Use of Nutrition and Health Claims*<sup>116</sup> provide definitions of legally permissible “health claims”<sup>117</sup> and “nutrition claims”<sup>118</sup> relating to sodium,<sup>119</sup> sugar<sup>120</sup> and trans fats,<sup>121</sup> in light of the potential indirect long-term NCD-related risks associated with the consumption of formula milk containing excessive amounts of such nutrients. To such extent, the Draft HK Code imposes an effective ban on the use of informational/educational materials to address such risks in an unsolicited manner.

The relevant national authority to which Article 4 (by virtue of Article 8.5.1(b)) refers is the GHK-SAR Health Department which has promulgated the HK Food and Drugs (Composition and Labelling) Regulations (Cap 132W).<sup>122</sup> Cap 132W is currently being revised to also cover formula milk and other food products intended for infants and young children up to the age of 36 months.<sup>123</sup> Draft

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110 A “label” is broadly defined to include “any tag, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed, attached or otherwise appearing on a container of a designated product.” *Id.*, Art. 3, p. 12.

111 *Id.*, Art. 4.2.1(e).

112 *Id.*, Art. 8.5.1(a).

113 *Id.*, Art. 8.5.1(b).

114 *Id.*, Art. 8.5.1(c).

115 *Id.*, Art. 8.5.1(d).

116 See Codex Alimentarius Commission, *Guidelines for Use of Nutrition and Health Claims*, (“CAC/GL 23-1997”) (Adopted in 1997, Revised in 2004, Amended in 2001, 2008, 2009, 2010, 2011 and 2012), available at: [www.codexalimentarius.org/input/download/standards/351/CXG\\_023e.pdf](http://www.codexalimentarius.org/input/download/standards/351/CXG_023e.pdf). These guidelines provide generally that, “Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.” *Id.*, at Sec. 1.4. “The only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex Guidelines for Nutrition Labelling.” *Id.*, at Sec. 4.1.

117 A “health claim” is “any representation that states, suggests or implies that a relationship exists between a food or constituent of that food and health.” *Id.*, at Sec. 2.2. Health claims include “nutrient function claims”, “other function claims” and “reduction of disease risk claims”. *Id.*, at Sections 2.2.1-2.2.3.

118 A “nutrition claim” is “any representation which states, suggests or implies that a food has particular nutritional properties including, but not limited to, the energy value and to the content of protein, fat, and carbohydrates, as well as the content of vitamins and minerals.” *Id.*, at Sec. 2.1. However, nutrition claims do not include: a) mention of substances in a list of ingredients; b) mention of nutrients required by law as part of nutrition labeling; or c) qualitative or quantitative labeling declarations of nutrients or ingredients required by law. *Id.*

119 *Id.*, at Sections 4.1, 5.2 and 6.3.

120 *Id.*, at Sections 5 and 7.1.

121 *Id.*, at Sections 5, fn. 1 and 6.4.

122 See *Cap 132W Food and Drugs (Composition and Labelling) Regulations* (2008), available at: [http://www.legislation.gov.hk/bliis\\_pdf.nsf/6799165D2FEE3FA94825755E0033E532/42F9D064EB7F23F7482575EE0042C3C4?OpenDocument&bt=0](http://www.legislation.gov.hk/bliis_pdf.nsf/6799165D2FEE3FA94825755E0033E532/42F9D064EB7F23F7482575EE0042C3C4?OpenDocument&bt=0).

123 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), available at: [http://www.cfs.gov.hk/english/food\\_leg/files/Formula\\_Products\\_CD\\_e.pdf](http://www.cfs.gov.hk/english/food_leg/files/Formula_Products_CD_e.pdf).

HK Code provisions on nutritional composition and labelling, including the use of nutrition and health claims, will control until the proposed Cap 132W amendments are enacted.<sup>124</sup>

A review of the legislative history underlying Cap 132 reveals that the GHK-SAR has long been concerned about the indirect long-term risks associated with consumption of foods containing excessive amounts of sugar, sodium, and trans-fats that could potentially lead to NCDs such as cardiovascular diseases and strokes.<sup>125</sup> The Draft HK Code's preamble reflects that the GHK-SAR has similar food safety-related concerns about the presence of excessive amounts of these core nutrients in formula milk and infant and young children's food products.<sup>126</sup>

## ii. Article 8 Prohibits/Restricts Formula Milk and Infant and Young Children's Food Product Containers and Labels From Making Health and Nutrition Claims Relating to Direct Short-term and Indirect Long-term Food Safety Risks

The Draft HK Code container and labeling provisions discussed above apply to all formula milk and infant and young children's food products intended for the general public, including pregnant women or mothers of children aged 36 months or below.

To recall, Draft HK Code Articles 8.2.1(c)(i) and 8.2.1(c)(ii)-(iii) require, respectively, that formula milk product containers and labels contain proper preparation, use and storage directions, and age-appropriate consumption recommendations, with accompanying warnings. Draft HK Code Article 8.2.1(c)(ix) requires that all formula milk product containers and labels comply with applicable Codex standards, including food safety-related standards. Draft HK Code 8.2.1(f)(i)-(iii), which relates back to Draft HK Code Article 8.2.1(c), provides specific instructions for formula milk product consumption, use and storage. In addition, Draft HK Code Article 8.3.1(b)(i)-(ii) provides both infant and young children's food product preparation, use and storage instructions, as well as, age-appropriate consumption instructions and accompanying warnings. Each of these provisions impose prohibitions/restrictions that prescribe new substantive requirements regarding the information that must be contained on formula milk product containers and labels to address the direct short-term food safety-related risks associated with such products.

Moreover, to recall, Draft HK Code Articles 8.2.1(c)(iv)(A)-(B) and 8.3.1(b)(iii)(A)-(B) require, respectively, that formula milk and (nonformula milk) infant and young children's food product containers and labels include a declaration of nutritive value which, among other things, helps to ensure against the inclusion of excessive amounts of nutrients, such as sodium, sugars and trans-fats, in such products. Draft HK Code Articles 8.2.1(c)(ix) and (x) require, respectively, that infant formula and follow-up formula product containers and labels include a declaration of consistency

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<sup>124</sup> *Id.*, at Sec. 3.9, p. 13.

<sup>125</sup> "The Amendment Regulation requires all prepackaged food<sup>7</sup> to label energy plus seven core nutrients, namely (i) protein, (ii) carbohydrates<sup>8</sup>, (iii) total fat, (iv) saturated fat, (v) trans fat, (vi) sodium and (vii) sugars, as well as any nutrient for which a claim is made...In addition to the Codex requirements on energy, protein, carbohydrates and fat, we have included saturated fat, sodium, sugars and trans fat as core nutrients because they are closely associated with cardiovascular diseases and strokes, the major causes of deaths in Hong Kong." See [Legislative Council Brief, Public Health and Municipal Services Ordinance \(Cap. 132\) Food and Drugs \(Composition and Labelling\) \(Amendment: Requirements for Nutrition Labelling and Nutrition Claim\) Regulation\) 2008, at par. 7, p. 3; par. 8.](#)

<sup>126</sup> [Draft HK Code preamble at p. 3, supra.](#)

with applicable Codex and national food safety and other standards relating to nutrient composition, which provides further reassurance of that fact. Draft HK Code Articles 8.2.1(b) and 8.3.1(a) require, respectively, together with Draft HK Code Articles 8.5.1-8.5.3(a), (c)-(d), that only permissible health and nutrition claims regarding sodium, sugars, and trans-fats will appear on formula milk and (nonformula milk) infant and young children's food product containers and labels, for the purpose of communicating information relating to factors that might potentially give rise to NCD risk. Finally, Draft HK Code Article 8.6.1, which effectively serves as a market authorization provision, prohibits formula milk and infant and young children's food products from entering the Hong Kong marketplace if they do not satisfy all of the Draft HK Code's container and labeling requirements. Each of these provisions impose prohibitions/restrictions that prescribe new substantive requirements regarding the information that must be contained on formula milk product containers and labels to address the indirect long-term food safety-related risks associated with such products.

iii. Article 5 Prohibits/Restricts Food Safety-Related Promotion, Including Advertising, of Formula Milk and Infant and Young Children's Food Products by Manufacturers & Distributors

The terms of Draft HK Code Article 5.1 are quite broad, and for this reason, Article 5 is being addressed here. It prohibits manufacturers and distributors from engaging directly or indirectly in any "promotional activities" of formula milk products to all members of the public.<sup>127</sup> Draft HK Code Article 5.2(a) prohibits the promotion by such persons of infant and young children's (nonformula milk) food products to healthcare facilities.<sup>128</sup> Draft HK Code Article 5.4 indicates that prohibited promotional activities include producing and distributing, or sponsoring the production and distribution of, formula-milk feeding-related informational/educational materials not otherwise permitted by Article 4.<sup>129</sup> Draft HK Code Article 5.4 also provides that prohibited promotional activities include "advertising".<sup>130</sup>

Draft HK Code Article 3 defines "advertising", consistent with Cap 132W,<sup>131</sup> as "any form of advertising intended for the general public which is published by any means".<sup>132</sup> It includes advertisements: published in a newspaper or other publication; aired on television or radio broadcast; transmitted via electronic messages (which could include websites and all internet-based

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<sup>127</sup> Draft HK Code Art. 5.1.

<sup>128</sup> Draft HK Code Art. 5.2. "Food products for infants and young children means any food, except formula milk, intended primarily for use during the normal infant's weaning period progressive adaptation of infants and young children to ordinary food, which may be either in ready-to-eat form or in dry form requiring reconstitution with water, milk or other suitable liquids, and includes complementary food." Draft HK Code Art. 3, pp. 9-10. It also means "any food, except formula milk, for special medical purposes which are specially processed or formulated and presented for the dietary management of infants and young children and may be used only under medical supervision and are 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." *Id.*, at p. 10.

<sup>129</sup> *Id.*, Art. 5.4(d).

<sup>130</sup> *Id.*, Art. 5.4(a).

<sup>131</sup> *Id.*, Art. 3. fn. 7; See *Cap 132W Food and Drugs (Composition and Labelling) Regulations* (2008), *supra* at Regulation 2(1), p. 1.

<sup>132</sup> Draft HK Code, Art. 3, p. 8.

communications rather than merely electronic mail messages)<sup>133</sup>; displayed on notices, signs, “labels”, show-cards or goods; distributed in the form of samples, circulars, catalogues, price lists or other materials; and exhibited on pictures, models or films.<sup>134</sup>

Codex defines “advertising” as a complement to its definition of “labeling”.<sup>135</sup> Advertising includes “any commercial communication to the public, by any means *other than labelling*, in order to promote directly or indirectly, the sale or intake of a food *through the use of nutrition and health claims in relation to the food and its ingredients*” (emphasis added).<sup>136</sup> In other words, to the extent food advertising claims bear upon food safety and could potentially affect the health of consumers, they fall within the jurisdiction of Codex – specifically, the Codex Committee on Food Labeling.<sup>137</sup>

Although the scope of Draft HK Code Article 5’s advertising provisions are much broader than that the provisions of Draft HK Code Articles 4 and 8 more narrowly aimed at more specific forms of product promotion, they are similarly food safety-related in two ways. First, Draft HK Code Article 5 indirectly reflects the GHK-SAR’s view that commercial advertising is being aggressively employed<sup>138</sup> to understate the direct short-term food safety-related risks to infant life or health associated with the improper preparation, use, and storage of powdered formula milk products. Second, Draft HK Code Article 5 also indirectly reflects GHK-SAR view that such product advertising is being employed to convey nutrition and/or health claims that understate the true sodium, sugar and trans-fats content of formula milk and (nonformula milk) infant and young children’s food products, and consequently, the long-term risks that excessive content of such nutrients poses to infant life or health as a potential contributory factor to non-communicable disease (e.g., hypertension, obesity)

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133 See U.S. Department of Agriculture, Foreign Agricultural Service, *U.S. Government Comments on the Draft Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Child* (Jan. 17, 2013), available at: [http://www.fhs.gov.hk/english/news/hkcode/written\\_comments/organisation/O0002.pdf](http://www.fhs.gov.hk/english/news/hkcode/written_comments/organisation/O0002.pdf).

134 *Id.*

135 “‘Labelling’ includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.” See Codex Alimentarius Commission, *General Standard for Labelling of Prepackaged Foods*, (“CODEX STAN 1-1985”), at Sec. 2, available at: [http://www.codexalimentarius.org/input/download/standards/32/CXS\\_001e.pdf](http://www.codexalimentarius.org/input/download/standards/32/CXS_001e.pdf).

136 See CAC/GL 23-1997, *supra* at Sec. 1.1, fn. 1.

137 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme Codex Committee on Food Labelling Thirty-fourth Session, *Discussion Paper on Advertising*, Agenda Item 8 (CX/FL 06/34/10) (May 1-5, 2006), available at: [ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl34/fl34\\_10e.pdf](ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl34/fl34_10e.pdf). “As indicated in the report of the FAO/WHO legal counsel of 1984, “there can be no doubt that advertising is an essential part of marketing, which in turn is an important part of trade. Nor can there be any doubt that some marketing practices, in particular when connected with advertising, may mislead the consumer to the point where their health may be endangered, or may constitute unfair practices in the food trade” (CX/FL 85/7, Appendix II)...*The 1984 legal opinion includes advertising within the scope of CCFL. Codex has within its mandate to address advertising with respect to protecting the health of the consumers and promoting fair practices in the food trade. The control of advertising may be considered as completely incidental and consequential, or complementary, to the control of labelling...*It should be noted that the Commission, at their 16th Session (July, 1985), noted that *the legal opinions of FAO/WHO had confirmed that work on advertising was within the terms of reference of CCFL*” (emphasis added). *Id.*, at pp. 5-6.

138 “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”. See Draft HK Code, Background, p. 2. “The Government has all along endeavoured to promote, protect and support optimal feeding of infants and young children. In February 2010, the *Steering Committee on Prevention & Control of Non-Communicable Diseases*, chaired by the Secretary for Food and Health, endorsed the proposal of developing and implementing a code of marketing of breastmilk substitutes, which is part of an action plan recommended by the Working Group on Diet and Physical Activities under the Steering Committee to promote healthy diet and physical activity in Hong Kong. The proposal was made in response to the aggressive marketing of formula milk in Hong Kong” (emphasis added). *Id.*, p. 3.

contracted later in life.<sup>139</sup> Therefore, to such extent, these Article 5 provisions can be construed as addressing direct short-term and indirect long-term food safety-related risks, and thus, as qualifying as “SPS measures” within the meaning of SPS Annex A(1).

The cumulative effect of these Article 4 (informational/educational material), Article 8 (product container and labeling), and Article 5 (advertising) provisions is to impose new food safety-related substantive requirements that ban the marketing in Hong Kong of formula milk (infant formula and follow-up formula) and (nonformula milk) infant and young children’s food products intended for the general public, especially, to pregnant women or mothers of children aged 36 months or below. This 30-month marketing ban will serve to deny manufacturers, distributors and licensees the opportunity to offer for sale and to sell such food products in the Hong Kong marketplace for a period of time that is far longer than the 6/24 month period of exclusive/partial breastfeeding recommended by the WHO Code. Since these provisions aim to address direct short-term and indirect long-term food safety-related risks to infant life or health, and are most certainly capable of directly and indirectly affecting international trade in such products, they, along with the provisions of Draft HK Code Articles 4 and 8, also qualify as “SPS measures” under SPS Article 1,<sup>140</sup> and thus, fall within the coverage of the SPS Agreement.

### 3. Various Draft HK Code Provisions Are Based On International Standards

#### a. SPS Measures Shall Be Based On International Standards Where They Exist

SPS Article 3.1 requires WTO Members to “base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist”.<sup>141</sup> The Appellate Body has determined that an SPS measure is “based on” an international standard “when the former ‘stands’ or is ‘founded’ or is ‘built’ upon or ‘is supported by’ the latter.”<sup>142</sup> A national SPS measure

139 “The risks of developing NCD accumulate with age and are influenced by factors acting at all stages of life. Thus, interventions throughout life can help prevent progress of diseases. Those that secure growth and development in early life, and maintain the highest possible level of health and function in adult life are important in reducing the risk of NCD in later years.” See Department of Health, Hong Kong Special Administrative Region of China, *Promoting Health in Hong Kong: A Strategic Framework for Prevention and Control of Non-communicable Diseases* (2011), at par. 6.6, p. 69, available at: [http://www.dh.gov.hk/english/pub\\_rec/pub\\_rec\\_ar/pdf/ncd/ENG%20whole%20DOC%2016-10-08.pdf](http://www.dh.gov.hk/english/pub_rec/pub_rec_ar/pdf/ncd/ENG%20whole%20DOC%2016-10-08.pdf). “For newborns (up to one month) and infants (up to one year), growth and development are of prime importance. *Prevention for these very young children should include issues like breastfeeding, appropriate and nutritious complementary foods, good hygiene practices, and caring behaviours that contribute to healthy development.*” *Id.*, at Exhibit 45, p. 70.

140 “[I]t is not necessary to demonstrate that an SPS measure has an actual effect on trade’...[SPS] Article 1.1...merely requires that an SPS measure ‘may, directly or indirectly, affect international trade.’” Panel Report, *US-Poultry (China)*, at par. 7.89, quoting Panel Report, *EC-Biotech Products*, at par. 7.435.

141 SPS Art. 3.1. This has led one commentator to conclude that “all Codex actions, including recommendations and guidelines that were intended by the [Codex Alimentarius] Commission to be non-binding, are actionable in WTO.” See Bruce A. Silverglade, *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?*, 55 Food and Drug Law Journal 517, 523, available at: <http://www.who.int/mta/Doc7.pdf>. “International standards, guidelines and recommendations are, by their very nature, non-binding norms. However, through their explicit recognition in the SPS Agreement, such norms do indeed, acquire a certain force, most importantly, by creating a presumption of WTO/SPS compatibility.” See United Nations Conference on Trade and Development, *Training Module on the WTO Agreement on Sanitary and Phytosanitary Measures* UNCTAD/DITC/TNCD/2004/3 (2004) at p. 6, available at: [http://unctad.org/en/Docs/ditctncd20043\\_en.pdf](http://unctad.org/en/Docs/ditctncd20043_en.pdf).

142 Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* (“*EC-Hormones*”) WT/DS26/AB/R WT/DS48/AB/R (Jan. 16, 1998), at par. 163.

will be considered to be “based on” an international standard if at least “some...of the elements of the standard are incorporated into the measure.”<sup>143</sup>

SPS Article 3.2 provides that national “[SPS] measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human...life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.”<sup>144</sup> According to the Appellate Body, “much more is required before one thing may be regarded as ‘conform[ing] to’ another: the former must ‘comply with’, ‘yield or show compliance’ with the latter. The reference of ‘conform to’ is to ‘correspondence in form or manner’, to ‘compliance with’ or ‘acquiescence’, to ‘follow[ing] in form or nature’.”<sup>145</sup> “A measure that ‘conforms to’ and incorporates a Codex standard is, of course, ‘based on’ that standard,” but a measure that contains “only some, not all, of the elements of [that] standard...might not conform to that standard.”<sup>146</sup>

The international standards, guidelines or recommendations to which SPS Article 3.1 refers consist of those developed by the “relevant international organizations”. These include “the Codex Alimentarius Commission (“Codex”), the International Office of Epizootics (“OIE”), and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention (“IPPC”).”<sup>147</sup> Although the WTO SPS Committee may recognize a new international standard, guideline or recommendation developed by another international organization open for membership to all WTO Members, such a standard, guideline or recommendation must concern a subject matter falling within the scope of the SPS Agreement and must not already be “covered by [the Codex, OIE or IPPC]”.<sup>148</sup>

Since various provisions of the WHO Code and subsequent WHA resolutions address food safety-related concerns,<sup>149</sup> they arguably concern a subject matter falling within the scope of the SPS

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143 *Id.*

144 SPS Art. 3.2.

145 Appellate Body Report, *EC-Hormones*, par. 163.

146 *Id.*

147 SPS Preamble par. 4; SPS Arts. 3.4, 12.3.

148 SPS Annex A(3)(d).

149 WHO Code Article 4.2 provides that when informational and educational materials contain information about the use of infant formula, they should include “the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes.” WHO Code, Art. 4.2. WHO Code Articles 2 and 5.1 prohibit “advertising and any other form of promotion to the general public” “of products within the scope of this Code”, which includes “infant formula; other milk products, foods and beverages, including bottled complementary foods” when marketed as breastmilk substitutes. WHO Code Arts. 2 and 5.1. WHO Code Article 9.2 provides that manufacturers and distributors of infant formula should ensure that each container or label include “(d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation.” WHO Code, Art. 9.2. In addition, two WHA resolutions which elaborate on the WHO Code address food safety-related matters. They both call upon WHO Member States to ensure that nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation”. See WHA 58.32 - Infant and Young Child Nutrition, 58th World Health Assembly (May 25, 2005), par. 1(2), available at: [http://www.who.int/nutrition/topics/WHA58.32\\_icycn\\_en.pdf](http://www.who.int/nutrition/topics/WHA58.32_icycn_en.pdf); WHA 63.23 - Infant and Young Child Nutrition (May 21, 2010), at par. 1(4), available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R23-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R23-en.pdf). Draft HK Code Art. 4.2.1(c) responds to this call. WHA 58.32 calls upon Codex to “establish standards, guidelines and recommendations on foods for infants and young children...that ensure[d] the development of safe and appropriately labeled products that meet their known nutritional and safety needs”. See WHA 58.32, par. 2(2). Draft HK Code Articles 8.2.1(b), 8.3.1(a), and 8.5.1-8.5.2 respond to this call. In addition, WHA 58.32 also calls upon Codex “to address[] the risk of

Agreement that is already covered by Codex standards. Consequently, consistent with SPS Annex A(3)(d), they have not been recognized by the WTO SPS Committee as relevant international standards for purposes of the SPS Agreement.<sup>150</sup>

#### b. Various Draft HK Code Provisions Addressing Direct Short-Term Bacterial Infection-Related Risks Are Based On Codex Standards

As previously discussed, the SPS Agreement explicitly refers to the Codex as a relevant international standards organization and to Codex standards as international standards. The Draft HK Code incorporates by reference ten Codex standards covering the safe use, preparation and storage of formula milk and (nonformula) infant and young child food products. Four of these Codex standards are definitional: “infant”,<sup>151</sup> “infant formula”,<sup>152</sup> “follow-up formula”,<sup>153</sup> and “young child”.<sup>154</sup> The Draft HK Code employs these definitions throughout the food safety-related subsections of Articles 4 (informational/educational materials), 5 (promotion/advertising), and 8 (product container and labeling). In addition to these Codex standards, the Draft HK Code also incorporates by reference in Article 8 six other Codex standards. They address declarations of nutritive value<sup>155</sup> for infant formula,<sup>156</sup> follow-up formula,<sup>157</sup> canned baby food,<sup>158</sup> processed cereal-based foods<sup>159</sup> and

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microbiological contamination of powdered infant formula and establish appropriate microbiological criteria or standards related to *E. sakazakii* and other relevant microorganisms in powdered infant formula”. *Id.*, par. 2(3).

150 This lack of recognition has prompted the International Baby Food Action Network (“IBFAN”) to demand that “*The International Code of Marketing of Breast-milk Substitutes and relevant subsequent World Health Assembly (WHA) resolutions should be totally and explicitly exempted from WTO trade agreements.* In that way they cannot be challenged as being ‘barriers to trade’ on the basis of these agreements” (emphasis in original). See IBFAN, *The International Code in Relation to Agreements of the World Trade Organisation: Health Versus Trade Interests*, Breastfeeding Brief No. 33 (Dec. 2001), at p. 1, available at: <http://www.ibfan.org/art/BB%2033.pdf>. This briefing makes abundantly clear that IBFAN had, at one time, considered the prospects of the SPS Agreement recognizing the WHO Code as an international standard, but decided against it in favor of pursuing an extra-WTO United Nations human rights advocacy approach devoid of economic considerations. “The so-called SPS and TBT agreements of the WTO acknowledge that governments have the right to take measures ‘necessary’ for the protection of human health. In these agreements Member States of the WTO are encouraged to base their measures on “international standards, guidelines or recommendations”. *The SPS agreement also explicitly refers to the Codex Alimentarius (food safety) standards. One of the key questions for the participants of the Amsterdam meeting was: would it be helpful if the Code were officially recognised in relevant WTO agreements?* At first sight one would say ‘yes’, because the WTO agreements are likely to outweigh decisions taken in the WHA, such as the Code, because of WTO’s authority to impose sanctions. The industry might then have more respect for the Code. However, we see a number of dangers here. WTO is less transparent than UN organisations and heavily influenced by industry. Since the Codex Alimentarius is officially recognised under WTO there is an apparent shift from addressing public interests to facilitating trade (i.e. lowering trade barriers). *Attempts to get the Code included in WTO agreements or standards may turn out to be counterproductive. In other words, the Code may then be transformed from a ‘minimum requirement’ (for governments to implement into a measure for the protection of health) to a ‘maximum requirement’ (that protects public health while posing minimal barriers to international trade).* The Code should be defended from a human rights perspective: that is that life and health are of an intrinsic value which should not be compromised by trade or commercial interests” (emphasis added). *Id.*, at p. 1.

151 Draft HK Code, Art. 3, p. 11, fn.1, citing CODEX STAN 72 – 1981, *supra*, at Sec. 2.2.

152 Draft HK Code, Art. 3, p. 12, fn. 1 and 10, citing CODEX STAN 72 – 1981, *supra*, Sec. 2.1.1; CAC/RCP 66 – 2008, *supra*, at Sec. 2.3.

153 Draft HK Code, Art. 3, p. 9, fn. 2 and 10, citing CAC/RCP 66 - 2008, *supra*, at Sec. 2.3; CODEX STAN 156-1987, *supra* at Sections 2.1.1 and 2.2.

154 Draft HK Code Art. 3, p. 15, fn. 2, citing CODEX STAN 156-1987, *supra*, at Sec. 2.1.3.

155 Draft HK Code Art. 3, p. 14.

156 See Draft HK Code Arts. 8.2.1(c)(iv)(A) and 8.2.1(c)(ix), referencing CODEX STAN 72-1981, *supra* at Sec. 9.3, pp. 12 and 20.

157 See Draft HK Code Art. 8.2.1(c)(iv)(B), referencing CODEX STAN 156-1987, *supra* at Sec. 9.3, pp. 8-9.

158 See Draft HK Code Art. 8.3.1(b)(iii)(A), referencing CODEX STAN 73-1981, *supra* at Sec. 9.3, p. 5.

159 See Draft HK Code Art. 8.3.1(b)(iii)(B); CODEX STAN 074-1981, REV. 1-2006, *supra* at Sec. 8.4, pp. 8-9.

prepackaged foods generally.<sup>160</sup> These latter six Codex standards concern mostly direct short-term food safety-related risks associated with formula milk products.<sup>161</sup> These food safety-related subsections of such Draft HK Code provisions are based on, and go beyond international standards.

### c. Various Draft HK Code Provisions Addressing Indirect Long-Term Diet-Related NCD Risks Are Based On Evolving Codex Standards

To recall, Hong Kong's Cap 132W regulations currently "cover[] all food including formula products and foods intended for infants and young children under the age of 36 months," and it is being revised because it has "no specific provisions...governing the requirements and standards of nutritional composition" of such products.<sup>162</sup> Corresponding Draft HK Code "[p]rovisions on nutritional composition and labelling, including the use of nutrition and health claims" (i.e., Article 8 subsections requiring declarations of nutritive value, nutrient composition and/or nutrient and health claims)<sup>163</sup> will control until the proposed Cap 132W amendments are enacted.<sup>164</sup> These provisions, as well as the Draft HK Code Article 4 subsections restricting informational/educational materials to declarations of health and nutrition claims and other textual information required by the Code's labeling provisions,<sup>165</sup> reflect GHK-SAR concerns about indirect long-term diet-related NCD risks arising over time from consumption of formula milk and (nonformula milk) infant and young children's food products.

These Draft HK Code Article 8 provisions, which effectively impose an "additional requirement on labeling the sodium content in non-cereal-based foods for infants and young children",<sup>166</sup> and which may also serve as the basis for further limiting the textual content of informational/educational materials for purposes of Draft HK Code Article 4, arguably go beyond current Codex standards. Current Codex standards "only require[] sodium to be labelled in processed cereal-based foods intended for infants and young children under the age of 36 months."<sup>167</sup> "Codex does not have mandatory labelling requirement on sodium in all non-cereal-based foods for infants and young children under the age of 36 months"<sup>168</sup>

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160 See Draft HK Code Art. 8.3.1(b)(iii)(C); CODEX STAN 146-1985, *supra* at Sec. 4.3, p.1.

161 To the extent Codex standards applicable to declarations of nutritive value are intended to address purely consumer informational concerns they are arguably non-food safety-related non-SPS measures. See discussion *supra*.

162 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), *supra*, at Sections, 1.3 and 3.9.

163 See Draft HK Code Arts. 8.2.1(c)(iv)(A)-(B), 8.3.1(b)(iii)(A)-(B); 8.2.1(c)(ix)-(x); 8.5.1-8.5.3.

164 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), *supra*, at Sec. 3.9.

165 See Draft HK Code Arts. 4.2.1(a) and (c); 8.5.1-8.5.3.

166 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), *supra* at par. 5.1.

167 See LegCo Panel on Food Safety and Environmental Hygiene, *Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months* (March 12, 2013) ("*LegCo Panel Paper - March 2013*"), at par. 29, available at: [http://www.cfs.gov.hk/english/food\\_leg/files/Formula\\_Products\\_for\\_Infants/Panel\\_Paper\\_e.pdf](http://www.cfs.gov.hk/english/food_leg/files/Formula_Products_for_Infants/Panel_Paper_e.pdf). See also CODEX STAN 074-1981, REV. 1-2006, *supra* at Sec. 3.6.1.

168 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), *supra* at par. 5.3.

The record reveals that the GHK-SAR based its decision to seek adoption of these provisions on “the widely recognized...impacts of early nutrition on long-term health,”<sup>169</sup> the belief that “[e]xcessive intake of sodium should be avoided at a young age”,<sup>170</sup> and “evidence suggesting that Chinese people are particularly susceptible to dietary salt-induced high blood pressure because [they] lack an efficient mechanism to facilitate kidney excretion of salt (sodium)”.<sup>171</sup> Apparently, the GHK-SAR also decided to seek adoption of such measures because it found that “the United States, Australian, New Zealand and the European Union have also required labeling of sodium content in other foods intended for infants and young children.”<sup>172</sup> In addition, the GHK-SAR may have likely anticipated the adoption of evolving Codex standards that mandate the labeling of nutrients such as sodium and saturated fats deemed associated with diet-related NCD risks.<sup>173</sup>

The record also reveals, however, that the GHK-SAR pursued such measures even though these Draft HK Code/Cap 132W labeling provisions lack any supporting scientific “data to show that high sodium intake by humans at early age would lead to...hypertension...in later life.”<sup>174</sup> Although the GHK-SAR had considered that Hong Kong “would not be challenged at the World Trade Organization for setting up a trade barrier,”<sup>175</sup> it may have miscalculated.

#### 4. SPS Measures Shall Be Subject to Scientific Justification Where International Standards Do Not Exist or Are Deemed Insufficient to Meet a WTO Member’s Appropriate Level of Protection [“ALOP”]

SPS Article 3.3 states that where international standards do not exist or a WTO Member chooses, as a matter of qualified right,<sup>176</sup> to adopt “SPS measures which result in a higher level of protection than would be achieved by measures based on...international standards, guidelines or recommendations”, the WTO Member must provide scientific justification to substantiate that choice.<sup>177</sup> A WTO Member will be deemed to have provided scientific justification if it has shown that it has “evaluat[ed] available scientific information in conformity with the relevant provisions of this Agreement [and] determin[e] that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary

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169 *LegCo Panel Paper - March 2013*, supra at par. 2.

170 *Id.*, at par. 29. “Sodium is necessary for the proper functioning of the body. However, prolonged excessive intake of sodium may increase the risk of developing high blood pressure.” *Id.*

171 *Id.*

172 *Id.* See also Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), supra at par. 5.3.

173 See discussion, *infra*.

174 See Hong Kong Food and Health Bureau, Food and Environmental Hygiene Department Centre for Food Safety, *Consultation Document - Legislative Proposals Relating to Formula Products and Foods Intended for Infants and Young Children under the Age of 36 Months in Hong Kong* (Nov. 2012), supra at par. 5.2.

175 *Id.*, at par. 5.3.

176 “Under Article 3.3 of the SPS Agreement, a Member may decide to set for itself a level of protection different from that implicit in the international standard, and to implement or embody that level of protection in a measure not “based on” the international standard. The Member’s appropriate level of protection may be higher than that implied in the international standard. The right of a Member to determine its own appropriate level of sanitary protection is an important right.” See Appellate Body Report, *EC-Hormones* at par. 172. “The right of a Member to define its appropriate level of protection is not, however, an absolute or unqualified right.” *Id.*, at par. 173.

177 SPS Art. 3.3.

protection [‘ALOP’].”<sup>178</sup> A WTO Member may otherwise show that it has “determine[d]...the level of sanitary or phytosanitary protection...to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5”<sup>179</sup> – by undertaking a risk assessment meeting the requirements of SPS Article 5, as defined by Annex A(4).<sup>180</sup>

While the text of Article 3.3 would appear to present two real options, the Appellate Body, in *EC-Hormones*, ruled that they are actually one and the same.<sup>181</sup> As the Panel in *EC-Biotech Products* ultimately concluded, this means that a WTO Member seeking to scientifically justify national measures which result in a higher level of protection than what could be achieved under an international Codex standard “is obliged to meet the requirements of Article 5.1 and base its measures on a risk assessment.”<sup>182</sup>

a. A Higher Level of Protection Measure Must Be Scientifically Justified Pursuant to a Risk Assessment As Defined by SPS Article 5 and Annex A(4)

SPS Article 5.1 “enunciates the basic principle that SPS measures<sup>183</sup> must be based on a risk assessment,”<sup>184</sup> “as appropriate to the circumstances,” of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”<sup>185</sup> “[O]ne of the purposes of a risk assessment [as defined by Annex A(4)] is to allow

178 SPS Art. 3.3, fn. 2.

179 SPS Art. 3.3.

180 Appellate Body Report, *EC-Hormones* at par. 175.

181 *Id.*, at pars. 175-176. Article 3.3 is evidently not a model of clarity in drafting and communication. The use of the disjunctive ‘or’ does indicate that two situations are intended to be covered. These are the introduction or maintenance of SPS measures which result in a higher level of protection: (a) ‘if there is a scientific justification’; or (b) ‘as a consequence of the level of...protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5’. It is true that situation (a) does not speak of Articles 5.1 through 5.8. Nevertheless, two points need to be noted. First, the last sentence of Article 3.3 requires that ‘all measures which result in a [higher] level of ... protection’, that is to say, measures falling within situation (a) as well as those falling within situation (b), be ‘not inconsistent with any other provision of [the SPS] Agreement’. ‘Any other provision of this Agreement’ textually includes Article 5. Secondly, the footnote to Article 3.3, while attached to the end of the first sentence, defines ‘scientific justification’ as an ‘examination and evaluation of available scientific information in conformity with relevant provisions of this Agreement...’. This examination and evaluation would appear to partake of the nature of the risk assessment required in Article 5.1 and defined in paragraph 4 of Annex A of the SPS Agreement...[Thus,] the distinction made in Article 3.3 between two situations may have very limited effects and may, to that extent, be more apparent than real.” *Id.* The Appellate Body ultimately found that the European Communities was “bound to comply with the requirements established in Article 5.1. *Id.* at par. 176.

182 See Panel Report, *EC-Biotech* at par. 4.623. “Article 3.3 is not merely a ‘qualified exemption’ from the basic obligation in Article 3.1 to base such measures on international standards. It is the expression of the ‘autonomous right’ of WTO Members to establish their own appropriate levels of protection, including levels of protection that are higher than those implied by the relevant international standards. However, a Member choosing the second option is obliged to meet the requirements of Article 5.1 and base its measures on a risk assessment consistent with the definition found in Annex A.1 of the SPS Agreement” (emphasis added). *Id.*

183 “In our view, the term ‘SPS measure’ in Article 5.1 should be taken to refer to a measure applied for achieving the relevant Member’s appropriate level of sanitary or phytosanitary protection. We note in this regard that Article 5.3 of the SPS Agreement provides in relevant part that ‘[i]n determining the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection, Members shall take into account [certain] economic factors’. Thus, Article 5.3 establishes a link between the assessment of risk and the determination of ‘the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk” (emphasis in original). See Panel Report, *EC-Biotech Products*, par. 7.1388.

184 Panel Report, *US-Poultry(China)* at par. 7.170.

185 SPS Art. 5.1

the importing Member to determine ‘the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection’ [ALOP]. And one of the purposes of the requirement that SPS measures be based on a risk assessment is to ensure that the measure actually applied for achieving the appropriate level of sanitary or phytosanitary protection [ALOP] bears a rational relationship to the risk.”<sup>186</sup> A risk assessment is fundamentally a “‘scientific process aimed at establishing the scientific basis’ for the SPS measure.”<sup>187</sup>

SPS Article 5.2 instructs WTO Members on how to conduct such a risk assessment, and “sheds light on the elements that are of relevance in the assessment of risks foreseen in” SPS Article 5.1.<sup>188</sup> SPS Article 5.2 provides that risk assessments are to be conducted by “tak[ing] into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine and other treatment.”<sup>189</sup> It must first be determined whether a risk assessment was conducted at all. Then, it must be determined whether the required risk assessment was performed, and whether the SPS measure in question was based on the required risk assessment.<sup>190</sup>

SPS Annex A(4) defines the type of risk assessment needed to analyze ‘the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food, beverages or feedstuffs’.<sup>191</sup> A risk assessment under SPS Annex A(4) “require[s] the imposing Member to: (i) identify the additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs at issue (if any); (ii) identify any possible adverse effect on human or animal health; and (iii) evaluate the potential for that adverse effect to arise from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”<sup>192</sup> Said “requirement to conduct a risk assessment is not satisfied merely by a general discussion of the disease sought to be avoided by the imposition of an SPS measure.”<sup>193</sup> “Rather, the risk assessment must address the specific risk at issue.”<sup>194</sup> “[A] risk assessment should refer in general to the harm concerned as well as to the precise agent that may possibly cause the harm.”<sup>195</sup>

SPS Article 5.1 does not require a WTO Member adopting/imposing a sanitary measure to “have carried out its own risk assessment.”<sup>196</sup> A WTO Member adopting/imposing a sanitary measure may rely on “‘a risk assessment carried out by another Member or an international organization’”.<sup>197</sup>

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186 Panel Report, *EC-Biotech Products* par. 7.1388, fn. 1242-1243. “[T]he requirement of a risk assessment ‘was intended as a countervailing factor in respect of the right of Members to set their appropriate level of protection’” *Id.*, quoting Appellate Body Report, *EC – Hormones*, par. 177.

187 Appellate Body *US - Continued Suspension*, at par. 527; Appellate Body Report, *EC - Hormones* at par. 187.

188 Panel Report, *US-Poultry(China)* at par. 7.172.

189 SPS Art. 5.2.

190 Panel Report, *US-Poultry(China)* at pars. 7.173-7.174.

191 *Id.*, at par. 7.176, quoting SPS Annex (A)4.

192 Panel Report, *US-Poultry(China)* at par. 7.178; Panel Report, *Canada - Continued Suspension*, WT/DS321/R, at par. 7.479 (March 31, 2008).

193 Panel Report, *US-Poultry(China)* at par. 7.179; Appellate Body Report, *Japan – Measures Affecting the Importation of Apples (“Japan – Apples”)*, WT/DS245/AB/R (Nov. 26, 2003) at par. 202.

194 Panel Report, *US-Poultry(China)* at par. 7.179; Appellate Body Report, *US - Continued Suspension*, at par. 559.

195 Panel Report, *US-Poultry(China)* at par. 7.179; Appellate Body Report, *Japan – Apples*, par. 202.

196 Panel Report, *US-Poultry(China)* at par. 7.182; Appellate Body Report, *EC – Hormones*, par. 194.

Furthermore, SPS jurisprudence reflects that, “a risk assessment can take into account ‘matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences’”<sup>198</sup> – i.e., by use of qualitative methods. In other words, “a ‘risk assessment’ involves an indication of potentiality, even though this need not be expressed in numerical terms or as a minimum quantification of the level of risk.”<sup>199</sup> Consequently, a WTO “Panel’s reference to ‘potential occurrence’ of adverse health effects could be read consistently with the definition of a risk assessment in [SPS Annex A(4)].”<sup>200</sup>

“Article 5.1...requires that the results of the risk assessment must sufficiently warrant – that is to say, reasonably support – the SPS measure at stake.’ In other words, there must be a ‘rational relationship’ between the SPS measure and the risk assessment”;<sup>201</sup> while the SPS measure must be “based on” a risk assessment, it need not “conform to” the risk assessment.<sup>202</sup> This means that, “the risk assessment need not ‘come to a monolithic conclusion that coincides with the scientific conclusion or view implicit in the SPS measure’”, or “‘embody only the view of a majority of the relevant scientific community.’”<sup>203</sup> Thus, “an approach based on a divergent opinion from a qualified and respected source, ‘does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute a clear and imminent threat to public health and safety.’”<sup>204</sup>

SPS jurisprudence also reflects that where a WTO Member “adopts an SPS measure resulting in a higher level of protection than would be achieved by measures based on international standards...it may need scientific information that was not examined in the process leading to the adoption of the international standards...[in order] to perform a risk assessment.”<sup>205</sup> In such cases, neither SPS Article 3.3 nor SPS Article 5.1 require the Member to “frame the scope and methods of its risk assessment, including the scientific information to be examined, in the same manner as the international body that performed the risk assessment underlying the international standard.”<sup>206</sup> “Thus, where the chosen level of protection is higher than would be achieved by a measure based on an international standard, this may have some bearing on the scope or method of the risk assessment – [i.e.,]...it may require [the Member] to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.”<sup>207</sup>

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197 Panel Report, *US-Poultry(China)* at par. 7.182; Appellate Body Report, *EC – Hormones*, par. 190; Panel Report, *EC – Biotech Products* at, par. 7.3024.

198 Panel Report, *US – Continued Suspension*, WT/DS320/R (March 31, 2008), at par. 7.520; Appellate Body Report, *EC – Hormones*, par. 187.

199 Appellate Body Report, *US - Continued Suspension*, WT/DS320/AB/R (Oct. 16, 2008) at par. 574.

200 *Id.*, at par. 575.

201 Panel Report, *US-Poultry(China)* at par. 7.180; Appellate Body Report, *EC - Hormones*, at pars. 193-194.

202 Panel Report, *US-Poultry(China)* at par. 7.180; Appellate Body Report, *US - Continued Suspension*, at par. 528.

203 Panel Report, *US-Poultry(China)* at par. 7.181; Appellate Body Report, *EC - Hormones*, at par. 194.

204 *Id.*

205 Appellate Body Report, *US - Continued Suspension*, at par. 685.

206 *Id.*

207 *Id.*

## b. The Higher Level of Protection Measure Must Be Based On the Risk Assessment

Moreover, a “risk assessment cannot be entirely isolated from the appropriate level of protection [ALOP]”,<sup>208</sup> especially where a WTO Member has “decide[d] not to adopt an SPS measure based on an international standard<sup>209</sup> because it seeks to set a higher level of protection.”<sup>210</sup> In such instances the higher ALOP “chosen by a Member [can] affect[] the scope or method of the risk assessment”,<sup>211</sup> since it “may require it to perform certain research as part of its risk assessment that is different from the parameters considered and the research carried out in the risk assessment underlying the international standard.”<sup>212</sup> Nevertheless, “the chosen level of protection must not affect the rigour or objective nature of the risk assessment, which must remain, in its essence, a process in which possible adverse effects are evaluated using scientific methods.”<sup>213</sup>

This means that a WTO “panel reviewing the consistency of an SPS measure with Article 5.1 must determine whether that SPS measure is ‘based on’ a risk assessment. [While i]t is the WTO Member’s task to perform the risk assessment...[it is t]he panel’s task...to review that risk assessment.”<sup>214</sup> A WTO panel risk assessment review entails 4 steps, all of which must be satisfied.

First a WTO panel “must identify the scientific basis upon which the SPS measure was adopted. This scientific basis need not reflect the majority view within the scientific community but may reflect divergent or minority views.”<sup>215</sup>

Second, a WTO panel “must then verify that the scientific basis comes from a respected and qualified source. Although the scientific basis need not represent the majority view within the scientific community, it must nevertheless have the necessary scientific and methodological rigour to be considered reputable science. In other words, while the correctness of the views need not have been accepted by the broader scientific community, the views must be considered to be legitimate science according to the standards of the relevant scientific community.”<sup>216</sup>

Third, a WTO panel “should also assess whether the reasoning articulated on the basis of the scientific evidence is objective and coherent. In other words, a panel should review whether the particular conclusions drawn by the Member assessing the risk find sufficient support in the scientific evidence relied upon.”<sup>217</sup>

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208 Panel Report, *US-Poultry(China)* at par. 7.179.

209 Appellate Body Report, *US - Continued Suspension*, at par. 5; Appellate Body Report, *EC-Hormones* at par. 104.

210 Appellate Body Report, *US - Continued Suspension*, at par. 534.

211 *Id.*

212 *Id.*

213 According to the Appellate Body, “whatever the level of protection a Member chooses does not pre-determine the results of the risk assessment. Otherwise, the purpose of performing the risk assessment would be defeated.” *Id.*

214 Appellate Body Report, *US - Continued Suspension*, at par. 590. “Therefore, the review power of a panel is not to determine whether the risk assessment undertaken by a WTO Member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.” *Id.*

215 *Id.*, par. 591.

216 *Id.*

217 *Id.*

Fourth, a WTO panel “must determine whether the results of the risk assessment ‘sufficiently warrant’ the SPS measure at issue. Here, again, the scientific basis cited as warranting the SPS measure need not reflect the majority view of the scientific community provided that it comes from a qualified and respected source.”<sup>218</sup>

c. An SPS Measure Must Alternatively Be Based on Sufficient Scientific Evidence

SPS Article 2.2 generally provides that an SPS measure must not be maintained without sufficient scientific evidence.<sup>219</sup> A measure will be considered maintained with sufficient scientific evidence under SPS Article 2.2 if “the scientific evidence...bear[s] a rational relationship to the measure, [is] sufficient to demonstrate the existence of the risk which the measure is supposed to address, and [is] of the kind necessary for a risk assessment” – i.e., it [is]...‘relevant’ (emphasis added).<sup>220</sup> However, the sufficiency of scientific evidence upon which an SPS measure must be based to satisfy SPS Article 2.2 may be determined even if a risk assessment has not actually been performed.<sup>221</sup>

In *US-Poultry(China)*, the WTO panel held that the “evidence of [China’s] food safety enforcement problems presented by the United States [was] not ‘sufficient’ [scientific evidence] within the meaning of Article 2.2.”<sup>222</sup> In addition to FSIS reports discussing such problems, the U.S. “[had] produced a number of newspaper articles and publications related to avian influenza, poultry smuggling, and melamine in chicken feed...[as] evidence...[of] China’s food safety enforcement issues.”<sup>223</sup> The panel found that, while such evidence dealt “generally with food safety issues in China, it [did] not specifically address China’s poultry inspection system”, did “not concern the safety of Chinese poultry products”,<sup>224</sup> and did not “address the existence of the risk which the measure [was] supposed to address.”<sup>225</sup> In other words, the panel found that the U.S. had failed to provide “any specific scientific justification [for its measure], notably through a risk assessment carried out according to the principles and disciplines in Article 5 and paragraph 4 of Annex A of the

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218 *Id.*

219 SPS Art. 2.2. SPS Article 2.2 also requires Member States to ensure that SPS measures are also “applied only to the extent necessary to protect human, animal or plant life or health” and “are based on scientific principles.” SPS Art. 2.2 In other words, SPS Article 2.2 actually “contains three separate requirements: (i) the requirement that SPS measures be applied only to the extent necessary to protect human, animal or plant life or health; (ii) the requirement that SPS measures be based on scientific principles; and (iii) the requirement that SPS measures not be maintained without sufficient scientific evidence.” Panel Report, *US-Poultry(China)* at par. 7.144; *EC-Biotech Products* at par. 7.1424.

220 *US-Poultry(China)* at pars. 7.198 and 7.200; Appellate Body Report, *Japan – Agricultural Products II*, par. 84 upholding the Panel Report, *Japan – Agricultural Products II*, pars. 8.29 and 8.42.

221 “There may be situations where the relevant scientific evidence is sufficient to perform a risk assessment, a WTO Member performs such a risk assessment, but does not adopt an SPS measure either because the risk assessment did not confirm the risk, or the risk identified did not exceed that Member’s chosen level of protection. Also, there may be situations where there is no pertinent scientific information available indicating a risk such that an SPS measure would be unwarranted even on a provisional basis.” Appellate Body Report, *US - Canada – Continued Suspension*, at par. 681.

222 Panel Report, *US-Poultry(China)* at par. 7.202.

223 *Id.*

224 The panel “note[d] that the evidence submitted by the United States on China’s food safety enforcement issues does not concern the safety of Chinese poultry products. The evidence presented by the United States rather refers to other food products such as seafood or pork.” *Id.*, at accompanying fn. 422.

225 *Id.* Although “the general science on the safety of poultry products was well established prior to the imposition of [the U.S. measure in dispute]...the evidence referred to by the United States [did] not establish the existence of a risk of consuming unsafe poultry from China.” *Id.*, at par. 7.202.

SPS Agreement, concerning the risk posed by poultry products from China” (emphasis added).<sup>226</sup> Therefore, since the disputed U.S. measure was neither based on a risk assessment (and thus in violation of Article 5.1 and 5.2) nor maintained with sufficient scientific evidence, the Panel held that said measure was also “not consistent with Article 2.2 of the SPS Agreement” (emphasis added).<sup>227</sup>

## 5. Various Draft HK Code Provisions Are Based On International Risk Assessments and Codex Standards, But The Draft HK Code’s 30-month Marketing Ban Goes Beyond Them

### a. Various Draft HK Code Provisions Addressing Direct Short-Term Bacterial Infection-Related Risks Are Based On and Go Beyond FAO/WHO Risk Assessments and Codex Risk Management Recommendations

The GHK-SAR did not conduct its own scientific risk assessment(s) to confirm the presence of any direct short-term food safety-related risks, generally, or with respect to specific formula milk and (nonformula milk) infant and young children’s food products. However, consistent with SPS jurisprudence,<sup>228</sup> it does appear to have based the Draft HK Code provisions addressing direct short-term food safety-related risks (Draft HK Code Articles 4.4.1(e)(iii)(F)-(G); 5; 8.2.1(c)(i)-(iii) and (v); 8.2.1(d); 8.2.1(f)(i)-(iii); 8.3.1(b)(i)-(ii)) on several joint risk assessments performed and recommendations made by the United Nations Food & Agricultural Organization and the World Health Organization. Generally speaking, these risks assessments were performed to examine the natural presence of pathogens, particularly, *E. sakazakii* and *Salmonella enterica*, in powdered infant formula and follow-up formula.

The initial 2004 risk assessment study (*Enterobacter sakazakii*)<sup>229</sup> found that “[i]ntrinsic contamination of powdered [infant] formula with *E. sakazakii* or *Salmonella* can cause infection and illness in infants, including severe disease, and can lead to serious developmental sequelae and death. Other means for *E. sakazakii* illness in infants are plausible.”<sup>230</sup> It found that children under 12 months of age, and particularly, neonates under the age of 28 days were at risk from *E. sakazakii*.<sup>231</sup> The initial study recommended that FAO/WHO Member countries undertake certain risk mitigation/management measures. These included encouraging health professional monitoring and reporting of incidences of bacterial infection, warning and instructing healthcare providers about and developing guidelines outlining proper preparation, use and storage of powdered infant

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226 *Id.*, at par. 7.202.

227 *Id.*, at pars. 7.203-7.204.

228 Panel Report, *US-Poultry(China)* at par. 7.182; Appellate Body Report, *EC – Hormones*, at pars. 190 and 194; Panel Report, *EC – Biotech Products* at par. 7.3024.

229 See Food and Agriculture Organization of the United Nations and the World Health Organization, *Microbiological Risk Assessment Series 6: Enterobacter Sakazakii and Other Microorganisms in Powdered Infant Formula*, Meeting Report (2004), available at: <http://www.fao.org/docrep/007/y5502e/y5502e00.htm>.

230 *Id.*, at Sec. 8.1.

231 In particular, the study concluded that, “*E. sakazakii* has caused disease in all age groups. From the age distribution of reported cases, it is deduced that infants (children <1 year) are at particular risk. The infants at greatest risk from *E. sakazakii* infection are neonates (<28 days), particularly pre-term infants, low-birth-weight infants or immunocompromised infants. Infants of HIV-positive mothers are also at risk, because they may specifically require infant formula and they may be more susceptible to infection.” *Id.* “The scientific review specifically addressed susceptible human populations, information from recent outbreaks of illness, new diagnostic assays, virulence and ecological factors of the organisms. The meeting also updated and/or expanded on previous information on industry and consumer practices relevant to *E. sakazakii*- and *Salmonella*-contaminated PIF.” *Id.*

formula, encouraging industry to take various manufacturing precautions including adoption of environmental management systems, and to develop commercial sterile alternative products.<sup>232</sup>

A second FAO/WHO 2006 (*Enterobacter sakazakii* and *Salmonella*) study, which employed a more complex risk assessment model,<sup>233</sup> examined *E. sakazakii* infections worldwide from consumption of powdered infant formula (“PIF”),<sup>234</sup> including both infant formula *and* follow-up formula within the meaning of Codex standards.<sup>235</sup> Its findings highlighted that neonates under the age of 28 days and infants under 2 months of age are at greatest risk.<sup>236</sup> They also confirmed the 2004 risk assessment’s findings that there was only “clear evidence of causality” for *E. sakazakii* and *Salmonella*; infections arising from other organisms that were examined could be characterized as only “causality plausible, but not yet demonstrated” or “causality less plausible or not yet demonstrated.”<sup>237</sup> The 2006 risk assessment focused on the risk of infection arising from both intrinsically contaminated PIF and from the improper handling and storage of it.<sup>238</sup> It found that then current PIF preparation instructions on PIF product labels and those recommended by health authorities were not suitable for all PIF types and could lead to increased risk of *E. sakazakii* illnesses,<sup>239</sup> and recommended that they be reviewed in light of the risk assessment results.<sup>240</sup> The 2006 risk assessment also made several recommendations to FAO/WHO Member countries. These included developing chain-of-custody-style prevention strategies addressing the risk of *E. sakazakii* infections from the PIF manufacturing process through to caregiver preparation and use, developing educational messages on the safe handling, storage and use of PIF along with the health hazards of inappropriate preparation and use directed especially at healthcare providers, reviewing and revising product labels to reflect safe handling, preparation and use, and developing and reviewing international guidelines concerning same.<sup>241</sup>

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232 *Id.*, at Sec. 8.2.1.

233 See Food and Agriculture Organization of the United Nations and the World Health Organization, *Microbiological Risk Assessment Series 10: Enterobacter sakazakii and Salmonella in Powdered Infant Formula*, Meeting Report (2006), available at: <http://ftp.fao.org/docrep/fao/009/a0707e/a0707e00.pdf>.

234 “In late 2004, consumption of *E. sakazakii*-contaminated PIF was linked to nine infections with two deaths in an outbreak among infants in France (InVS, 2006; Coignard et al., 2006) and to five infections with one death among infants in New Zealand (Ministry of Health, New Zealand, 2005). In 2005, *Salmonella* Agona linked to PIF caused an outbreak among infants in France (InVS, 2005).” *Id.*, at Sec. 1.1.

235 Examined PIFs “include[d] ‘products in powdered form ‘specially manufactured and presented to be used by infants, either as a breastmilk substitute after preparation with water, or to modify prepared breastmilk substitutes or fortify human milk. Included products [were], therefore, infant formula (as defined in Codex Stan 72-1981), follow-up formula (as defined in Codex Stan 156-1987), formula for special medical purposes intended for infants (as defined in Codex Alinorm 04/27/26, Appendix V5), formula for special medical purposes for the partial feeding of infants (covered by Codex Stan 180-1991) and human milk fortifiers’ as defined in the 2004 meeting (FAO/WHO, 2004).” *Id.*, at Sec. 1.3.

236 *Id.*, at Sec. 1.1.

237 *Id.*, at Sec. 1.4.

238 *Id.*, at Sec. 1.1. The more complex risk assessment model was applied “as a tool to provide estimates of relative risk reductions associated with different levels of contamination of PIF, different preparation and use scenarios, and a range of microbiological criteria and their associated sampling plans.” *Id.*, at Sec. 1.3.

239 While “a risk assessment for *Salmonella* in PIF was possible...extensive information [then] currently available on *Salmonella* and its behaviour provided a good basis for risk management decisions [, thereby obviating the] need for a quantitative risk assessment on *Salmonella* in PIF.” *Id.*, at Sec. 1.3; Executive Summary at viii.

240 *Id.*, at Sec. 1.3, Executive Summary at vii. “In general, the use of 70°C mixing water to reconstitute PIF significantly reduced risk. In other scenarios, reconstitution of PIF with 40° and 50°C mixing water (unless consumed immediately), holding bottles at room temperature and long feeding periods were associated with increased relative risk.” *Id.*

241 *Id.*, at Sec. 1.3; Executive Summary at xix-xx.

The second FAO/WHO risk assessment prompted the Codex Committee of Food Hygiene (“CCFH”) in 2006 to revise and rename the *Code of Hygienic Practice for Foods for Infants and Children* (“CAC/RCP 21-1979”), which was eventually replaced by the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (“CAC/RCP 66 – 2008”).<sup>242</sup> These revisions “address[ed] all issues related to contamination with pathogenic microorganisms, in particular *Enterobacter sakazakii* and *Salmonella*, and including relevant labeling aspects.”<sup>243</sup> The revised code ultimately included three annexes, two of which (Annexes I and III<sup>244</sup>) “address[] powdered formula for ‘infants at greatest risk’ with a focus on *Enterobacter sakazakii* and *Salmonella enterica*”.<sup>245</sup> It thus covers powdered infant formula (used as a breastmilk substitute consistent with Section A of CODEX STAN 72 – 1981<sup>246</sup>), as well as, formula for special medical purposes (used either as a total or partial breastmilk substitute or replacement consistent with revised Section B of CODEX STAN 72 – 1981<sup>247</sup>). A third annex (Annex II) “address[es] all powdered products for infants and young children”,<sup>248</sup> which covers follow-up formula and formula for special medical purposes for young children.<sup>249</sup> Annexes I and III were adopted along with the revised code in 2008.<sup>250</sup>

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242 See CAC/RCP 66 – 2008, *supra* at p. 1 (“This Code replaces CAC/RCP 21-1979”). See also Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene, Thirty-eighth Session (Sept. 2006), *Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (at Step 3)* CX/FH06/38/7, at Background p.1, available at: [http://ftp.fao.org/codex/Meetings/CCFH/ccfh38/fh38\\_07e.pdf](http://ftp.fao.org/codex/Meetings/CCFH/ccfh38/fh38_07e.pdf).

243 See Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirtieth Session, *Report of the 28th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, ALINORM 07/30/26-Rev. (July 2-7, 2007), at par. 74, available at: [http://dnrc.nih.gov/pdf/al30\\_26eALINORM.pdf](http://dnrc.nih.gov/pdf/al30_26eALINORM.pdf).

244 See CAC/RCP 66 – 2008, *supra* at Annex I – *Microbiological Criteria for Powdered Infant Formula, Formula for Special Medical Purposes and Human Milk Fortifiers* (“Microbiological criteria should be established in the context of risk management options...for pathogens...[and] applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary package is opened. Microorganisms: *Enterobacter sakazakii* (*Cronobacter species*)...*Salmonella*”). *Id.* Annex III provides “[g]uidance for the establishment of monitoring programmes for *Salmonella*, *Enterobacter sakazakii* (*Cronobacter species*) and other *Enterobacteriaceae* in high-hygiene processing areas and in powdered formula preparation units.” *Id.*

245 See Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene, Thirty-eighth Session (Sept. 2006), *Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (at Step 3)* CX/FH06/38/7, *supra* at Background p. 1.

246 See CODEX STAN 72 – 1981, *supra* at Sections A. 1.1; A2.1.1.

247 *Id.*, at Section s B.1.1; B2.1.1. See also CAC/RCP 66 – 2008, *supra* at Annex I, fn. 19.

248 See Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene, Thirty-eighth Session (Sept. 2006), *Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (at Step 3)* CX/FH06/38/7, *supra* at Background p. 1.

249 See CAC/RCP 66 – 2008, *supra* at Annex II – *Microbiological Criteria for Powdered Follow-up Formula and Formulae for Special Medical Purposes for Young Children*.

250 “In view of the considerable progress made on the Code, the Committee agreed to forward the proposed draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children including Annexes I and III for final adoption by the Commission at Step 5/8 with the recommendation to omit Steps 6 and 7.” See Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirty first Session (June 30 – July 5, 2008) ALINORM 08/31/13, *Report of the Thirty-Ninth Session of the Codex Committee on Food Hygiene*, at par. 62, available at: [http://www.codexalimentarius.net/input/download/report/686/al31\\_13e.pdf](http://www.codexalimentarius.net/input/download/report/686/al31_13e.pdf). “The Committee also agreed to return Annex II to Step 2 for further revision...” *Id.*, at par. 63. See also Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirty-first Session, *Report*, (June 30-July 4, 2008) ALINORM 08/31/REP, at par. 45, available at: <http://www.codexalimentarius.org/input/download/report/698/al31REPe.pdf> (“The Commission adopted the Proposed Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at Steps 5/8, with the omission of Steps 6 and 7, with the amendment to use both *Cronobacter* and *E. sakazakii* in the Code.”) *Id.*

A third 2008 FAO/WHO risk assessment (*Cronobacter spp*)<sup>251</sup> was intended to facilitate “the development of a microbiological criterion for *Enterobacter sakazakii* (*Cronobacter spp.*) for [follow-up formula] FUF intended for infants 6–12 months of age.”<sup>252</sup> This risk assessment was a response to a 2007 CCFH request for scientific advice which would have enabled it to finalize Annex II of CAC/RCP 66 – 2008.<sup>253</sup> Annex II was subsequently adopted in 2009.<sup>254</sup> Said risk assessment had been undertaken in light of “roughly 120 individually documented cases...from 1961 to 2008<sup>255</sup>” of *E. sakazakii* (*Cronobacter spp.*) infections worldwide “among infants and young children up to 3 years of age. Six of these cases [were] known to have occurred among infants 6–11 months and two cases among children in the 12–36 months age group.”<sup>256</sup> In five of the six cases the patients were known to have consumed prepared (powdered) infant formula (“PIF”).<sup>257</sup> Since, however, “[d]ata [was] scarce on the prevalence of *E. sakazakii* (*Cronobacter spp.*) in products categorized as FUF for infants between 6 and 11 months,”<sup>258</sup> the risk assessment relied on then recent university “surveys for *E. sakazakii* (*Cronobacter spp.*) in FUF,” which found *E. sakazakii* (*Cronobacter*) present in less than 1% of the 18 FUF brands tested.<sup>259</sup> From these surveys, the third risk assessment was able to identify “two main differences between the manufacturing processes for prepared infant formula (PIF) and follow-up formula (FUF)” - namely, a broader array of FUF ingredients needed to satisfy older children’s greater dietary needs and less stringent FUF hygiene controls<sup>260</sup> - that led to the conclusion that FUF engendered a greater risk of *E. sakazakii* (*Cronobacter spp.*) infection for infants and young children less than 6 months of age.<sup>261</sup> While this risk assessment had “reviewed all the available information in the context of whether or not a microbiological criterion for *E. sakazakii* (*Cronobacter spp.*) should be established for FUF, and weighed the scientific evidence for and against...[it did not make] an explicit [risk management] recommendation on this.”<sup>262</sup> This likely

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251 See Food and Agriculture Organization of the United Nations and the World Health Organization, *Microbiological Risk Assessment Series No. 15: Enterobacter sakazakii (Cronobacter spp.) in Powdered Follow-up*

*Formulae*, Meeting Report (2008), available at: [http://typo3.fao.org/fileadmin/templates/agns/pdf/jemra/mra15\\_sakazaki.pdf](http://typo3.fao.org/fileadmin/templates/agns/pdf/jemra/mra15_sakazaki.pdf).

252 *Id.*, Executive Summary at xi. Apparently, “*E. sakazakii* ha[d] been reclassified as 6 species in a new genus...*Cronobacter* [which] is synonymous with *Enterobacter sakazakii*...[all species of which]...ha[d] been linked retrospectively to clinical cases of infection in either infants or adults and [were] therefore...considered pathogenic.” *Id.*, Executive Summary at xi.

253 *Id.*, at p. 1.

254 See Codex Alimentarius Commission, *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*, (CAC/RCP 66 – 2008), *supra* at p. 1.

255 See Food and Agriculture Organization of the United Nations and the World Health Organization, *Microbiological Risk Assessment Series No. 15: Enterobacter sakazakii (Cronobacter spp.) in Powdered Follow-up* *Formulae*, Meeting Report (2008), *supra* at p. 13.

256 *Id.*, at Executive Summary, at xi. “Eight cases are known to have occurred among children 6–35 months old.” *Id.*, at p. 13.

257 *Id.*, at p. 13.

258 *Id.*, at p. 29.

259 *Id.*, at p. 30.

260 “Firstly, due to the need for an increasingly diverse diet as infants get older, FUF may contain a wider variety of dry-mix ingredients (e.g. cocoa powder, fruit and vegetable powders or flakes, and flavours)...[in which]...*E. sakazakii* (*Cronobacter spp.*) is likely to be present unless appropriate control measures are implemented by suppliers.” Secondly, microbiological criteria, and therefore hygiene control measures, are more stringent for PIF. [Where] manufacturing facilities, production lines [are]...shared, i.e. used to manufacture both PIF and FUF...the hygiene requirements necessary to ensure compliance with the microbiological criteria for PIF are also applied to FUF. However, in cases where FUF is produced on a dedicated line or on a line shared with other powdered products, the hygiene control measures may not be as stringent.” *Id.*, at Executive Summary at xii.

261 “Although most countries [had] reported that FUF [was] marketed for infants 6 months of age or older, the [then] available data showed that FUF [was] consumed by infants less than 6 months of age in both developing and developed countries, and [was] sometimes consumed by infants less than 1 month...[even though]...there [was] no mandated requirement for testing FUF for *E. sakazakii* (*Cronobacter spp.*)” *Id.*, at xii.

262 *Id.*

reflected the limitations of its assumptions regarding the risk posed by FUF to infants and young children.<sup>263</sup>

As previously discussed, the Draft HK Code provisions focusing on direct short-term food safety-related bacterial risks arising from consumption of infant formula and formula for special medical purposes suitable for use as a breastmilk substitute, appear to be based on the three FAO/WHO risk assessments noted above, and the Codex recommendations and code revisions adopted in response to them. These risk assessments had ascertained that infants up to 3 months of age were at greatest risk of bacterial infection from consumption of infant formula products. Therefore, it is arguable that the GHK-SAR was scientifically justified in employing risk management techniques, particularly, Draft HK Code labeling prescriptions and informational/educational material restrictions that require explanations about proper preparation, handling, storage and use of powdered infant formula products to mitigate those risks.<sup>264</sup> To such extent, these measures appear consistent with applicable Codex recommendations as well as with WHO Code recommendations concerning the disclosure and explanation of infant formula product-related health hazards.

However, to the extent that Draft HK Code informational/educational and advertising provisions ban the promotion of follow-up formula, and complementary food products on direct short-term food safety-related grounds, based, presumably, on the inconclusive findings of the third risk assessment that follow-up formula posed a risk of infection to infants 6-11 months of age, they go beyond Codex standards providing internationally recognized and accepted risk management recommendations. In such case, the GHK-SAR is required to provide scientific justification in accordance with SPS Agreement Article 5 and Annex A(4).

For example, such Draft HK Code provisions arguably violates CODEX STAN 156-1987 (*for Follow-up Formula*),<sup>265</sup> which applies by its terms to “food *intended for use* as a liquid part of the weaning diet for the infant *from the 6th month on* and for young children” (emphasis added).<sup>266</sup> This Codex standard defines an infant as “a person of not more than 12 months of age”, and a young child as a “person[] from the age of more than 12 months up to the age of three years (36 months).”<sup>267</sup> It also defines follow-up formula as encompassing both liquid foods and powdered foods *suitable for use* for infants *from the 6th month on* and for young children” (emphasis added).<sup>268</sup> Furthermore, this Codex standard states that, “follow-up formula is suitable for infants and young children aged

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263 “Little information is available of the prevalence and concentration of *E. sakazkai* (*Cronobacter* spp.) in FUF. While two surveys of FUF in the market place have been undertaken, the lack of data from more long-term studies seems to reflect the absence of requirements to test FUF for *E. sakazkai* (*Cronobacter* spp.). Thus, *in reality, there is not adequate data available to make a comparison between PIF and FUF in terms of microbiological quality*. This ultimately means that any assessment of the impact of microbiological criteria on the prevalence of contaminated FUF in the market place, and thus ultimately the risk of illness associated with this product, *is going to be based on a set of assumptions* regarding the levels of contamination” (emphasis added). *Id.*, at pp. 30-31.

264 In addition, the Draft HK Code also admonishes manufacturers and distributors not to offer for sale or sell infant formula unless the products are formulated industrially in accordance with CODEX STAN 72-1981 and CAC/RCP 66-2008. See Draft Art. 9.1.1(a) and (c).

265 See CODEX STAN 156-1987, *supra*.

266 *Id.*, at Sec. 2.1.1.

267 *Id.*, at Sections 2.1.2-2.1.3.

268 *Id.*, at Sections 2.2 and 2.4.

between 6 and 36 months,”<sup>269</sup> and that “[t]he products covered by this standard are not breast-milk substitutes and shall not be presented as such” (emphasis added).<sup>270</sup> These Draft HK Code provisions arguably reflect GHK-SAR and activist<sup>271</sup> efforts to exploit the “divergence in approaches between member countries as to whether follow-up formula is defined as a breast-milk substitute”.<sup>272</sup> 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.”<sup>273</sup> 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,<sup>274</sup> which would ultimately result in the presentation of a “draft revised standard for consideration by the CCNFSDU at Step 2.”<sup>275</sup> These efforts are intended to foster greater harmonization of international standards in follow-up/follow-on formula products intended “Formula for older infants and young children aged 6-36 months”, “tak[ing] into account technological developments.”<sup>276</sup>

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269 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. 61, available at: [https://www.ccnfsdu.de/fileadmin/user\\_upload/Download/2012/REP13\\_NFSDUe.pdf](https://www.ccnfsdu.de/fileadmin/user_upload/Download/2012/REP13_NFSDUe.pdf).

270 See CODEX STAN 156-1987, *supra*, at Sec. 9.6.

271 “[T]he International Code of Marketing of Breast-milk Substitutes...was developed with the principal aim of regulating the inappropriate marketing of breast-milk substitutes, bottles and teats. As such the Code provides much less guidance related to the appropriate marketing of complementary foods, except to the extent that these products might be marketed as a partial or total replacement for breast milk. This has led to confusion regarding how the Code applies to commercially produced complementary foods and supplements. *The principles of the Code, however, can inform the labelling and marketing of these complementary food and supplement products in a way that supports optimal infant feeding*” (emphasis added). See Victoria Quinn, Elizabeth Zehner, Dominic Schofield, Agnes Guyon and Sandra Huffman, *Using the Code of Marketing of Breast-milk Substitutes to Guide the Marketing of Complementary Foods to Protect Optimal Infant Feeding Practices*, GAIN Working Paper Series No. 3 (March 2010), at Sec. 1.1, pp. 2-3, available at: <http://hftag.gainhealth.org/sites/hftag.gainhealth.org/files/Using%20the%20Code%20of%20Marketing%20of%20Breastmilk%20Substitutes%20GAIN%20publications.pdf>. “Because optimal infant feeding includes six months of exclusive breastfeeding and continued breastfeeding for two years or beyond, the Code and the related WHA resolutions have implications for the way complementary foods and supplements are marketed and labelled. The Code focuses on breast-milk substitutes which are defined as ‘any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose’. Read in conjunction with the global guidelines for optimal infant and young child feeding, this means that any product that is represented as suitable for use during a child’s first six months of life or for replacing the part of the diet that is best satisfied by breast milk after the child reaches six months of age until the age of two years would fall within the scope of the International Code...Moreover...WHA provisions state that complementary foods and supplements should never be marketed or labeled as suitable for feeding infants below the age of six months or in a way that undermines sustained breastfeeding after the age of six months until the age of two years or beyond” (emphasis in original). *Id.*, at Sec. 2.2, pp. 9-10.

272 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, *supra* at Sec. 3, p. 62.

273 *Id.*, at Sec. 4.1, p. 63.

274 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.

275 *Id.*, at par. 147(v).

276 *Id.*, at par. 137. The review would “initial[ly] focus on the essential composition of Follow-up Formula for older infants and young children aged 6-36 months” (emphasis added) and “[c]onsider if any differences are required in the essential composition for older infants (6-12 months) and young children (12-36 months).” *Id.*, at pars. 147(i)-(ii).

Furthermore, such Draft HK Code provisions arguably violate the draft revision of the Codex *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991)<sup>277</sup> which the CCNFSDU also very recently advanced “to Step 8 for adoption at the 36th Session of the Codex.”<sup>278</sup> The draft revised guidelines “provide guidance on nutritional and technical aspects of the production of formulated complementary foods for older infants and young children,”<sup>279</sup> which “include but are not limited to porridges containing cereals, ready-to-use products and food-based home fortificants.”<sup>280</sup> Formulated complementary foods for older infants and young children are “foods that are suitable for use during the complementary feeding period.”<sup>281</sup> The “[c]omplementary feeding period” is defined as “the period when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating the family diet.”<sup>282</sup> 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).<sup>283</sup> The draft revised guidelines define the terms “older infants” and “young children,” respectively, consistent with CODEX STAN 156-1987, as “persons from the age of 6 months and not more than 12 months of age”,<sup>284</sup> and “persons from the age of more than 12 months up to the age of three years (36 months).”<sup>285</sup>

Industry adherence to CODEX STAN 156-1987 and draft revised CAC/GL 8-1991, in other words, would assure that marketed follow-up formula and complementary food products are intended and suitable for use<sup>286</sup> by infants *older than 6 months* as *supplements* to, and not, as substitutes or replacements for breastmilk. It would also strongly suggest that follow-up formula products are being promoted consistent with the WHO Code and the WHO *Global Strategy for Infant and Young Child Feeding*<sup>287</sup> (“WHO Feeding Strategy”) endorsed via WHA Resolution 55/25.<sup>288</sup> The Code recommends that infant formula products intended for infants up to 4-6 months of age and

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277 *Id.*, at Appendix II – *Guidelines on Formulated Complementary Foods for Older Infants and Young Children (Step 8)*.

278 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 par. 41.

279 *Id.*, at Appendix II – *Guidelines on Formulated Complementary Foods for Older Infants and Young Children (Step 8)*, at Sec. 1, p. 45.

280 *Id.*, at Sec. 2. “These Guidelines should be used in accordance with the *Global Strategy for Infants and Young Child Feeding* and World Health Assembly Resolution WHA54.2 (2001).” *Id.*

281 *Id.*, at Sec. 3.1.

282 *Id.*, at Sec. 3.4.

283 *Id.*, at fn. 3, citing World Health Organization, *Complementary Feeding, Report of the Global Consultation* (2002), available at: [http://www.who.int/nutrition/publications/Complementary\\_Feeding.pdf](http://www.who.int/nutrition/publications/Complementary_Feeding.pdf); World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003), 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), available at: <http://whqlibdoc.who.int/publications/2005/9241593431.pdf>.

284 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 Appendix II – *Guidelines on Formulated Complementary Foods for Older Infants and Young Children (Step 8)*, at Sec. 3.2.

285 *Id.*, at Sec. 3.3.

286 *Id.* See also CODEX STAN 156-1987, *supra* at Sections 2.1.1 and 2.2.

287 See World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), *supra*.

288 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\\_ycn\\_en.pdf](http://www.who.int/nutrition/topics/WHA55.25_ycn_en.pdf). 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](http://apps.who.int/gb/archive/pdf_files/WHA55/ea5515.pdf).

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.<sup>289</sup> The WHO Feeding Strategy 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 or beyond.<sup>290</sup> Since, however, the Draft HK Code marketing ban provisions effectively apply to follow-up milk and complementary food products intended for infants and young children *up to 36 months of age* even if such products are exclusively marketed and suitable for use by infants and young children older than 6 months as *supplements to partial breastfeeding*, they clearly go beyond these international standards, and thus, must be scientifically justified.

The GHK-SAR bears the burden of providing such justification. As previously discussed, it can meet this burden by performing a scientific risk assessment that qualifies under SPS Article 5.1 and Annex A(4), or by proffering sufficient scientific evidence not quite amounting to a risk assessment establishing specific bacterial risks to human life or health. However, as discussed *infra*, if it fails to undertake either of these efforts, it will be unable to invoke the provisional measures of SPS Article 5.7 as justification for banning the promotion of such follow-up formula and complementary food products on food safety grounds.

#### b. Various Draft HK Code Provisions Addressing Indirect Long-Term Diet-Related NCD Risks Are Based On and Go Beyond FAO/WHO Risk Assessments and Codex Risk Management Recommendations

Various Draft HK Code provisions also broadly ban the promotion of formula milk and (nonformula milk) infant and young children's food products intended for infants and children up to 36 months of age on the grounds that the salt, sugar and/or trans-fat content of such products pose long-term diet-related NCD risks to Hong Kong infants and young children. These provisions arguably exceed relevant Codex standards and/or FAO/WHO risk assessments that have begun to yield risk management tools that are less stringent and trade-disruptive than the Draft HK Code's effective 30-month marketing ban. The following discussion reveals how evolving Codex standards responding to FAO/WHO initiatives have continued to incorporate new scientific data and to employ new risk management methods and protocols, including maximum nutrient reference values for nutrients associated with NCD risks ("NRVs-NCD), to address the diet-related NCD risks<sup>291</sup>

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289 WHO Code Articles 2 and 3, p. 9. See also 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](http://whqlibdoc.who.int/hq/2001/WHO_NHD_01.09.pdf).

290 The WHO Feeding Strategy recommends that, after "the first six months of life to achieve optimal growth, development and health...[and] 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." See World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), *supra* at par. 10.

291 According to the WHO, "[s]tudies have revealed that there is a consistent relationship between unhealthy diet and the emergence of a range of chronic non-infectious diseases – including coronary heart disease, cerebrovascular disease, various cancers, diabetes mellitus, dental caries, and various bone and joint diseases." See World Health Organization, *Globalization, Diets and Noncommunicable Diseases* (2002), at Introduction at p. 1, available at: <http://whqlibdoc.who.int/publications/9241590416.pdf>. "Dietary globalization usually increases the variety in the traditional, formerly monotonous diets, and thus, improves their energy and nutrient adequacy. At the same time, care should be taken that the diets do not become too Westernized in terms of substantial increases in the intakes of fat, especially saturated fat, salt and refined carbohydrate, but that they stay prudent and health promoting." *Id.*, at p. 10. "NCDs are caused, to a large

that food products pose to the general population (i.e., persons 36 months of age and older). Had the GHK-SAR taken these evolving Codex standards into account, it would have likely endeavored to establish NRVs-NCD in connection with such products and then incorporated them into the Draft HK Code and/or the Cap 132W regulations now under revision.

If salt and sugar are naturally occurring in a food ingredient the United States Government treats them as a “nutrient,”<sup>292</sup> However, if salt and sugar are added to an ingredient for some purposeful effect they are treated as an “additive”.<sup>293</sup> The Codex *Guidelines on Nutrition Labelling*<sup>294</sup> currently include naturally occurring sugar in “the list of ‘nutrients’ that are always declared on a voluntary or mandatory basis”.<sup>295</sup> Salt, however, is not included on this list.

In 2006, the WHO and FAO issued a draft action plan for implementing the WHO *Global Strategy on Diet, Physical Activity and Health* and WHA Resolution 57.17<sup>296</sup> in addressing the global burden of diet-related NCDs. The FAO/WHO draft action plan “proposed that the CCNFSDU and the Codex Committee on Food Labelling (CCFL) consider the development of NRVs for nutrients that are associated with risk of NCDs (abbreviated hereafter as “NRVs-NCD”) (CL 2006/44-CAC).”<sup>297</sup> “In identifying nutrients to review for these potential NRVs, the CCNFSDU’s first priority was nutrients that the CCFL referred to the Committee for consideration of NRVs—which to date includes saturated fatty acids (SFA) and sodium (ALINORM 09/32/22, para 42).”<sup>298</sup> During 2008-2009, the WHO accelerated its effort to improve the feeding of *infants and young children 6-23 months of age*, in furtherance of its *Global Strategy on Infant and Young Child Feeding* and *International Code of Marketing of Breast Milk Substitutes*. In particular, it “review[ed] the possibility of updating the

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extent, by four behavioural risk factors...[including] unhealthy diet.” See World Health Organization, *Global Status Report on Noncommunicable Diseases 2010* (2011) at Introduction at vii, available at: [http://whqlibdoc.who.int/publications/2011/9789240686458\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789240686458_eng.pdf). An “unhealthy diet” is marked by consumption of much higher levels of salt than recommended by WHO for disease prevention...[H]igh salt consumption is an important determinant of high blood pressure and cardiovascular risk. High consumption of saturated fats and trans-fatty acids is linked to heart disease.” *Id.*, at Executive Summary at p. 2.

292 “Nutrient” means any substance normally consumed as a constituent of food: (a) which provides energy; or (b) which is needed for growth, development and maintenance of life; or (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.” See U.S. Food and Drug Administration, *Overview of Food Ingredients, Additives & Colors*, International Food Information Council (IFIC) and U.S. Food and Drug Administration (Nov. 2004; Revised April 2010), at Sec. 2.5, available at: <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm>.

293 “Food additive” is defined by the Food and Drug Administration (FDA) as any substance used to provide a technical effect in foods. The use of food additives has become more prominent in recent years, due to the increased production of prepared, processed, and convenience foods. Additives are used for flavor and appeal, food preparation and processing, freshness, and safety.” See U.S. Department of Agriculture Food Safety and Inspection Service, *FACT SHEET – Food Labeling: Additives in Meat and Poultry Products*, available at: [http://www.fsis.usda.gov/factsheets/Additives\\_in\\_Meat\\_&\\_Poultry\\_Products/index.asp](http://www.fsis.usda.gov/factsheets/Additives_in_Meat_&_Poultry_Products/index.asp).

294 “Sugars” means all mono-saccharides and di-saccharides present in food.” See Codex Alimentarius Commission, *Guidelines on Nutritional Labelling (CAC/GL 2-1985)*, at Sec. 2.7, available at: <http://www.fao.org/docrep/005/y2770e/y2770e06.htm>.

295 *Id.*

296 See World Health Assembly, *WHA57.17 - Global Strategy on Diet, Physical Activity and Health* (May 22, 2004), available at: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA57/A57\\_R17-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA57/A57_R17-en.pdf).

297 See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations CX/NFSDU 12/34/5* (Dec. 3-7, 2012), at Sec. 1, par. 2, available at: [ftp://ftp.fao.org/codex/meetings/ccnfsdu/ccnfsdu34/nf34\\_05e.pdf](ftp://ftp.fao.org/codex/meetings/ccnfsdu/ccnfsdu34/nf34_05e.pdf).

298 *Id.*, at Sec. 1, par. 3.

nutrient requirements for these age groups which [would] provide scientific bases for reviewing the nutrient requirements for *complementary foods*" (emphasis added).<sup>299</sup>

At its 31st sessional meeting in 2009, the CCNFSDU considered a proposal document the United States and Thai Governments had introduced providing for draft principles to establish NRVs for nutrients associated with the risk of diet-related non-communicable diseases (NRVs-NCD) for the general population.<sup>300</sup> This proposal was accompanied by "a draft Project Document...[subsequently] approved by the [Codex Alimentarius] Commission in July 2010"<sup>301</sup> [that had] identifie[d] the relevance of this work to the WHO *Global Strategy on Diet, Physical Activity and Health*."<sup>302</sup> The Project Document's aim was "to: a) [e]stablish Codex principles and criteria for the development of NRVs for labelling purposes for nutrients associated with risk of diet-related noncommunicable diseases for the general population *aged older than 36 months*; and b) [e]stablish NRVs for selected nutrients based on these principles and criteria" (emphasis added).<sup>303</sup> There appears to have been general agreement at the physical working group level to define "Nutrient Reference Values-Noncommunicable Diseases (abbreviated as NRVs-NCD)" as "*Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of*

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299 In furtherance of the Global Strategy and since the "Joint WHO/UNICEF Technical Consultation on Strengthening Action to improve feeding of infants and young children 6-23 months of age in nutrition and child health programmes held in October 2008...the WHO, UNICEF, and their partners are reviewing regulations on foods for infants and young children, including fortified *complementary foods* and micronutrient supplementation, *in accordance with the Global Strategy on Infant and Young Child Feeding and the International Code of Marketing of Breast Milk Substitutes*. As part of the follow up to the October 2008 meeting, WHO is reviewing the possibility of updating the nutrient requirements for these age groups which will provide scientific bases for reviewing the nutrient requirements for *complementary foods*" (emphasis added). See Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, 33rd Session, *Report of the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, (ALINORM 10/33/26) (July 5-9, 2010), at par. 33, available at: [http://www.codexalimentarius.org/input/download/report/732/al33\\_26e.pdf](http://www.codexalimentarius.org/input/download/report/732/al33_26e.pdf).

300 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses (Thirty Second Session), *Principles and Criteria for the Development of NRVs for Labelling Purposes for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases at Step 4* (CX/NFSDU 10/32/7) (Sept. 2010), at pars. 1-2, available at: [ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu32/nf32\\_07e.pdf](ftp://ftp.fao.org/codex/Meetings/CCNFSDU/ccnfsdu32/nf32_07e.pdf).

301 In July 2010, the Codex Alimentarius Commission approved new work for the CCNFSDU. This entailed its development of "Codex principles and criteria for the establishment of Nutrient Reference Values for labelling purposes (NRVs) for nutrients associated with risk of diet-related noncommunicable diseases (NCDs) *for the general population*", which were to be included in an Annex to the Guidelines for Nutrition Labelling." See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations* (CX/NFSDU 12/34/5) (Dec. 3-7, 2012), *supra* at Sec. 1, par. 1. In addition, the CCNFSDU was tasked with proposing "amendments to the listing of NRVs in Section 3.4.4 of the Guidelines based on these principles." *Id.*

302 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses (Thirty Second Session), *Principles and Criteria for the Development of NRVs for Labelling Purposes for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases at Step 4* (CX/NFSDU 10/32/7) (Sept. 2010), *supra* at pars. 1-2.

303 *Id.*, at par. 2. "[T]he Committee agreed that these NRVs were for nutrients associated with diet-related noncommunicable diseases for the general population aged older than 36 months (ALINORM 10/33/26, para 133-134). There appeared to be general support in the physical working group to abbreviate these NRVs as 'NRVs-NCD'...[W]e would anticipate widespread agreement that intake recommendations for healthy populations should be the basis for establishing NRVs-NCD." *Id.*, at pars. 23, and 25. See also Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, 33rd Session, *Report of the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, (ALINORM 10/33/26), *supra* at Appendix VII, p. 57.

*diet-related noncommunicable [chronic] diseases”* (emphasis added).<sup>304</sup> This definition of NRVs-NCD was ultimately changed.<sup>305</sup>

The CCNFSDU, furthermore, indicated that it had intended to use this work as the basis for “propos[ing] amendments to the listing of NRVs in Section 3.4.4 of the Codex *Guidelines on Nutrition Labelling*...and [to] include the principles and criteria in an Annex to the Guidelines.”<sup>306</sup> In this regard, the Project Document indicated that its first priority was to address nutrients that the CCFL had referred to the CCNFSDU “for consideration for NRVs for nutrients associated with risk of diet-related noncommunicable diseases---*sodium and saturated fat* (ALINORM 09/32/22, para 41)” (emphasis added).<sup>307</sup> The CCNFSDU noted, however, that although “the CCFL had proposed to add saturated fat and sodium or salt to the list of nutrients that must be declared when a nutrient declaration is required,” it had “agreed to defer the discussion of this question until it had considered the outcome of the physical working group on NRVs associated with risk of non-communicable diseases.”<sup>308</sup> Furthermore, while “the [CCFSDU] considered that there [was] merit in establishing claims in relation to salt...there was no clear agreement for claims for added sugars and trans-fatty acids.”<sup>309</sup>

At its 38th sessional meeting in July 2010, the CCFL reported that the CCNFSDU “had agreed to recommend to the CCFL to establish a definition for the term ‘nutrient reference values’”.<sup>310</sup> The CCFL also reported that the CCNFSDU had proposed, but had not yet agreed “to extend this definition to include the basis on which NRVs are determined by adding [the phrases] ‘and are based on scientific data on nutrient requirements’ and ‘and/or *nutrient levels associated with risk of*

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304 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses (Thirty Second Session), *Principles and Criteria for the Development of NRVs for Labelling Purposes for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases* (at Step 4) (CX/NFSDU 10/32/7) (Sept. 2010), *supra* at par. 40.

305 The definition of NCDs-NRV was ultimately changed as follows: “Nutrient Reference Values - Noncommunicable Disease (NRVs-NCD) refer to Codex nutrient reference values for food labelling purposes for nutrients that are associated with risk of diet-related noncommunicable diseases not including nutrient deficiency diseases or disorders.” 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 Appendix III – Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases for the General Population (at Step 5/8), at Sec. 2.1.

306 *Id.*, at par. 3.

307 *Id.*, at par. 4 and accompanying fn. 1. “The Committee considered the request from the [CCFL] concerning the proposed amendments to section 3.2 of the Guidelines on Nutrition Labelling regarding the list of nutrients that are always declared on a voluntary or mandatory basis, in relation to the recommendations in the WHO Global Strategy on Diet, Physical Activity and Health...The Committee recalled that the CCFL had proposed to add saturated fat and sodium or salt to the list of nutrients that must be declared when a nutrient declaration is required and noted a proposal to consider as a priority for establishing NRVs for those nutrients referred by the [CCFL]” (emphasis added). See Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme (33rd Session), *Report of the 31st Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses*, (ALINORM 10/33/26) (July 5-9, 2010), *supra* at pars. 15-16.

308 *Id.*, at par. 16.

309 *Id.*, at par. 22. In addition, the CCFL had not yet identified “the claims for which conditions should be established” or provided “information on the types of claims for which CCFL wishes CCNFSDU to establish criteria, the purpose of the claims, and CCFL’s priorities for the development of criteria for the claims.” *Id.*

310 See Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission Thirty-third Session, *Report of the Thirty-Eighth Session of the Codex Committee on Food Labelling* (ALINORM 10/33/22) (July 5-9, 2010), par. 11., available at: [http://www.codexalimentarius.org/input/download/report/742/al33\\_22e.pdf](http://www.codexalimentarius.org/input/download/report/742/al33_22e.pdf).

diet-related noncommunicable diseases” (emphasis added).<sup>311</sup> The CCFL also reported that following its review of a discussion paper on issues related to mandatory nutrition labeling, it had agreed “to clarify that nutrients associated with either an increased or decreased risk of non-communicable diseases should be considered for *mandatory* labelling” (emphasis added).<sup>312</sup> Furthermore, the CCFL reported that there had been consensus on adding “sodium/salt”,<sup>313</sup> and on *not* adding either “added sugars”<sup>314</sup> or “trans-fatty acids,”<sup>315</sup> to the list of nutrients that are always declared on a voluntary or mandatory basis, during its review of the proposed draft revision of the *Guidelines on Nutrition Labelling*.<sup>316</sup>

At its 39th sessional meeting in May 2011, the CCFL considered proposed amendments to the *Codex Guidelines on Nutrition Labelling* relating to the list of nutrients that are always declared on a voluntary or mandatory basis, in partial “response to the implementation of the *WHO Global Strategy on Diet, Physical Activity and Health*.”<sup>317</sup> The CCFL noted that “there was consensus that the nutrient sodium and/or salt should be included in the list[, but that there was] no agreement on the preferred [salt/sodium] terminology.”<sup>318</sup>

During its 33rd sessional meeting in 2011, the CCNFSDU “made significant progress on the proposed draft general principles for establishing NRVs-NCD with the only remaining text in brackets...address[ing] the strength of the scientific evidence for the relationship between a nutrient and risk of diet-related NCDs.”<sup>319</sup> The e-Working Group assigned to this task arrived at several textual choices for addressing the strength of the scientific evidence needed to establish a relationship between a nutrient and NCD risk that were based on observed WHO terminology.<sup>320</sup>

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311 *Id.*

312 *Id.*, at par. 60; Appendix III.

313 *Id.*, at par. 22. However, no consensus had been reached concerning the use of either term in the nutrient declaration. *Id.*, at pars. 25-32.

314 “The Committee agreed not to include added sugars in the list of nutrients in section 3.2.1.2.” *Id.*, at par. 37.

315 “[T]he Committee agreed not to include trans-fatty acids in the list in 3.2.1.2 and to include a footnote to section 3.2.1.4 to indicate that in countries where the level of intake of trans-fatty acids is a public health concern, consideration should be given to declaration of trans-fatty acids in nutrition labelling.” *Id.*, at par. 52.

316 The CCFL had been working on the revision of the *Guidelines on Nutrition Labelling* as part of its implementation of the *WHO Global Strategy on Diet, Physical Activity and Health*. *Id.*, at p. 3.

317 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling Thirty-ninth Session, *Recommendations on the Declaration of Sodium (Salt)*, Report of the Electronic Working Group (CX/FL 11/39/5), (May 9-13, 2011), at Introduction, available at: [ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/fl39\\_05e.pdf](ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/fl39_05e.pdf).

318 See Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labelling Thirty-ninth Session, *Recommendations on the Declaration of Sodium (Salt)*, Report of the Electronic Working Group (CX/FL 11/39/5), (May 9-13, 2011), *supra* at Introduction. “While there was recognition by all respondents that sodium is the technically and scientifically correct term for the nutrient of public health concern, and that consumer understanding of the declaration (whether it be salt or sodium) is an issue, there was a divergence of views as to how best to present the content of the nutrient on the label and in particular in the nutrient declaration. There was no consensus on whether the declaration in the list of nutrients that should always be declared on a voluntary or mandatory basis should be as ‘salt’ or as ‘sodium’ and there was limited support for any of the options considered that would result in both terms being used in the nutrient declaration.” *Id.*, at Conclusion, p. 3.

319 See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations* CX/NFSDU 12/34/5 (Dec. 3-7, 2012), *supra* at par. 6.

320 See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk*

The CCNFSDU also agreed at this session “to advance the proposed draft NRVs of 20g for SFA [saturated fatty acids] and 2000mg for sodium to Step 5/8 for adoption by the 35th Codex Alimentarius Commission”, which the Commission subsequently agreed to adopt at Step 5.<sup>321</sup>

During its 34th sessional meeting in 2012, the CCNFSDU, once again, discussed the criteria for evaluating the strength of scientific evidence needed to demonstrate a relationship between a nutrient and NCD risk. The CCNFSDU e-Working Group was advised by WHO representatives to modify its text because of changes in WHO methodology and terminology for assessing the quality of evidence.<sup>322</sup> Following its consideration of the matter, the Committee “agreed to advance the Proposed Draft General Principles, to Step 5/8” for adoption at the Codex Commission’s 36th session,<sup>323</sup> along with the recommended modified language.<sup>324</sup> The CCNFSDU added identical terminology to the *General Principles for Establishing Nutrient Reference Values for the General Population* (individuals older than 36 months), to be incorporated in the Proposed Draft Annex to the *Codex Guidelines on Nutrition Labelling*. “The Committee agreed to forward the consolidated

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*of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations (CX/NFSDU 12/34/5) (Dec. 3-7, 2012), supra at pars. 20-40.*

321 See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations (CX/NFSDU 12/34/5) (Dec. 3-7, 2012), supra at par. 7, referencing REP12/CAC, pars. 30-32. See also Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Thirty fifth Session, Report of the Thirty Third Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (REP12/NFSDU) (July 2-7, 2012), at par 76, available at: [https://www.ccnfsdu.de/fileadmin/user\\_upload/Download/2011/REP11\\_Finale.pdf](https://www.ccnfsdu.de/fileadmin/user_upload/Download/2011/REP11_Finale.pdf). “After some discussion, the Committee agreed to advance the proposed draft nutrient reference values, 20 g for saturated fatty acid and 2000 mg for sodium, to Step 5/8 for adoption by the 35th Session of the Codex Alimentarius Commission and inform them to CCFL.” *Id.**

322 “[T]he Committee...decided to consider the terminology used in relevant reports of joint FAO/WHO expert consultations to describe the strength of the scientific evidence for the relationship between a nutrient and NCD risk...[These] reports used the same criteria for “convincing” and “probable” evidence...[However,] the WHO representative indicated that new terms would replace the use of “probable” and “convincing” scientific evidence (in the development of WHO guidelines) (REP 12/NFSDU, para 47)...[and that] the e-WG [should] consider that new terminology may replace “convincing” and “probable” evidence in future reports of FAO/WHO scientific advice that are relevant to updating these NRVs-NCD or establishing new NRVs-NCD...” See Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session, *Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-related Noncommunicable Diseases for General Population (NRVs-NCD) at Step 4, Consolidation of the General Principles of Establishing NRVs-NCD and Other Recommendations (CX/NFSDU 12/34/5) (Dec. 3-7, 2012), supra at pars. 13-15, 17-18. See also 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 par. 47. (“[T]he Representative of WHO explained that the categorization and criteria for “convincing, probably, possible or insufficient” evidence were used for the first time by the 2002 Joint WHO/FAO Expert Consultation and were also used by the 2008 Joint FAO/WHO Expert Consultation. However, starting the implementation of the new guideline development process in WHO in 2009, WHO uses the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) approach to assess the quality of a body of evidence. GRADE categorizes the quality of evidence as “high, moderate, low or very low”.) *Id.**

323 *Id.*, at par. 51.

324 The final text reads as follows: “The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD: Relevant convincing/generally accepted scientific evidence or the comparable level of evidence under the GRADE classification for the relationship between a nutrient and noncommunicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g., adults); Public health importance of the nutrient-noncommunicable disease risk relationship(s) among Codex member countries.” 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 Appendix III – Proposed Draft General Principles for Establishing Nutrient Reference Values for Nutrients Associated With Risk of Diet-Related Noncommunicable Diseases for the General Population (at Step 5/8), at Sec. 3.1.*

text for consideration by the 41st Session of CCFL and to the 36th Session of the Commission for adoption.”<sup>325</sup>

In sum, Codex standards developed in response to FAO/WHO scientific research initiatives have begun to yield useful risk management tools for governments. These include principles for establishing NRVs for nutrients that are associated with diet-related NCD risks, such as sodium and saturated fatty acids, guidelines for monitoring health and nutrient food product claims, and requirements for nutrient declarations on food product labels that should provide consumers older than 36 months of age with important safety information about the foods they consume. That these Codex standards and related WHO guidelines on sodium intake for adults and young children<sup>326</sup> do not presently cover infants and young children 0-36 months of age, does not excuse the GHK-SAR from fulfilling its obligation to perform a science-based risk assessment, within the meaning of SPS Article 5.1 and Annex A(4), to justify the Draft HK Code’s higher level of protection. In the other words, the absence of an international risk assessment precisely on point, does not absolve the GHK-SAR from undertaking its own scientific risk assessment, or relying upon that of another WTO Member, that identifies specific formula milk or complementary food products that contain an amount of nutrients associated with diet-related NCD risks.

Furthermore, neither the WHO Code nor its accompanying resolutions may be relied upon to nullify this WTO obligation. 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 and young children older than 6 months of age 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. In addition, WHA 55/5 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 or beyond.<sup>327</sup> Since, however, the Draft HK Code’s food safety-related provisions effectively manage diet-related NCD risks by imposing a marketing ban on all follow-up milk and complementary food products intended for infants and young children up to 36 months of age, even if such products are exclusively marketed and suitable for use by infants and young children older than 6 months as *supplements* to partial breastfeeding, they clearly go beyond these international standards, as well, and must be scientifically justified.

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325 *Id.*, at par 59; *Appendix IV - Proposed Draft Annex to the Codex Guidelines on Nutrition Labelling – Consolidated Version: General Principles for Establishing Nutrient Reference Values for the General Population*, at Sec. 3.2.2.1.

326 See World Health Organization, *Guideline: Sodium Intake For Adults and Children* (2012), at p. 18, available at: [http://www.who.int/nutrition/publications/guidelines/sodium\\_intake\\_printversion.pdf](http://www.who.int/nutrition/publications/guidelines/sodium_intake_printversion.pdf). During its 34th sessional meeting in 2012, the CCNFSU was informed by a WHO representative that, in addition, “guidelines on total fat and sugars will soon be posted for public consultation before being submitted to the Guideline Review Committee in early 2013.” 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/NFSU, *supra* at par. 23.

327 *Cf.* Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Codex Committee on Food Labeling, *Matters of Interest Arising from FAO and WHO* (CRD-15, Agenda Item 2) (May 9-13, 2011), at p. 4, available at: [ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/CRD/CRD-15\\_fl39\\_on%20Item%20steming%20from%20FAO-WHO-Eng.pdf](ftp://ftp.fao.org/codex/Meetings/CCFL/ccfl39/CRD/CRD-15_fl39_on%20Item%20steming%20from%20FAO-WHO-Eng.pdf) (discussing how, the WHO and UNICEF had previously formed a working group to prepare a paper “to evaluated the the usefulness and applicability of the Code of Marketing of Breast-milk Substitutes to possibly guide the marketing of complementary foods as part of initial scoping of the process for developing a WHO framework for marketing of foods for children 6 - 23 months of age”). *Id.*

i. The GHK-SAR's Study and Questionnaire-Based Surveys Neither Qualify as Scientific Risk Assessments Nor Constitute Sufficient Scientific Evidence Under the SPS Agreement

To recall, SPS Annex A(4) states that a risk assessment should “(i) identify the additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs at issue (if any); (ii) identify any possible adverse effect on human or animal health; and (iii) evaluate the potential for that adverse effect to arise from the presence of the identified additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.”<sup>328</sup> And, it “should refer in general to the harm concerned as well as to the precise agent that may possibly cause the harm.”<sup>329</sup> A review of the GHK-SAR's self-reporting questionnaire-based surveys reveals that they did not satisfy these requirements, and thus, do not qualify as scientific risk assessments within the meaning of SPS Articles 5.1 and 5.2.

The studies the GHK-SAR performed during 2012 prior to the release of the Draft HK Code,<sup>330</sup> which implements the 2008 *Strategic Framework for Prevention and Control of Non-Communicable Diseases* (“Strategic Framework”)<sup>331</sup> and 2010 *Action for Prevention and Control of Non-Communicable Diseases* (“Action Plan”),<sup>332</sup> do not meet the definition of a scientific risk assessment; nor does the 2005 report upon which all of these initiatives are based.

The Strategic Framework<sup>333</sup> and Action Plan were based on a 2005 report issued by the GHK-SAR's Department of Health Committee on Promoting the Holistic Development of Preschool Children that had expressed “concerns about obesity, unbalanced dietary intake, and [the] low physical activity level in Hong Kong children”,<sup>334</sup> and about “the relatively low breastfeeding rate in Hong Kong”.<sup>335</sup> The 2005 report cited prior studies based on *nonscientific survey data* that had identified

328 Panel Report, *US-Poultry(China)* at par. 7.178; Panel Report, *Canada - Continued Suspension*, WT/DS321/R, at par. 7.479 (March 31, 2008).

329 Panel Report, *US-Poultry(China)* at par. 7.179; Appellate Body Report, *Japan – Apples*, par. 202.

330 Draft HK Code, Background at p. 3.

331 See Department of Health, Hong Kong Special Administrative Region of China, *Promoting Health in Hong Kong: A Strategic Framework for Prevention and Control of Non-communicable Diseases* (Oct. 28, 2008), available at: [http://www.change4health.gov.hk/filemanager/common/image/strategic\\_framework/promoting\\_health/promoting\\_health\\_e.pdf](http://www.change4health.gov.hk/filemanager/common/image/strategic_framework/promoting_health/promoting_health_e.pdf).

332 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](http://www.change4health.gov.hk/filemanager/common/image/strategic_framework/action_plan/action_plan_e.pdf).

333 “The overall goal of the strategic framework is to increase the positive health and quality of life of the people in Hong Kong. To optimize health gains, the strategic framework focuses on the major risk factors that are potentially modifiable and have significant impact on the health of the Hong Kong population.” See *Action Plan to Promote Healthy Diet and Physical Activity Participation in Hong Kong*, supra at par. 1.8.

334 See Shirley Leung, Cynthia Leung and Ruth Chan, *A Needs Assessment Report of Children 0-5 Years*, Committee on Promoting Holistic Development of Preschool Children (2005), at Executive Summary at i, available at: <http://www.fhs.gov.hk/english/archive/files/reports/report.pdf>. The report made the general observation that “[o]besity in childhood persists into adulthood as lifestyle habits established early in life are frequently carried into adulthood. It is well known that obesity in adulthood is a risk factor for many chronic conditions including diabetes and hypertension.” *Id.*, at p. 20. The report found that 11.7% and 9.8% of the Hong Kong males and females studied “were classified as overweight” and that 3.1% and 1.8% of the Hong Kong males and females studied (“ranking second highest” and “third highest” among “Brazil, U.K., Hong Kong, Netherlands, Singapore and U.S.A.”) were classified as obese. *Id.*

335 In reviewing prior annual breastfeeding surveys, the report's authors found that while the percentage of babies exclusively breastfed beyond 1 month and from 4-6 months in Hong Kong had actually increased, the “Hong Kong percentage of babies

“signs of high protein intake among Hong Kong children and...low fruit and vegetable intake” (emphasis added),<sup>336</sup> and medical “data from the routine neonatal thyroid screening programme in...Hong Kong hospitals...[that had] revealed mild iodine deficiency among 22% of neonates in Hong Kong.”<sup>337</sup> The report concluded that such data provided “some indication that unbalanced diet is an issue of concern,”<sup>338</sup> and recommended the adoption of health promotion policies capable of reshaping people’s choices - public behavior - in furtherance of the development of a national agenda for children.<sup>339</sup>

The Strategic Framework noted how this prior research had “identified [that]...certain unhealthy behaviours such as unhealthy eating habits...are common in the local population”, that most of Hong Kong’s disease burden is attributable to preventable NCD, and that due to certain demographic and environmental factors, “more people are expected to suffer from NCD”.<sup>340</sup> It recommended that, among the “[l]ife-course approaches to promot[ing] health and prevent[ing] illness”, *illness prevention “[f]or newborns (up to one month) and infants (up to one year)...include issues like breastfeeding [and] appropriate and nutritious complementary foods”* (emphasis added).<sup>341</sup>

The Action Plan cited the previously reported Hong Kong post-hospital discharge breastfeeding rate<sup>342</sup> and the WHO recommendation of “exclusive breastfeeding up to 6 months for newborns” as a matter of “dietary habit”.<sup>343</sup> It also noted that, “[f]or infant and toddlers, there is growing evidence suggesting that breastfeeding can prevent subsequent childhood overweight and that longer breastfeeding period gives greater protection for children” (emphasis added).<sup>344</sup> The Action Plan, however, conceded that “information on the prevalence of *unhealthy* dietary habit and participation in physical activity among children, *especially infants and young children, remain[ed]*

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exclusively breastfed [was] still low compared with other developed countries.” *Id.*, at Executive Summary, at i, and p. 60. The report found that the “most common reasons for stopping breastfeeding were “not enough milk” and “back to work”. *Id.*

336 *Id.*

337 *Id.*, at pp. 22-23.

338 *Id.*, at p. 23.

339 *Id.*, at p. 164.

340 “In 2006, approximately 61% of total registered deaths in Hong Kong were attributed to four major preventable NCD. They were cancer (32.3%), heart diseases (15.0%), stroke (8.8%) and chronic lower respiratory diseases (5.1%).” *Id.*, at Executive Summary, at x. “In Hong Kong, a limited number of NCD account for a significant proportion of disease burden on the community and healthcare system...Accumulated knowledge and experience in health promotion and disease prevention shows that strategically focused interventions on a ‘cluster’ of modifiable behavioural risk factors and environmental determinants can induce parallel changes in those biomedical risk factors, thereby reduce the risk of developing NCD.” *Id.*, at Executive Summary, at xi. “NCD account for most of the disease burden in Hong Kong and the burden is expected to continue to rise in the decades ahead owing to multiple factors, including the rapidly ageing population and changing risk profile in the population.” *Id.*, at par. 1.4, p. 3.

341 *Id.*, Exhibit 45 at p. 70.

342 “Although many infants in Hong Kong have been breastfed on discharge from hospital, the exclusive breastfeeding rate remains low...[at 73.7%].” *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.

343 “The overall goal of the strategic framework is to increase the positive health and quality of life of the people in Hong Kong. To optimize health gains, the strategic framework focuses on the major risk factors that are potentially modifiable and have significant impact on the health of the Hong Kong population.” *Action Plan to Promote Healthy Diet and Physical Activity Participation in Hong Kong*, supra at par. 1.8.

344 *Id.*, at par. 2.2.

*inadequate*” (emphasis added).<sup>345</sup> It also conceded that there was a lack of “*health promotion activities on healthy diet and physical activity participation for infants and young children*” in Hong Kong (emphasis added).<sup>346</sup> It also recommended various “*health promotion activities...on healthy eating and physical activity participation targeting...young children and their parents*”,<sup>347</sup> including “*a new parenting programme on weaning [that] target[ed] all infants and young children in MCHCs [Maternal and Child Health Centers]*.”<sup>348</sup>

To address the lack of information, the Action Plan reflected that the GHK-SAR had decided to “*conduct[] population-based surveys related to the dietary habit and physical activity participation of the local population*” (emphasis added).<sup>349</sup> These *nonscientific* interview-based surveys conducted by the GHK-SAR Department of Health through self-reporting questionnaires<sup>350</sup> focused “*on parental knowledge, attitude and practice of feeding infants and young children, milk consumption of infants and young children, level of physical activity of infants and young children, and food and nutrient intakes of infants and young children*” (emphasis added).<sup>351</sup>

The first such *nonscientific* survey identified the child feeding perceptions and practices of Chinese parents of 6- to-48 month old Hong Kong children that “*had registered with Maternal and Child Health Centres (MCHCs), which covered more than 90% of children born to local parents.*”<sup>352</sup> It observed that the feeding of young children serves both “*a biological function to meet the nutrient requirements of children for daily activities and growth*” and “*also a social function that involves complex parent-child interaction in the context of the home environment.*”<sup>353</sup> The survey concluded that, “*parent over-concern about their children being under-weight and not eating enough was associated with various controlling feeding practices (e.g. pressure to eat) which might result in a negative eating atmosphere and avoidant eating behaviours, or over-eating and over-weight.*”<sup>354</sup>

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345 *Id.*, at par. 2.37.

346 *Id.*, at par. 3.19.

347 *Id.*

348 *Id.*, at par. 3.20.

349 *Id.*, at par. 2.38. While “[t]he *Food Consumption Survey 2005-2007* and the *Total Diet Study (TDS) of the Food and Environmental Hygiene Department (FEHD)* are being conducted to collect information on the food consumption patterns of the local adult population...[and] are expected to shed light on the behavioural and biomedical risk factors affecting the population at large, information focusing on infant and young children remains limited” (emphasis added). *Id.* Furthermore, the Action Plan conceded that, while the *Department of Health’s “Child Health Survey* to collect health information of local children aged 14 and below, such as health-related behaviours...*may add to the current knowledge on health status of infants and young children, the survey has not been specifically designed for collecting data on dietary habit and physical activity, and the information generated from the survey may not be comprehensive to guide interventions that focus on children’s dietary habit and physical activity*” (emphasis added). *Id.*, at par. 2.39.

350 *Id.*, at par. 3.16.

351 *Id.*

352 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. 6, available at: [http://www.fhs.gov.hk/english/archive/files/reports/Survey\\_IYCF\\_parents%20perception.pdf](http://www.fhs.gov.hk/english/archive/files/reports/Survey_IYCF_parents%20perception.pdf). “This [was] the first large scale survey of feeding practices of parents of preschool children in Hong Kong.” *Id.*, at p. 8.

353 *Id.*, at p. 57.

354 *Id.* To address this home-dynamic, the survey’s authors set forth recommendations which parents (mostly mothers) should follow in order to “*create a pleasant eating environment for [their] children.*” *Id.*, at pp. 6, 57.

The second such *nonscientific* survey focused exclusively on infant and young child (12-48 month old) consumption of milk in Hong Kong.<sup>355</sup> It found that 85.7% of toddlers and preschool children consumed follow-up formula, with “[c]lose to half of the 18- and 24-month groups dr[inking] more than the recommended volume of 480 ml per day”,<sup>356</sup> and “89.4% and 55.2% [, respectively,] of the 24- and 48-month groups...persistent[ly] us[ing a]...bottle for milk drinking.”<sup>357</sup> The survey drew a connection between children’s high consumption of follow-up formula and bottle usage and their body-mass index (“BMI”), finding that “the mean BMI of the bottle users...[t]aking [into account both]...the 24- and 48-month-old groups...was significantly higher than that of the non-bottle users.”<sup>358</sup> The survey also correlated higher follow-up formula and bottle usage with obesity: “In a recent report of a large cohort study in the US, continual bottle use at 2 years was associated with children being overweight and obese at 5.5 years.”<sup>359</sup> The survey attributed the high formula consumption by 2-4 year olds, which “[made] it difficult for children to establish a healthy eating habit”, to a high rate of bottle usage, which reflected that most children were being put to bed with and not adequately being weaned from the bottle.<sup>360</sup> It then attributed this feeding practice to parents’ beliefs that “follow-up formula was more suitable for 1- to 4- year- olds than cow milk” because “formula milk was supplemented with ‘nutrients that promote children’s brain development that cannot be provided by other foods’, and “that ‘follow-up formula can replace other food to provide nutrients’.”<sup>361</sup> The survey concluded, without providing any supporting evidence, that “[t]he findings *probably reflect the permeation of aggressive formula advertising* and parents’ lack of awareness of the nutritive value of homemade food using everyday ingredients” (emphasis added).<sup>362</sup>

The third such *nonscientific* study was the first to focus on the dietary and nutrition intake of children aged 0-5 years in Hong Kong.<sup>363</sup> The study “showed that the use of formula milk was

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355 See Wai-yin Luk, Shirley Leung, and Cynthia Leung, *A Survey of Infant and Young Child Feeding in Hong Kong: Milk Consumption* (2012), at pp. 5 and 8, available at: [http://www.fhs.gov.hk/english/archive/files/reports/Survey\\_IYCF\\_milkconsumption\\_1904.pdf](http://www.fhs.gov.hk/english/archive/files/reports/Survey_IYCF_milkconsumption_1904.pdf). The survey’s authors interviewed 1063 parents of 12-to 48 month old children registered at Maternal and Child Health Centres (MCHCs). It focused on identifying the parents’ “practices and beliefs in milk feeding.” *Id.*

356 *Id.*, at pp. 5, 20.

357 *Id.*

358 *Id.*, at pp. 16-17.

359 *Id.*, at p. 21.

360 “High milk consumption was associated with drinking from the bottle. Few children reported using cup to drink milk at 18 months, which is the recommended age when a child should stop using the bottle for milk drinking.” *Id.*, at p. 21. According to the survey’s authors, since bottle weaning is “a significant developmental milestone for children”, the failure to bottle wean suggested the potential for future developmental problems. In addition, “night feeding with [a] bottle or sleeping with bottles are common feeding practices that are associated with severe childhood [dental] caries.” *Id.*

361 *Id.*, at pp. 18, 20. “Excessive milk intake in Hong Kong [among] 12 to 24 month[] olds and in a significant proportion of preschool children at 48 months” is attributable largely to “[p]ersistent use of [the] bottle for milk drinking” and “parent’s belief [i]n the omnipotent formulae milk”. *Id.*, at p. 24.

362 *Id.*, at p. 20.

363 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 Executive Summary p. viii, available at: [http://www.fhs.gov.hk/english/archive/files/reports/Survey\\_IYCF\\_Dietnutrient%20intake.pdf](http://www.fhs.gov.hk/english/archive/files/reports/Survey_IYCF_Dietnutrient%20intake.pdf). This was a cross-sectional survey involving various age groups (6-7 months, 9-10 months, 12-13 months, 18-19 months, 24 months and 48 months) of children registered at Maternal and Child Health Centres (MCHCs). “Assessment of the nutrient adequacy of the studied children was made by comparison with the Estimated Average Requirement (EAR) (or the average individual requirement if the EAR is not available), and the Reference Nutrient Intake (RNI) of the World Health Organization/Food and Agricultural Organization

prevalent among children at all age groups<sup>364</sup> and [that] the breastfeeding rate at 6 months and beyond was low”.<sup>365</sup> It concluded that prevalent use of formula milk resulted in an unbalanced diet “characterized by inadequate intake of vegetables and fruits, high intake of protein-rich foods and formula milk.”<sup>366</sup> It also concluded that “children who drank more milk (mainly formula milk) than the recommended volume generally consumed a smaller amount of grains, vegetables and fruits.”<sup>367</sup> In addition, the survey reported and implied a relationship between these practices and “the emergence of some unhealthy dietary patterns in older children. The number of children consuming desserts, snacks, sweets, processed meat, fruit and carbonated drinks greatly increased at four years of age.”<sup>368</sup> The survey failed to conclude, however, that the nutritional status of these Hong Kong children had been compromised by their formula consumption.<sup>369</sup>

Significantly, the anecdotal findings from these *nonscientific* surveys and the prior 2005 report added little to the GHK-SAR’s limited knowledge about these issues, as reflected in its 2010 Action Plan. The Action Plan had recommended as “Action 9”, the “develop[ment] of a Hong Kong Code of Marketing of Breastmilk Substitutes” – i.e., the Draft HK Code.<sup>370</sup> The Action Plan indicated that the objective of the Draft HK Code would be to ensure that infants received the “*ideal nutrients for...healthy growth and development...[that b]reastfeeding provides*”, as well as, “[t]he *anti-infective properties of breastmilk [that] also help protect infants against certain diseases*” (emphasis added).<sup>371</sup> The Action Plan also concluded, in the absence of new information, that such objective could be achieved only by ensuring that “mothers are not discouraged from breastfeeding...[by]...wide-spread and aggressive...marketing of formula milk...and that substitutes are used safely if needed.”<sup>372</sup>

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(WHO/FAO). Other overseas dietary recommendations were also applied if daily requirement of a nutrient is not available from the WHO/FAO.” *Id.*, at Executive summary at viii.

364 “The survey revealed a high consumption of milk by children, with 69.6% in 12-month group, 47.6% in 18-month group, 35.7% in 24-month group and 9.9% in 48-month group consuming more than the recommended amount of 2 cups (480 ml) per day.” *Id.*, at Executive Summary at x.

365 *Id.*, at Executive Summary, 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.*

366 *Id.* “Over 60% had vegetable intake and over 30% had fruit intake below the recommended level.” *Id.* See also p. 129.

367 *Id.*, at Executive Summary at x, pp. 129-130.

368 *Id.* “Among the 48-month group, approximately 90% consumed desserts, snacks and sweets, and nearly 50% included processed meat in their diet. Over 40% of children had fruit drinks whereas a total of 17.8% of children consumed carbonated drinks.” *Id.*, at Executive Summary at x, pp. 130-131.

369 The survey found that “protein intakes were adequate compared to the WHO/FAO average requirement”, partly due to high consumption of meat and fish among children older than 6 months and 9 months of age – younger infants did not consume much meat and fish, and consequently had lower iron and zinc intakes; “children aged two and four years had fibre intake...from consumption of plant foods...lower than the recommended level”; “intake of calcium, iron and zinc was adequate as a whole”, but a “higher proportion of children had a low intake of iron and zinc before 12 months”; “intake of dietary calcium...in the 48-month group...[was]...below the WHO/FAO EAR”; “the proportion of children with sodium intake higher than the recommended level increased greatly after the age of two”; measured against the “WHO child growth standard, 12.7% of children aged between 0 and 5 years were classified as “having possib[ility] of overweight” and 2.7% as “overweight or obese”...data...suggested that overweight or obesity started to increase at 24 months onwards”. *Id.*, at pp. 126-128. “These findings therefore suggest that the nutritional status of the studied children were unlikely to be inadequate” despite their formula consumption. *Id.*, at p. 317.

370 *Id.*, at par. 3.21.

371 *Id.*

372 *Id.*

Clearly, the GHK-SAR has arrived at a solution - i.e., the Draft HK Code's 30-month marketing ban - without having adequately assessed on a scientific basis the extent, if any, to which the follow-up formula and complementary food products offered for sale and sold in the Hong Kong marketplace pose any actual diet-related NCD food safety problem at all for infants and young children 6-36 months of age. These surveys confirm that the GHK-SAR has failed to identify, either generally or with respect to specific brands or products, an indirect long-term diet-related NCD food safety risk arising from their consumption. In other words, these surveys do not qualify as "scientific risk assessments" within the meaning of Article 5.1 and Annex A(4) of the WTO SPS Agreement.

Arguably, these surveys are also of limited reliability and use as other than scientific risk assessments because they did not adhere to any kind of scientific method or protocol. The GHK-SAR failed to scientifically observe the children and parents who were the subjects of these surveys to verify whether the feeding practices reported had actually occurred. In addition, the GHK-SAR had failed to establish a control group for subsequent comparison purposes, to medically examine the children to assess their actual nutrient intake and body fat compositions before, during and after the surveys were performed, or to undertake any scientific analysis of the results gathered for purposes of comparing the diet-related NCD risks the consumption of such products engendered for each of the different groups of children surveyed. Therefore, it may be concluded that the data generated by the study and surveys performed in furtherance of the GHK-SAR's NCD-focused Strategic Framework and Action Plan and that underlie the Draft HK Code's food safety-related provisions, also fail to constitute sufficient scientific evidence that could serve as the basis for a risk assessment, as required by SPS Article 2.2.<sup>373</sup>

6. SPS Measures Aiming to Secure a Higher Level of Protection Than International Standards Afford May Be Adopted On a Provisional Basis Only If Relevant Scientific Evidence is Insufficient to Conduct a Risk Assessment And Certain Other Requirements Are Satisfied

a. The Four Requirements of SPS Article 5.7

As previously discussed, SPS Article 2.2 requires WTO Members to ensure that SPS measures are "not maintained without sufficient scientific evidence, *except as provided for in paragraph 7 of Article 5*" (emphasis added).<sup>374</sup> According to the Appellate Body, "Article 5.7...to which Article 2.2 explicitly refers, is part of the context of the latter provision and should be considered in the interpretation of the obligation not to maintain an SPS measure without sufficient scientific evidence."<sup>375</sup> Since "Article 2.2 excludes from its scope of application the kinds of situations covered by Article 5.7", Article 5.7 does not operate as an exception to that provision.<sup>376</sup> Rather, Article 5.7 "operates as a *qualified exemption* from the obligation under Article 2.2 not to maintain SPS measures without sufficient scientific evidence" (emphasis added).<sup>377</sup> The Appellate Body has also concluded that "Article 5.7 operates as a *qualified exemption*...rather than as an exception...from the obligation under Article 5.1 to base SPS measures on a risk assessment."<sup>378</sup>

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373 Panel Report, *US-Poultry(China)* at pars. 7.203-7.204.

374 SPS Art. 2.2.

375 Appellate Body Report, *Japan – Agricultural Products II* at par. 80.

376 Panel Report, *EC-Biotech Products* at par. 7.2969.

377 Appellate Body Report, *Japan – Agricultural Products II* at par. 80.

378 Panel Report, *EC-Biotech Products* at par. 7.2997.

This means that SPS Article 5.7 may be invoked as an independent provision that “allows Members to adopt provisional SPS measures ‘[i]n cases where relevant scientific evidence is insufficient’ and certain other requirements are fulfilled.”<sup>379</sup> Article 5.7, in other words, “provides a ‘temporary ‘safety valve’ in situations where some evidence of a risk exists but not enough to complete a full risk assessment, thus making it impossible to meet the more rigorous standards set by Articles 2.2 and 5.1.”<sup>380</sup>

As the Panel in *EC-Biotech Products* has noted, the characterization of “Article 5.7 as a qualified right and not an exception also has implications for the allocation of the burden of proof concerning the issue of the consistency of an SPS measure with Article 5.7.”<sup>381</sup> “[W]here a complaining party alleges that an SPS measure is inconsistent with the obligation in Article 2.2 not to maintain SPS measures without sufficient scientific evidence, it is incumbent on [that] party...to demonstrate that the challenged SPS measure is inconsistent with at least one of the four requirements set forth in Article 5.7.” In other words, “it is incumbent on the complaining party to establish a *prima facie* case of inconsistency with both Articles 2.2 and 5.7.”<sup>382</sup>

There are “four requirements in Article 5.7 that must be met in order for a Member to adopt and maintain a provisional SPS measure”:<sup>383</sup> 1) “[The measure must be] imposed in respect of a situation where ‘relevant scientific information is insufficient’”;<sup>384</sup> 2) “[The measure must be] adopted ‘on the basis of available pertinent information’”; 3) “[The Member must] ‘seek to obtain the additional information necessary for a more objective assessment of risk’”; and 4) “[The Member must] ‘review the...measure accordingly within a reasonable period of time’.”<sup>385</sup> According to the WTO Appellate Body, these “four requirements...are ‘clearly cumulative in nature’”. In other words, “[w]henver one of these ‘four requirements is not met, the measure at issue is inconsistent with Article 5.7.”<sup>386</sup>

For purposes of the first requirement, “the sufficiency of relevant scientific evidence should be assessed at the time a provisional measure [is] adopted.”<sup>387</sup> “[R]elevant scientific evidence’ will be ‘insufficient’ within the meaning of Article 5.7 if the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks as

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379 SPS Art. 5.7; Appellate Body Report, *Japan – Agricultural Products II* at par. 80. “[A] Member may provisionally adopt [SPS] measures on the basis of available pertinent information, including that from the relevant international organizations as well as from [SPS] applied by other Members.” SPS Art. 5.7. For example, “[i]n emergency situations...a WTO Member will take a provisional SPS measure on the basis of limited information and the steps it takes to comply with its obligations to seek to obtain additional information and review the measure will be assessed in the light of the exigencies of the emergency.” Appellate Body Report, *US - Continued Suspension*, at par. 680.

380 Appellate Body Report, *US - Continued Suspension* at par. 678.

381 Panel Report, *EC-Biotech Products* at par. 7.2976.

382 *Id.*, at par. 7.2979.

383 Panel Report, *EC-Biotech Products* at pars. 7.2929 and 7.3218; Appellate Body Report, *Japan – Agricultural Products II*, at par. 89.

384 *Id.*

385 *Id.*

386 *Id.*

387 Panel Report, *EC-Biotech Products* at pars. 7.3253 and 7.3255.

required under Article 5.1 and as defined in Annex A to the SPS Agreement”.<sup>388</sup> “Scientific evidence could be considered to be insufficient in qualitative terms for instance when it is inconclusive or unreliable.”<sup>389</sup> The determination of whether available scientific evidence is insufficient to permit the performance of an “adequate risk assessment” should be made on a case-by-case basis. Yet, the protection goals of a Member’s legislators are not relevant to said determination.<sup>390</sup> This means that “the determination of whether scientific evidence is sufficient to assess the existence and magnitude of a risk must be disconnected from the intended level of protection.”<sup>391</sup>

In *US – Continued Suspension*, the Appellate Body also noted that, given its probative value, “the existence of an international standard for which a risk assessment was conducted could be offered as evidence in support of an assertion that the relevant scientific evidence is *not* insufficient within the meaning of Article 5.7 (emphasis added).”<sup>392</sup> It also emphasized, however, that, since “the legal test that applies to the ‘insufficiency’ of the evidence under Article 5.7 is not made stricter...in circumstances where a Member adopts a higher level of protection than that reflected in the international standard...it would be incorrect to use JECFA’s risk assessments as a legal benchmark for assessing insufficiency.”<sup>393</sup> According to the Appellate Body, “such evidence is not dispositive and may be rebutted by the Member taking the provisional SPS measure.”<sup>394</sup> In other words, “the existence of an international standard does not create a legal presumption of sufficiency for

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388 Panel Report, *EC-Biotech Products* at par. 7.3233; Appellate Body Report, *Japan - Apples*, at par. 179. The performance of an assessment of the risks will be considered “adequate” for these purposes if said assessment is “objective”, within the meaning of SPS Article 5.1, and otherwise meets the requirements of SPS Annex A(4)”. Panel Report, *EC-Biotech Products*, at par. 7.3235.

389 Panel Report, *EC-Biotech Products* at par. 7.3233; Appellate Body Report *Japan - Apples* at par. 185.

390 *Id.*, at par. 7.3238. The determination of whether scientific evidence is “insufficient” to conduct an adequate risk assessment does not reside with the legislator. “[T]he notion of ‘insufficiency’ [does not] impl[y] a relationship between the scientific evidence and the matters of concern to the legislator...[Rather, t]here is “only one relevant relationship: that between the scientific evidence and the obligation to perform a risk assessment under Article 5.1” (emphasis added). Panel Report, *EC-Biotech Products* at par. 7.3234. Thus, the protection goals of a Member’s legislators are not relevant in determining whether available scientific evidence is “insufficient” to permit the performance of an “adequate risk assessment”. *Id.*, at par. 7.3237. In other words, a risk assessment need not “be adequate for the purposes of a Member’s legislator”. *Id.*, at 7.3236-7.3237. While the “protection goals of a legislator may have a bearing on the question of which risks a Member decides to assess with a view to taking regulatory action, if necessary...[and] are certainly relevant to the determination of the...[risk management] ‘actions’...to be taken for achieving a Member’s level of protection against risk...there is no apparent link between a legislator’s protection goals and the task of assessing the existence and magnitude of potential risks.” *Id.*, at 7.3238. “There can be no doubt that a Member’s appropriate level of protection is relevant to determining the SPS measure to be applied, if any, to protect that Member from risks. Article 5.3 of the SPS Agreement refers to the determination of ‘the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from [...] risk’, and Article 5.6 relates to the establishment or maintenance of ‘[SPS] measures to achieve the appropriate level of sanitary or phytosanitary protection’”. *Id.*, at par. 7.3242.

391 Appellate Body Report, *US - Continued Suspension* at par. 686.

392 *Id.*, at par. 708. “It is an evidentiary issue in the sense that the scientific information underlying the international standard has probative value as to the sufficiency of the scientific evidence needed for conducting a risk assessment at a discrete point in time.” *Id.*

393 *Id.*, at par. 708. An international (JECFA) “risk assessment should not be used as a legal benchmark for assessing ‘insufficiency’”, “in particular where a WTO Member has elected to adopt an SPS measure that does not conform to the international standard.” *Id.*, at pars. 708 and 711. “[S]cientific evidence that may have been relied upon by an international body when performing the risk assessment that led to the adoption of an international standard at a certain point in time may no longer be valid, or may become insufficient in the light of subsequent scientific developments. Therefore, the existence of a risk assessment performed by JECFA does not mean that scientific evidence underlying it must be considered to be sufficient within the meaning of Article 5.7.” *Id.*, at par. 695.

394 *Id.*, at par. 696.

purposes of Article 5.7,”<sup>395</sup> and thus, alleged insufficiencies in the relevant scientific evidence underlying an international risk assessment must be evaluated on their own terms.<sup>396</sup>

Furthermore, the Appellate Body, in *US – Continued Suspension*, emphasized that the insufficiency of evidence necessary to conduct a risk assessment may be determined by the extent to which “new evidence calls into question the relationship between the body of scientific evidence and the conclusions concerning risk”.<sup>397</sup> However, “[t]he ‘insufficiency’ requirement in Article 5.7 does not imply that new scientific evidence must entirely displace the scientific evidence upon which an international standard relies. It suffices that new scientific developments call into question whether the body of scientific evidence still permits of a sufficiently objective assessment of risk.”<sup>398</sup> In other words, it is not necessary for “a paradigmatic shift in...scientific knowledge...[that] call[s] into question the ‘fundamental precepts of previous knowledge and evidence’” to have occurred “in order to render the scientific evidence relied upon by [a prior risk assessment]...now ‘insufficient’ within the meaning of Article 5.7.”<sup>399</sup> It is only “where the new scientific developments themselves do not permit the performance of a new risk assessment that is sufficiently objective...[that a situation will ] fall within the scope of Article 5.7 of the SPS Agreement.”<sup>400</sup>

Available pertinent information, for purposes of the second requirement, “may include information from ‘the relevant international organizations’ or deriving from SPS measures applied by other WTO Members.”<sup>401</sup> “Article 5.7 contemplates situations where there is some evidentiary basis indicating the possible existence of a risk, but not enough to permit the performance of a risk assessment. Moreover, there must be a rational and objective relationship between the information concerning a certain risk and a Member’s provisional SPS measure.”<sup>402</sup> Although “[i]nformation from relevant international organizations [such as JEFCA] may not necessarily be considered ‘sufficient’ to perform a risk assessment...it may be part of the ‘available pertinent information’ which provides the basis for a provisional SPS measure under Article 5.7.”<sup>403</sup>

The third requirement that a WTO Member shall seek to obtain the additional information necessary for a more objective assessment of risk “implies that, as of the adoption of the provisional measure, a WTO Member must make best efforts to remedy the insufficiencies in the relevant scientific evidence with additional scientific research or by gathering information from relevant international organizations or other sources.”<sup>404</sup> The additional information to be collected

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395 *Id.*, at par. 697.

396 *Id.*, at par. 711.

397 *Id.*, at par. 721. For example, “scientific progress may lead a WTO Member and international organizations to reconsider the risk assessment underlying an SPS measure. In some cases, new scientific developments will permit a WTO Member to conduct a new risk assessment with the sufficient degree of objectivity.” *Id.*, at par. 701.

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399 *Id.*, at pars. 721 and 725. “[T]he Panel’s ‘critical mass’ test imposed an excessively high threshold in terms of the change in the scientific evidence that would make previously sufficient evidence insufficient.” *Id.*, at par. 721.

400 *Id.*, at par. 701.

401 *Id.*, at par. 678.

402 *Id.* “In this sense, Article 5.7 provides a ‘temporary ‘safety valve’ in situations where some evidence of a risk exists but not enough to complete a full risk assessment, thus making it impossible to meet the more rigorous standards set by Articles 2.2 and 5.1.” *Id.*

403 *Id.*, at par. 695.

404 *Id.*, at par. 679. In *US-Continued Suspension*, the Appellate Body found that, although Article 5.7 “does not set out ‘explicit prerequisites regarding the additional information to be collected or a specific collection procedure’...the WTO Member

must be 'germane' to conducting the assessment of the specific risk."<sup>405</sup> However, the 'more objective' risk assessment to which Article 5.7 refers need not satisfy the definition provided in Annex A(4).<sup>406</sup> It is more likely something "which is closer to satisfying the definition in Annex A(4) than consideration of 'available pertinent information'".<sup>407</sup>

"What constitutes a 'reasonable period of time' for purposes of the fourth requirement of SPS Article 5.7 depends, *inter alia*, on the difficulty of obtaining the information necessary for a more objective assessment of risk."<sup>408</sup> However, "where additional information obtained by a Member is objectively sufficient to perform 'a more objective assessment of risk', [there would be no]...justification for delaying the performance of such an assessment on the grounds that an assessment incorporating the additional information would not allow the importing Member to determine 'with a sufficient degree of precision' whether a measure different from its provisional measure would achieve its appropriate level of protection."<sup>409</sup> To the extent "there are factors which affect scientists' level of confidence in 'a more objective assessment of risk' they have performed, the importing Member may take this into account when reviewing its provisional [risk management] measure in the light of the 'more objective assessment'."<sup>410</sup> A WTO Member must withdraw or modify a provisional measure "if [its] review establishes that the measure is no longer justified."<sup>411</sup> In other words, "once sufficient relevant scientific evidence has been obtained and a risk assessment meeting the definition of Annex A(4) has been carried out, the provisional SPS measure must be withdrawn or modified if it cannot be 'based on' the risk assessment in question."<sup>412</sup>

#### b. The GHK-SAR May Not Adopt the Draft HK Code's 30-Month Marketing Ban as a Temporary Provisional Measure

To recall, the GHK-SAR intends to adopt Draft HK Code provisions addressing the indirect long-term diet-related NCD risks associated with the consumption in Hong Kong of formula milk and (nonformula milk) infant and young children's food products deemed to contain excessive amounts of sodium, sugars and/or trans-fats. The GHK-SAR, however, has failed to conduct any scientific studies to ascertain the scope and magnitude of the actual diet-related NCD risks these products pose to human health or life in Hong Kong that is capable of meeting the definition of a risk assessment contained in SPS Article 5.1 and Annex A(4). In addition, the study and surveys the GHK-SAR did perform as the basis for, in implementation of, and/or in response to Hong Kong's NCD-focused Strategic Framework and Action Plan did not follow scientific methods or protocols, and thus, the information they provide does not constitute sufficient scientific evidence within the

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adopting a provisional SPS measure should be able to identify the insufficiencies in the relevant scientific evidence, and the steps that it intends to take to obtain the additional information that will be necessary to address these deficiencies in order to make a more objective assessment and review the provisional measure within a reasonable period of time." *Id.*

<sup>405</sup> *Id.*

<sup>406</sup> "[A]ny risk assessment which might be required by the first sentence of Article 5.7 would not need to meet the definition of a risk assessment contained in Annex A(4)." *Id.*, at par. 7.2992.

<sup>407</sup> Panel Report, *EC-Biotech Products* at par. 7.2988; Appellate Body Report, *Japan - Agricultural Products II* at par. 92.

<sup>408</sup> *Id.*, at par. 7.3245; Appellate Body Report, *Japan - Agricultural Products II*, par. 93.

<sup>409</sup> Panel Report, *EC-Biotech Products* at par. 7.3245.

<sup>410</sup> *Id.*

<sup>411</sup> *Id.*, at par. 7.3257.

<sup>412</sup> *Id.*

meaning of SPS Article 2.2 that could serve as the basis for the type of risk assessment required by SPS Article 5.1 and Annex A(4).

The GHK-SAR may be expected to invoke the provisional safeguard provisions of SPS Article 5.7 in an effort to adopt the Draft HK Code measures concerned with diet-related NCD risks while excusing itself from the burden of meeting these SPS Agreement obligations. SPS Article 5.7, however, imposes four requirements all of which must be satisfied before the GHK-SAR will be eligible to adopt the Draft HK Code. Unfortunately, the GHK-SAR will be unable to meet the most important of these requirements.

As previously discussed, the FAO/WHO and Codex have developed new science concerning diet-related NCD risks associated with several nutrients contained in excess of certain quantities in food products heavily consumed by members of the general population (persons older than 36 months of age). Arguably, this new scientific evidence calls into question prior science surrounding such risks. Evolving FAO/WHO science has already identified sodium and saturated fatty acids as two such nutrients that require special attention, and is in the process of developing guidelines on total fat and sugars which will be released in the near future. This new science has been incorporated into new and revised Codex standards which show that diet-related NCD risks associated with such nutrients can be managed responsibly with an appropriate degree of precaution by conscientious governments. These Codex standards, for example, provide recommendations for developing and/or revising relevant nutrient reference values, defining and limiting the scope of food-related health and nutrient claims, and requiring that food product labels contain declarations of NCD nutrient reference values (NRVs-NCD), where a relationship between a particular product nutrient and diet-related NCD risk has been identified.

While various Draft HK Code provisions seem to adhere to these Codex recommendations, others which effectively impose a 30-month marketing ban on the promotion/advertising of follow-up formula and (nonformula milk) infant and young children's food products (including complementary foods) go significantly beyond them. In proposing the adoption of such a marketing ban to achieve the higher level of protection it has chosen for Hong Kong residents the GHK-SAR has apparently decided that the new risk science and related Codex risk management protocols are somehow inadequate. This it cannot do without substantiating why.

SPS Article 5.7 jurisprudence reflects that the GHK-SAR is obliged to establish that the current and evolving body of relevant available FAO/WHO scientific information does not allow (i.e., is "insufficient"), in quantitative or qualitative terms, for the performance of an adequate assessment of diet-related NCD risks arising from the consumption of formula milk and (nonformula milk) infant and young children's food products, particularly, follow-up formula and complementary foods, by Hong Kong infants and young children up to 36 months of age. Such jurisprudence also reflects that the GHK-SAR is obliged, in the alternative, to demonstrate that it possesses additional new scientific evidence that calls into question the FAO/WHO's recent scientific findings, as applied to follow-up formula and complementary food products consumed by Hong Kong infants and young children up to 36 months of age.

The GHK-SAR, however, has thus far failed to satisfy either of these obligations. Indeed, the GHK-SAR would be hard pressed to show that it could not use this new FAO/WHO science and the plethora of ongoing ancillary academic and institutional research to extrapolate data points which can then serve as the basis for conducting a risk assessment that identifies unique diet-related NCD risks associated with the consumption of specific follow-up formula and complementary food brands and products intended for Hong Kong infants and young children up to 36 months of age.

If scientific information were indeed insufficient to conduct a risk assessment to identify the potential diet-related NCD risks engendered by the consumption of follow-up formula and complementary food products ostensibly containing excessive amounts of sodium, saturated fatty acids, trans fats and sugars, how then was it possible for the GHK-SAR to develop, in 2011, both the *Nutrition Guidelines for Children Aged 2 to 6*<sup>413</sup> and the *Physical Activity Guide for Children Aged 2 to 6*?<sup>414</sup> These official government documents clearly target the 0-36 month age group of infants and young children falling within the Draft HK Code's scope and coverage. They also indicate that the GHK-SAR recognizes how diet-related NCD risks for child hypertension, cardiovascular disease, diabetes and obesity arise from factors *other than* formula milk and complementary food manufacturer, distributor and marketer promotional/advertising practices. These documents focus, in particular, on the need for Hong Kong preprimary institutions ("PPIs") to ensure adequate nutrition and physical activities for children aged 2-6 years.<sup>415</sup>

Furthermore, the GHK-SAR has not provided, and is unlikely to provide, any evidence indicating that the consumption of such products poses "risks of irreversible, e.g. life-terminating, damage to human health", and thus, a public health emergency in Hong Kong, which has prompted it as a "responsible, representative government" to adopt the 30-month marketing ban "from the perspectives of prudence and precaution".<sup>416</sup> The situation in Hong Kong is clearly unlike that in the People's Republic of China which has triggered the fears and concerns of Chinese residents about the safety of domestic Chinese manufactured infant formula and the bulk-buying of foreign infant formula products imported into Hong Kong,<sup>417</sup> and has prompted Chinese Premier Li Keqiang's

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413 See Government of Hong Kong Special Administrative Region, Department of Health, *Nutrition Guidelines for Children Aged 2 to 6* (Dec. 2011), available at: [http://www.chp.gov.hk/files/pdf/nutritional\\_eng.pdf](http://www.chp.gov.hk/files/pdf/nutritional_eng.pdf).

414 See Government of Hong Kong Special Administrative Region, Department of Health, *Physical Activity Guide for Children Aged 2 to 6* (Dec. 2011), available at: [http://www.chp.gov.hk/files/pdf/physical\\_eng.pdf](http://www.chp.gov.hk/files/pdf/physical_eng.pdf).

415 "With about 140,000 young children attending preprimary institutions (PPIs) in Hong Kong every year, PPI is considered an important place other than the home for supporting children's positive development. Indeed, the PPI setting plays important roles in fostering young children's lifestyle habits, thereby promoting their health and preventing childhood obesity." See Government of Hong Kong Special Administrative Region, Department of Health, *Nutrition Guidelines for Children Aged 2 to 6*, supra at Executive Summary, p. iii. "It is hoped that teachers in PPIs can design and incorporate a wider range of school-based physical activity into classroom teaching so that active play can be enjoyable, interesting and stimulating for children. In this way, children are best able to learn basic life skills, build good physique and develop a habit of regular physical activity as part of healthy living." See Government of Hong Kong Special Administrative Region, Department of Health, *Physical Activity Guide for Children Aged 2 to 6*, supra at Executive Summary, p. iv.

416 Appellate Body Report, *US - Continued Suspension* at par. 680.

417 Chinese consumer demand for foreign infant formula sold in Hong Kong has been so great that it has resulted in infant formula shortages in Hong Kong that have triggered the Government of the Hong Kong Special Administrative Region ("GHK-SAR")'s imposition of import and export quotas on such products, the violation of which is subject to stiff monetary fines and punishable by imprisonment. See 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](http://www.chinadaily.com.cn/china/2013-03/04/content_16271673.htm). "Under an amendment to Hong Kong's export and import law, from March 1, a person can carry only two cans, or 1.8 kg, of baby formula out of Hong Kong, and the person must be at least 16 years old. Violators face fines of up to HK\$500,000 (\$64,500) and two years in jail." *Id.*

recent vow to ensure “the safety of infant formula” in China, which he claimed was critical to “the nation’s future,<sup>418</sup> and the Chinese Government’s launch of “a public-health campaign to encourage breast-feeding”,<sup>419</sup> consistent with the World Health Organization (“WHO”)’s recommendation that mothers breast-feed “for six months after an infant’s birth” (emphasis added).<sup>420</sup>

Unless the GHK-SAR is able to satisfy its burden of proof with respect to these obligations, it is unlikely to be eligible to secure the protection of SPS Article 5.7. Without the ability to invoke SPS Article 5.7, the GHK-SAR’s decision to adopt and maintain those Draft HK Code provisions effectively imposing a 30-month marketing ban on follow-up formula and complementary food products in Hong Kong would plainly contravene the letter and spirit of the SPS Agreement. In that instance, the odds that the Draft HK Code would invite a WTO challenge would greatly increase.

### III. Conclusion – The Draft HK Code’s Food Safety-Related Provisions Violate SPS Agreement Articles 2.2, 5.1, 5.2, 5.7, and Annex A(1) and (4)

The Draft *Hong Kong Code of Marketing and Quality of Formula Milk and Related Products, and Food Products for Infants & Young Children* (“the Draft HK Code”) recently issued by the Government of the Hong Kong Special Administrative Region (“GHK-SAR”) arguably violates the WTO SPS Agreement. Various Draft HK Code provisions prohibit and/or restrict the dissemination of informational/educational materials (Article 4), the information contained on formula milk product containers and labels (Article 8), and the promotion/marketing of formula milk and complementary food products to the public (Article 5), intended for use as breastmilk substitutes or supplements by infants and young children up to 36 months of age.

These Draft HK Code provisions, in part, are primarily concerned with mitigating the direct short-term and indirect long-term food safety-related risks of illness/disease arising from the consumption of such products, and adversely affect international trade in foreign manufactured follow-up formula and complementary food products. Consequently, they qualify, in part, as “SPS measures”, within the meaning of SPS Article 1 and Annex A(1), and fall under the coverage of the SPS Agreement. Direct short-term risks to life or health considered include those posed primarily to young infants (1-6 months of age) from bacterial infections arising from the consumption of powdered infant and follow-up formula. Indirect long-term risks to life or health considered include those posed primarily to older infants and young children 6-36 months of age arising from the consumption of follow-up formula and complementary food products containing excessive amounts of nutrients (namely, sodium, saturated fatty acids, trans-fats and sugars) deemed associated with diet-related non-communicable diseases (“NCDs”) (e.g., hypertension, diabetes, obesity).

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418 See 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>.

Mr. Li’s public statement was a response to Chinese citizens’ legitimate “[c]oncerns about the safety of domestic milk powder [which] have fueled Chinese demand for foreign-made infant formula, leading to bulk-buying in Hong Kong, Britain and some other countries.” It is well known that, “[i]n 2004, fake Chinese milk powder left at least a dozen babies dead from malnutrition. [And, i]n 2008, infant formula that was tainted with an industrial chemical, melamine, killed at least six babies and sickened nearly 300,000 others with kidney stones and other illnesses. Melamine was added to watered-down milk to make it appear to have higher protein content.” *Id.*

419 See Te-Ping Chen and Laurie Burkitt, *Infant Formula Scare Spurs China Breast-feeding Push*, Wall Street Journal (5/31/13), available at: <http://online.wsj.com/article/SB10001424127887324412604578517380659012240.html>.

420 *Id.*

While the Draft HK Code SPS measures concerned with the direct short-term risks of bacterial infection are based largely on current international FAO/WHO risk assessments and related Codex standards providing prudent risk mitigation recommendations, they arguably go beyond such assessments and standards and unnecessarily disrupt international trade, to the extent they impose, without scientific substantiation, an effective 30-month marketing ban on follow-up formula and complementary food products. Similarly, while the Draft HK Code SPS measures concerned with indirect long-term diet-related NCD risks arising from daily intake of such nutrients are based largely on new international FAO/WHO risk assessments and evolving soon-to-be adopted Codex standards that incorporate prudent risk management tools, they, too, arguably go beyond such assessments and standards and unnecessarily disrupt international trade, to the extent they impose, without scientific substantiation, an effective 30-month marketing ban on such products.

The SPS Agreement requires that WTO Members adopting and/or applying SPS measures that aim to secure a higher level of protection of human life or health than international standards afford justify their measures by means of a science-based risk assessment. Alternatively, WTO Members may provide sufficient scientific evidence within the meaning of SPS Article 2.2 that is capable of serving as the basis for such a risk assessment. SPS Articles 5.1 and 5.2 set forth a detailed description of the type of risk assessment that must be undertaken for this purpose. Unfortunately, the study and consumer questionnaire-based surveys the GHK-SAR has undertaken concerning the relative breastfeeding and formula milk bottle-feeding behaviors of parents, infants and young children in Hong Kong fail to qualify as the type of risk assessment required by SPS Articles 5.1 and Annex A(4) or as scientific evidence sufficient to support the performance of a qualified risk assessment. If, and to the extent the Draft HK Code, when adopted, contains an effective 30-month marketing ban of such products in Hong Kong, it will be considered as being unsubstantiated by a qualified risk assessment or sufficient scientific evidence, and thus, in violation of the SPS Agreement.

The SPS Agreement, nevertheless, also provides WTO Members with the opportunity to invoke the provisional safeguard protection available under SPS Article 5.7 if they are unable to provide the scientific substantiation required by SPS Articles 5.1 and 2.2. However, SPS jurisprudence reflects that the GHK-SAR must first demonstrate that the current and/or evolving body of relevant available scientific information is insufficient, in quantitative and qualitative terms, to perform an adequate assessment of the bacterial and/or diet-related NCD risks arising from the consumption of follow-up formula and/or complementary food products by infants and young children 6-36 months of age. Alternatively, the GHK-SAR must demonstrate that it possesses additional new scientific evidence with respect to both kinds of risks that calls into question the FAO/WHO's recent scientific findings and the Codex' recent reviews of and revisions to long- prevailing standards. Arguably, the GHK-SAR will be hard pressed to show that it could not use this new FAO/WHO science and the plethora of ongoing ancillary academic and institutional research to extrapolate data points which can then serve as the basis for conducting a risk assessment capable of identifying the risks posed by specific infant formula, follow-up formula and complementary food brands and products consumed by Hong Kong infants and young children. If, the GHK-SAR is unable to satisfy its burden of proof with respect to these obligations, it will be ineligible to secure the protection of SPS Article

5.7 as legal justification for the temporary adoption of Draft HK Code SPS measures effectively imposing a 30-month marketing ban on such products on food safety grounds. Therefore, should the GHK-SAR decide to adopt the Draft HK Code in its current version, it should prepare for a potential WTO SPS Agreement challenge.

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