Lawrence A. Kogan on

The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law (Part 1 of 2)

2013 Emerging Issues 7066

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TABLE OF CONTENTS

I. Introduction:

The Republic of "[t]he Philippines has fervently advocated for the implementation of the [World Health Organization ("WHO")] International Code of Marketing of Breast milk Substitutes" ("WHO Code") as national law, and has thereby "become an example internationally".[1] "[T]he Philippine Government [has also endeavored] to increase breastfeeding rates (with the support of WHO, United Nations Children's Fund [("UNICEF")] and nongovernmental organizations) including [through] development and implementation of a national policy and plan of action on Infant and Young Child Feeding [("IYCF")] and…to promote breastfeeding counselling in communities."[2]

To improve the health and nutrition[3] and to reduce the mortality rate of its youngest citizens,[4] the first Philippine Congress convened following the abolition of the presidency of Ferdinand E. Marcos and the drafting of a new Federal Constitution,[5] enacted the *Rooming-In and Breast-Feeding Act of 1992* ("Act No. 7600).[6] Act No. 7600's sole purpose was to encourage, protect and support the practice of breastfeeding, and it ultimately "served as the legal basis for the [national] Mother Baby Friendly Hospital Initiative (MBFHI)."[7] During May 2005, the Philippines Department of Health ("PHDOH") also issued Administrative Order ("AO") 2005-0014[8] which set forth the Philippines

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1 *See* World Health Organization Western Pacific Region, *WHO Country Cooperation Strategy for the Philippines 2011-2016* (2010) at Sec. 2.6, p. 20, available at: http://www.wpro.who.int/countries/phl/ccs_phl_en.pdf.

2 *Id*.

3 *See, e.g.*, Republic of the Philippines, Department of Health, *Prevention and Control of Chronic Lifestyle-Related Noncommunicable Diseases in the Philippines - Manual of Operations* (2009), available at: http://www.wpro.who.int/philippines/publications/manual_of_operations_prevention_and_control_of_ncds_in_the_philippines.pdf. "***Build healthy nutrition-related practices***. Encourage client to consume adequate and well-balanced diet and adopt desirable food and nutrition practices…Exclusively breastfeed infants up to 6 months and then give them appropriate complementary foods while breastfeeding up to 24 months…" (emphasis in original). *Id*., at p. 29. *See also* World Health Organization, *Report of the WHO Representative - The Work of the World Health Organization in the Philippines (Jan. - Dec. 2011)* (2012), available at: http://www.wpro.who.int/philippines/about/who_philippines_2011_annual_report.pdf. "Breastfeeding promotes better health in infants and young children. WHO supported DOH in a joint effort with other United Nations agencies in food security and child nutrition by helping develop a communications plan for the social marketing of exclusive breastfeeding. The DOH–WHO partnership led to a communication package - Breastfeeding TSEK! (Tama, Sapat, EKsklusibo) - that incorporates key infant-and-young-child-feeding nutrition messages to address specific hurdles that inhibit breastfeeding. Early results have been encouraging." *Id*., at p. 10.

4 "The first few hours of life are extremely important for any newborn child, and a programme developed in the Philippines with WHO support - *Unang Yakap* or First Embrace - is making a critical difference…It calls for the baby to be thoroughly dried and then immediately given to the mother for skin-to-skin contact - with washing delayed for at least six hours…More than 40 000 Filipino newborns die every year, with the majority of deaths occurring in the first two days after birth. That puts the Philippines among a group of 42 countries that account for 90% of global deaths of children under 5. But the adoption of Unang Yakap is expected to bring down the number of infant deaths by 50% and boost exclusive breastfeeding - the most important factor in the health of newborn children - by 90%." *See* World Health Organization, *Report of the WHO Representative - The Work of the World Health Organization in the Philippines (Jan. - Dec. 2011)* (2012), supra at p. 9.

5 The February 22-25, "1986 People Power Revolution…ushered in a new political regime. President Corazon Aquino, backed by a coalition of forces from both ends of the political spectrum, forged a new government, triggering a chain of events that dramatically changed the political landscape of the country and signalled the rebirth of democracy. These political changes were: the abolition of the Batasang Pambansa following the proclamation of a new revolutionary government; the organization of a Constitutional Commission that drafted a new charter which, in turn, was ratified in February 1987; the rebirth of the old bicameral system; and the election of Members to the new Congress." *See* Republic of the Philippines, House of Representatives 16th Congress, *Brief History of the Philippine Congress*, available at: http://www.congress.gov.ph/about/?about=history.

6 *See* Republic of the Philippines, 8th Congress of the Philippines, Republic Act No. 7600 - *The Rooming-In and Breast-Feeding Act of 1992*, Sixth Regular Session (June 2, 1992), available at: http://www.milkcodephilippines.org/milkcodereport/files/147173464351f07d95054ed.pdf.

7 *See* UNICEF/NY, *Infant and Young Child Feeding Programme Review Case Study: The Philippines* (June 2009), at Executive Summary p. vi, available at: http://www.aednutritioncenter.org/update_docs/IYCF_Feeding_Prog_Rev_Case_Study_Philippines.pdf.

8 *See* Republic of the Philippines Department of Health, Administrative Order 2005-0014 – *National Policies on Infant and Young Child Feeding* (May 23, 2005), at Item III, available at: http://www.milkcodephilippines.org/milkcodereport/files/10955265985027fcf3557a8.pdf. "The policy framework will build on gains and achievements of the implementation of existing laws, policies and initiatives specifically: Executive Order 51 – Philippine Code of Marketing of Breastmilk Substitutes (1986); Republic Act 7600 – "The Rooming-In and Breastfeeding Act of 1992" – February 5, 1992…" *Id*., at Item II.3.

National Policy on Infant and Young Child Feeding[9] in implementation of the country's first National IYCF Plan of Action 2005-2010.[10] AO 2005-0014's objective was "to improve the survival of infants and young children by improving their nutritional status, growth and development through optimal feeding.[11] It closely tracks the WHO *Global Strategy for Infant and Young Child Feeding*[12] ("WHO IYCF Strategy"), which recommends exclusive breastfeeding from 0-6 months and partial breastfeeding and safe and adequate complementary feeding from 6-24 months or beyond.[13] Act No. 7600 was ultimately amended in 2009 by Act No. 10028,[14] which further encouraged breastfeeding by providing specific measures to enable working mothers to continue expressing their milk and/or breastfeeding their infant or young child in the workplace.[15]

Obviously the Philippine Government promulgated these reasonable public health measures to establish a regulatory foundation for implementing the WHO IYCF recommendations. However, in its zeal to achieve these important public policy objectives the Government of the Philippines went astray. It developed a national framework for regulating the marketing of breastmilk substitutes and breastmilk supplements (including, follow-up formula and other bottle-fed and solid complementary foods) that far exceeds international WHO Code standards to unnecessarily impair international trade in such products. Said framework consists of a number of related legal instruments promulgated over the course of successive constitutions and administrations.

The Philippines *National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Other Related Products* (the "Milk Code") was enacted on October 20, 1986, by former President Corazon Aquino via Presidential Executive Order No. 51.[16] President Aquino had issued E.O. No. 51 pursuant to her then consolidated legislative and executive emergency powers. Those powers had been vested in the Office of the Presidency by Presidential Proclamation No. 3 issued during March

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9 *See* Republic of the Philippines Department of Health National Center for Disease Prevention and Control, *Philippine IYCF Strategic Plan of Action for 2011 - 2016* (May 8, 2011) at p.1, available at: https://extranet.who.int/nutrition/gina/sites/default/files/PHL%202011%20IYCF%20%20Strategic%20Plan.pdf.

10 *Id.*

11 *See* Republic of the Philippines Department of Health, Administrative Order 2005-0014 – *National Policies on Infant and Young Child Feeding* (May 23, 2005), at Item III, available at: http://www.milkcodephilippines.org/milkcodereport/files/10955265985027fcf3557a8.pdf. "The policy framework will build on gains and achievements of the implementation of existing laws, policies and initiatives specifically: Executive Order 51 – Philippine Code of Marketing of Breastmilk Substitutes (1986); Republic Act 7600 – "The Rooming-In and Breastfeeding Act of 1992" – February 5, 1992…" *Id*., at Item II.3.

12 "The Global Strategy for Infant and Young Child Feeding jointly developed by the World Health Organization and UNICEF…emphasized the need for comprehensive national policies on infant and young child feeding. The Philippines adopted this strategy to revitalize our attention and commitment to infant and young child nutrition and its impact on survival and development of children." *Id*., at Item I, p. 2. *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, endorsed via World Health Assembly Resolution 55/25. *See* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition*, Resolution WHA55.25 (May 18, 2002), at par. 1, available at: http://www.who.int/nutrition/topics/WHA55.25_iycn_en.pdf.

13 AO 2005-0014, Sections III; V.B-C.

14 *See* Republic of the Philippines, Congress of the Philippines, Republic Act No. 10028 – *An Act Expanding the Promotion of Breastfeeding, Amending for the Purpose Republic Act No. 7600, Otherwise Known as "An Act Providing Incentives to All Government and Private Health Institutes With Rooming-In and Breastfeeding Practices and for Other Purposes"* (July 27, 2009), available at: http://www.milkcodephilippines.org/milkcodereport/files/145336442251f082ba048b7.pdf.

15 *Id*., at Sec. 2. For example, it amended Section 4 of Act No. 7600 so that applies "to all private enterprises as well as government agencies, including their subdivisions and instrumentalities, and government-owned and -controlled corporations." *Id*., at Sec. 4.

16 *See* Executive Order No. 51, *Adopting a National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements and Related Products, Penalizing Violations Thereof, and For Other Purposes* (Oct. 20, 1986), available at: http://www.pcw.gov.ph/sites/default/files/documents/laws/executive_order_51.pdf. The Milk Code is intended to implement Article 11 of the World Health Organization ("WHO")'s *International Code of Marketing of Breast-milk Substitutes*. *Id.*, Preamble.

1986[17] and by Article II Section 1 of the Provisional ("Freedom") Constitution of the Philippines. Proclamation No. 3 was adopted pending the ratification of the current 1987 Constitution.[18] In addition, the Milk Code was enacted with the extensive involvement of the United Nations (WHO/UNICEF) in Philippines national affairs.[19] UNICEF has since continued to play an active role in helping to shape Filipino national health policy, even to this day.[20]

During May 2004, the PHDOH issued AO No. 18 S. 1997 which mandated "the use of the term 'breastmilk supplement' to refer to 'follow-on formula' on the labeling of…follow-on

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17 *See* Presidential Proclamation No. 3, s. 1986, DECLARING A NATIONAL POLICY TO IMPLEMENT REFORMS MANDATED BY THE PEOPLE PROTECTING THEIR BASIC RIGHTS, ADOPTING A PROVISIONAL CONSTITUTION, AND PROVIDING FOR AN ORDERLY TRANSITION TO A GOVERNMENT UNDER A NEW CONSTITUTION, dated 25 March 1986, 82 OG 1567 (31 March 1986), available at: http://www.gov.ph/1986/03/. "Under the Provisional Commission, all existing laws, decrees, executive orders, proclamations, letters of instructions and other executive issuances, not inconsistent with this Proclamation, were to remain operative until amended, modified or repealed by the President or the regular legislative body to be established under a new Constitution. The President continued to exercise legislative power." *See* ASEAN Law Association, "Legal Systems in ASEAN – Philippines", *Chap. 1 – Historical Overview* at p. 8, available at: http://www.aseanlawassociation.org/papers/phil_chp1.pdf.

18 "Until a legislature is elected and convened under a New Constitution, *the President shall continue to exercise legislative power*" (emphasis added). Provisional Constitution of the Philippines, Art. II, Sec. 1. "The incumbent President continued to exercise legislative powers until the first Congress was set to be convened", following the people's ratification of the new constitution by plebiscite on February 2, 1987 and the May 1987 Philippines congressional elections. *See* ASEAN Law Association, "Legal Systems in ASEAN – Philippines", *Chap. 1- Historical Overview*, supra at p. 9.

19 "The Department of Health ([PH]DOH), UNICEF and other partners began to actively promote breastfeeding in the early 1980s, with the National Movement for the Promotion of Breastfeeding established in 1983. The Milk Code (Executive Order (E.O). 51) was signed by President Cory Aquino in 1986…After five years of struggle in the 1980s to get a national Milk Code adopted to implement the International Code of Marketing of Breast-milk Substitutes, it was finally signed into law in 1986. In the mid-1990s the DOH appointed a Milk Code Task Force and tried to enforce strict implementation of its provisions until 2000, when a Health Secretary with close ties to the milk companies revised the regulations in their favor. In 2004 the push to close the loopholes began again, with many drafts of Revised Implementing Rules and Regulations (RIRR) prepared and active lobbying against their adoption by the companies. The DOH, along with dedicated breastfeeding advocacy groups and technical support from UNICEF and WHO, waged an intense struggle over the next three years for adoption of the RIRRs, with a daunting set back, when the Supreme Court issued a Temporary Restraining Order (TRO) to halt implementation of the RIRR, after pressure from the companies and even the US Chamber of Commerce. Eventually in 2007, after creative and forceful lobbying on the part of the breastfeeding advocates, including demonstrations and active participation in public inquiries and a court hearing, with UNICEF and WHO using their "brands" to support the DOH, the TRO was lifted and all but 3 of 57 RIRR provisions allowed. While this was a major victory, much work must be completed to insure that a sustainable monitoring and enforcement system is put in place." *See* UNICEF/NY, *Infant and Young Child Feeding Programme Review Case Study: The Philippines* (June 2009), supra at Executive Summary pp. vi-vii. *See also* World Health Organization Western Pacific Region, *Report - WHO/UNICEF Consultation on Breastfeeding Protection, Promotion and Support* (June 20-22, 2007), available at: http://www.wpro.who.int/nutrition/documents/docs/WHO_UNICEF_BF_Consultation_FINAL_REPORT.pdf. Viewing breastfeeding in the context of the Regional Child Survival Strategy, looking at possible ways to measure the economic value of breastfeeding, and analysing available country data for setting country action priorities, primed the participants for the two main parts of the consultation…In Part 2, participants were urged to think of new ways to prevent a bottle-feeding culture from proliferating. The current battle in the Philippines' Supreme Court (and in the media) over the expansion of the coverage of the Milk Code and the launch of UNICEF's documentary Formula for Disaster: Violations of the Philippine Milk Code provided a real-time action framework for in-depth discussions on ways to monitor and enforce the Code, the importance of "doing the homework" (including technical updates) for advocacy, and the need to make clear commitments to achieve targets." *Id*., at Sec. 1.3, p. 2. *See also* Leila Salaverria, *Unicef, WHO Back Philippines' Milk Code*, Inquirer (6/18/07), available at: http://newsinfo.inquirer.net/breakingnews/nation/view/20070618-71966/Unicef,_WHO_back_Philippines%92_milk_code; Carlos H. Conde, *Breast-feeding: A Philippine Battleground*, New York Times (July 17, 2007), available at: http://www.nytimes.com/2007/07/17/world/asia/17iht-phils.1.6692639.html?pagewanted=all&_r=0; UNICEF Philippines, *The Milk Code is For Our Children – Protect the Milk Code, Protect Our Children*, paid advertisement (2007), available at: http://www.unicef.org/philippines/RIRR-Supplement.pdf; UNICEF Philippines, *The Miracle of Breastfeeding* (2007), available at: http://www.unicef.org/philippines/children/breastfeeding_1.html ("*Making breastfeeding the only choice*. Help us urge the Supreme Court to lift the ban on the revised Implementing Rules and Regulation of the National Milk Code") (emphasis added). *Id*.

20 "Together with two United Nations agencies, the Department of Health condemned a proposed House bill which allegedly threatens Philippine breastfeeding-supportive laws. The World Health Organization (WHO), the United Nation's Children's Fund (UNICEF) and the DOH believe that the bill entitled "An Act Promoting a Comprehensive Program on Breastfeeding Practices and Regulating the Trade, Marketing and Promotions of Certain Foods for Infants and Children" will loosen regulation against 'misleading advertisements' of infant formulas with 'unfounded claims.' Furthermore, in a joint statement, the U.N. agencies joined the Health department in saying that the bill benefits the milk industry over Filipino children countrywide." *See* Patricia Denise Chiu, *DOH, WHO, UNICEF Warn Against Bill Amending the Milk Code*, GMA Newsonline (Sept. 1, 2012), available at: http://www.gmanetwork.com/news/story/272184/news/nation/doh-who-unicef-warn-against-bill-amending-the-milk-code.

formula/breastmilk substitute [products]".[21] During November 2005, the PHDOH Bureau of Food and Drugs ("BFAD"/"FDA) issued a memorandum directed at nongovernment parties including milk manufacturers, distributors, advertising agencies and other concerned parties. It advised them of BFAD/FDA's policy of strict implementation and enforcement of those Milk Code and implementing guidelines provisions concerning advertisements and promotions.[22]

Furthermore, during May 2006, pursuant to Milk Code Section 12(b)(1), the PHDOH issued AO No. 2006-0012 setting forth the *Revised Implementing Rules and Regulations* ("RIRR"). The RIRR's purpose was to implement and enforce the Milk Code's provisions[23] and to further support the Philippines' national adoption of the WHO IYCF Strategy.[24] During January 2008, the PHDOH issued Department Circular 2008-0006 pursuant to RIRR, Rule VII, which provides mandatory guidelines establishing labeling standards for "breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products."[25]

Moreover, during December 2012, the various Philippine federal agencies comprising the Inter-Agency Committee ("IAC") established pursuant to Milk Code Sections 12(a)(3) and 6(a) issued Joint AO No. 2012-0027. AO 2012-0027 provides guidelines, pursuant to RIRR, Rule V Section 12, for the IAC to employ in fulfilling its duties and functions under the Milk Code and RIRR. AO 2012-0027 focuses, in part, on the IAC's review of all advertising, marketing, promotional and other materials for products falling within the scope of the Milk Code and the IAC Secretariat's role in ensuring enforcement of such provisions.[26]

In addition to the above, the PHDOH issued a September 2011 Memorandum directing BFAD/FDA "not to allow any kind of trademarks that contain health and nutrition claims or that may

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21 *See* Republic of the Philippines Department of Health, Administrative Order No. 18S 1997 - *Labelling of Infant Formula "Breastmilk Supplement" or "Follow-on Formula* (May 7, 2004), available at: http://www.fda.gov.ph/attachments/article/15835/A.O%2018%20s%201997.pdf. "In the alternative, if the manufacturer intends to maintain the term 'follow-on formula' on the labeling of the product, a conspicuous message or statement shall have to be printed stating that 'This product is not a breastmilk substitute' immediately below the term 'follow-on formula', in addition to the other primary standards messages required by Executive Order No. 51." *Id*.

22 *See* Republic of the Philippines, Department of Health Bureau of Food and Drugs, *BFAD Memorandum – Strict Implementation and Enforcement of the Regulatory Components of Executive Order No. 51 (National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplement and Other Related Products* (Nov. 21, 2005), available at: http://old.fda.gov.ph/BC/bfad%20memo%20-%20strict%20implementation%20of%20the%20regulatory%20component%20of%20EO%2051.pdf. This BFAD memorandum had superseded a much broader prior BFAD memorandum advising of the agency's strict implementation and enforcement of Milk Code provisions "on advertisement, promotion, *labeling, sponsorship and donation of* breastmilk substitutes, breastmilk supplements and related products…" *See* Republic of the Philippines, Department of Health Bureau of Food and Drugs, *BFAD Memorandum – Strict Implementation of the Regulatory Component of E.O. 51 (Philippine code of Marketing of Breastmilk Substitutes)* (Nov. 17, 2005), available at *Id*.

23 Milk Code, Sec. 12(b)(1); Republic of the Philippines Department of Health, Administrative Order 2006-0012 – *Revised Implementing Rules and Regulations of Executive Order No. 51, Otherwise Known as The "Milk Code", Relevant International Agreements, Penalizing Violations Thereof, and for Other Purposes ("Revised Implementing Rules and Regulations ('RIRR')")* (May 15, 2006), available at: http://old.fda.gov.ph/AO/ao2006-0012.pdf.

24 RIRR, Preamble pars. 3-5.

25 *See* Republic of the Philippines Department of Health Circular 2008-0006 – *Amendments to Department Circular No. 2007-0276 Dated 07 December 2007, Re: Guidelines for the Labeling of Breastmilk Substitutes, Infant Formula, Other Milk Products, Food and Beverages, and Other Related Products Within the Scope of E.O. 51, Otherwise Known as the "Milk Code", and to Department Circular No. 2007-0272 Dated 17 December 2007, Re: Containers and Labels of Milk Products Within the Scope of EO 51 Otherwise Known as the "Milk Code"* (Jan. 9, 2008), available at: http://www.milkcodephilippines.org/milkcodereport/files/10183584135027ffb6d6413.pdf.

26 *See* Republic of the Philippines Department of Health, Joint DOH-DOJ-DTI-DSWD Administrative Order No. 2012-0027 – *The Inter-Agency Committee (IAC) Guidelines in the Exercise of the Powers and Functions as Stated in Executive Order (E.O.) No. 51 s. of 1986, Otherwise Known as, "The National Code of Marketing of Breastmilk Substitute, Breastmilk Supplements and Other Related Products", and its Revised Implementing Rules and Regulations (RIRR)* (Dec. 3, 2012), available at: http://milkcodephilippines.org/milkcodereport/files/124614522251c2baa02c9b9.pdf. These guidelines were jointly issued by the Philippine Departments of Health, Justice, Trade and Industry, and Social Welfare and Development.

undermine breastfeeding and breastmilk to be placed on the labels" of Milk Code-covered products on the basis "that labels are marketing materials".[27] The BFAD/FDA's legal authority "to prohibit milk companies from using their…registered trademarks" was subsequently affirmed and then reaffirmed in two separate legal opinion letters issued by the Philippine Department of Justice ("DOJ") during May and September 2012.[28]

Within ten days of the issuance of the second PHDOJ opinion letter, the PHDOH issued another memorandum on behalf of the IAC. This September 2012 Memorandum directed the BFAD/FDA to strictly enforce the provisions of the Milk Code, RIRR, and Circular 2008-0006 governing BFAD/FDA reviews of covered product labels, by constraining "the use of…registered trademarks of milk products that contain health and nutrition claims or that may undermine breastfeeding and breastmilk." The September 2012 Memorandum also set forth a list of product brand names that "should not be approved" for advertising and promotion purposes.[29]

According to "Dr. Julie Hall, WHO Philippines Representative...'the National Milk Code and related laws are among the best in the world, and have served as models for several countries"[30] in the region, most recently, Vietnam.[31] While this may be true, this article argues that the Philippine breastmilk substitute and breastmilk supplement marketing framework ("PH BMS Framework") hailed by WHO/UNICEF, the PHDOH and the breastfeeding activist community, nevertheless, violates the Philippines' obligation to ensure compliance with the World Trade Organization ("WTO") Agreements.

This article has been divided into two parts. Part 1 will analyze these restrictions under the terms of the Technical Barriers to Trade ("TBT") Agreement, and Part 2 will analyze them under the terms of the Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement.

Parts 1 and 2 will focus on how the PH BMS Framework's non-food safety-related advertising/marketing, labeling and trademark-use restrictions applicable to follow-up formula and complementary food products intended for infants and young children *older than* 6-12 months of age, are more trade-restrictive and trademark-encumbering than necessary to achieve the PH BMS Framework's legitimate public policy objectives, considering the risks nonfulfillment would create. They will each undertake a detailed multistep analysis that compares and contrasts such provisions with relevant international standards, examines the degree to which such objectionable provisions are capable of achieving their policy objectives, identifies reasonably available less trade-restrictive and trademark-encumbering alternatives, and assesses the risk that the PH BMS Framework's policy

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27 PHDOH Memorandum (Sept. 5, 2011).

28 *See* Republic of the Philippines, Department of Justice *Secretary Opinion No. 29, series 2012* (May 11, 2012); Republic of the Philippines Department of Justice, *Secretary Opinion No. 69, series 2012* (Sept. 4, 2012), at p. 2.

29 *See* Republic of the Philippines, Department of Health Office of the Secretary, *Memorandum – Strict Enforcement on the Use of Intellectual Property-Registered Trademarks of Milk Products That Contain Health and Nutrition Claims or That May Undermine Breastfeeding and Breastmilk* (Sept. 10, 2012), hereinafter, "PHDOH Memorandum (Sept. 10, 2012)". *See* discussion, Part III, *infra*.

30 *See* UNICEF Philippines, *UN in PH Joins Celebration of World Breastfeeding Week 2013*, Joint Press Release by ILO, UNICEF and WHO (Aug. 1, 2013), available at: http://www.unicef.org/philippines/mediacentre_21231.html.

31 "[E]arlier this year…UNICEF joined forces with Alive and Thrive, Viet Nam Institute of Legislative Studies, World Health Organisation and others to hold a regional advocacy workshop for ASEAN countries. We wanted to share the Viet Nam Government's recent experience in extending paid maternity leave to six months and expanding the ban on advertising of breast milk substitutes for infants up to 24 months. Both policies were passed by the Viet Nam National Assembly with more than 90 per cent of the vote." *See* France Begin, UNICEF Regional Advisor on Nutrition, *World Breastfeeding Week – Bringing Support Closer to Mothers*, UNICEF Blog (July 31, 2013) available at: http://unicefeapro.blogspot.com/2013/07/world-breastfeeding-week-bringing.html.

objectives would not be satisfied if such alternatives were adopted in their place. Although this article identifies the ongoing debate among health professionals concerning the benefits and risks associated with exclusive breastfeeding for the first 6 months of life, and partial breastfeeding thereafter, especially in a developing country such as the Philippines,[32] this article does not dispute WHO Code and IYCF recommendations.[33]

Various provisions of the Milk Code,[34] the RIRR[35] and DOH Circular 2008-0006[36] expressly address the direct short-term risk of bacterial infection from consumption and/or ill preparation, use or storage of powdered infant formula and follow-up formula products. Consequently, they also have a food safety-related purpose, and, thus likely qualify as "SPS" measures within the meaning of Annex A(1)(b) and Article 1 of the SPS Agreement. Although these measures likely affect international trade in such products, this article does not contend that these measures, at this time, have created unnecessary obstacles to trade, and therefore, does not discuss them. However, if the PHDOH were to employ these SPS measures as the basis for prohibiting or restricting the advertising, labeling and promotion of powdered breastmilk *supplement* products to infants and young children older than 6-12 months of age to address the risk of bacterial infection,[37] without having conducted a scientific risk assessment or presenting sufficient scientific evidence in support thereof, it would conceivably violate applicable Codex Alimentarius Commission standards, and consequently, the SPS Agreement.[38]

II. The PH BMS Framework Subject to Dispute

1. Identifying the Philippine Government Measures for WTO Review

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32 *See* Section III.3.b.iv.A.I, *infra*.

33 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding*, WHA54 A54/INF.DOC./4 (May 1, 2001), available at: http://apps.who.int/gb/archive/pdf_files/WHA54/ea54id4.pdf.

34 Section 2 of the Milk Code reflects that, "[t]he aim of the Code is to contribute to the provision of safe…nutrition for infants…by ensuring the proper use of breastmilk substitutes and breastmilk supplements…on the basis of adequate information and through appropriate marketing and distribution." Milk Code Sec. 2. Section 11(b) of the Milk Code provides that, "[f]ood products within the scope of this Code shall, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children." Milk Code Sec. 11(b).

35 Rule I, Section 2 of the RIRR is also focused, in part, on "provid[ing] safe…nutrition for infants and young children…by ensuring the proper use of breastmilk substitutes, breastmilk supplements…on the basis of adequate information and through appropriate marketing and distribution. RIRR, Rule I Sec. 2. RIRR Rule III, Section 7 provides that "[i]t is the responsibility of the State to inform the general public on the hazards of the production, preparation and use of breastmilk substitutes and other products covered by the Code. RIRR, Rule III Sec. 7. RIRR Rule VII, Section 25 provides that "[c]ontainers and labels shall be designed to provide the necessary information about the appropriate use of the products within the scope of the Code…" RIRR, Rule VII Sec. 26. "Each container label shall contain such message…relative [to] the following points:…e) Instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation, and f) The health hazards of (the use) unnecessary or improper use of infant formula and other related products including information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately." RIRR, Rule VII Sec. 26. RIRR Rule VIII, Section 29 reaffirms that "[t]he quality of products is an essential element for the protection of the health of infants and young children." RIRR, Rule VIII Sec. 29. "Food products within the scope of this Code shall, when sold or otherwise distributed meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Young Children." RIRR, Rule VIII Sec. 30.

36 Item VI.B.3.1 discusses how the label should provide information about the appropriate shelf-life of covered products. Item VI.B.3.2 focuses on how the label should provide information about proper product storage practices. Item VI.B.4 identifies how the label should provide proper preparation and utilization instructions and information about bacterial hazards arising from ordinary product use and/or unnecessary or improper product use.

37 For example, the PHDOH Bureau of Food and Drugs ("BFAD") could deny to issue on such grounds the required Certificate of Registration under Item V.1 of Circular 2008-0006 for powdered infant formula products, or the IAC could deny to issue on such grounds a Certificate of Marketing Approval under Section 17 of AO 2012-0027 for powdered infant formula products.

38 *See, e.g.,* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 1 of 3)*, LexisNexis Emerging Issues 7046 (Aug. 2013), available at: http://www.itssd.org/HK%20Infant%20Formula%201.pdf.

In *US-COOL*,[39] the Panel determined that the COOL statute and Final Agricultural Marketing Service ("AMS") Regulations, two separate and distinct legal instruments, should be treated as a single measure for WTO analysis purposes. It also determined that a third instrument, a letter issued by the Secretary of the U.S. Department of Agriculture to industry representatives announcing the implementation of the US COOL statute and containing "suggestions for voluntary action,"[40] should be evaluated separately for such purposes. Among other factors,[41] the Panel considered "the legal status of the requirements or instrument(s), including the operation of, and the relationship between, the requirements or instruments, namely whether a certain requirement or instrument has autonomous status."[42] It ultimately concluded that the COOL statute and the 2009 Final Rule (AMS) "operate[d], legally or substantively, in conjunction with each other" since they both were "instruments of statutory and regulatory authorities respectively, whereas the [Vilsack letter did] not have such legal status."[43]

The Panel reasoned that the COOL statute and the Final Rule were "closely connected to each other in terms of "legal status",[44] because "the provisions in the COOL statute and the 2009 Final Rule (AMS) [- i.e., the basic framework laid out in the statute and regulations, including the scope of the specific categories of labels applied to meat products were the same] were closely linked in the operation of the specific COOL requirements."[45] It did not "find any significant difference between these two instruments in substance that could render them separate and distinct measures."[46] It also found that "[t]hey both pertain[ed] to the country of origin labelling requirements", and that the "2009 Final Rule (AMS) elaborate[d] on the specific manner in which subject entities must comply with the labelling rules embodied in the COOL statute".[47] Consequently, the Panel "consider[ed] it appropriate to examine the relevant elements of both the COOL statute and the 2009 Final Rule (AMS) pertaining to the COOL requirements for meat products 'as an integral part' of one single COOL measure", and "[found] sufficient 'legal, logical and factual' bases to treat the COOL statute and 2009 Final Rule (AMS) as *the COOL measure*" (emphasis added).[48]

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39 Panel Report, *United States - Certain Country of Origin Labeling (COOL) Requirements ("US-COOL")*, WT/DS384/R, WT/DS386/R (Nov. 18, 2011).

40 *Id*., at par. 7.174. "[T]he Vilsack letter [was] not a piece of legislation or regulation legally binding in US law… In outlining action by industry, the Vilsack letter uses permissive, hortatory terms such as 'might', 'should' and 'would'; it mentions the word 'voluntary' at least four times; and it notes that it contains 'suggestions for voluntary action'. It is also not followed up by a classic legal enforcement mechanism." *Id*.

41 The Panel observed that "[a]mong the main factors considered by panels and the Appellate Body in relation to this question were…(i) the manner in which the complainant presented its claim(s) in respect of the concerned instruments; [and] (ii) the respondent's position." Panel Report, *US-COOL* at par. 7.50 and accompanying footnotes.

42 *Id*.

43 *Id*., at par. 7.53.

44 "[T]he COOL statute forms the framework and foundation for the 2009 Final Rule (AMS). Following the completion of the legislative process for the COOL statute, the 2009 Final Rule (AMS) was subsequently adopted to implement the country of origin labelling requirements embodied in the COOL statute according to the authority granted to the Secretary of Agriculture. Legally, therefore, the 2009 Final Rule (AMS) does not have autonomous status; it lays out the specificities pertaining to the country of origin labelling requirements that are necessary to implement the contents of the COOL statute. The COOL statute and the Final Rule are thus closely connected to each other in terms of legal status." *Id*., at par. 7.54.

45 "For example, the basic framework relating to the COOL requirements laid out in the statute, including the scope of the specific categories of labels applied to meat products, remains the same in the 2009 Final Rule (AMS). The 2009 Final Rule (AMS) then further expands the rules on how these different categories can be flexibly used by entities subject to the COOL requirements through the so-called commingling provisions." *Id*., at par. 7.56, *citing* Panel Report, *US – Section 301 Trade Act* at pars. 7.26-7.28.

46 Panel Report, *US-COOL* at par 7.60.

47 *Id*.

48 *Id*., at par. 7.61.

The Panel found that the Vilsack letter, however, "[did] not have a formal legal link to either the COOL statute or the 2009 Final Rule (AMS),"[49] and that it "[did] not have the same statutory or regulatory status as the COOL statute or the 2009 Final Rule (AMS)."[50] While "aspects of the letter, including its reference to implementation and the authority who issued the letter…connect it to the COOL statute and 2009 Final Rule (AMS)," the Panel was "not presented with any solid evidence showing that the Vilsack letter is connected to the COOL statute or the 2009 Final Rule (AMS) such that they, in combination, form the substantive legal basis for the country of origin labelling requirements as set out in the COOL measure."[51]

Consequently, the Panel determined that it was appropriate to consider the Vilsack letter "as a separate measure distinguishable from the COOL statute and the 2009 Final Rule (AMS)", which did not preclude its being examined separately under the TBT Agreement or the GATT 1994.[52]

2. The Milk Code, RIRR, AOs, Circular, and Memoranda Collectively Constitute a Single Measure for WTO Analysis Purposes

The Philippines BMS Framework arguably consists of various separate legal instruments that can be considered integrally related, substantively conjunctive and interdependent, both as a matter of legal status and operationally.

a. Milk Code and RIRR

E.O. No. 51 (the "Milk Code") constitutes an executive order, which is an "Act[] of the President providing for rules of a general or permanent character in implementation or execution of constitutional or statutory powers."[53] The Milk Code's objective is "to contribute to the provision of safe and adequate nutrition for infants by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes and breastmilk supplements when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."[54] The RIRR issued via AO 2006-0012 constitutes an "administrative issuance" by the Secretary of the PHDOH, an executive department deemed "necessary for the functional distribution of the work of the President and for the performance of their functions,"[55] and the mandate of which is to be discharged under the authority and responsibility of the Secretary.[56] Administrative orders, which are directed to particular governmental offices, officials or employees,

49 *Id*., at par. 7.55.
50 *Id*.
51 *Id*., at par. 7.62. "The Vilsack letter starts with the statement that it pertains to the implementation of the Final Rule (AMS).95 It also contains matters relating to the mandatory country of origin labelling requirements, including concerns of the Secretary of Agriculture himself regarding the contents of the Final Rule at issue. The fact that the letter was issued by the Secretary of Agriculture – the top authority heading the USDA – gives the letter a certain level of significance." *Id*.
52 *Id*., at pars. 7.63; 7.74.
53 *See* Republic of the Philippines Official Gazette, Administrative Code of 1987, Book III, Chapter 2, Section 2, available at: http://www.gov.ph/?cat=15.
54 Milk Code, Sec. 2.
55 *See* Republic of the Philippines Administrative Code of 1987, Book IV, Chap. 11, Sec. 50, available at: http://seatca.org/dmdocuments/Philippines%20-%20Administrative%20Code%20-%20national.pdf.
56 *Id*., at Book IV, Chap. 2, Sec. 6.

are one of two main kinds of administrative issuances.[57] Both the Milk Code and the RIRR thus arose from acts of the executive branch of the Philippine Government pursuant to the Philippine Administrative Code of 1987.

The RIRR's objective is the same as the Milk Code it is intended to implement.[58] The scopes of the Milk Code and the RIRR are substantially the same and, therefore, both cover the substantially the same types of products and activities. They "apply to the marketing, and practices related thereto, of the following products: breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats."[59] Also, the Milk Code and RIRR have a similar structure because they each have definitional, information/education, advertising/promotion, health worker/healthcare facility, container/labeling and implementation/enforcement sections with similar terms,[60] and the RIRR contains elaborations of the Milk Code in various areas. In a landmark 2007 decision, the Philippine Supreme Court held that RIRR, Rule I Section 4(f), Rule V Section 11, and Rule XII Section 46 were inconsistent with the Milk Code, unconstitutional and of no legal force and effect.[61]

b. PHDOH Circular

DOH Circular 2008-0006 constitutes another form of authorized executive branch administrative issuance from the Secretary of the PHDOH.[62] Circulars are directed to individuals and organizations outside the government.[63] PHDOH Circular 2008-0006 amended previously issued mandatory guidelines for containers and labels of Milk Code-covered products.[64] The stated objectives of PHDOH Circular 2008-0006 are to "set a standard for labeling" for Milk Code-covered products[65] and to "guide milk companies as defined in AO 2006-0012 [the RIRR]"[66] in "provid[ing] the necessary information [on containers and labels] about the appropriate use of [Milk Code-covered]

57 "The administrative issuances of Secretaries and heads of bureaus, offices or agencies shall be in the form of circulars or orders." *Id*., at Book IV, Chap. 11, Sec. 50. "Orders shall refer to issuances directed to particular offices, officials, or employees, concerning specific matters including assignments, detail and transfer of personnel, for observance or compliance by all concerned." *Id*., at Sec. 50(2).
58 RIRR, Rule I Sections 1-2.
59 Milk Code Sec. 3; RIRR, Rule I Sec. 3.
60 Milk Code Sections 4-8, 10-12; RIRR Rules II-X.
61 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, Supreme Court of the Philippines En Banc (Oct. 9, 2007), available at: http://www.lawphil.net/judjuris/juri2007/oct2007/gr_173034_2007.html. "WHEREFORE, the petition is PARTIALLY GRANTED. Sections 4(f), 11 and 46 of Administrative Order No. 2006-0012 dated May 12, 2006 are declared NULL and VOID for being *ultra vires*. The Department of Health and respondents are PROHIBITED from implementing said provisions." *Id*.
62 "The administrative issuances of Secretaries and heads of bureaus, offices or agencies shall be in the form of circulars or orders." *See* Republic of the Philippines Administrative Code of 1987, Book IV, Chap. 11, Sec. 50, *supra*.
63 "Circulars shall refer to issuances prescribing policies, rules and regulations, and procedures promulgated pursuant to law, applicable to individuals and organizations outside the Government and designed to supplement provisions of the law or to provide means for carrying them out, including information relating thereto." Id., at Sec. 50(1).
64 *See* Republic of the Philippines Department of Health Circular 2008-0006 – *Amendments to Department Circular No. 2007-0276 Dated 07 December 2007, Re: Guidelines for the Labeling of Breastmilk Substitutes, Infant Formula, Other Milk Products, Food and Beverages, and Other Related Products Within the Scope of E.O. 51, Otherwise Known as the "Milk Code", and to Department Circular No. 2007-0272 Dated 17 December 2007, Re: Containers and Labels of Milk Products Within the Scope of EO 51 Otherwise Known as the "Milk Code"* (Jan. 9, 2008), supra.
65 Circular 2008-0006, Item II.1.
66 *Id*., at Items II.2 and VIII.1.

products and in such a way as not to undermine or equate it to breastfeeding."[67] The scope of Circular 2008-0006 is consonant with that of the Milk Code and the RIRR.[68]

c. PHDOH Administrative Orders and Memoranda

PHDOH/IAC AO 2012-0027 and PHDOH AO No. 18 S. 1997 constitute yet another form of authorized executive branch administrative issuance from the Secretary of the PHDOH.[69] AO 2012-0027 sets forth mandatory operational and procedural guidelines for the Inter-Agency Committee ("IAC") created pursuant to Milk Code Section 12(a)(3) and RIRR, Rule V Section 12.[70] In addition, it provides guidelines which the IAC should employ when undertaking review of promotional, marketing and advertising materials related to Milk Code-covered products, in implementation of Milk Code Sections 6(a) and 12(a)(1)-(2) and (4), and RIRR, Rule V Sections 13-15. AO No. 18 S. 1997 required that follow-on formula product labeling contain the term "breastmilk supplement" in lieu of "follow-on formula".

The September 5, 2011 PHDOH Memorandum issued to the BFAD/FDA, a bureau falling under PHDOH's jurisdiction and control,[71] directing it to prohibit trademarks containing health and nutrition claims or claims that may undermine breastfeeding and breastmilk from being placed on Milk Code-covered product labels and containers, constitutes an agency "rule". According to the Philippine Administrative Code of 1987, a "rule" is "any agency statement of general applicability that implements or interprets a law, fixes and describes the procedures in, or practice requirements of, an agency, including its regulations"[72] – here, Milk Code Section 10 and RIRR Rule VII.[73]

The September 10, 2012 PHDOH Memorandum also constitutes an agency rule under the Philippine Administrative Code of 1987. Said memorandum was issued by a delegate of the Secretary (an Assistant Secretary) of the PHDOH, which was acting in its capacity as IAC Chairman and member, on behalf of the IAC, in fulfillment of the PHDOH's principal responsibility "for the implementation and enforcement of the provisions of [the] Milk Code.[74] It constitutes an agency "rule" because it directed the BFAD/FDA, in fulfillment of its responsibility to implement the provisions of the Milk Code.[75] Specifically, it directed the BFAD/FDA to strictly enforce the provisions of the Milk Code and the RIRR, and the AO 2008-006 labeling guidelines governing BFAD/FDA reviews of covered

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67 *Id*., at Item I; RIRR, Rule VII Sec. 25.
68 "These guidelines apply to the labeling of the following products: breastmilk substitutes, including infant formula, other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breaastmilk; feeding bottles and teats…" *Id*., at Item III.
69 "The administrative issuances of Secretaries and heads of bureaus, offices or agencies shall be in the form of circulars or orders." *See* Republic of the Philippines Official Gazette, Administrative Code of 1987, Book IV, Chap. 11, Sec. 50, *supra*.
70 AO 2012-0027, Preamble, par. 4. Sections 3-5 concern the structure, composition and operation of the IAC and the IAC Secretariat; Sections 8-11 describe the process of applying for IAC review of proposed marketing/advertising materials; Sections 15-18 and 22 discuss the IAC deliberation process and possible findings; Sections 19-20 set forth substantive standards for determining whether or not proposed materials should be approved/disapproved in implementation of Milk Code Sec. 6(a) and RIRR Rule V; Section 21 sets forth mandatory standard labeling messages in implementation of Milk Code Sec. 10 and RIRR Rule VII.
71 *See* Republic of the Philippines Administrative Code of 1987, *supra* at Book IV, Chap. 1, Sec. 4.
72 *Id.,* at Book VII, Chap. 1, Sec. 2(2).
73 It includes "memoranda or statements concerning the internal administration or management of an agency not affecting the rights of, or procedure available to, the public. *Id*. The September 2011 memorandum certainly affects the rights of certain stakeholders, particularly, trademark owners and their licensees.
74 Milk Code Sections 12(a)-(b); RIRR, Rule X, Sec. 38.
75 Milk Code Section 10(f); RIRR, Rule VII Sec. 28.

products, by prohibiting the use of trademarks on product labels that contain nutrition and health claims or that may otherwise undermine breastfeeding and breastmilk.

In sum, the PHDOH promulgated the AO, Circular and Memoranda to further implement parts of the RIRR in furtherance of RIRR, Rule IV Section 54.[76] Consistent with the criteria employed by the Panel in *US-COOL*, therefore, these executive and agency issuances operate in concert and in conjunction with one another in an effort to achieve a common policy objective of the Philippines – the protection of breastfeeding and prevention of deceptive advertising and labeling practices. Consequently, they should be treated as a single measure – the PH BMS Framework – for purposes of WTO analysis.

d. PHDOJ Opinion Letters

On May 11, 2012 and September 4, 2012, the Secretary of the Philippines Department of Justice ("DOJ") issued two opinion letters in furtherance of the Department's powers and functions, including the provision of "legal services to the national government and its functionaries."[77] These opinion letters affirmed and reaffirmed the BFAD/FDA's legal authority "to prohibit milk companies from using their…registered trademarks" on Milk Code-covered products where they contain health and nutrition claims or may undermine breastfeeding and breastmilk.[78] Unlike the legal instruments discussed above, these PHDOJ opinion letters would arguably not constitute a "rule" within the meaning of the Philippines Administrative Code, because they do not "implement[] or interpret[] a law, fix[] and describe[] the procedures in, or practice requirements of, an agency [here, PHDOH], including its regulations."[79] The PHDOJ opinion letters also do not constitute an administrative issuance such as an order or circular because they do not direct the PHDOH or any nongovernment party to take or not take any action.[80]

Furthermore, the PHDOJ opinion letters do not have a formal legal link to the Milk Code, RIRR, PHDOH AO, Circular or Memoranda, and do not have the same executive or regulatory legal status as these other instruments; nor do they have the same framework or structure. Aspects of the PHDOJ opinions letters, including their references to implementation of the Milk Code, RIRR, and/or PHDOH Circular 2008-0006, do reflect a connection to such legal instruments. The Milk Code specifies that the PHDOJ is a member of the IAC that reviews Milk Code-covered product marketing, advertising and promotional activities,[81] and the RIRR charges the PHDOJ with the responsibility of bringing criminal prosecution for Milk Code violations.[82] However, there is no solid evidence that *these* PHDOJ opinions are connected such that they, in combination with those other instruments, form the substantive legal basis for protecting breastfeeding in the Philippines as set out in the PH BMS Framework.

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76 "The Secretary of Health, or his duly authorized representative, may issue such additional implementing rules and regulations as may be necessary to further clarify any part of this IRR." RIRR, Rule XIV Sec. 54.
77 *See* Republic of the Philippines Administrative Code of 1987, *supra* at
78 *See* Republic of the Philippines, Department of Justice *Secretary Opinion No. 29, series 2012* (May 11, 2012), supra at p. 2; Republic of the Philippines Department of Justice, *Secretary Opinion No. 69, series 2012* (Sept. 4, 2012), supra at p. 2.
79 *See* Republic of the Philippines Administrative Code of 1987, *supra* at Book VII, Chap. 1, Sec. 2(2).
80 *Id.*, at Book IV, Chap. 11, Sec. 50(1)-(2).
81 Milk Code Sec. 12(a).
82 RIRR, Rule XI Sec. 45.

Thus, like the Vilsack letter in *US-COOL*, it would be appropriate to treat the two DOJ opinion letters as a separate measure distinguishable from the PH BMS Framework for WTO analysis purposes.

III. The PH BMS Framework Violates the WTO TBT Agreement

The WTO Panel in *EC-Biotech Products*[83] established a general rule of thumb to be followed in distinguishing between a measure's food-safety and non-food safety-related purposes that is germane to an evaluation of the PH BMS Framework. It provides 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)" – i.e., it is not an SPS measure (emphasis added).[84]

The Philippines BMS Framework imposes severe restrictions on the advertising/marketing and labeling of follow-up formula and liquid and solid complementary food products intended for infants and young children older than 6-12 months of age on health and nutrition grounds that arguably fall within the scope and coverage of the TBT Agreement. Although these restrictions qualify as non-SPS measures, it cannot be presumed that they fall within the scope and coverage of the TBT Agreement.[85]

1. The BMS Framework Constitutes a Technical Regulation

A given measure will be subject to the provisions of the TBT Agreement only if it qualifies either as a "technical regulation" or a "standard," as defined by TBT Annexes 1.1 and 1.2. "[T]echnical regulations [are]…mandatory documents,"[86] [while]…standards [are] voluntary… documents."[87]

A "technical regulation" is a "[d]ocument which lays down [either] *product* characteristics or *their related processes and production methods*, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method" (emphasis added).[88] According to the Appellate Body, the "determination of whether a particular measure constitutes a technical regulation must [therefore] be made in the light of the characteristics of the measure at issue and the circumstances of the case."[89] "This exercise may involve considering whether the measure consists of a law or a regulation enacted by a WTO Member, whether it prescribes or prohibits particular conduct, whether it sets out specific

83 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).
84 *Id.*, at pars. 7.413-7.414.
85 SPS Art. 1.4; TBT Art. 1.5.
86 TBT Annex 1.1.
87 TBT Annex 1.2, Explanatory Note.
88 TBT Annex, 1.1.
89 *Id.*, at par. 188; Appellate Body Report, *European Communities - Measures Affecting Asbestos and Asbestos-Containing Products ("EC - Asbestos")*, WT/DS135/AB/R (Mar. 12, 2001) at par. 64; Appellate Body Report, *European Communities - Trade Description of Sardines ("EC - Sardines")* WT/DS231/AB/R (Sept. 26, 2002), at pars. 192-193. "In some cases, this may be a relatively straightforward exercise. In others, the task…may be more complex." *Id.*, par. 188; Appellate Body Report, *China – Measures Affecting Imports of Automobile Parts ("China - Auto Parts")* WT/DS339/AB/R, WT/DS340/AB/R, WT/DS342/AB/R, (adopted Jan. 12, 2009) at par. 171.

requirements that constitute the sole means of addressing a particular matter, and the nature of the matter addressed by the measure."[90]

a. Various PH BMS Framework Provisions Satisfy the Technical Regulation Three-Part Test

A document must meet three criteria in order to fall within the definition of a technical regulation. "First, the document must apply to an 'identifiable' product or group of products [which]…need not, however, be expressly identified in the document."[91] "Second, the document must lay down one or more characteristics of the product [which]...may be intrinsic or…related to the product [and]…be prescribed or imposed in either a positive or negative form."[92] "Third, compliance with the product characteristics must be mandatory."[93]

i. The Products Identified

The first criterion has been recognized as underlying a WTO Member's core obligation under TBT Article 2.9.2, namely, to notify other members "of the products to be covered" by a proposed technical regulation.[94] Milk Code Section 3, RIRR, Rule I Section 3, and Circular 2008-0006, Item III identify three groups of products subject to the PH BMS Framework. They each apply to "the marketing, and practices related thereto…of breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breastmilk; feeding bottles and teats."[95] The TBT notification filed by the Philippine Government during 2006 similarly identifies the products covered by the RIRR.[96]

Thus, the PH BMS Framework satisfies the first criterion of the three-part technical regulation test.

ii. The Product Characteristics Described

The second criterion has been interpreted as incorporating a rather broad scope of product characteristics. They can include any "definable 'features', 'qualities', 'attributes' or other 'distinguishing mark' of a product."[97] This means that characteristics can relate directly to the "features and qualities intrinsic to the product itself," *as well as indirectly to the means by which products are identified, presented, and made to appear*.[98]

The PH BMS Framework defines "breastmilk substitute" as "any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that

90 Appellate Body Report, *US - Tuna II (Mexico)* at par. 188.
91 TBT Annex 1.1.
92 *Id.*
93 *Id.*, as interpreted in Appellate Body Report, *EC – Sardines* at par. 176; Appellate Body Report, *EC – Asbestos* at pars. 66–70; Panel Report, *US - Tuna II (Mexico)*, at par. 7.58; Panel Report, *US - COOL* at par. 7.147.
94 Appellate Body Report, *EC – Asbestos* at par. 70.
95 Milk Code Sec. 3; RIRR, Rule I Sec. 3; Circular 2008-0006, Item III.
96 *See* Philippines, *Notification to WTO Committee on Technical Barriers to Trade*, G/TBT/N/PHL/76 (Dec. 20, 2006), available at: http://www.moital.gov.il/NR/rdonlyres/4258F6A3-4FC5-4B5B-86FF-05903ECEC420/0/Not1220PHL76.doc.
97 Appellate Body Report, *EC - Asbestos* at par. 67.
98 *Id.*

purpose."[99] It defines "infant formula" as "a breastmilk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the normal nutritional requirements of infants up to between four to six months of age."[100] The Milk Code and Circular 2008-0006 define "complementary food" as any food…suitable as a complement to breastmilk or to infant formula when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called 'weaning food' or 'breastmilk supplement.'"[101] The RIRR, meanwhile, redefines "complementary" food as "any food, *except milk substitutes*…suitable as a complement *to breastmilk to satisfy the nutritional requirements of the infant*" (emphasis added).[102] The RIRR effectively distinguishes complementary foods from breastmilk substitutes and eliminates the possibility that a breastmilk substitute could be used alongside (i.e., as a complement to) breastfeeding.

The RIRR broadly defines the phrase "other milk products, foods and beverages" as including "*any provision or drink* marketed as a partial or total replacement of breastmilk" (emphasis added).[103] Circular 2008-0006 defines "milk supplement" consistently with AO 18 S. 1997, as "a food intended for use as a liquid part of the complementary food for the infant *from the 6th month on and for young children*," and as a product name that "shall be used in place of 'follow-up' formula" (emphasis added).[104] The RIRR defines "medically indicated" products as "special milk formula indicated for infants with inborn errors of metabolism, i.e., galactosemia, phenylketonuria, and maple syrup urine disease."[105] However, there are other medical reasons why breastfeeding may not be recommended in certain situations.[106]

The PH BMS Framework sets forth detailed rules prescribing the types of information that must be included in and excluded from informational/educational materials dealing with infant feeding with respect to various Milk Code-covered products to ensure the benefits and superiority of breastfeeding and the proper use of breastmilk substitutes in light of the known health hazards they present.[107] In addition it also provides detailed content rules for ensuring that the presentation, description, and/or representation of Milk Code-covered products for purposes of marketing, advertising and other forms of promotion will not undermine or equate to breastmilk or breastfeeding.[108] Furthermore, the PH BMS Framework prescribes in detail the types of information that can be used to present, describe, and/or represent Milk Code-covered products on product containers and labels to ensure appropriate use and storage of such products and that such products will not undermine or equate to breastfeeding.[109]

Therefore, the PH BMS Framework provides ample descriptions of the types of products that it covers, and thus, satisfies the second criterion of the three-part technical regulation test.

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99 Milk Code Sec. 4(a); RIRR, Rule II Sec. 5(c); Circular 2008-0006, Item IV.
100 Milk Code Sec. 4(h); RIRR, Rule II Sec. 5(o); Circular 2008-0006, Item IV.
101 Milk Code Sec. 4(b); Circular 2008-0006, Item IV.
102 RIRR, Rule II Sec. 5(e).
103 RIRR, Rule II Sec. 5(y).
104 Circular 2008-0006, Item IV.
105 RIRR, Rule II Sec. 5(v).
106 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7048 (Aug. 2013) at Section II.6.c.v, available at: http://www.itssd.org/HK%20Infant%20Formula%202.pdf.
107 Milk Code Sections 5(a)-(b); RIRR, Rule III Sections 7, 8(b).
108 Milk Code Sections 6(a)-(f); RIRR, Rule V Sections 12-13, 15; Circular 2012-0027, Sections 19, 19A, 20, 21.
109 Milk Code Sections 19(a)-(e); RIRR, Rule VII Sections 25-27; Circular 2008-0006, Items VI.A.1-3; B.1-B.4.

iii. Mandatory Compliance With Product Characteristics

To satisfy the third criterion ("mandatory"), a measure must "lay down…set forth, stipulate or provide [the] characteristics," (e.g., qualities or attributes) "of products in a binding or compulsory fashion" or "ha[ve] the effect of prescribing or imposing" them.[110] A measure must be "examined as an integrated whole, taking into account, as appropriate, the prohibitive and the permissive elements that are part of it."[111] The mandatory nature of a given measure may be revealed by the following indicia: 1) whether the measure is composed of classic legal instruments that are legally binding under the law of the home country jurisdiction;[112] 2) whether the measure uses the word "shall" in laying down its requirements;[113] 3) whether the measure is supported by an "enforcement" mechanism that foresees the possibility of imposing a fine/penalty in the event of noncompliance;[114] and 4) whether the measure consistently refers to its core requirement as a "mandatory" requirement.[115]

The Milk Code, RIRR, AOs, Circular and Memoranda comprising the PH BMS Framework are each legally binding governmental measures issued by the executive branch of successive Philippine Governments. Their provisions set forth detailed rules prescribing the types of information to be included in and excluded from public informational/educational materials dealing with infant feeding with respect to Milk Code-covered products, the content rules for the presentation, description, and/or representation of Milk Code-covered products for marketing, advertising and promotional purposes, the types of information that can be used to present, describe, and/or represent Milk Code-covered products on product containers and labels, the types of sponsorship, donative and promotional activities that can and cannot be undertaken in healthcare facilities, and the types of information that can be shared with health workers. Each of these rules employs the words "shall",[116] "shall not",[117] "no…shall",[118] "must",[119] and/or "must not"[120] in laying down their requirements.

In addition, the PH BMS Framework is supported by a robust enforcement mechanism that supplements the multi-stakeholder monitoring regime the PHDOH established at the national, regional, provincial and municipal levels to achieve the purposes and objectives of the Milk Code.[121]

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110 Appellate Body Report, *EC - Asbestos* at pars. 67–69.
111 *Id*., at pars. 64, 75.
112 Panel Report, *US - COOL* at par. 7.157.
113 *Id*. at par. 7.158. The *US - COOL* Panel noted that the use of the word "shall" is indicative of mandatory compliance. *Id*., at par. 7.160; Appellate Body Report, *EC - Sardines* at par. 194.
114 Panel Report, *US - COOL*, at par. 7.159.
115 *Id*. at pars. 7.160–7.16; Appellate Body Report, *EC - Asbestos* at par. 72.
116 *See* Milk Code Sections 5(b), 6(e), 7(e), 8(b), 10(a)-(b) and (e)-(f), 11(b); RIRR, Rule III Sec. 8(b), Rule VII Sections 25-28, Rule VIII Sec. 30; Circular 2008-0006, Items VI.A.1 and A.3, B.1-B.9; AO 2012-0027, Sections 8.5-8.9, 9-11, 17, 18, 21.
117 *See* Milk Code Sections 6(b)-(c), 7(c)-(d), 8(d), 9, 10(d), 11(c); RIRR, Rule V Sec. 15, Rule VI Sections 16-17 and 21, Rule VIII Sec. 31; Rule IX Sec. 35; Circular 2008-2006, Items V.4-.5 and V.8; AO 2012-0027, Sections 14, 19, 20.
118 *See* Milk Code Sections 6(a) and (d), 7(b), 8(c), 10(c); RIRR, Rule V Sections 12 and 14, Rule VI Sections 18 and 22-24; AO 2012-0027, Sections 13, 17.
119 RIRR, Rule V Sec. 12; Circular 2008-0006, Items V.1, V.6, VI.B.10, VII; AO 2012-0027, Sections 8.1, 8.4.
120 RIRR, Rule V Sec. 13.
121 Milk Code Sec. 12(b); RIRR, Rule X Sec. 36. "In coordination with other agencies involved in the implementation of the Code, the Department shall adopt such appropriate monitoring guidelines for the national, regional and provincial levels. It shall likewise provide regular training on monitoring compliance and enforcement on violations of the Milk Code for all persons engaged in or volunteering to help in the monitor[ing] and implementation of the Code. The Department may request…the assistance of non-governmental organizations, civil society,

This mechanism includes IAC review of proposed marketing, advertising and promotional activities.[122] The enforcement regime can be anticipated to result, upon conviction of noncompliance by PHDOJ,[123] in the imposition of fines *and/or* possible imprisonment.[124] Administrative fines of unstated amounts[125] and criminal fines ranging from one thousand Philippine pesos (P1,000.00) to thirty thousand Philippine pesos (P30,000.00) may be assessed, and/or a term of imprisonment of at least two (2) months to one (1) year may be imposed as a penalty.[126] In addition, a conviction for noncompliance can also result in the revocation or suspension of government-issued business or professional licenses, permits or authorities, if the perpetrator is a distributor, manufacturer, or marketing firm or a health worker.[127] Both the Milk Code and RIRR provide for direct administrative and criminal liability of individual corporate officers and board members in the event a company (a juridical entity) is found guilty of noncompliance.[128] The RIRR also imposes liability on manufacturers' and distributors' agents and representatives to the extent of their complicity in such violations.[129] Consequently, the PH BMS Framework satisfies the third criterion of the three-part technical regulation test.

Since the PH BMS Framework satisfies all three criteria of the three-part technical regulation test, it arguably constitutes a technical regulation within the meaning of TBT Annex 1.1.

b. The PHDOJ Opinion Letters Do Not Constitute a Technical Regulation

As noted above, the PHDOJ opinion letters are not mandatory within the meaning of Annex 1.1 to the TBT Agreement. Therefore, by definition, they cannot constitute a technical regulation, and need not be evaluated under the three-part technical regulation test to see whether they apply to an identifiable product or group of products.[130] (This article does not assess whether the PHDOJ opinion letters individually or collectively constitute an "unreasonable administration" of the PH BMS Framework, within the meaning of GATT Article X:3(a),[131] as the *US-COOL* Panel did with respect to the Vilsack letter[132]).

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and concerned international agencies in order to better monitor the implementation of these rules." *Id*. "Monitoring teams comprised of duly accredited teams from non-governmental organizations, and/or civil society may report their findings to the Office of the Secretary of Health who shall appropriately respond thereto with sufficient dispatch." RIRR, Rule X Sec. 37.

122 RIRR, Rule X, Sec. 38.

123 Milk Code, Sec. 12(b)(3); RIRR, Rule XI Sec. 45.

124 Milk Code Sec. 13(a); RIRR, Rule XI Sections 39-40.

125 RIRR, Rule XII Sec. 47.

126 Milk Code Sec. 13(a); RIRR, Rule XII Sec. 47, Rule XIII Sec. 50. The Philippines Supreme Court ruled, in a 2007 landmark case, that the sanctions provision contained in RIRR Rule XII Sec. 46 was unconstitutional and of no legal force and effect. *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, Supreme Court of the Philippines En Banc (Oct. 9, 2007), supra.

127 Milk Code Sec. 13(b); RIRR, Rule XII Sec. 48.

128 Milk Code Sec. 13(a); RIRR, Rule XII Sec. 49, and Rule XIII Sec. 50.

129 *Id*.

130 *See* Panel Report, *US-COOL* at pars. 7.208, 7.215, 7.217 and 7.236.

131 GATT Article X:3(a) provides that "[e]ach contracting party shall administer in a uniform, impartial and reasonable manner all its laws, regulations, decisions and rulings of the kind described in paragraph 1 of this Article." *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 ["GATT"]; Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

132 In *US-COOL*, Canada and Mexico "claim[ed] that the United States acted inconsistently with its obligations under [GATT] Article X:3(a) with respect to its administration of the COOL measure." *See* Panel Report, *US-COOL*, supra at par. 7.809. Canada argued that "[t]he Vilsack letter created uncertainty as to the precise requirements of the COOL measure, thereby administering the COOL measure in an unreasonable manner." *Id*., at par. 7.817. Mexico argued that "that the inconsistent and unpredictable guidance from USDA was not part of the legislative or rulemaking process, but the action of an agency not reflected in statutes or regulations", and that the Vilsack letter contributed to "the continuing changes in USDA policy" that disrupted Mexican industry. *Id*., at par. 7.818. The Panel ultimately concluded that the issuance of the

2. The PH BMS Framework is Based on the WHO Code Which is a Relevant International Standard[133]

a. Ascertaining Whether a Relevant International Standard Exists

TBT Article 2.4 requires WTO Members to use all or part of "relevant international standards" that exist or the completion of which are imminent *as the basis for* their technical regulations.[134] The complaining Party bears the burden of "demonstrating that a relevant international standard exists and that this standard was not used *as a basis for* the technical regulation" (emphasis added).[135] And, the defending Party bears the burden of "demonstrat[ing] that the international standard is an ineffective or inappropriate means to fulfill the legitimate objectives pursued by the Regulation."[136]

In order to constitute an "international standard" for purposes of TBT Article 2.4, a standard must be adopted by an "international standardizing body" rather than by an "international organization".[137] The Appellate Body, in *US-Tuna II (Mexico)*, ruled that an "international standardizing body" "is a body[138] that has recognized activities in standardization[139] and whose membership is open[140] to the relevant bodies of at least all Members."[141] A standardizing body will be considered "international" for purposes of the TBT Agreement if the body is "open 'at every stage of standards development'"[142] and "on a non-discriminatory basis".[143]

Vilsack letter "constitute[d] an act of administering the COOL measure. *Id*., at pars. 7.829-7.830. The Panel also concluded, but only with respect to Canada's claim, that the issuance of the Vilsack letter amounted to an "unreasonable" administration of the COOL measure in violation of GATT Article X:3(a). *Id*., at pars. 7.863-7.864. *Cf*. par. 7.870.

133 For a more detailed discussion of this topic, *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7046, *supra* at Sections II.3 and II.4.

134 TBT Art. 2.4. However, technical regulations need not be based on relevant international standards when such standards, in whole or in part, "would be an ineffective or inappropriate means for the fulfillment of the legitimate objectives pursued, [e.g.,] because of fundamental climatic or geographical factors or fundamental technological problems." *Id*.

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

136 *Id*., at par. 7.52.

137 Appellate Body Report, *US-Tuna II (Mexico)* at par. 356. According to the Appellate Body, this result obtains because "the definitions in Annex 1 to the TBT Agreement prevail over the definitions in the ISO/IEC Guide 2: 1991." *Id*. "Annex 1.2 to the TBT Agreement refers to a 'body', not to an 'organization', and Annex 1.4 defines an 'international body or system', but not an 'international organization'. This suggests that, for the purposes of the TBT Agreement, 'international' standards are adopted by 'bodies', which may, but need not necessarily, be 'organizations'. This is also supported by the context provided by other provisions of the TBT Agreement. For example, Articles 2.6, 10.1.4, 11.2, 12.5, and 12.6, as well as Annexes 3.G and 3.H to the TBT Agreement envisage that international standards are prepared by 'international standardizing bodies'". *Id*. "[A] body…may, but need not necessarily be [an] organisation." *Id*., at par. 356. In other words, "for purposes of the TBT Agreement, international standards need to be adopted by 'international standardizing bodies', which may, but need not necessarily, be 'international standardizing organizations'. *Id*., at par. 395.

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

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

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

141 *Id*., at par. 359.

142 *Id*., at par. 374. "[I]t is not sufficient for the body to be open, or [to] have been open, at a particular point in time." *Id*.

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

An international standardizing body will be deemed "recognized" if, at a minimum, WTO Members "are aware, or have reason to expect, that the international body in question is engaged in standardization activities."[144] Evidence of recognition by WTO Members, such as through their participation in such body's standardization activities,[145] and/or evidence of recognition by national standardizing bodies would be relevant[146] for purposes of such analysis. Furthermore, "evidence of a body's compliance with procedural and substantive safeguards formulated by WTO Members would be relevant for the question of whether its standardizing activities are 'recognized' for the purposes of the TBT Agreement."[147] The WTO Appellate Body, for example, has ruled that, an international standardizing body that has "set[] out principles and procedures that WTO Members have decided 'should be observed' by international standardizing bodies",[148] such as those set forth in the TBT Committee *Decision on Principles for the Development of International Standards, Guides and Recommendations With Relation to Articles 2, 5 and Annex 3 of the Agreement*,[149] will be "recognized" within the meaning of the TBT Agreement.[150] This means that, in addition to elaborating international standards, guides and recommendations, a "recognized" international standardizing body shall adopt principles and procedures that "ensure[151] transparency,[152] openness,[153] impartiality and consensus,[154] effectiveness and relevance,[155] coherence,[156] and…address the concerns of developing countries."[157]

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144 *Id*., at par. 362. However, "a 'standardizing body'…with 'recognized activities in standardization', does not need to have standardization as its principal function, or even as one of its principal functions." *Id*.

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

146 *Id*., at par. 363.

147 *Id*., at par. 377.

148 *Id*., at par. 378.

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

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

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

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

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

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

155 "[I]nternational standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries. They should not distort the global market, have adverse effects on fair competition, or stifle innovation and technological development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Whenever possible, international standards should be performance based rather than based on design or descriptive characteristics." *Id*., at par. D.10.

In order for an international standard to be "relevant" it must "bear[] upon or relat[e] to the matter in hand; [i.e., it must be] pertinent."[158] The WTO Appellate Body has ruled that "an international standard is used 'as a basis for' a technical regulation 'when it is used as the principal constituent or fundamental principle for the purpose of enacting the technical regulation'".[159] "[T]here must be a very strong and very close relationship between two things in order to be able to say that one is 'the basis for' the other."[160] Thus, more than a showing of "a rational relationship" between an international standard and a technical regulation will be required "to find that the former is used 'as a basis for' the latter", for purposes of TBT Article 2.4.[161] And, at a minimum, "under Article 2.4, if the technical regulation and the international standard contradict each other, it cannot properly be concluded that the international standard has been used 'as a basis for' the technical regulation."[162]

b. The WHO is a Recognized International Standardizing Body[163]

The WHO is a specialized agency of the United Nations[164] with nearly universal membership. The WHO Constitution sets forth the organization's objective as "the attainment by all peoples of the highest possible level of health".[165] To achieve this objective, the WHO's core functions have included the *development, establishment and promotion of international standards* with respect to food, biological, pharmaceutical and similar products" (emphasis added).[166] The WHO's 11th "General Programme of Work" clearly reiterates that one of its six core functions is "[s]etting norms and standards, and promoting and monitoring their implementation."[167] It is arguable that the WHO is actively engaged in the development of non-food safety-related public health standards, and thus, constitutes a "standardizing body", within the meaning of TBT Article 2.4.

For example, recent WHO Director-General and Secretariat reports underscore the identification of "health governance" as one of the WHO's eight leadership priorities, and that its role in future

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156 "[I]t is important that international standardizing bodies avoid duplication of, or overlap with, the work of other international standardizing bodies. In this respect, cooperation and coordination with other relevant international bodies is essential." *Id*., at par. E.12.
157 "Tangible ways of facilitating developing countries participation in international standards development should be sought. The impartiality and openness of any international standardization process requires that developing countries are not excluded de facto from the process." *Id*., at par. E.13.
158 Appellate Body Report, *EC-Sardines* at pars. 229-230. In *EC-Sardines*, the Appellate Body found that, "although the [disputed] EC Regulation expressly mention[ed and dealt with] only [preserved] *Sardina pilchardus*, it ha[d] legal consequences for other fish species that could be sold as preserved sardines, including preserved *Sardinops sagax*". Id., at par. 232. It also found that "Codex Stan 94 cover[ed] 20 fish species in addition to *Sardina pilchardus* [which] also are legally affected by the exclusion in the [disputed] EC Regulation." Id. Since Codex Stan 94 and the EC Regulation both referred to preserved *Sardina pilchardus*, the Appellate Body concluded that "Codex Stan 94 bears upon, relates to, or is pertinent to the EC Regulation." Id., at pars. 231-232.
159 Panel Report, *US-Tuna II (Mexico)*, at par. 7.711; Appellate Body Report, *EC – Sardines*, at pars. 240-245.
160 Appellate Body Report, *EC-Sardines* at par. 245.
161 Panel Report, *US-Tuna II (Mexico)* at par. 7.713; Appellate Body Report, *EC-Sardines* at pars. 247-248.
162 Appellate Body Report, *EC-Sardines* at par 248.
163 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7046 (Aug. 2013), *supra* at Sections II.3 and II.4.
164 See *Constitution of the World Health Organization* (1946), Final preambular paragraph, available at: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf.
165 *Id*., Arts. 1.
166 *Id*., Art. 2(u). "The WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends." *See* World Health Organization, *About WHO*, available at: http://www.who.int/about/en/.
167 *See* World Health Organization, *Engaging for Health Eleventh General Programme of Work 2006-2015 A Global Health Agenda* (May 2006), at Executive Summary p. iii, pp. 27-28, available at: http://whqlibdoc.who.int/publications/2006/GPW_eng.pdf.

health governance will entail "position[ing] and promot[ing] health in a range of *global, regional and national processes*" (emphasis added), including "the development of norms, *standards*, policies and strategies" (emphasis added).[168] The WHO also arguably constitutes an "international" standardizing body on non-food safety-related public health matters for purposes of TBT Article 2.4. As WHA rules and procedures reflect, WHO/World Health Assembly membership and standards development activities have long been "open" to the relevant designates of at least all United Nations Members, including developing country Members, and at least all WTO Members, on a non-discriminatory basis, at every stage of the standards development process.[169]

Although standardization is not the WHO's principal function, WTO Members are likely aware or have reason to expect that the WHO is engaged in public health-related standardization activities given the current and past involvement of their corresponding government delegations in such activities. And, WTO Member awareness and expectation of WHO standards activities is only likely to grow in the future given the WHO's reform agenda which reflects a broader future "health governance" role for the organization building on the WHO's current constitutionally sanctioned role in global health governance-related standards.[170]

Nevertheless, the WHO has not formally embraced the WTO TBT Committee *Decision on Principles for the Development of International Standards, Guides and Recommendations*.[171] And, while it is arguable that the WHO's primary governance documents already contain several of these requirements, such instruments and the mechanisms underlying them arguably do not fully adhere to or address such principles. If a strict interpretation of the Appellate Body's holding on this issue in *US-Tuna II (Mexico)* were applied, the WHO would *not* constitute a "recognized" international standardizing body within the meaning of TBT Article 2.4. As a result, the WHO Code arguably would *not* constitute a "relevant international standard" for purposes of TBT Article 2.4. If, however, TBT Article 2.4 is interpreted liberally, it is arguable that the WHO *does* constitute a recognized international standardizing body within the meaning of TBT Article 2.4. In that case, the WHO Code *would* arguably constitute a "relevant international standard" under TBT Article 2.4.[172]

c. The WHO Code is a Relevant International Standard Vis-à-Vis the PH BMS Framework

i. Aim and Scope

The WHO Code is generally regarded as an international "minimum requirement".[173] Its "aim is to contribute to the provision of safe and adequate nutrition *for infants*, by the protection and

168 *Id*., See at pars. 39-61, pp. 9-15. *See also* World Health Organization Executive Board, *WHO's Role in Global Health Governance*, Provisional agenda item EB132/5 Add.5), 132nd Session (Jan. 18, 2013), at pars. 6-7 and 23, available at: http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_5Add5-en.pdf.
169 *Id*.
170 *See* World Health Organization Executive Board, *WHO Governance Reform* – Report by the Secretariat, Provisional agenda item 5 (EB133/16), 133rd Session (May 17, 2013) at par. 34, available at: http://apps.who.int/gb/ebwha/pdf_files/EB133/B133_16-en.pdf. The WHO Constitution states that the WHO's first objective is to "act as the directing and co-ordinating authority on international health work". *See* WHO Constitution, Art. 2(a).
171 *See* G/TBT/9, supra.
172 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7046 (Aug. 2013) supra at Sec. II.4.
173 The WHA has referred to national government "adoption of and adherence to" the WHO Code as "a minimum requirement and only one of several important actions required in order to protect healthy practices in respect of infant and young child feeding." *See* WHA Resolution 34.22 at p. 2.

promotion of breast-feeding, and by ensuring the proper use of *breast-milk substitutes*, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution" (emphasis added).[174] The WHO Code "applies to the marketing, and practices related thereto, of…breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottlefed complementary foods, *when marketed or otherwise represented to be suitable*…for use *as a partial or total replacement of breast milk*" (emphasis added).[175] WHO Code Annex 3 provides that "[p]roducts *other than* bona fide breast-milk substitutes, including infant formula, *are covered* by the code *only when* they are 'marketed or otherwise represented to be suitable...for use as a partial or total replacement of breastmilk'" (emphasis added).[176]

WHO Code Article 3 defines "infant formula" as a Codex Alimentarius Commission-compliant industrially formulated breastmilk substitute satisfying "the normal nutritional requirements of infants up to *between four and six months [4-6 months] of age*" (emphasis added).[177] WHO Code Article 3 defines "complementary food" as "any food…suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant."[178] The WHO Codes does not define the term "infant". WHO Code Annex 3 provides that "the code's references to products used as *partial or total replacements of breast milk are not intended to apply to complementary foods unless these foods are actually marketed - as breast-milk substitutes*" – i.e., "as being suitable for the partial or total replacement of breast milk" (emphasis added).[179] In other words, the WHO Code presumes that "[d]uring the first four to six months of life, breast milk alone is usually adequate to sustain the normal infant's nutritional requirements."[180] WHO Code Annex 3 thus equates the term "breastmilk substitutes" used during the first 4-6 months of life with the "total or partial replacement of breastmilk."[181]

The WHO Code's relevance to the PH BMS Framework is arguably demonstrated by the latter's similar objective, use of terminology and product coverage. The PH BMS Framework's objective is substantially similar to but considerably broader than that of the WHO Code. It is to "ensure the provision of safe and adequate nutrition for infants *and young children* by the protection and promotion of breastfeeding[182] and by ensuring the proper use of breastmilk substitutes *and breastmilk supplements* when these are necessary,[183] on the basis of adequate information and through appropriate marketing and distribution" (emphasis added). For these purposes, the PH BMS Framework describes an "infant" as "a person falling within the age bracket of 0-12

174 WHO Code Art. 1.
175 WHO Code Art. 2.
176 WHO Code Annex 3, p. 23.
177 WHO Code Art. 3, p. 9.
178 WHO Code Art. 3, p. 8.
179 WHO Code Annex 3, p. 23.
180 *Id*.
181 *Id*. "Breast milk may be replaced (substituted for) during this period by bona fide breast-milk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semisolid food intended for infants and given after this initial period, can no longer be considered as a replacement for breast milk (or as its bona fide substitute). Such foods only complement breast milk or breast-milk substitutes, and are thus referred to in the draft code as complementary foods." WHO Code Annex 3, p. 23.
182 The Milk Code retains the "to contribute to the provision" language. *See* Milk Code Sec. 2. The RIRR adds "by the…support of breastfeeding." RIRR, Rule I Sec. 2.
183 The RIRRs alter this language somewhat – "…ensuring the proper use of…and related products *when these are medically indicated and only when necessary*, on the basis…" (emphasis added). RIRR, Rule I Sec. 2.

months,"[184] and a "young child" as "a person from the age of more than twelve (12) months up to the age of three (3) years (36 months)."[185]

The PH BMS Framework similarly defines the term "breastmilk substitute" as "any food being marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose."[186] It similarly defines the term "complementary food" as "any food, except milk substitutes…suitable as a complement *to* breastmilk[187] to satisfy the nutritional requirements of the infant" and as a *breastmilk supplement*.[188] The PH BMS Framework similarly "applies to the marketing, and practices related thereto, of…breastmilk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, *when marketed or otherwise represented to be suitable…for use as a partial or total replacement of* breastmilk" (emphasis added).[189] The PH BMS Framework declares as "underlying principles" both that "[e]xclusive breastfeeding is for infants from 0 to (6) months", and that "[b]reastfeeding is still appropriate for young children up to two (24 months) years of age or beyond."[190] Consequently, it covers complementary foods/breastmilk supplements even if they are *not* marketed or intended as breastmilk substitutes.

ii. Informational/Educational Materials Disseminated to the Public

WHO Code Article 4.2 imposes prohibitions and restrictions on the dissemination of informational/educational materials intended to reach pregnant women and mothers of infants and young children that are related to infant feeding and concern the use of infant formula. Materials concerning the use of infant formula may not "use any pictures or text which may idealize the use of breast-milk substitutes".[191] Materials related to infant feeding must contain language discussing the following non-food safety-related points: "(a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; [and] (d) the difficulty of reversing the decision not to breast-feed."[192] When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; 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."[193]

184 Milk Code Sec. 4(e); RIRR, Rule II Sec. 5(n).
185 RIRR, Rule II Sec. 5(ff).
186 Milk Code Sec. 4(a); WHO Code Art. 3.
187 The Milk Code retains the same language as WHO Code Art. 3 – "…as a complement to breastmilk *or to infant formula*" (emphasis added). " Milk Code Sec. 4(b).
188 The Milk Code retains the same language as WHO Code Art. 3 – "Such food is also commonly called 'weaning food' *or 'breastmilk supplement'*" (emphasis added). " Milk Code Sec. 4(b). *See also* AO 18 S. 1997, which mandated "the use of the term 'breastmilk supplement' to refer to 'follow-on formula' on the labeling of…follow-on formula/breastmilk substitute [products]".
189 Milk Code Sec. 3; RIRR, Rule I Sec. 3.
190 RIRR, Rule I Sections 4(a) and (d). The PH DOH recognizes that appropriate infant and young child feeding practices include "exclusive breastfeeding from 0-6 months", "appropriate complementary feeding from 6 months onwards", and continuous breastfeeding up to two (2) years of age or beyond." RIRR, Rule III Sec. 6.
191 *Id*., Art. 4.2.
192 *Id*.
193 *Id*.

Milk Code Section 5(b) and RIRR, Rule III Section 8(b) of the PH BMS Framework employ virtually identical language, and then some.[194] Although these PH BMS Framework provisions go beyond the WHO Code's corresponding requirements, they nevertheless can be considered to address similar subject matter falling within the scope of the WHO Code.

iii. Promotional, Marketing and Advertising Materials

WHO Code Article 5 precludes all advertising or other form of promotion to the general public of breastmilk substitutes when marketed or otherwise represented to be suitable for use as a partial or total replacement of breastmilk.[195] It prohibits manufacturers and distributors from: 1) providing product samples to pregnant women, mothers or members of their families;[196] 2) distributing to pregnant women or mothers or infants and young children gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding;[197] and 3) point-of-sale advertising, sampling, or any other promotion device to induce product sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.[198] In addition, the WHO Code Article 5 prohibits third-party marketing agents employed by formula milk product manufacturers and distributors from seeking direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.[199]

The PH BMS Framework employs virtually identical language,[200] but does not expressly ban breastmilk substitute and breastmilk supplement product advertising because of the Philippine Supreme Court's determination that it would be unconstitutional to do so.[201] In lieu thereof, the PH BMS Framework goes into great detail to describe the standards for the IAC to employ in evaluating whether the proposed advertising materials for specific breastmilk substitute and breastmilk supplement products should be permitted, as well as to describe advertising materials that are not permitted.[202] These standards can be employed to indirectly and effectively ban breastmilk substitute and breastmilk supplement product advertising. The PH BMS Framework also prescribes different messages for advertisements of Milk Code-covered products and milk supplements.[203] While such PH BMS Framework provisions track and sometimes go beyond corresponding WHO Code requirements, they nevertheless can be considered to address similar subject matter falling within the scope of the WHO Code.

iv. Product Containers and Labels

194 RIRR, Rule III Sec. 8(b) also states that such information about health hazards should "includ[e] information that powdered infant formula may contain pathogenic microorganisms and must be prepared and used appropriately."
195 WHO Code Articles 3 and 5.1.
196 *Id*., Art. 5.2.
197 *Id*., Art. 5.4.
198 *Id*., Art. 5.3.
199 WHO Code, Art. 5.5.
200 Milk Code Sec. 6(b)-(d); RIRR, Rule V Sec. 15(c), Rule VI Sections 18-19, 21-23.
201 The Philippines Supreme Court ruled, in a 2007 landmark case, that the sanctions provision contained in RIRR, Rule V Sec. 11 was unconstitutional and of no legal force and effect. *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, Supreme Court of the Philippines En Banc (Oct. 9, 2007), *supra*.
202 RIRR, Rule V Sections 13, 15 (a)-(c) and 16; AO 2012-0027, Sections 19, 19A, 20, 21.
203 *Cf*. AO 2012-0027, Sections 21A and 21B.

WHO Code Article 9.2 imposes non-food safety-related labeling restrictions to ensure that breastmilk substitute product labels are designed so as "not to discourage breast-feeding."[204] Formula milk product containers and labels must contain "(a) the words 'Important Notice' or their equivalent;"[205] "(b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;…and (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation."[206] It prohibits formula milk product containers and labels from having any "pictures of infants [or]…other pictures or text which may idealize the use of infant formula."[207] Graphics are permitted only "for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation."[208] Containers and labels may not use the terms "humanized", "materialized" or similar terms.[209]

The PH BMS Framework employs virtually identical language,[210] and prescribes the inclusion of additional content on containers and labels that goes beyond the requirements of the WHO Code.[211] Although these PH BMS Framework provisions go beyond such WHO Code requirements, they nevertheless can be considered to address similar subject matter falling within the scope of the WHO Code.

v. Trademarks, Logos, Brand Names and Company Names

WHO Code Articles 4.3 and 6.8 provide that informational or educational materials or equipment donated by manufacturers or distributors to the public or to healthcare facilities "may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of the Code."[212] A "proprietary product" is a "product sold under a brand name owned by a company".[213] There is no evidence to suggest that the WHO Code recommends that WHO Members prohibit references on such materials to any more than a branded covered product's *name*. This means, in effect, that covered branded product-related *non-word marks (logos and symbols)* may be used on such materials where such images do not otherwise "idealize the use of breast-milk substitutes" in contravention of WHO Article 4.2.

AO 2012-0027 approximates, but goes beyond this language. It provides that milk company, representative and agent donations of products, equipment and materials "not otherwise falling within the scope of" the Milk Code or the RIRR[214] shall contain "no name/no logo of the donating company nor brand names of covered products on the donated items."[215] Circular 2008-0006 also goes beyond this language to the extent it precludes the use on the principal panel of a covered

204 *Id*., Art. 9.1.
205 *Id*., Art. 9.2.
206 *Id*.
207 *Id.*
208 *Id*.
209 *Id*.
210 Milk Code Sections 10(b)(i)-(iv), (c)-(d); RIRR, Rule VII Sections 25-26.
211 Circular 2008-0006, Items VI.A.1(v), A.3(i).
212 WHO Code Articles 4.3 and 6.8.
213 See *Proprietary Product*, Financial Times Lexicon, available at: http://lexicon.ft.com/Term?term=proprietary-product.
214 RIRR, Rule VI Section 21 prohibits manufacturer, distributor or agent gifts of Milk Code-covered products "to any member of the general public, to hospitals and other health facilities…*without or without company name or logo or product or brand name*" (emphasis added).
215 AO 2012-0027, Section 14.

product label a "brand name and/or trademark [of] any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar import."[216] In addition, two PHDOH Memoranda also go beyond the WHO Code, insofar as they direct the BFAD/FDA "not to allow any kind of trademarks that contain health and nutrition claims or that may undermine breastfeeding and breastmilk to be placed on labels."[217] While these PH BMS Framework provisions go beyond corresponding WHO Code requirements, they nevertheless can be considered to address similar subject matter falling within the scope of the WHO Code.

In sum, to the extent the Milk Code, RIRR, Circular 2008-0006, AO 2012-0027, and PHDOH Memoranda) cover subject matter that falls within the scope of WHO Code Articles 3, 5.1-5.5, 6.8, and 9.2, it is arguable that the WHO Code "bears upon, relates to, or is pertinent to" these PH BMS Framework instruments, and is thus, a relevant international standard for purposes of the TBT Agreement.

d. The PH BMS Framework is Based on the WHO Code

To recall, "an international standard is used 'as a basis for' a [de jure or de facto] technical regulation 'when it is used as the principal constituent or fundamental principle for the purpose of enacting" it.[218] The Milk Code's second preambular paragraph unmistakably links the PH BMS Framework to the WHO Code. It states, that "WHEREAS, consistent with Article 11 of the *International Code of Marketing of Breast-milk Substitutes*, the present government should adopt appropriate legislation *to give effect to the principles and aim of the aforesaid International Code*.[219] The RIRR's third, fourth and fifth preambular paragraphs indicate that the RIRR was intended to give force and effect to the Milk Code's national implementation of the WHO Code. They also indicate that the RIRR was intended to further support the Philippines' national implementation of the WHO *Global Strategy on Infant and Young Child Feeding*. The WHO IYCF Strategy includes as a priority and operational target of all governments the enactment of "new legislation or other suitable measures…as part of a comprehensive policy on infant and young child feeding, to give effect to the principles and aim of the *International Code of Marketing of Breast-milk Substitutes*…" (emphasis added).[220] It is thus arguable that the PH BMS Framework has objectives that are very similar to those of the WHO Code and WHO IYCF Strategy. Since the PH BMS Framework addresses subject matter that is similar to that covered by various WHO Code provisions in order to achieve those objectives, it is arguable that the PH BMS Framework was based on the WHO Code for purposes of the TBT Agreement.[221]

Notwithstanding the above analysis, it could be argued that the Philippines is a developing country WTO Member facing specific socio-economic conditions that is entitled to special and differential treatment under TBT Article 12.4, including a suspension of developed country WTO Members'

216 Circular 2008-0006, Item VI.1.(v).
217 PHDOH Memorandum (Sept. 5, 2011); PHDOH Memorandum (Sept. 10, 2012).
218 Panel Report, *US-Tuna II (Mexico)*, at par. 7.711; Appellate Body Report, *EC – Sardines*, at pars. 240-245.
219 Milk Code, Preamble par. 2.
220 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), supra at par. 30, p. 14; par. 33, p. 15; par. 34 pp. 16 and 17; par. 40, pp. 20 and 21; par. 41, p. 22; par. 48, p. 25
221 It is assumed that the WHO IYCF Strategy is *not* a relevant international standard for purposes of this analysis, because the legal instruments adopted by the Philippine Government to implement the WHO IYCF Strategy on a national level are distinct from and address different subject matter than the PH BMS Framework.

expectation that it use international standards, such as the WHO Code, as the basis for its domestic technical regulations (PH BMS Framework) on the grounds that it is not appropriate to its development needs. However, the Philippines' ability to exempt itself from the obligation of TBT Article 2.4 in order to deviate from the WHO Code for domestic regulatory purposes consistent with its development needs, does not excuse it from ensuring that the domestic regulations it has enacted comply with the obligations of other TBT Agreement provisions, particularly, Article 2.2.[222]

3. Various PH BMS Framework Provisions Create Unnecessary Obstacles to Trade Within the Meaning of TBT Article 2.2

The WTO Appellate Body ruled in *US-Clove Cigarettes*[223] that "the object and purpose of the TBT Agreement is to strike a balance between, on the one hand, the objective of trade liberalization and, on the other hand, Members' right to regulate."[224] One of the TBT Agreement's primary objectives is to prevent WTO Members from using regulations as unnecessary barriers to trade while ensuring that they retain their sovereign right to regulate "for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels [they] consider appropriate."[225] Thus, where national measures go beyond and are more stringent than relevant international standards and may affect international trade, a complaining WTO Member must present a *prima facie* case showing that they are more trade-restrictive than necessary to fulfill the measure's legitimate policy objectives considering the risks nonfulfillment of those objectives would create.

a. Ascertaining Whether a Disputed Measure Imposes an Unnecessary Obstacle to Trade

TBT Article 2.2[226] sets forth a framework to discern whether a disputed measure imposes an unnecessary obstacle to trade that entails a multistep inquiry.[227]

First, a measure must be shown to be "trade-restrictive." A measure will be deemed "trade-restrictive" within the meaning of TBT Article 2.2 if it affects "the competitive opportunities available to imported products".[228] Such a finding requires a showing of some "limiting effect on trade."[229]

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222 *See* Alexander Djazayeri, *Main Features of World Trade Law, With Special Focus on the TBT Agreement: A Guideline*, Physikalisch Technische Bundesanstalt and International Technical Cooperation (2012), at p. 19, available at: http://www.ptb.de/de/org/q/q5/docs/broschueren/GATT_en_web.pdf.

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

224 *Id*., at par. 174.

225 TBT Agreement Preamble, Sixth Recital.

226 "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology, or intended end-uses of products" (first emphasis added). TBT Art. 2.2.

227 Panel Report, *US-COOL* at pars. 7.554–7.557.

228 *Id*., at par. 7.572.

229 Appellate Body Report, *US-Tuna II (Mexico)* at par. 319; Appellate Body Report, *US-COOL* at par. 375. The Appellate Body also found "that the reference in Article 2.2 to 'unnecessary obstacles' implies that 'some' trade-restrictiveness is allowed . . . ." *Id*. Such a finding requires neither "the demonstration of any actual trade effects" nor a showing of the "level" of trade-restrictiveness. Panel Report, *US-COOL* at pars. 7.572 and 7.575.

Second, TBT Article 2.2 requires complaining Members to demonstrate that the identified objective(s) of a disputed technical regulation is not "legitimate" based on the information they have obtained prior to or during the dispute settlement proceeding.[230] Typically, the objective of a disputed technical regulation can be identified in the "notification" that a Member submitted to the WTO TBT Committee pursuant to TBT Article 2.9, which enjoys a rebuttable presumption of truthfulness and good faith consistent with international law.[231] A measure's text as well as its design, architecture, and structure must be evaluated to determine whether a technical regulation's stated objective is, indeed, the regulation's actual objective. Such an analysis must also be undertaken where a technical regulation's objective has not been expressly stated.[232] The legitimacy of a technical regulation "must be found in the 'genuine nature' of the objective, which is 'justifiable' and 'supported by relevant public policies or other social norms.'"[233] A complaining WTO Member bears the burden of establishing that the objective of a disputed regulation is not legitimate within the meaning of Article 2.2.[234] TBT Article 2.2 sets forth a non-exclusive open list of legitimate objectives. These include, *inter alia*, national security requirements; the prevention of deceptive practices; protection of human health or safety; animal or plant life or health; or the environment.[235] Since "a policy objective pursued by a technical regulation [need not] be specifically linked in nature to those objectives explicitly listed in Article 2.2",[236] a wide range of objectives could potentially fall within the scope of "legitimate" objectives for purposes of meeting this requirement.

Third, a disputed technical regulation must be shown to have not "fulfilled" its identified objective(s). A technical regulation will be deemed to have "fulfilled" an identified objective if it "*makes a contribution to* the objective pursued", which means that "there is a genuine relationship of ends and means between the objective pursued and the measure at issue" (emphasis added).[237] Such a determination "is concerned with *the degree of contribution* that the technical regulation

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

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

232 Although the Panel in *US—COOL* found that the COOL measure did not expressly state its objective, the Panel nevertheless concluded that said measure's objective was to provide consumer information on origin, as the United States had declared, because it was "devoted exclusively to the labelling requirements on origin." Panel Report, *US-COOL* at pars. 7.680, 7.685. While the significance of statements made by legislators during the legislative process may be considered, the WTO Appellate Body has found that they are typically unhelpful. The Appellate Body has deemed such an inquiry unnecessary and unadvisable given the difficulties of ascertaining and second-guessing the intent behind a measure that has multiple objectives. *See* Panel Report, *US-COOL* at par. 7.686-7.691 (citing Appellate Body Report, *Japan — Taxes on Alcoholic Beverages*, WT/DS8/AB/R (Oct. 4, 1996)) at pars. 27–28; *See also* Appellate Body Report, *Chile — Taxes on Alcoholic Beverages*, WT/DS87/AB/R (Dec. 13, 1999), at par 62.

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

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

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

236 Panel Report, *US-COOL* at pars. 7.634, 7.637. For example, although "consumer information" is not expressly listed as a "legitimate objective" in the text of Article 2.2, the Panel in US-COOL determined that "consumers generally are interested in having information on the origin of the products they purchase" and that, consequently, "providing consumer information on origin is a legitimate objective within the meaning of Article 2.2." *Id*., at pars. 7.650–7.651. The Panel in *US-COOL* found that many WTO Members, including the complainants and third-party amici, had "maintain[ed] some form of mandatory country of origin labelling for food and other products intended for human consumption" that "apply to food products at the retail level." *Id*., at par. 7.637. This "suggest[ed] that consumer information on country of origin [was] considered by a considerable proportion of the WTO Membership to be a legitimate objective under the TBT Agreement." *Id.*, at par. 7.638.

237 Panel Report, *US-COOL* at par. 7.693. The determination of whether a measure "fulfills" its objective under TBT Article 2.2 does not necessitate a finding that the measure "must meet some minimum threshold of fulfillment." Appellate Body Report, *US-COOL* at par. 461.

makes towards the achievement of the legitimate objective," which "may be discerned from the design, structure, and operation of the technical regulation, as well as from evidence relating to the application of the measure" (emphasis added).[238] In other words, the fulfillment of an objective by a technical regulation depends on how much that regulation helps to actually achieve that objective, taking into account the regulation's overall contribution[239] – i.e., the extent to which the contribution is capable of achieving the objective pursued.[240]

Fourth, it must be demonstrated that a disputed technical regulation is "more trade-restrictive than necessary to fulfill its objectives." A complaining member must determine: a) "the degree of contribution made by the measure to the legitimate objective at issue";[241] b) "the trade-restrictiveness of the measure";[242] and c) "the nature of the risks at issue as well as the gravity of consequences that would arise from non-fulfillment of the objective pursued by the Member through the measure".[243] Thus, "the assessment of "necessity" involves a relational analysis of the trade-restrictiveness of the technical regulation, the degree of contribution that it makes to the achievement of a legitimate objective, and the risks non-fulfillment would create."[244] In other words, it must be discerned "whether such trade-restrictiveness is required to fulfill the legitimate objectives pursued by the Member at its chosen level of protection"[245] – i.e., "whether the restrictions on international trade…exceed what is necessary to achieve the degree of contribution that a technical regulation makes to the achievement of a legitimate objective."[246]

Recent WTO jurisprudence reflects that, "[t]o the extent that a measure is capable of contributing to its objective, it would be more trade-restrictive than necessary if an alternative measure that is less trade-restrictive is reasonably available, that would achieve the challenged measure's objective *at the same level*" (emphasis added).[247] Consequently, a comparison of the trade-restrictiveness of the disputed measure with other reasonably available alternatives is required.[248] The complaining party bears the burden of identifying a reasonably available alternative that is capable of achieving the objective pursued by the disputed measure at the same level of protection, taking into account the risks non-fulfillment would create.[249] This requires consideration of "the likelihood and the gravity of potential risks (and any associated adverse consequences) that might arise in the event the legitimate objective being pursued would not be fulfilled,"[250] taking into account inter alia "relevant…available scientific and technical information, related processing technology, or intended end-uses of products."[251] Therefore, "an alternative means of achieving the objective that would

238 *Id*.
239 Appellate Body Report, *US-Tuna II (Mexico)* at pars. 315–17; Appellate Body Report, *US-COOL* at pars. 461–66.
240 Appellate Body Report, *Brazil - Measures Affecting Imports of Retreaded Tyres* WT/DS332AB/R (Dec. 3, 2007) at par. 149.
241 Appellate Body Report, *US-Tuna II (Mexico)* at par. 322; Appellate Body Report, *US-COOL* at par. 471.
242 *Id*.
243 *Id*.
244 Appellate Body Report, *US-Tuna II (Mexico)* at par. 318. *See also* Panel Report, *US-Tuna II (Mexico)* at par. 7.460 ("[T]he aspect of the measure to be justified as 'necessary' [in the context of TBT Article 2.2] is its trade restrictiveness rather than the necessity of the measure [itself] for the achievement of the objective.").
245 Appellate Body Report, *US-Tuna II (Mexico)* at par. 318.
246 *Id*., at par. 319.
247 Panel Report, *US-Tuna II (Mexico)* at par. 7.465.
248 Appellate Body Report, *US-Tuna II (Mexico)* at par. 322.
249 Panel Report, *US-Tuna II (Mexico)*, at par. 7.468.
250 *Id*., at pars. 7.466-7.467.
251 *Id*., at par. 7.466.

entail greater 'risks of non-fulfillment' would not be a valid alternative, even if it were less trade-restrictive."[252]

b. Various PH BMS Framework Provisions Impose an Unnecessary Obstacle to Trade That Is More Trade-Restrictive Than Necessary to Fulfill a Legitimate Objective Considering the Risks Non-Fulfillment Would Create

i. Various PH BMS Framework Provisions are Trade-Restrictive

The PH BMS Framework imposes prohibitions and severe restrictions on the public dissemination of informational/educational materials relating to infant and young child feeding,[253] on the public marketing, advertising and promotion of infant formula, follow-up formula and liquid and solid complementary food products,[254] on the labeling of such products,[255] and on the use of properly registered and legally valid proprietary trademarks, logos and brand names in product marketing, advertising and promotional materials and on product labels and packaging.[256] The WHO Code, however, only anticipates coverage of such products if they are marketed or intended as breastmilk substitutes for infants *up to 6 months of age*.

The executive branch of the Philippine Government has designed and the PHDOH has primarily implemented the *non-legislated* PH BMS Framework to operate in a manner that aims to ensure exclusive breastfeeding *for up to 24 months of age or beyond* as best to promote public health. In effect, breastmilk supplements (follow-up formula and complementary foods) are equated with and treated as breastmilk substitutes inappropriately marketed to infants 12 months and younger, even if they are not actually marketed to or intended for such audiences.[257] In addition, breastmilk supplements are also deemed as inappropriately marketed to young children 12-24 months or even 36 months of age, which UNICEF and activists support through public promotion of breastfeeding as the necessary and least costly means of addressing the malnourishment of children under 5 years of age.[258] RIRR, Rule I Section 4 declares as a fundamental principle that "[b]reastfeeding is still appropriate for young children *up to two (24 months) years of age or beyond*" (emphasis added).[259] It also places responsibility upon the DOH to inform health workers and the public that "[a]ppropriate IYCF [infant and young child feeding practices] include…continuous breastfeeding *up to two (2) years of age or beyond*" (emphasis added).[260] In addition, PHDOH Circular 2008-0006, which implements RIRR Rule VII, requires that "[t]he principal panel of each container/label shall contain the following message…printed bold in all capital letters at the center uppermost level of

252 *Id.*, at par. 7.467. This conclusion is consistent "with the fact that each Member is entitled, as expressed in the preamble of the TBT Agreement…to define its own level of protection." *Id*.
253 Milk Code Sec. 5(a)-(b); RIRR, Rule II, Sections 6-8.
254 Milk Code Sec. 6(a)-(e); RIRR, Rule V, Sections 12-15; Rule VI, Sections 16-23; AO 2012-0027, Sec. 14.
255 Milk Code Sec. 10(a)-(f); RIRR, Rule VII, Sections 25-28; Circular 2008-0006, Items V, VI.A-.B.
256 RIRR, Rule XIV Sec. 56; Circular 2008-006, Item VI.A.1(v); AO 2012-0027; PHDOH Memorandum (Sept. 5, 2011); PHDOH Memorandum (Sept. 10, 2012).
257 *See* Carlos H. Conde, *Breast-feeding: A Philippine Battleground*, New York Times (July 17, 2007), *supra*.
258 "According to the Food and Nutrition Research Institute (FNRI) under the Department of Science and Technology (DOST), the nutrition status of children under 5 has not improved in the last 10 years in the Philippines. The ILO, UNICEF and WHO are, therefore, calling on the public and private sectors, including CSOs, to ensure that the National Milk Code and related laws are implemented and monitored across the country." *See* UNICEF Philippines, *UN in PH Joins Celebration of World Breastfeeding Week 2013*, Joint Press Release by ILO, UNICEF and WHO (Aug. 1, 2013), supra.
259 RIRR, Rule I Section 4(d).
260 RIRR, Rule III Sec. 6.

the principal display panel…ENGLISH: "BREASTMILK IS THE BEST FOR BABIES *UP TO 2 YEARS OF AGE AND BEYOND*" (emphasis added).[261] Consequently, the PH BMS Framework has already affected and is likely to continue to affect international trade in such products, within the meaning of TBT Article 2.2.

The PH BMS Framework's adverse impact on international trade becomes readily apparent when one considers that dairy products have remained "the country's second largest agricultural import after wheat."[262] Indeed, despite the country's growing population, improving demographics[263] and increasing preference/demand for milk products, especially reconstituted milk,[264] the Philippines "produces less than one percent of its total annual dairy requirement and imports the balance".[265] The Philippines' dependency on foreign producers of milk[266] - a key food staple[267] - has been attributed, in part, to Philippine milk producers' inability "to maintain the quality of fresh milk",[268] which, in turn, is due to the local industry's community-based dairy production[269] and "lack of processing and distribution systems[] and a dependable continuous[] cold chain".[270]

Notwithstanding the Philippines' small milk-producing sector, a "[h]uge importing and processing sector that supplies over 95% of the milk requirements of the country" has arisen, having an estimated worth of $3 billion as of 2010.[271] For example, during 2010, "NonFat Dry Milk (NFDM) and Whole Milk Powder (WMP) imports generally comprise[d] about 60 percent of total dairy imports" in volume M/T, while during 2011 NFDM imports increased slightly…[and] high[er] prices led to a [12 percent] decline in WMP."[272] During the first quarter of 2013, the Philippines National

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261 PHDOH Circular 2008-0006, Item VI.A.3(i).

262 *See* Pia A. Ang, *Philippines - Dairy and Products Annual Situation and Outlook*, USDA Foreign Agricultural Service Global Agricultural Information Network Report (Dec. 14, 2012) at p. 1, available at: http://www.thefarmsite.com/reports/contents/pdadec12.pdf.

263 "[U]nlike many other emerging markets such as China, the Philippines' boasts favorable demographic trends with a large working age population through 2050." *See* James Parker, *Asia's Rising Economic Star: The Philippines?*, The Diplomat – Pacific Money (May 3, 2013), available at: http://thediplomat.com/pacific-money/2013/05/03/asias-rising-economic-star-the-philippines/; Michelle V. Remo, *Philippines to Leapfrog to be 16th Largest Economy by 2050*, Inquirer Business (Jan. 13, 2012), available at: http://business.inquirer.net/39327/philippines-seen-among-top-20-economies-in-next-4-decades.

264 "In answer to the country's cold chain challenges and limited production, a significant amount of Philippine fluid milk supply is actually Ultra High Temperature (UHT) milk reconstituted from imported milk powder." *Id.*, at p. 3.

265 *See* Pia A. Ang, *Philippines - Dairy and Products Annual Situation and Outlook*, USDA Foreign Agricultural Service Global Agricultural Information Network Report (Dec. 14, 2012) at p. 2, available at: http://www.thefarmsite.com/reports/contents/pdadec12.pdf.

266 "In [the]…Philippines…where tariff levels are very low and consumers are familiar with and favour *reconstituted milk products*, import dependency *has reached over 80 percent*" (emphasis added). *See* Animal Production and Health Commission for Asia and the Pacific, Food and Agriculture Organization of the United Nations Regional Office for Asia and the Pacific, *Smallholder Dairy Development: Lessons Learned in Asia* (Jan. 2009), at p. 4, available at: ftp://ftp.fao.org/docrep/fao/011/i0588e/i0588e00.pdf.

267 "A staple food is one that is eaten regularly and in such quantities as to constitute the dominant part of the diet and supply a major proportion of energy and nutrient needs…Most people live on a diet based on one or more of the following staples: rice, wheat, maize (corn), millet, sorghum, roots and tubers (potatoes, cassava, yams and taro), and animal products such as meat, milk, eggs, cheese and fish." *See* United Nations Food and Agriculture Organization, *Dimensions of Need – An Atlas of Food and Agriculture*, *Staple Foods: What Do People Eat?* (1995), available online at: http://www.fao.org/docrep/u8480e/u8480e00.htm; http://www.fao.org/docrep/u8480e/U8480E01.htm#Contents.

268 *See* Pia A. Ang, *Philippines - Dairy and Products Annual Situation and Outlook*, USDA Foreign Agricultural Service Global Agricultural Information Network Report (Dec. 14, 2012), supra at p. 3.

269 "There are four main types of dairy farms in the Philippines: individual smallholder producers (who consume and sell locally what they produce), smallholder cooperatives (who deliver their milk to a collection point for transport to a processing plant), commercial farms (which supply processors), and government farms (which supply school and rural community feeding programs)." *Id.*

270 *Id.*, at p. 3. "The Philippine Department of Agriculture (DA) continues to make the development of the Philippine dairy industry a priority with a special emphasis on improving local supply of fresh milk. While the DA accepts that the Philippines cannot compete in the powdered milk market, it believes that it can greatly augment the supply of fresh milk to the market." *Id.*, at p. 5.

271 *See* Republic of the Philippines, Board of Investments Industry Studies Department, *Philippine Dairy Industry* (March 2011) at p. 1, available at: http://www.boi.gov.ph/pdf/industryprofiles/Agri%20Business/Dairy.pdf.

272 *See* Pia A. Ang, *Philippines - Dairy and Products Annual Situation and Outlook*, USDA Foreign Agricultural Service Global Agricultural Information Network Report (Dec. 14, 2012), *supra* at p. 4.

Dairy Authority reported that "[p]owdered milk [, including whey powder used in *local* infant formula production,[273]] account[ed] for 85% of the imports", with New Zealand (49%), USA (23%), Australia (10%) and France (2%) representing the four largest suppliers.[274] It estimates that imports of whey powder during the first quarter of 2013 increased more than 17% from the same period in 2012.[275]

Perhaps, the Philippine Government should be more circumspect about its public treatment of follow-up formula and other milk products locally processed by mostly foreign companies,[276] and seriously reconsider those PH BMS Framework provisions which are more trade-restrictive, particularly, those restricting or prohibiting the labeling, advertising and marketing of BMS products, as well as, the use of related trademarks. Such foreign companies have made significant financial, intellectual and human capital investments in the Philippines that have continued to have a positive impact on local employment and technical skills development and to benefit the national economy at large.[277]

ii. Various PH BMS Framework Provisions Reflect Legitimate Public Policy Objectives

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273 *See* Republic of the Philippines, Philippine Department of Agriculture National Dairy Authority, *Volume of Milk & Milk Products Imports ('000 MT or mil. liters, in LME)*, available at: http://www.nda.da.gov.ph/2013/data/data2013.html. "Based on the recognition that human milk contains a predominance of whey proteins, while in cow milk, caseins are higher, formulas with a whey:casein ratio similar to human milk were introduced in 1962. By 2000 whey-predominant formulas were the most widely used milk-based formulas." *See* Institute of Medicine at the National Academies, *Infant Formula: Evaluating the Safety of New Ingredients* (2004), at p. 43, available at: http://www.nap.edu/catalog.php?record_id=10935#; http://www.nap.edu/openbook.php?record_id=10935&page=41. During 2012, five of the top seven largest milk product importers in the Philippines were global brand milk formula companies. *See* Republic of the Philippines, Philippine Department of Agriculture National Dairy Authority, *supra* at *Milk and Dairy Products – Importers 2012*. The first seven importing companies were listed as follows: "1 Wyeth Philippines, Inc. 2 Nestle Philippines, Inc. 3 Alaska Milk Corp. 4 Fonterra Brands (Phils.) Inc. 5 Abbott Laboratories (Phils) Inc. 6 Monde Nissin Corporation 7 Mead Johnson Nutrition (Phil.) Inc." From 2008 to 2012, whey powder imports comprised approximately 16.2% of total dairy imports in terms of volume (M/T LME). During the first quarter of 2013, whey powder imports comprised approximately 18.3% of total dairy imports in terms of volume (M/T LME). *See* Republic of the Philippines, Philippine Department of Agriculture National Dairy Authority, *Volume of Milk & Milk Products Imports ('000 MT or mil. liters, in LME)*, supra. See also *Whey and Lactose Markets Keep Growing*, Nutraceuticals World (Aug. 17, 2012), available at: http://www.nutraceuticalsworld.com/contents/view_breaking-news/2012-08-17/whey-and-lactose-markets-keep-growing/. "For whey, the high-end protein products - WPC80, isolates and hydrolysates – [whey protein concentrate] are growing by double digit figures, whereas whey powder and other low-end products are stagnating. The nutritional sectors including infant formula, clinical nutrition and sports nutrition products are mainly responsible for the strong growth in the high-end protein ingredients." *Id*.

274 *Id.,* at *Philippine Dairy Update (Jan-March 2013)*, available at: http://www.nda.da.gov.ph/2013/data/data2013.html.

275 *Id.,* at *Particulars – B. Importation - Value in M US$ (CIF)*.

276 "The Philippine pharmaceutical market is valued at US$2.51 Billion (Php111.6 Billion) in 2008, and forecasted to reach US$3.91 Billion by 2013…The Philippines is continuously ranked as the 11th most attractive pharmaceutical market in the Asia-Pacific region, and the third biggest market in ASEAN after Indonesia and Thailand… The local market includes all products classified as drug or non-drug. Drugs are either ethical (prescription) or over-the-counter (OTC) products used for medication or in the diagnosis, cure, mitigation, treatment or prevention of diseases in human beings, while non-drug items include nutritionals (health food), *infant milk preparations*, baby care, cosmetics, diagnostic and other medical devices" (underlining in original; italicized emphasis added). *See* Republic of the Philippines, Board of Investments Industry Studies Department, *Philippine Pharmaceutical Industry* (May 2011), available at: http://www.boi.gov.ph/pdf/industryprofiles/Pharmaceuticals/Pharmaceuticals.pdf. *See also* Republic of the Philippines, Board of Investments Industry Studies Department, *Philippine Dairy Industry* (March 2011), *supra* at p. 1.

277 *See* World Intellectual Property Organization, Committee on Development and Intellectual Property (CDIP), *Report on An Analysis of the Economic/Legal Literature on Intellectual Property (IP) Rights: A Barrier to Entry?*, prepared by the Secretariat, CDIP/8/INF/6 CORR. (Jan. 16, 2012), at par. 42, available at: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_6_corr.pdf. "Other articles use a geographic focus to explore the impact of TRIPS on foreign direct investment (FDI).41 Some of these articles study the interplay between TRIPS and FDI in the pharmaceutical industry within a specific geographic area.42 These articles explore how strong IP rights create a market-friendly enabling environment that will encourage FDI.43". *Id*., and accompanying footnotes, *citing inter alia* Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, International Journal of Economic Development 8(1-2) (2006): 15, at Sec. IV.A pp. 157-174, Sec. V.B-F pp. 235-282, available at: http://www.spaef.com/file.php?id=970.

On December 20, 2006, the BFAD/FDA filed a WTO TBT Committee notification pursuant to TBT Article 2.9.2 informing WTO Members of the issuance of AO 2006-0012 (the RIRR) implementing the Milk Code.[278] This notification describes the RIRR as having two plausible non-food safety-related objectives which enjoy a rebuttable presumption of truthfulness and good faith in accordance with international law. It states that the objectives of the RIRRs' objective are to

"(1) protect and promote the right to health of the people and instill health consciousness among them; [and] (2) to ensure the provision of safe and adequate nutrition for infants and young children by the promotion, protection and support of breastfeeding and by ensuring the proper use of breastmilk substitutes, breastmilk supplements and related products when these are medically indicated and only when necessary, on the basis of adequate information and through appropriate marketing and distribution."[279]

Objectives (1) and (2) above clearly indicate that the RIRR is intended to protect public health, which is expressly included among the nonexclusive list of TBT Article 2.2 objectives. It effectively links the promotion of public health to "the promotion, protection and support of breastfeeding…to ensure the provision of…adequate nutrition for infants and young children" set forth as Objective (2) above, which is not included among the list of TBT Article 2.2 objectives. The RIRR's sixth and seventh preambular paragraphs confirm this linkage. They together state that "adequate and proper nutrition is an important and universally recognized component of each child's right to the enjoyment of the highest attainable standard of health," and that "the use of breastmilk…is widely recognized as the best source of nutrition for babies."[280]

Objectives (1) and (2) above also reflect a second objective of the RIRR. This second underlying objective is arguably "to…instill health consciousness among…the people…by *ensuring the proper use of* breastmilk substitutes, breastmilk supplements and related products when these are medically indicated and only when necessary, *on the basis of adequate information and through appropriate marketing and distribution*" (emphasis added).[281]The RIRR's first preambular paragraph confirms that it is the role of the State, here, the PHDOH, to "protect and promote the right to health of the people and instill health consciousness among them."[282] The promotion of health consciousness is not expressly among the non-exclusive list of TBT objectives, but most likely falls within the first objective of promoting public health, which is.

Arguably, a second key unstated objective underlying the RIRR and the Milk Code (the foundation of the PH BMS Framework) can be discerned from the text of RIRR, Rule V Section 11, which the Philippine Supreme Court ultimately held was unconstitutional and thus legally unenforceable by the PH DOH.[283] The PHDOH had previously sought to employ this provision to ban all advertising and promotion of such products, "*because advertising*, promotions, sponsorships, or *marketing materials* and activities for breastmilk substitutes intended for infants and young children up to twenty-four (24) months…*tend to convey or give subliminal messages or impressions* that

278 *See* Philippines, *Notification to WTO Committee on Technical Barriers to Trade*, G/TBT/N/PHL/76 (Dec. 20, 2006), supra.
279 *Id*. (2) is a virtual restatement of RIRR, Rule I Section 2.
280 RIRR, Preamble pars. 6 and 7.
281 G/TBT/N/PHL/76, supra.
282 RIRR, Preamble par. 1.
283 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, supra.

undermine breastmilk and breastfeeding or otherwise *exaggerate breastmilk substitutes and/or replacements*, as well as related products covered within the scope of" the Milk Code (emphasis added).[284] In other words, Section 11 was drafted to prevent *deceptive marketing/advertising practices* relating to the *inappropriate* promotion of breastmilk substitute and breastmilk supplement products which could mislead consumers and undermine the protection of public health (health consciousness) via breastfeeding. Since the Philippine Supreme Court's ruling on this matter, the PHDOH has continued to rely upon Section 11's underlying purpose when comprehensively reviewing and restricting breastmilk supplement and complementary food product advertising and promotion materials that it deems to undermine breastfeeding and breastmilk on public health *and/or consumer protection* grounds. For this reason, RIRR, Rule VII Section 13 effectively places the burden of proof on the product promoter to establish that "the 'total effect' [of]…the advertising concept…does not equate or make the product appear to be as good or equal to breastmilk or breastfeeding…[and does] not in any case undermine breastmilk or breastfeeding."[285] Section 13 provides that "[t]he 'total effect' should not directly or indirectly suggest that buying their product would produce better individuals, or resulting in greater lover, intelligence, ability, harmony or in any manner bring better health to the baby or other such exaggerated and unsubstantiated claim."[286] RIRR, Rule VI Sections 16-17 reaffirm this purpose by prohibiting "[a]ll health and nutrition claims" and "false or misleading information or claims of products within the scope of" the Milk Code.[287]

This second PH BMS Framework objective of consumer protection can be further subdivided. First, it seeks to prevent breastmilk substitute and breastmilk supplement product advertising and labeling from deceiving consumers so that they believe such products are equivalent or superior to breastfeeding and breastmilk. Second, it seeks to prevent breastmilk substitute and breastmilk supplement product advertising and labeling from being employed to confuse consumers regarding the proper use of each such product vis-à-vis the other, with and without regard to whether they are "medically indicated" and/or "necessary."[288]

The PHDOH has since reinforced these two objectives with its issuance of Circular 2008-0006 and AO 2012-0027. These legal instruments collectively impose more detailed standards and procedures for reviewing breastmilk substitute and breastmilk supplement labeling, packaging and advertising/marketing materials to ensure that they are not "false or misleading"[289]/"false, misleading or deceptive or likely to create a false impression,"[290] such that they undermine breastfeeding and breastmilk. These objectives have also been referred to as the bases for the PHDOH's September 5, 2011 and September 10, 2012 Memoranda. They instruct the BFAD/FDA to curtail the use of breastmilk substitute and breastmilk supplement product-related trademarks in advertising/marketing materials and product labels if they are found to contain health or nutritional claims deemed misleading or to otherwise undermine breastfeeding and breastmilk.*[291]

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284 RIRR, Rule III Sec. 11.
285 RIRR, Rule III Sec. 13.
286 *Id*.
287 RIRR, Rule VI Sections 16-17.
288 RIRR, Rule I, Sec. 12.
289 AO 2012-0027, Sec. 19.1.5.
290 Circular 2008-0006, Item V.4.
291 *The Philippine Government, through the PHDOH, failed to notify WTO Members about the issuance of Circular 2008-0006, AO 2012-0027 and the September 2011 and 2012 Memoranda. It is arguable that such notification failure contravened TBT Article 2.9.2. This TBT Article 2.9

In sum, since the protection of public health via breastfeeding and the protection of consumers via prevention of deceptive (marketing/advertising) practices[292] are included among the non-exclusive list of TBT Article 2.2 objectives, it is arguable that the PH BMS Framework objectives expressly and implicitly contained in the Philippine Government's TBT notification describing the RIRR constitute "legitimate" objectives within the meaning of TBT Article 2.2.

iii. Various PH BMS Framework Provisions Are Arguably More Trade-Restrictive Than Necessary to Fulfill its Legitimate Public Policy Objectives

To recall, recent WTO jurisprudence indicates that a disputed measure will be considered to have fulfilled its identified objectives depending on the degree of contribution that the measure is capable of making or actually makes towards the achievement of the legitimate objective. The degree of contribution may be discerned from the design, structure, and operation of the technical regulation, as well as from evidence relating to the application of the measure.

The PH BMS Framework's objectives are to protect public health (breastfeeding) and to protect consumers by preventing deceptive or misleading breastmilk substitute and breastmilk supplement product marketing practices (that undermine breastfeeding and promote inappropriate use of such products). To achieve these objectives, the PHDOH has ensured that the PH BMS Framework covers more products and a broader target audience than the WHO Code, and has prescribed onerous, duplicative and costly administrative procedures and strict and presumptive substantive standards for reviewing product advertising, labeling and packaging materials, including proprietary trademarks, logos and brand names incorporated within them.

A. The PH BMS Framework's Broader-Than-WHO Code Breastmilk Supplement Coverage

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obligation is triggered when either no relevant international standard exists *or* the proposed technical regulation is not in accordance with the technical content of the relevant international standard, *and* the technical regulation may have a significant effect on the trade of other WTO Members. TBT Art. 2.9; Panel Report, Panel Report, *United States - Measures Affecting the Production and Sale of Clove Cigarettes ("US-Clove Cigarettes")* WT/DS406/R (Sept. 2, 2011) at pars. 7.521-7.522. To substantiate its failure to comply with TBT Article 2.9.2, the Philippine Government would need to demonstrate that it had determined that the WHO Code constituted a relevant international standard with which the technical content of these measures was consistent; in addition, it would need to demonstrate that it had concluded that such measures may not have a significant effect ("encompass[ing] all non-de minimis effects") on the trade of other Members. *Id.*, at pars. 7.529-7.530. Alternatively, it would need to demonstrate that these measures do not constitute "technical regulations" within the meaning of TBT Article 2.2. In light of the analysis provided herein, it would be difficult for the Philippine Government to establish that Circular 2008-0006, AO 2012-0027 and the September 2011 and 2012 Memoranda were not separate technical regulations or integral to and part of (i.e., an enhancement and elaboration of) the same RIRR which it recognized as a technical regulation in its 2006 TBT notification. It would also be difficult for the Philippine Government to establish that no relevant international standard existed when it had previously identified the WHO Code as such a standard in its prior TBT notification. And, since the Philippine Government had already identified the RIRR as containing technical content that was not consistent with the relevant international standard (i.e., the WHO Code), it would be difficult for it now to establish that these more recent instruments which implement the RIRR are consistent with said relevant international standard. Furthermore, it would also be inconceivable for the Philippine Government to establish that these measures may not have a significant effect on the international trade of other WTO Members. Thus, consistent with the WTO Panel determination in *Clove Cigarettes*, the Philippine Government was obliged to notify other WTO Members of the promulgation of such instruments by describing "the product coverage, the objective and the rationale of [its] proposed technical regulations, at an early appropriate stage." *Id.*, at pars. 7.541-7.542.

292 The protection of human health or safety and the prevention of deceptive practices and consumer protection have been the two most frequently cited policy objectives notified to the WTO for each of the years 2003 through 2011. *See* Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure Has Matured into an Actionable Non-Tariff Barrier to Trade*, 28 Am. U. Int'l L. Rev. 489, 498-499 and accompanying footnotes, available at: http://www.koganlawgroup.com/uploads/REACH_Revisited___A_Framework_For_Evaluating_Whether_a_Non-Tariff-_Measure_Has_Matured_Into_a_Non-Tariff_Barrier.pdf.

The WHO Code "applies to the marketing, and practices related thereto, of…breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, *when marketed or otherwise represented to be suitable*…for use *as a partial or total replacement of breast milk*" (emphasis added).[293] The WHO Code presumes that "[d]uring the first four to six months of life, breast milk alone is usually adequate to sustain the normal infant's nutritional requirements."[294] WHO Code Annex 3 provides that "[p]roducts *other than* bona fide breast-milk substitutes, including infant formula, *are covered* by the code *only when* they are 'marketed or otherwise represented to be suitable...for use as a partial or total replacement of breastmilk'" (emphasis added).[295] In other words, "the [WHO] code's references to products used as partial or total replacements of breast milk are not intended to apply to complementary foods *unless these foods are actually marketed - as breast-milk substitutes*" – i.e., "as being suitable for the partial or total replacement of breast milk" (emphasis added).[296] This means that WHO Code WHO Code Annex 3 thus equates the term "breastmilk substitutes" used during the first 4-6 months of life with the "total or partial replacement of breastmilk."[297]

In light of the WHO IYCF Strategy[298] and other related WHO complementary feeding recommendations,[299] the WHO Code is best understood as applying to infant formula, follow-up formula and complementary food products marketed, represented or intended to replace/substitute breastfeeding as an exclusive food source during the first 6 months of life. In addition, the WHO Code is best understood as applying to follow-up formula and other liquid and solid food (e.g., complementary food) products marketed, represented or intended to displace/substitute breastfeeding as a partial food source after the first six months of life, and potentially up to two years of age or beyond, depending on the needs of the child and preference of the mother. Thus, the WHO Code is best understood as not covering infant and young children's food products, including follow-up formula and liquid and solid complementary foods, if they are marketed, represented or intended to *supplement* partial breastfeeding for infants older than 6-12 months of age.

The PH BMS Framework, meanwhile, applies to breastmilk substitute *and* breastmilk supplement products directly or indirectly marketed to or intended for infants from 0-12 months of age, *and*

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293 WHO Code Art. 2.
294 WHO Code Annex 3, p. 23.
295 *Id*.
296 *Id*.
297 *Id*. "Breast milk may be replaced (substituted for) during this period by bona fide breast-milk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semisolid food intended for infants and given after this initial period, can no longer be considered as a replacement for breast milk (or as its bona fide substitute). Such foods only complement breast milk or breast-milk substitutes, and are thus referred to in the draft code as complementary foods." *Id*.
298 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), supra. This strategy recommends that infant formula products intended for infants up to 4-6 months of age and complementary food products intended for infants older than 6 months of age and young children not be marketed to 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. *Id*., at pars. 10, 28 and 30. It was endorsed by WHO Members via World Health Assembly Resolution WHA55/25. *See* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition*, Resolution WHA55.25 (May 18, 2002), at par. 1, available at: http://www.who.int/nutrition/topics/WHA55.25_iycn_en.pdf.
299 *See* World Health Organization, *Complementary Feeding, Report of the Global Consultation* (2002), at p. 1, available at: available at: http://www.who.int/nutrition/publications/Complementary_Feeding.pdf; World Health Organization, *Guiding Principles for Complementary Feeding of the Breastfed Child* (2003), at pp. 11 and 18, available at: http://whqlibdoc.who.int/paho/2003/a85622.pdf; World Health Organization, *Guiding Principles for Feeding Non-Breastfed Children 6-24 Months of Age* (2005), at pp. 7 and 9, available at: http://whqlibdoc.who.int/publications/2005/9241593431.pdf.

to/for young children *12-24 months of age*[300] *or even up to 36 months of age*.[301] The Philippine Supreme Court determined that, because the Milk Code "treats infant formula, bottle-fed complementary food (breastmilk supplements), and breastmilk substitute as separate and distinct product categories", its coverage "is not dependent on the age of the child but on the kind of product being marketed to the public."[302] It thus found that since the term "breastmilk substitute" is not defined with "reference to any particular age-group of children", it could as easily "be intended for young children more than 12 months of age" as it is for infants 0-12 months of age.[303] The Court thus ruled that the Milk Code and the RIRR which implement it are concerned not only with "the nourishment of…infants or children aged 0-12 months", but also with the "nourishment of children *more than 12 months old*"[304] (emphasis added). According to the Court, "as long as what is being marketed falls within the scope of the Milk Code as provided in Section 3, then it can be subject to regulation pursuant to said law, even if the product is to be used by children aged over 12 months."[305] The PHDOH has obviously interpreted this Supreme Court decision as granting it broad monitoring and oversight authority to extensively review the substance and form of breastmilk supplement as well as breastmilk substitute product advertising, labeling and packaging[306] for purposes of determining whether such media contain prohibited health or nutrition claims or otherwise directly or indirectly undermines breastfeeding or breastmilk.

The PH BMS Framework's much broader than-WHO Code product coverage also apparently reflects the ongoing influence and support of the national and regional breastfeeding activist communities and the local UNICEF Office in the Philippines. These stakeholders have endeavored to expand the marketing ban on breastmilk substitutes for infants *up to 24 months*,[307] and to treat follow-up formulas as *de facto* breastmilk substitutes – i.e., as being marketed as breastmilk *substitutes* rather than as *supplements*, for such purposes.[308]

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300 *See* Sec. III.3.b.i, *supra*.

301 For example, AO 2012-0027, Section 12 provides that the Inter-Agency Committee ("IAC") Secretariat may automatically deny, "motu proprio, any application for advertising/promotional campaign [containing] materials with health and nutrition claims [relating to product use by infants and/or young children] *0-36 months*" of age (emphasis added). In addition, AO 2005-0014, Item V.A provides that the "Target Beneficiaries" of the Philippine National Policy on Infant and Young Child Feeding, which prescribes for "[b]reastfeeding to be continued up to two years and beyond", are "Infants 0-11 months [and] Young children, 1 year *up to 3 years old*" (emphasis added).

302 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, supra.

303 *Id*.

304 *Id*.

305 *Id*.

306 According to the Court, it is for this reason that "the Milk Code specifically delegated to the…[PH]DOH…the power to ensure that there is adequate, consistent and objective information on breastfeeding and use of breastmilk substitutes, supplements and related products; and the power to control such information." *Id*.

307 *See* France Begin, UNICEF Regional Advisor on Nutrition, *World Breastfeeding Week – Bringing Support Closer to Mothers*, UNICEF Blog (July 31, 2013), supra. ("[E]arlier this year…UNICEF joined forces with Alive and Thrive, Viet Nam Institute of Legislative Studies, World Health Organisation and others to hold a regional advocacy workshop for ASEAN countries. We wanted to share the Viet Nam Government's recent experience in extending paid maternity leave to six months *and expanding the ban on advertising of breast milk substitutes for infants up to 24 months*…It is my heartfelt hope that the landmark decision by Viet Nam to expand the ban on advertising of breast milk substitutes for children up to 24 months, and to extend maternity leave to six months, *will have a domino effect in the region, and that other countries will follow their example*" (emphasis added)). *Id*. *See also* Alive & Thrive, *All Asia-Pacific Countries Can Implement a Strong National Code of Marketing of Breast-Milk Substitutes (BMS Code)* (April 20, 2013), available at: http://www.aliveandthrive.org/sites/default/files/IYCF%20advocacy%20in%20Asia-Pacific%20April%202013.pdf. ("The first 24 months of life provide a critical window of opportunity to prevent life-long and irreversible damage caused by poor nutrition, including stunting and impaired social and cognitive development. Research shows that advertising and marketing of breast milk substitutes can undermine a mother's choice to breastfeed, thereby reducing her child's chances of having the healthiest and most productive life.") *Id*.

308 *See* World Health Organization, Nutrition for Health and Development, *Follow-up Formula in the Context of the International Code of Marketing of Breastmilk Substitutes* (June 2001), available at: http://www.who.int/nutrition/follow-up_formula_eng.pdf; World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), available at: http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf. *See also* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7046, *supra* at Sec. II.6.d.i.A.

B. The PH BMS Framework's Broader-Than-WHO Code Breastmilk Supplement Labeling Restrictions

WHO Code Article 9.1 mandates that breastmilk *substitute* product labels "should be designed…so as not to discourage breast-feeding."[309] WHO Code Article 9.2 provides that formula milk product containers and labels must contain "(a) the words 'Important Notice' or their equivalent;"[310] "(b) a statement of the superiority of breastfeeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;…and (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation."[311] It prohibits formula milk product containers and labels from having any "pictures of infants [or]…other pictures or text which may idealize the use of infant formula."[312] Graphics are permitted only "for easy identification of the product as a breastmilk substitute and for illustrating methods of preparation."[313] Containers and labels may not use the terms "humanized", "materialized" or similar terms.[314]

The language employed in Milk Code Sections 10(b)(i)-(iv) and (c)-(d), and RIRR, Rule VII Sections 25-26 is virtually identical to these WHO Code Articles.[315] However, RIRR, Rule VI Section 16 and Circular 2008-0006, Item 5(7) go beyond the WHO Code to prohibit all breastmilk substitute *and supplement* labels from containing health and nutritional claims,[316] except those relating to special dietary needs or special medical purposes made in accordance with Codex STAN 180-1991, Codex STAN 72-1981 (Rev. 2007), and applicable Milk Code and RIRR requirements.[317] Circular 2008-0006 also prescribes the inclusion of additional content on breastmilk substitute and breastmilk *supplement* containers and labels that goes beyond WHO Code requirements,[318] presumably, to prevent consumer product confusion – i.e., the marketing of breastmilk supplements as breastmilk substitutes. For example, Circular 2008-0006 prescribes the use on product labels of distinct product names to distinguish between "Infant Formula", "Formula for Special Medical Purposes Intended for Infants" and "Milk Supplement[s]".[319]

Circular 2008-0006, defines the term "milk supplement"[320] (not contained in RIRR, Rule V Sections 15(a) and (c)) for such purposes consistent with Codex STAN 156-1987 (*for Follow-up Formula*).[321] Codex STAN 156-1987 states that, "follow-up formula is suitable for infants and young children aged *between 6 and 36 months*," and that "[t]he products covered by this standard *are not breast-milk*

309 *Id*., Art. 9.1.
310 *Id*., Art. 9.2.
311 *Id*.
312 *Id.*
313 *Id*.
314 *Id*.
315 Milk Code Sections 10(b)(i)-(iv), (c)-(d); RIRR, Rule VII Sections 25-26.
316 RIRR, Rule IV Sections 16 and 17; Circular 2008-0006, Item V.6.
317 Circular 2008-0006, Item V.6.
318 Circular 2008-0006, Items VI.A.1(v) and A.3(i).
319 *Id*., at item VI.A.1.(i).
320 "Milk supplement [is the] product name [that] shall be used in place of 'follow-up' formula. It means a food intended for use as a liquid part of the complementary food for the infant from the 6th month on and for young children." Circular 2008-0006, Item IV, p. 3.
321 *See* 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.

substitutes and shall not be presented as such" (emphasis added).[322] Breastfeeding activists, assisted by UNICEF, however, have aggressively sought to revise this standard[323] so that it comports with the *evolved* UNICEF/WHO view "that follow-up formula is just as much of a breast-milk substitute as infant formula, and so falls within the scope of the WHO Code."[324] If successful, such a change would dovetail well with the same *de facto* presumption incorporated within the PH BMS Framework.

In addition, Circular 2008-0006, Item VI.A.3(i) requires that the "principal [display] panel of each container/label…contain the following message" in English and Filipino: ENGLISH: BREASTMILK IS THE BEST FOR BABIES *UP TO 2 YEARS OF AGE AND BEYOND*" (emphasis added).[325] "This message shall be printed bold in all capital letters at the center uppermost level [in]…Arial…font type and [the]…font size…must be one-third (1/3) of the size of the biggest letter on the label."[326] In furtherance of Circular 2008-0006, Item V.4 (prohibiting false, misleading or deceptive descriptions or presentations in labeling of breastmilk substitute and supplement products) and RIRR, Rule IV Sections 16-17 (generally prohibiting health and nutrition claims and false or misleading statements for breastmilk substitutes and supplements), Circular 2008-0006, Item VI.A.1(v) prohibits as "contrary to public policy [the] use as [a] brand name and/or trademark any word or set of words that may be considered as nutritional,[327] healthful[328], and superlative[329] and other terms of similar import."[330] Lastly, Circular 2008-0006, ItemsV.3 provides that "[a]ny information, whether in text or graphical form, which are not mentioned in these guidelines may be a ground for the denial of the label applied for."[331] This vests the PHDOH with virtually unlimited and unaccountable authority to deny a breastmilk supplement product label depending on its subjective determination that the content, look or feel of a label will discourage or undermine breastfeeding.

C. The PH BMS Framework's Broader-Than-WHO Code Breast Milk Supplement Advertising Restrictions

322 *See* CODEX STAN 156-1987, *supra*, at Sections 2.2 and 9.6. *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 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

323 *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)* supra.

324 *See* Joint FAO/WHO Food Standards Programme, Codex Committee on Nutrition and Foods for Special Dietary Uses, Thirty-fourth Session (CX/NFSDU 12/34/11) (Dec. 3-7, 2012), *Proposal to Review the Codex Standard for Follow-up Formula (CODEX STAN 156-1987)*, Prepared by New Zealand, at Sec. 3.3.2, p. 5, available at: ftp://ftp.fao.org/codex/meetings/ccnfsdu/ccnfsdu34/nf34_11e.pdf. "Many UNICEF publications state that follow-up formula is just as much of a breast-milk substitute as infant formula, and so falls within the scope of the WHO Code. In a 2008 UNICEF report it was proposed that national legislation should strengthen marketing and labelling provisions for all foods marketed as suitable for infants and young children including follow-up formula (UNICEF 2008). The WHO briefing note on "Follow-Up Formula in the Context of the International Code of Marketing of Breast-milk Substitutes" is presently being considered for revision by the WHO pending review of new and emerging information on the subject. The revision of the WHO briefing note on follow-up formula in the context of the WHO Code will aid Codex in determining whether labelling provisions should be aligned with the WHO Code." *Id*.

325 *Id*., at Item VI.A.3(i).

326 *Id*.

327 "Nutritional [means] nutritious, nourishing, nutritive, food etc.; of or relating to or providing nutrition." Circular 2008-0006, Item IV, p. 4.

328 "Healthful means good for one's wellness. Healthy is a positive descriptive of a person's physical state; healthful of something that favorably affects or promotes that state." *Id*., at Item IV, p. 3.

329 "Superlative [means] relating to, or constituting the degree of grammatical comparison that denotes an extreme or unsurpassed level or extent; surpassing all others like supreme; very high quality like excellent." *Id*., at Item IV, p. 4.

330 *Id*., at Item VI.A.1(v).

331 Circular 2008-0006, Item V.3.

WHO Codes Articles 2 and 5.1 preclude all advertising or other form of promotion to the general public of breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, *when marketed or otherwise represented to be suitable…for use as a partial or total replacement of breast milk*. The WHO Code presumes that breastmilk alone is usually adequate, during the first 4-6 months of life, to sustain the normal infant's nutritional requirements.[332] It also equates breastmilk substitutes marketed during the first 4-6 months of life with the total or partial replacement of breastmilk, and thus prohibits the marketing of such products.[333] According to WHO Code Annex 3, the Code covers products *other than* bona fide breast-milk substitutes, including infant formula [i.e., other milk products and bottle-fed complementary foods], *only when* they are 'marketed or otherwise represented to be suitable for use as a partial or total replacement of breastmilk. Therefore, follow-up formula and liquid and solid complementary food products (bona fide breastmilk supplements) may not be advertised if intended to displace breastfeeding as a total or partial food source up to the first 4-6 months of life, or if intended to displace breastfeeding as a partial food source after the first 6-12 months of life, and potentially up to 2 years of age or beyond.

The Philippine Supreme Court held unconstitutional and legally unenforceable RIRR, Rule V Section 11's blanket ban on the advertising and marketing of breastmilk substitutes and breastmilk supplements intended for infants and young children *up to 24 months of age*.[334] Nevertheless, Milk Code Section 12(a) and RIRR, Rule V Section 12 vest the PHDOH with expansive authority and discretion to establish and chair an Inter-Agency Committee ("IAC") and to develop substantive and procedural standards and guidelines which the IAC may employ for purposes of reviewing and examining all proposed breastmilk substitute and breastmilk supplement product advertising, promotion and marketing materials.[335] The Philippine Supreme Court determined that, through RIRR, Rule V Section 13, the PH "DOH exercises control over the information content of advertising, promotional and marketing materials on breastmilk vis-a-vis breastmilk substitutes, *supplements* and other related products" (emphasis added).[336]

I. Substantive Standards

The Philippine Supreme Court found that RIRR, Rule V Section 13 establishes substantive standards that "bind the IAC in formulating its rules and regulations on advertising, promotion, and marketing."[337] Said provision, for example, provides that the promotion of breastmilk substitute and breastmilk *supplement* products "must be objective and…the advertising concept…should not equate or make the product appear to be as good or equal to breastmilk or breastfeeding. It must not in any case undermine breastmilk or breastfeeding."[338] In addition, "[t]he 'total effect' should not directly or indirectly suggest that buying their product would produce better individuals, or

332 WHO Code Annex 3, p. 23.
333 *Id*.
334 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, supra.
335 "Section 12(b) of the Milk Code designates the [PH]DOH as the principal implementing agency for the enforcement of the provisions of the Code." *Id*.
336 "[PH]DOH is authorized by the Milk Code to control the content of any information on breastmilk vis-à-vis breastmilk substitutes, supplement and related products…It bears emphasis, however, that the [PH]DOH's power under the Milk Code to control information regarding breastmilk vis-a-vis breastmilk substitutes is not absolute as the power to control does not encompass the power to absolutely prohibit the advertising, marketing, and promotion of breastmilk substitutes. *Id.*
337 *Id*.
338 RIRR, Rule V Sec. 13.

result[] in greater love, intelligence, ability, harmony or in any manner bring better health *to the baby* or other such exaggerated and unsubstantiated claim" (emphasis added).[339] According to the Philippine Supreme Court, the standards by which the 'total effect' is to be evaluated are "set forth in Sections 5(b),[340] 8(b),[341] and 10[342] of the [Milk] Code."[343] These standards are repeated and supplemented in RIRR, Rule V Sections 15(a)-(c), which are largely consistent with the labeling content restrictions imposed by WHO Code Article 9.2.[344]

Subsequently enacted AO 2012-0027,[345] Sections 19.1.6 and 19A*[346] generally reiterated this "total effect" standard and added to it in several ways. First, all health and nutrition claims for breastmilk substitute and breastmilk supplement products, consistent with AO 2012-0027, Sections 19.1.4-19.1.5, and RIRR, Rule VI Sections 16-17,[347] are disallowed based on the presumption that such claims "may undermine breastfeeding"[348] and "are potentially misleading."[349] Second, the application of the "total effect" test of RIRR, Rule V Section 13 was extended to include young children as well as babies. AO 2012-0027, Section 20b.2 provides that "the 'total effect' should not directly or indirectly suggest that…[p]atronizing the product will be better health to the baby *and young child*" (emphasis added).[350] Collectively, AO 2012-0027, Section 15 and Circular 2008-0006, Item V.8 provide that "[t]he approved *label* of all food products within the scope of the Code",[351] i.e., "breastmilk substitutes, breastmilk supplements, milk formula, milk supplement, complementary foods, [etc.]…"[352]"shall not be construed as an authority or approval for advertising promotion, or marketing materials and activities"[353]; "the latter shall be subject to specific IAC

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339 *Id*.
340 Milk Code Sec. 5(b) provides that information about infant feeding "shall include contain "clear information on: (1) the benefits and superiority of breastfeeding; (2) maternal nutrition, and the preparation for and maintenance of breastfeeding; (3) the negative effect of breastfeeding of introducing partial bottle-feeding; (4) the difficulty of reversing the decision not to breastfeed; and (5) where needed, the proper use of infant formula…the social and financial implications of its use; the health hazards of inappropriate foods of feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breastmilk substitutes. Such materials shall not use any picture or text which may idealize the use of breastmilk substitutes." Milk Code Sec. 5(b).
341 Milk Code Sec. 8(b) provides that manufacturer and distributor information to health professionals "shall be restricted to scientific and factual matters and such information shall not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding…and shall also include the information specified in Section 5(b)." Milk Code Sec. 8(b).
342 Milk Code Sec. 10 provides that "[containers and/or labels shall be designed to provide the necessary information about the appropriate use of the products, and in such a way as not to discourage breastfeeding." Milk Code Sec. 10(a). Among other messages, the label shall include the following points…(ii) a statement of the superiority of breastfeeding; (iii) a statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper methods of use; and (iv) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation." Milk Code Sec. 10(b).
343 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, *supra*.
344 RIRR, Rule V Sec. 15(a)-(c); WHO Code Art. 9.2. For example, such materials shall not include [t]exts, pictures, illustrations or information which discourage or tend to undermine the benefits or superiority of breastfeeding or which idealize the use of breastmilk substitutes and milk supplements. In this connection, no pictures of babies and children together with their mothers, fathers, siblings, grandparents, or other relatives or caregivers…shall be used in any advertisements for infant formula and breastmilk substitutes." RIRR, Rule V Sec. 15(a). They should also not include "[t]he term 'humanized',' maternalized', 'close to mother's milk' or similar words in describing breastmilk substitutes or milk supplements". *Id*., at Sec. 15(b). Also, they should not include "[p]ictures or texts that idealize the use of infant and milk formula." *Id*., at Sec. 15(c).
345 *Id*; AO 2012-0027, Sections 19.1.6 and 20.b.b.1-b.2.
346 *Due to a drafting error, AO 2012-0027 has two Article 20's. For purposes of this analysis, the first Article 20 has been redesignated as Article 19A – "Prohibited Acts". The second Article 20 continues to be referred to as Article 20.
347 RIRR, Rule VI Sections 16-17 prohibit all product health and nutrition claims (e.g., "phrases or words that connote[] to increase emotional, intellectual abilities of the infant and young child"), and all false or misleading statements. RIRR, Rule VI Sections 16-17.
348 AO 2012-0027, at Sec. 19.1.4.
349 *Id.*, at Sections 19.1.5 and 20.a.
350 *Id*., at Sec. 20.b.2.
351 Circular 2008-0006, Item V.8; AO 2012-0027, Sec. 15.
352 AO 2012-0027, Sec. 15.
353 Circular 2008-0006, Item V.8; AO 2012-0027, Sec. 15.

approval."[354] In other words, although the PHDOH treats labeling as a form of marketing, formula companies should not assume that BFAD/FDA approval of a covered breastmilk supplement product label assures IAC (predominantly PHDOH) approval of related breastmilk supplement product advertising, marketing and/or promotional materials.

II. Procedural Standards and Guidelines

RIRR, Rule V Section 14 sets forth the basic procedural standard for seeking review of proposed breastmilk substitute and/or breastmilk supplement product advertising, promotion or other marketing materials. No such materials for any such products "which are marketed as partial or total replacement[s] of breastmilk, including bottle-fed complementary foods, shall be printed, published, distributed, exhibited, and broadcasted or in any manner released to the public *without the prior written consent and approval of the [IAC]*" (emphasis added).[355]

AO 2012-0027, Sections 8-11 provide detailed procedures, pursuant to RIRR, Rule V Section 12, that must be followed to ensure the IAC's review of breastmilk substitute and breastmilk supplement product advertising, promotion or marketing materials. These procedures appear to have been intentionally designed to impose maximum duplication, administrative burden, and cost.

The most troubling aspect of these procedures is the extent of the PHDOH's direct and indirect involvement via the BFAD/FDA in, and ostensible dominance over, the advertising materials review process. Milk Code Section 12(a)(1) and RIRR, Rule V Section 12, provide that the *Inter-Agency Committee*, comprised of the representatives of the PHDOH, PHDOJ, PHDTI *and* PHDSWD,[356] and *not the PHDOH alone*, shall have the "power[]…[t]o review and examine…[and t]o approve or disapprove, delete objectionable portions from and prohibit...all advertising, promotion or other marketing materials."[357] The IAC shall also have the "power[]…to prescribe the internal and operational procedure for the exercise of its powers and functions as well as the performance of its duties and responsibilities."[358] However, in drafting AO 2012-0027, Section 5 and creating what appears to be a single agency-dominated IAC Secretariat comprised only of PHDOH BFAD/FDA officials, the PHDOH has arguably misconstrued these Milk Code and RIRR provisions and conflated them with Milk Code Sec. 12(b). Although Milk Code Section 12(b) holds the "Ministry of Health [PHDOH]…principally responsible for the implementation and enforcement of the provisions of this Code", it does *not* designate the PHDOH as the sole arbiter of, or hold the PHDOH as solely responsible for, reviewing, examining and rendering determinations regarding submitted advertising, promotion or other marketing materials. Is that not the task of the IAC?

In apparent contravention of the Milk Code, AO 2012-0027, Section 5 holds the IAC Secretariat (BFAD/FDA) responsible for conducting a pre-evaluation/review (screening) and examining proposed advertising, marketing and/or promotional materials pursuant to IAC substantive standards, in addition to accepting applications, investigating, verifying and addressing via sanctions

354 Circular 2008-0006, Item V.8.
355 RIRR, Rule V Sec. 14. "No blanket or general approval shall be allowed. Such written approval must be specific in product and time bound." *Id.*
356 Milk Code Sec. 12(a); AO 2012-0027, Sections 2.2 and 3.
357 Milk Code Sec. 12(a)(1)-(2); RIRR, Rule V, Sec. 12.
358 Milk Code Sec. 12(a)(3); RIRR, Rule V, Sec. 12.

reported violations and performing other ministerial tasks, including the issuance of cease-and-desist orders.[359] AO 2012-0027 Section 16 states that the IAC Secretariat (BFAD/FDA) also "shall issue the result of deliberation" as either approved or disapproved,[360] even while AO 2012-0027, Section 8.6 indicates that *the IAC* is the entity making the deliberation. Arguably, AO 2012-0027 contains various drafting inconsistencies between Sections 5, 8, 15 and 16 that reflect indecision concerning whether the IAC Secretariat and/or the IAC will be the entity conducting the advertising materials pre-evaluation/review screening and the detailed examination, and making the final deliberation. Section 5 states that "the IAC Secretariat…[is] designated to…conduct the pre-evaluation/review *and* examination of advertising materials" (emphasis added),[361] but also refers to "IAC deliberation/screening".[362] Sections 8.4 and 8.7 indicate that the IAC shall be the entity performing the screening,[363] while Section 8.5 states that the material "shall be *prescreened by the IAC Secretariat and reviewed by the IAC Members*, respectively" (emphasis added).[364] Meanwhile, AO 2012-0027, Section 15 states that "[t]he *IAC* shall screen advertisements" (emphasis added).[365] Moreover, AO 2012-0027, Sections 17 and 18 are unclear concerning whether it is the IAC or the IAC Secretariat (BFAD/FDA) which issues the Certificate of Approval at the end of this process.[366] In the absence of bright lines clearly defining the respective roles that the IAC and the IAC Secretariat (BFAD/FDA) serve in the advertising/marketing materials review process, said process is, at best, susceptible to agency (PHDOH) and civil society (breastfeeding activist group) capture (bias and influence), and is, at worst, contrary to the intent of the Milk Code. In other words, it is arguable that AO 2012-0027, Sections 5, 8, 15-18, as drafted, are *ultra vir*es, beyond the authority of the PHDOH to promulgate, and in contravention of the Milk Code.

The first step in the application process is to file with the newly constituted IAC Secretariat (BFAD/FDA)[367] the prescribed completed application form,[368] "Application Form for Approval of Advertisement",[369] including all of the required information.[370] The application form, which is to be filed in seven colored copies and one black/white copy,[371] must be accompanied by submission of the specific visual print, audio, audio-visual, and/or "new technology" materials to be used.[372] "For audio-visual material, an electronic copy must be submitted."[373] "Material shall be submitted in seven (7) original copies."[374] The application "must be filed on or before the first Friday of each

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359 *Id.*, at Sec. 5. BFAD/FDA also possesses the authority to apply administrative sanctions against violators and to issue a Cease and Desist Order signed by the IAC Chairman when a violation has been found. *Id*.
360 *Id*., at Sec. 16.
361 *Id*., at Sec. 5.
362 *Id*., at Sec. 5(b)-(c).
363 *Id*., at Sections 8.4 and 8.7.
364 *Id*., at Sec. 8.5.
365 *Id*., at Sec. 15.
366 *Id.*, at Sec. 17. The first and third paragraphs of Section 17 are conflicting, if not confusing, in this regard.
367 *Id*., at Sec. 8.1.
368 AO 2012-0027, Sec. 8.1.
369 *See* Republic of the Philippines, Department of Health Office of the Secretary, Inter-Agency Committee Created Under E.O. 51 s. 1986, *Application Form for Approval of Advertisement*, available at: http://old.fda.gov.ph/FORMS_new/forms%20RE%20Milk%20Code/Inter-Agency%20Committeee%20created%20under%20EO%2051%20s.%201986.pdf.
370 *Id*;, AO 2012-0027, Sections 9.c.2.1 thru 9.c.2.13. Also, Section 9.c.2.14 requires that the applicant submit a "[d]eclaration that no milk advertisement shall be aired/printed before/within/after any government TV/radio programs, or any other health related programs." AO 2012-0027, Sec. 9.2.14.
371 *Id*., at Sec. 9.
372 *Id*., at Sec.10.
373 *Id*., at Sec. 11.3.
374 *Id*., at Sec. 11.4.

month in order to be included in" that month's Secretariat (BFAD/FDA) screening.[375] "The IAC Secretariat shall determine the number of applications that shall be accepted and pre-screened per month prior to deliberation."[376] In addition to an application, applicants must remit payment of a nonrefundable and nontransferable application fee[377] *for "each type of advertising material, whether it is part of an entire advertisement or not, which must be applied for separately*" (emphasis added).[378]

If the submitted materials are modified in any way prior to IAC deliberation the application will be deemed withdrawn, and the resubmission of a new application with attendant fees will be required.[379] If the submitted materials are modified in any way after they have been screened by the IAC, they must be applied for anew and be accompanied by a new application fee.[380] And, if any materials require an extension of time, they will be treated as new materials and must be submitted in a new application accompanied by the required fees.[381] Thus, an application can be infected with any number of infirmities or be considered incomplete or tardy, which can result in the advertising materials review process for a given applicant being delayed for months at a time. This result obtains, even though AO 2012-0027, Section 16 limits the time period for deliberation to just 10 working days after initial screening.[382]

In addition to filing an application and accompanying attachments per AO 2012-0027, Sections 9-10, the advertising Application Form also requires applicants to provide written "substantiation of [all] health claims" made", and any "[o]ther materials which may be deemed necessary for the examination and review of the advertising material."[383] Furthermore, AO 2012-0027, Section 11 requires applicants to submit other documents to the IAC Secretariat (BFAD/FDA). These include a copy of a valid BFAD/FDA Certificate of Product Registration (CPR)[384] that has been valid for at least ninety (90 days) prior to the advertising/marketing application filing date, and a BFAD/FDA-approved product label.[385]

The application must also include a copy of all supporting documents, presentation materials and references which the advertising marketing firm had previously submitted for review to the Philippine Board of Advertising, a self-regulatory body.[386] The role of the Philippine Board of Advertising in the IAC Secretariat (BFAD/FDA) advertising materials review process has since been taken over by another self-regulatory body - the Philippine Advertising Standards Council

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375 *Id*., at Sec. 8.4.
376 *Id*., at Sec. 8.9.
377 "Fees and charges of advertisement and promotion permits" shall be assessed as indicated in Department of Health Administrative Order no. 2001-0050."
378 *Id*., at Sections 8.1-8.2.
379 *Id*., at Sec. 8.6.
380 *Id*., at Sec. 8.7.
381 *Id*., at Sec. 8.8.
382 "The IAC Secretariat shall issue the result of deliberation ten (10) days after the screening…" *Id*., at Sec. 16.
383 *See* Republic of the Philippines, Department of Health Office of the Secretary, Inter-Agency Committee Created Uncer E.O. 51 s. 1986, *Application Form for Approval of Advertisement*, supra.
384 "All breastmilk substitutes, infant formula, other milk products, foods and beverages, and other related products within the scope of E.O. 51, that are to be advertised, imported and exported must have the approval of BFAD and must be covered with a Certificate of Product Registration (CPR)." PHDOH Circular 2008-0006, Item V.1.
385 AO 2012-0027, Sec. 11.1.
386 *Id*., at Sec. 11.2.

("PHASC").[387] Members of the Philippine infant formula and complementary foods industry regularly submit their marketing materials to the PHASC for evaluation and review and incur an additional cost in doing so.[388] Since AO 2012-0027 requires the industry self-regulatory review undertaken by the PHASC *in addition to* the two levels of regulatory review involving both the PHDOH *and* the BFAD/FDA-dominated IAC, it is not difficult to see how the entire process tends to be costly, largely redundant and time consuming, and consequently, impedes international trade in foreign branded breastmilk substitute and breastmilk supplement products.

AO 2012-0027, Section 15 provides that the IAC shall screen advertisements pursuant to the provisions of Milk Code Sections 5(a)-(b) and RIRR, Rule III 6(a).[389] Said provision also provides that these "[d]eliberations shall cover both the general concept and the details of the text as well as the particular medium used", and be based on "the overall impact or the total effect of the advertisement on the public to which it is addressed or to those who would generally have access to the publication."[390] Once the submitted application and advertising materials have been determined compliant and approved by the IAC, the applicant must endure another level of bureaucratic review by the IAC Secretariat (BFAD/FDA), to which it must then submit the final copy of such materials for final evaluation.[391] The IAC Secretariat (BFAD/FDA) will issue a Certificate of Approval within five (5) days of receipt only if it finds that the final copy it receives conforms to the advertising materials the IAC approved.[392] If, however, the Secretariat withholds issuance of a Certificate of Approval because it harbors any doubt about whether the final copy of the advertising materials it receives conforms to the materials approved by the IAC, it shall then return such materials to the IAC for a recommendation.[393]

When a Certificate of Approval has finally been issued, the applicant is forbidden from making any "material variations or changes in the approved advertising materials."[394] This means that "the published/released [advertising] material [must] conform[] exactly to the approved copy on file with the IAC Secretariat."[395] Should the IAC or the IAC Secretariat (BFAD/FDA) identify any discrepancy between the approved material and the published/released material, "the IAC Secretariat (BFAD/FDA) shall issue a recall order of the Certificate of Approval at any time."[396] Once

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387 "The ASC is a tripartite body, composed of the Kapisanan ng mga Brodkaster ng Pilipinas (KBP), the Philippine Assn. of National Advertisers (PANA) and the Assn. of Accredited Advertising Agencies of the Philippines (4As-P). Formed in late March 2008, the ASC was formed to take over media regulation from the Advertising Board of the Philippines (Adboard). The responsibility of screening and clearing advertising materials (broadcast, print, cinema, outdoor and out-of-home, and new media) is now under the ASC." See *How Now, Advertising Standards Council?* Adobo Magazine (2009), available at: http://www.adobomagazine.com/global/module.php?LM=articles.level3&id=1234335825466; *One Ad Mother: The Advertising Standards Council Streamlines the Review of Philippine Ads*, Adobo Magazine (2009), available at: http://www.adobomagazine.com/global/module.php?LM=news.level1&id=1212565199527 (["T]he Advertising Standards Council (ASC) [is] a newly created organization affiliated with the KBP (Kapisanan ng mga Brodkaster sa Pilipinas) which took over the reviewing duties of the Advertising Board of the Philppines last March 31.") *Id*. *See also* Ad Standards Council for Responsible Advertising, *Our Standards - Introduction*, available at: http://www.asc.com.ph/our-standards/code-of-ethics/introduction. "The AdBoard Advertising Content & Regulations Committee (ACRC) had been the main implementing arm of advertising self-regulation in the Philippines until March 2008 when the Ad Standards Council (ASC) took over this function." *Id*.

388 *See* Ad Standards Council for Responsible Advertising, *Guide to ASC Rates*, available at: http://www.asc.com.ph/ad-pre-screening/guide-to-asc-rates.

389 AO 2012-0027, Section 15.

390 *Id*.

391 *Id*., at Sec. 17.

392 *Id*.

393 *Id*.

394 *Id*.

395 *Id.*

396 *Id*.

issued, a Certificate of Approval is valued for a period of only three months, and may be renewed, at most, three times within a period of one (1) year.[397]

Given all of the time, effort and expense that a foreign manufacturer and/or local distributor of breastmilk substitute and breastmilk supplement products and their advertising agents must devote to emerge intact from this Rube Goldberg-like[398] regulatory apparatus, it is manifestly unfair and trade-restricting to limit the applicant's earned right to air its advertising campaign to a period of only 1 year. This is especially true with respect to breastmilk supplement products which are typically marketed, in compliance with the WHO Code, to reach potential audiences *older than* 6-12 months of age.

Arguably, the less than transparent advertising review procedure of AO 2012-0027 was adopted to indirectly endow the PHDOH with the type of broad administrative discretion it had previously possessed under prior RIRR, Rule V Section 11 to directly ban the advertising of follow-on formula breastmilk *supplement* products.[399] To recall, the PHDOH and UNICEF had aggressively lobbied in 2006 to secure Section 11, which extended "the promotion ban to milk substitutes for children *up to 2 years old*" (emphasis added),[400] as a revision to the Milk Code. Section 11 had been intended to respond to concerns "about the steady decline in breastfeeding and [claims] that formula companies had been violating marketing regulations".[401] In 2007, the Philippine Supreme Court declared said provision an *ultra vires*, unconstitutional, and legally void and unenforceable implementation of the Milk Code.[402]

Since at least 2007, however, the PHDOH and local UNICEF Office in the Philippines have known quite well that formula companies "have largely complied with the Milk Code restrictions pertaining to formula for infants up to 12 months," and that "commercial promotions [were] not the only factor [responsible] for the decline in breastfeeding."[403] The New York Times then reported, for example, that "although [the PHDOH] ha[d] ordered all government and public offices to provide breastfeeding stations or at least open their clinics to breast-feeding mothers, it ha[d] been less successful in persuading private establishments such as shopping malls to do the same."[404] Such knowledge notwithstanding, the PHDOH, the local UNICEF Office and breastfeeding activist groups have continued to falsely allege that formula companies' "promotion of milk substitutes for older children is dissuading mothers from breast-feeding newborns."[405]

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397 *Id*., at Sec. 18.
398 "A Rube Goldberg machine, contraption, invention, device, or apparatus is a deliberately over-engineered or overdone machine that performs a very simple task in a very complex fashion, usually including a chain reaction. The expression is named after American cartoonist and inventor Rube Goldberg (1883–1970). See *Rube Goldberg Machine*, Wikipedia, available at: http://en.wikipedia.org/wiki/Rube_Goldberg_machine.
399 RIRR, Rule V Sec. 11.
400 *Id*.
401 *See* Carlos H. Conde, *Breast-feeding: A Philippine Battleground*, New York Times (July 17, 2007), *supra*.
402 *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034,
403 *Id.* "The companies have largely complied with the Milk Code restrictions pertaining to formula for infants up to 12 months; what they distribute are samples of products intended for kids 12 months and older…To be sure, health experts say, commercial promotions are not the only factor for the decline in breast-feeding…[Dr. Nicholas Alipui, the Unicef representative to the Philippines]…said that formula is a convenient fallback for many Filipino mothers who work outside the home." *Id*.
404 *Id*.
405 *Id*. "'They're using follow-on milk as a backdoor,' Alipui, of Unicef, said of the companies. *See also* UNICEF, *A Weak Formula for Legislation: How Loopholes in the Law are Putting Babies at Risk* (2007), available at: http://www.savethechildren.org.uk/sites/default/files/docs/report-formula_legislation.pdf. "Formula manufacturers are exploiting two loopholes in the law. First, they are promoting follow-on milks in a way

D. The PH BMS Framework's Broader-Than-WHO Code Restrictions on the Use of Proprietary Intellectual Property

As previously discussed in Section III.2.c.v, the PH BMS Framework imposes prohibitions and restrictions on the use of proprietary trademarks, logos, brand names and company names on breastmilk substitute and breastmilk supplement product labels and advertising materials that go beyond those imposed by WHO Code Articles 4.3 and 6.8 on donated informational or educational materials or equipment.

For example, Circular 2008-0006, Item VI.A.1(v) precludes the use on the principal panel of breastmilk substitute and breastmilk supplement product labels of a "brand name and/or trademark [of] any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar import."[406] In addition, pursuant to Circular 2008-0006, Items V.3[407] and VI.A.1(v), the PHDOH issued a controversial September 5, 2011 Memorandum directing the BFAD/FDA, when reviewing breastmilk substitute and breastmilk *supplement* product labels in furtherance of RIRR, Rule VII Section 28, "'not to allow any kind of trademarks that contain health and nutrition claims or that may undermine breastfeeding and breastmilk to be placed on the labels (Note that labels are marketing materials)'."[408] The memorandum, however, did not point to any standard, beyond a general reference to non-registrable "deceptive or deceptively descriptive marks",[409] that the BFAD/FDA should employ for evaluating how and whether *a trademark*, alone, could contain a health or nutrition claim or otherwise undermine breastfeeding and breastmilk.

On September 10, 2012, the PHDOH issued a second controversial memorandum, in its capacity as IAC Chair, and pursuant to its broad authority to review advertising materials under RIRR, Rule V Sections 12-13 and AO 2012-0027, Sections 19-20. To ensure that breastmilk substitute *and breastmilk supplement* advertising, marketing and promotional materials do not confuse or otherwise mislead consumers, the memorandum mandated that the BFAD/FDA strictly enforce, with respect to all such materials, the prohibition against the use of *registered trademarks* on breastmilk substitute *and breastmilk supplement* product labels to make health and nutrition claims or to undermine breastfeeding or breastmilk.[410] While the PH DOH referenced as support for this mandate the amorphous standards of Circular 2008-0006, Items V.3[411] and VI.A.1(v),[412] as well as, RIRR, Rule V Sections 13 and 15-17, it very closely resembled the September 5, 2011 memorandum's labeling directive.

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that makes them difficult to distinguish from normal infant formula. Second, they are deliberately confusing their company name and logo with their formula milk brand names…This is not in breach of the law at the moment because the advertising ban
only applies to infant formula. However, by naming and labelling follow-on milks almost identically to infant formula, manufacturers ensure that both products are promoted at the same time." *Id*. at p. 2.

406 Circular 2008-0006, Item VI.1.(v).

407 Circular 2008-0006, Item V.3, which provides that, "[a]ny information, whether in text or graphical form, which are not mentioned in these guidelines may be a ground for the denial of the label applied for." Circular 2008-0006, Item V.3.

408 *See* Republic of the Philippines Department of Justice, *Secretary Opinion No. 29, series 2012* (May 11, 2012), *supra* at p. 2. *See also* Republic of the Philippines Department of Justice, *Secretary Opinion No. 69, series 2012* (Sept. 4, 2012), *supra* at p. 2.

409 *See* Republic of the Philippines Department of Justice, *Secretary Opinion No. 29, series 2012* (May 11, 2012), *supra* at p. 5.

410 *See* PHDOH Memorandum (Sept. 10, 2012), *supra*.

411 "Any information, whether in text or graphical form, which are not mentioned in these guidelines may be a ground for the denial of the label applied for." Circular 2008-0006, Item V.3.

412 "It shall be contrary to public policy to use as brand name and/or trademark any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar support." Circular 2008-0006, Item VI.A.1(v).

Circular 2008-0006, Items V.3 and the September 2011 and 2012 PHDOH Memoranda go considerably beyond the WHO Code, insofar as they direct the BFAD/FDA "not to allow any kind of trademarks that contain health and nutrition claims or that may undermine breastfeeding and breastmilk to be placed on labels" or in advertising.[413] These restrictions are discussed in more detail in Part 2 of this analysis.[414]

E. The PH BMS Framework's Redundant Multiple-Level Greater-Than-Anticipated WHO Code Monitoring and Enforcement Regime

The PH BMS Framework's enforcement regime entails three distinct levels of regulatory and self-regulatory monitoring and enforcement engendering administrative fines, criminal fines, terms of imprisonment, termination/revocation of business permits and professional licenses, advertising cease-and-desist orders, recalls of advertising clearance, or future advertising bans that arguably go way beyond what the WHO Code anticipates is a reasonable approach to protecting breastfeeding.

Pursuant to "level 1" of said framework, Milk Code Section 12(b)(2) and RIRR, Rule X Section 36 empower the PHDOH to create a multi-stakeholder monitoring regime, consisting of governmental agencies and civil society nongovernmental organizations ("NGOs") at the national, regional, provincial and municipal levels, to achieve the purposes and objectives of the Milk Code.[415] In addition, Milk Code Section 12(b)(3), RIRR, Rule XI Section 45 and Rule XII, Section 47 generally empower the PHDOH to impose administrative fines,[416] and more specifically empower the PHDOJ to impose criminal fines *and/or* possible imprisonment for conviction of Milk Code violations.[417] Criminal fines and penalties, which range from one thousand Philippine pesos (P1,000.00) (USD$44.37) to thirty thousand Philippine pesos (P30,000.00) (USD$1,331.05) may be assessed, and/or a term of imprisonment of at least two (2) months to one (1) year may be imposed.[418] Upon a conviction, the PHDOH is empowered to a revoke or suspend prior government-issued business (manufacturer, distributor or marketing firm) or (health) professional licenses, permits or authorities.[419] Individual corporate officers and board members are also subject to personal administrative and criminal liability where a company (a juridical entity) is found guilty of noncompliance,[420] as are their agents and representatives to the extent of their complicity in such violations.[421]

Pursuant to "level 2" of said enforcement framework, the false or misleading advertising of infant formula, follow-up formula and complementary food products may also be subject to the provisions

413 PHDOH Memorandum (Sept. 5, 2011); PHDOH Memorandum (Sept. 10, 2012).
414 *See* Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 2 of 2), LexisNexis 2013 Emerging Issues ("Part 2").
415 Milk Code Sec. 12(b); RIRR, Rule X Sec. 36. "Monitoring teams comprised of duly accredited teams from non-governmental organizations, and/or civil society may report their findings to the Office of the Secretary of Health who shall appropriately respond thereto with sufficient dispatch." RIRR, Rule X Sec. 37.
416 RIRR, Rule XII Sec. 47. The Philippines Supreme Court ruled, in a 2007 landmark case, that the sanctions provision contained in RIRR Rule XII Sec. 46 was unconstitutional and of no legal force and effect. *See Pharmaceutical and Health Care Association of the Philippines v. Secretary Francisco T. Duque III, et al.*, G.R. No. 173034, Supreme Court of the Philippines En Banc (Oct. 9, 2007), *supra*.
417 Milk Code Sec. 13(a); RIRR, Rule XI Sections 39-40.
418 Milk Code Sec. 13(a); RIRR, Rule XII Sec. 47, Rule XIII Sec. 50.
419 Milk Code Sec. 13(b); RIRR, Rule XII Sec. 48.
420 Milk Code Sec. 13(a); RIRR, Rule XII Sec. 49, and Rule XIII Sec. 50.
421 *Id*.

of the Consumer Act of the Philippines (Republic Act 7394 - "RA 7394")[422] and to Joint DTI-DOH-DA Administrative Order No. 1 implementing RA 7394.[423] AO 1 extends RA 7394 requirements to electronic commerce (i.e., to advertising on commercial websites, emails, Facebook, Twitter, etc.).[424] These legal instruments, which exist in addition to the PH BMS Framework, apply to false or misleading advertising and labeling of food products.[425] For example, Title II, Chapter II, Article 40(b) prohibits "the misbranding of any food", while Article 40(e) prohibits "falsely representing or without proper authority using any mark…label, or other identification device authorized or required by regulations promulgated under the provisions of this Act."[426] The PHDOH and the BFAD/FDA also oversee the implementation of these provisions.[427]

Title III, Chapter IV, Article 84 imposes additional labeling requirements for food products, including a declaration of "nutritive value" and "such other labeling requirements as the concerned department [here, PHDOH] may deem necessary and reasonable."[428] Article 85 provides that, "food shall also be deemed mislabeled: a) if its labeling or advertising is false or misleading in any way…f) if any word, statement or other information required by or under authority of this Act to appear on the principal display panel of the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs or devices in the labeling and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use…j) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin or mineral or other dietary properties as the concerned department determines to be, or by regulations prescribed as necessary in order fully to inform purchasers as its value for such uses."[429] Article 76 provides that, "[i]t shall be unlawful for any person, either as principal or agent, engaged in the labeling or packaging of any consumer product, to display or distribute or to cause to be displayed or distributed in commerce any consumer product whose package or label does not conform to the provisions of this Chapter."[430] The implementation of these provisions is overseen by the PH Department of Trade and Industry ("PHDTI").[431] Article 95(a) provides that any person who violates these provisions "shall be subject to a fine of not less than Five hundred pesos (P500.00) (USD$11.22) but not more than Twenty thousand pesos (P20,000.00) (USD$448.63) or

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422 *See* Republic of the Philippines, Congress of the Philippines, *Consumer Act of the Philippines (Republic Act 7394* (April 13, 1992), available at: http://dtincr.ph/files/LawsAndPolicies-ConsumerAct.pdf; http://www.wipo.int/wipolex/en/text.jsp?file_id=224742#LinkTarget_877. Among the purposes of the Consumer Act of the Philippines are the following: a) protection against hazards to health and safety; b) protection against deceptive, unfair and unconscionable sales acts and practices; [and] c) provision of information and education to facilitate sound choice and the proper exercise of rights by the consumer". *Id*., at Title I, Art. 2.

423 *See* Republic of the Philippines, Joint Department of Trade and Industry, Department of Health and Department of Agriculture *(Joint DTI-DOH-DA) Administrative Order No. 1, s. 2008 – Rules and Regulations for Consumer Protection in a Transaction Covered by the Consumer Act of the Philippines (R.A. 7394) Through Electronic Means Under the E-Commerce Act (R.A. 8792)* (Oct. 20, 2008), available at: http://www.dti.gov.ph/uploads/DownloadableForms/DTI-DOH-DA%20JDAO%201%20-%20E-Consumer%20Protection%20Guidelines.pdf.

424 Article 4 of AO No. 1 provides that, "[r]etailers, sellers, distributors, suppliers or manufacturers engaged in electronic commerce with consumers shall refrain from engaging in any false, deceptive and misleading advertisement prohibited *under the provisions of Title III, Chapter VI of the Consumer Act of the Philippines and its IRR*, and shall comply with the advertising and promotion requirements therein, and other advertising and promotion guidelines issued by the respective departments in compliance with other relevant laws" (emphasis added). *Id*.

425 "'Food' means any substance, whether processed, semi-processed or raw, intended for human consumption and includes chewing gum, drinks and beverages and any substance which has been used as an ingredient or a component in the manufacture, preparation or treatment of food." Id., at Title I, Art. 4(ag).

426 *Id*., at Chap. II, Articles 4(b) and (e).

427 *Id*., at Art. 21.

428 *Id*., at Title III, Chap. IV, Articles 84(c) and (e).

429 *Id*., at Articles 85(a), (e) and (j).

430 *Id*., at Art. 76.

431 *Id*., at Art. 75.

imprisonment of not less than three (3) months but not more than two (2) years or both, at the discretion of the court."[432]

Furthermore, Title IV, Chapter VI, Article 108 provides generally that the "State shall protect the consumer from misleading advertisements and fraudulent sales promotion practices",[433] and Article 109 provides that the implementation of this Chapter's provisions is overseen by the PHDTI, except for the application of these provisions to food products which shall be overseen by the PHDOH.[434] Article 110 provides that, "[i]t shall be unlawful for any person to disseminate or to cause the dissemination of any false, deceptive or misleading advertisement by Philippine mail or in commerce by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of consumer products or services. An advertisement shall be false, deceptive or misleading if it is not in conformity with the provisions of this Act or if it is misleading in a material respect."[435] Article 112 imposes special advertising requirements with respect to food products. It provides that, "a) No claim in the advertisement may be made which is not contained in the label or *approved by the concerned department*. b) No person shall advertise any food…in [a] manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit, or safety…f) No person shall advertise any food…unless such product is duly registered and approved by the concerned department for use in any advertisement" (emphasis added).[436]

Article 122 authorizes the concerned department – here, the PHDOH and/or PHDTI - to seek a court order enjoining a company from disseminating advertising materials if it has "reason to believe (1) that any person, partnership or corporation is engaged in or is about to engage in the dissemination or the causing of dissemination of any advertisement in violation of Articles 110 to 115, and (2) that the enjoining thereof would be to the interest of the public."[437] Article 123 imposes monetary penalties and a possible term of imprisonment for proven dissemination of false or misleading advertising. It provides that, "a) any person, association, partnership or corporation who shall violate any of the provisions of Articles 110 to 115 shall, upon conviction, be subject to a fine of not less than Five Hundred Pesos (P500.00) (USD$11.22) but not more than Five thousand pesos (P5,000.00) (USD$112.16) or an imprisonment of not less than one (1) month but not more than (6) months or both upon the discretion of the court."[438]

Title V, Chapter III provides consumers with the ability to file a complaint or petition that could potentially prompt the PHDOH or PHDTI to undertake an investigation pursuant to prescribed procedures.[439] The concerned department may thereafter "commence a formal administrative action against any person responsible…[u]pon a finding by the department of prima facie violation

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432 *Id*., at Title III, Chap. IV, Art. 95(a).
433 *Id*., at Title IV, Chap. VI, Art. 108.
434 *Id*., at Art. 109.
435 *Id*., at Art. 110.
436 *Id*., at Articles 112(a)-(b) and (f).
437 *Id*., at Art. 122(a).
438 *Id*., at Art. 123(a).
439 *Id*., Title VI, Chap. III, Articles 159 ad 163.

of any provisions of th[e] Act or any rule or regulation promulgated under its authority."[440] RA 7394 also provides for an administrative hearing and a final appeals process.[441]

"Level 3" of the PH BMS Framework involves the Philippine Advertising Standards Council ("PHASC"), which AO 2012-0027, Section 11.3 already requires to review all infant formula, follow-up formula and complementary food product advertising materials prior to their submission for IAC and IAC Secretariat regulatory review. In addition, the PHASC also investigates consumer, industry competitor and government complaints of alleged violations of its prior decisions regarding the release of previously proposed advertising materials. The PHASC can impose various sanctions where false or misleading advertising materials have been aired or otherwise released: 1) without proper initial PHASC clearance; 2) because PHASC clearance had been secured under false pretenses; or 3) contrary to an adverse PHASC Hearing Board final decision rendered following a PHASC investigation.[442] These sanctions may engender the issuance of cease-and-desist orders, recalls of advertising clearance, or prospective advertising bans,[443] and/or they may entail the levying of monetary fines for 1st, 2nd and 3rd level offenses ranging from (P55,000) (USD$1,239.62) for 1st offences to (P660,000) (USD$14,875.49) for 3rd offenses.[444]

These three levels of advertising monitoring and enforcement impose significant administrative burdens and economic and opportunity costs on foreign breastmilk substitute and breastmilk supplement manufacturers and distributors that more than insignificantly impede international trade in such products. These trade restrictions go beyond what is necessary to achieve the PH BMS Framework's objectives of protecting public health via breastfeeding and protecting consumers from deceptive advertising.

iv. The Degree to Which PH BMS Framework Advertising, Labeling and Trademark-Use Restrictions Will Achieve Their Legitimate Public Policy Objectives is Uncertain

As previously discussed, the PH BMS Framework's objectives of promoting public health via protection of exclusive breastfeeding up to 24 months of age or beyond, and of preventing the deceptive marketing of breastmilk substitute and breastmilk supplement ("BMS") products intended for infants and young children up to 24-36 months of age are legitimate and laudable goals.

However, the WHO Code, which is a relevant international public health standard, recommends that infant formula or complementary food products intended for infants up to 4-6 months of age, not be marketed *to replace* breastfeeding *as the sole food source* (i.e., as a breastmilk *substitute*) *during the first 6 months* of an infant's life.[445] In addition, the WHO IYCF Strategy [446]endorsed by

440 *Id*., at Art. 159.
441 *Id*., at Articles 163, 165-166.
442 *See* Ad Standards Council for Responsible Advertising, *How Complaints are Processed*, available at: http://www.asc.com.ph/complaints-dispute/how-complaints-are-processed; Ad Standards Council for Responsible Advertising, *Consumer Complaints*, available at: http://www.asc.com.ph/complaints-dispute/consumer-complaints;
443 *See* Ad Standards Council for Responsible Advertising, *Cease and Desist Orders*, available at: http://www.asc.com.ph/complaints-dispute/cease-and-desist-order.
444 *See* Ad Standards Council for Responsible Advertising, *Offenses and Penalties*, available at: http://www.asc.com.ph/complaints-dispute/offenses-and-penalties.
445 WHO Code Articles 2 and 3, p. 9.
446 *See* World Health Organization, *Global Strategy for Infant and Young Child Feeding* (2003), supra.

WHA 55/25,[447] which recommends introduction of complementary foods after the first 6 months of life, does not suggest that follow-up formula and other complementary food products can be marketed to displace breastfeeding's role as a *partial food source* (i.e., as a breastmilk substitute) *after the first 6 months* of an infant's life, *up to 2 years or beyond*.[448] Clearly, therefore, to the extent the PH BMS Framework exceeds this standard by restricting and/or prohibiting the advertising and labeling of (and use of trademarks related to) bona fide breastmilk *supplement* products marketed or intended for young children *older than 6-12 months of age* as a complement *to partial breastfeeding*, it is more trade-restrictive than necessary to achieve its policy objectives. This is especially true if the degree to which PH BMS Framework's policy objectives of protecting public health and preventing deceptive marketing practices can be achieved is uncertain, for the following reasons.

A. Achievement of PH BMS Framework Public Health Objectives is Uncertain Because Multiple Other Factors Are Responsible for Reduced Breastfeeding Rates and Infant and Young Children's Malnutrition

Unfortunately, many Filipino communities continue to face the challenges of endemic poverty and malnourishment, as well as the pressures of employment. But, it is precisely because of these other challenges and still other exogenous factors, *which are unrelated to the commercial advertising/marketing, labeling and promotion of foreign branded breastmilk supplement products* in the Philippines, that the degree to which the PH BMS Framework can achieve its objectives must be seriously questioned. Through its broad product coverage of both breastmilk substitute *and* breastmilk supplement products[449], the PH BMS Framework has effectively set out to address three different public health problems. These three problems consist of the following: 1) the malnutrition of the pregnant woman which can affect the development and health of the unborn child/fetus; 2) the malnutrition of the infant during the first year of life; and 3) the malnutrition of the young child from 12-36 months of age. The PH BMS Framework restrictions and prohibitions imposed on the advertising/marketing and labeling of breastmilk substitute and breastmilk supplement products intended for infants 0-6 months, and perhaps also, 6-12 months of age appear capable of addressing the problem of *infant* malnutrition. However they do NOT appear capable of resolving the problem of malnutrition of young children because of the uncertainties surrounding the health benefits of long-term breastfeeding. And, they certainly do NOT appear capable of resolving the problem of malnutrition of pregnant women which is necessary to ensure the health of the unborn fetus and newborn infant.

I. Caveated Science

The health benefits associated with the WHO recommendation of exclusive breastfeeding for an infant's first 6 months of life are generally well recognized, but they are not without their caveats. The WHO has known, since at least 2001, that exclusive breastfeeding *to 6 months* "can lead to iron deficiency in susceptible infants…[and]…several other potential risks associated with exclusive breastfeeding for six months, including growth faltering and other micronutrient deficiencies, in

447 *See* World Health Organization, 55th World Health Assembly, *Infant and Young Child Nutrition*, Resolution WHA55.25 (May 18, 2002), at par. 1, available at: http://www.who.int/nutrition/topics/WHA55.25_iycn_en.pdf.
448 *Id*., at pars. 10, 28 and 30.
449 Milk Code Sec. 3; RIRR, Rule I Sec. 3.

some infants."[450] For this reason, the WHO expert consultation advised "that some mothers will be unable to, *or choose not to, follow* this recommendation [and that] they should be supported to optimize their infants' nutrition" (emphasis added).[451] In this regard, at least one study has found, that "[i]nfants who are *exclusively breast-fed for >6 months in developing countries* may be at increased risk of anemia, especially among mothers with a poor iron status" (emphasis added).[452] These findings were recently confirmed in a 2013 study which "documented a relationship between *breastfeeding beyond 12 months of age* and reduced iron stores" (emphasis added).[453] It concluded that "[c]hildren who are breastfed beyond 12 months of age appear to have a 1.7-fold increase in the odds of iron deficiency."[454]

The WHO recommendation for exclusive breastfeeding for six months with introduction of complementary foods and continued breastfeeding thereafter has continued to engender scientific debate.[455] For example, the results of one study alleging psychosocial benefits from exclusive breastfeeding *beyond the first 6 months of life* are rather limited, suggestive, circumstantial and dependent on various factors, such as "age, education, smoking, family income, family structure, life stress events and depression."[456] Other studies, meanwhile, have provided inconclusive

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450 World Health Organization, *Global Strategy for Infant and Young Child Feeding: The Optimal Duration of Exclusive Breastfeeding*, EXPERT CONSULTATION ON THE OPTIMAL DURATION OF EXCLUSIVE BREASTFEEDING, A54/INF.DOC./4 (May 1, 2001), at par. 10, p. 3, available at: http://apps.who.int/gb/archive/pdf_files/WHA54/ea54id4.pdf

451 *Id*., at par. 11.

452 *See* Jareen K. Meinzen-Derr, M. Lourdes Guerrero, Mekibib Altaye, Hilda Ortega-Gallegos, Guillermo M. Ruiz-Palacios, and Ardythe L. Morrow, *Risk of Infant Anemia Is Associated with Exclusive Breast-Feeding and Maternal Anemia in a Mexican Cohort*, The Journal of Nutrition (2006), Abstract available at: http://jn.nutrition.org/content/136/2/452.long. "In general, infants born at term and with an adequate birth weight have sufficient iron stores for the first 4–6 mo of life. However, evidence suggests that infants with adequate birth weight born to anemic mothers have low iron stores and are more likely to develop anemia (23–26). By 6 mo, complementary foods are required to provide the iron and other nutrients necessary for infant development… Although prevalence rates of anemia among healthy term infants 6–18 mo of age are reported to be as low as 2–6% in Western Europe and the United States (2–4), iron deficiency anemia was shown to affect more than half of the children in some developing countries (5). In Mexico, 27% of children <5 y old are anemic." *Id*.

453 *See e.g.*, Jonathon L. Maguire, Leila Salehi, Catherine S. Birken, Sarah Carsley, Muhammad Mamdani, Kevin E. Thorpe, Gerald Lebovic, Marina Khovratovich, and Patricia C. Parkin, *Association Between Total Duration of Breastfeeding and Iron Deficiency*, Journal of Pediatrics (April 2013), at p. e1530, available at: http://pedclerk.bsd.uchicago.edu/sites/pedclerk.uchicago.edu/files/uploads/Pediatrics-2013-Maguire-e1530-7.pdf.

454 *Id*. at p. e1535. This was a "cross-sectional study of [1647] healthy children, aged 1 to 6 years [(median age 36 months)], seen for primary health care between December 2008 and July 2011…Our study is unique in providing a relatively large sample of children with a wide range of total breastfeeding duration (0–48 months) allowing adjustment for multiple biologically plausible confounders. Furthermore, our study was not limited to exclusive breastfeeding but considered a broader, more inclusive definition of breastfeeding practices." *Id*., at pp. e1530, e1535.

455 Mary Fewtrell, David C Wilson, Ian Booth, Alan Lucas, *Six Months of Exclusive Breast Feeding: How Good is the Evidence?*, 342 British Medical Journal (2011), available at: http://www.bmj.com/content/342/bmj.c5955?hwoasp=authn%3A1368774369%3A5531153%3A1534235762%3A0%3A0%3A1uNZzgftfk7ch5ka3GQXKg%3D%3D. ("In the West, exclusive breast feeding for six months is linked to reduced risk of infection. Nevertheless, the studies are observational and some evidence suggests that introducing solids (rather than formula) before six months may not significantly affect risk of infection. By contrast, *exclusive breast feeding to six months raises concerns*" (emphasis added)) *Id*; UCL Institute of Child Health News, *Six Months of Exclusive Breast Feeding: How Good is the Evidence?* (Jan. 20, 2011), available at: http://www.ucl.ac.uk/ich/ich-news/Article13; Science Daily, *Is 'Breast Only' for First Six Months Best?* Press Release (Jan. 14, 2011), available at: http://www.sciencedaily.com/releases/2011/01/110113213100.htm; Sarah Boseley, *Six Months of Breastmilk Alone is Too Long and Could Harm Babies, Scientists Now Say*, The Guardian (Jan. 13, 2011), available at: http://www.guardian.co.uk/lifeandstyle/2011/jan/14/six-months-breastfeeding-babies-scientists; Mary S Fewtrell, Jane B Morgan, Christopher Duggan, Geir Gunnlaugsson, Patricia L Hibberd, Alan Lucas, and Ronald E Kleinman, *Optimal Duration of Exclusive Breastfeeding: What is the Evidence to Support Current Recommendations?*, 85(2) American Journal of Clinical Nutrition (Feb. 2007), available at: http://ajcn.nutrition.org/content/85/2/635S.long.

456 *See e.g.*, Wendy H. Oddy, Garth E. Kendall, Jianghong Li, Peter Jacoby, Monique Robinson, Nicholas H. de Klerk, Sven R. Silburn, Stephen R. Zubrick, Louis I. Landau, and Fiona J. Stanley, *The Long-Term Effects of Breastfeeding on Child and Adolescent Mental Health: A Pregnancy Cohort Study Followed for 14 Years*, 156(4) The Journal of Pediatrics (April 2010), available at: http://www.bpni.org/Article/Oddy.pdf. "[C]onsistent with our findings, infants who are breastfed for at least 6 months have a distinct developmental advantage over non-breastfed infants and infants breastfed for a short period of time." *Id.*, at p. 4. "Following adjustment of the associated socioeconomic, psychological and birth exposures in early life, breastfeeding for 6 months or longer was positively associated with the mental health and well-being of children and adolescents." *Id*., at p. 6. "Potential confounders were: maternal age at child's birth…maternal education…maternal smoking…family structure…and life stress events." *Id*., at p. 2. *See also* UNICEF UK, The Baby Friendly Initiative, *Breastfeeding May Have Protective Effect on*

evidence of the benefits of long-term breastfeeding, and the longer-term benefits of exclusive breastfeeding.[457]

In addition to these studies, one 2007 WHO-commissioned study found that while "[b]reastfeeding presents clear short-term benefits for child health, mainly protection against morbidity and mortality from infectious diseases…there is some controversy on the long-term consequences of breastfeeding…Whereas some studies reported that breastfed subjects present a higher level of school achievement and performance in intelligence tests, as well as lower blood pressure, lower total cholesterol and a lower prevalence of overweight and obesity, others have failed to detect such associations."[458] Consequently, "[t]he available evidence [only] *suggests* that breastfeeding *may* have long-term benefits" (emphasis added).[459]

A 2013 update of this WHO-commissioned study strongly suggests that the anticipated long-term benefits associated with exclusive breast-feeding are overstated, and remain largely questionable and uncertain. It concluded that: 1) "breastfeeding does not seem to protect against total cholesterol levels"; 2) "the protective effect of breastfeeding [on incidents of high blood pressure], if any, is too small to be of public health significance"; 3) there were "conflicting results (one showing an increase and another a reduction among breastfed subjects)" with respect to breastfeeding's effect on diabetes; 4) "breastfeeding may provide some protection against overweight or obesity, but residual confounding cannot be ruled out"; and 5) "there is strong evidence of a causal effect of breastfeeding on IQ, although the magnitude of this effect seems to be modest."[460] These conflicting findings raise the level of uncertainty surrounding whether the PH

Child and Adolescent Mental Health, available at: http://www.unicef.org.uk/BabyFriendly/News-and-Research/Research/Mental-development/Breastfeeding-may-have-protective-effect-on-mental-health/.

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

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

459 *Id.*

460 *See* Bernardo L. Horta and Cesar G. Victora, *Long-term Effects of Breastfeeding: A Systematic Review*, World Health Organization (2013) at p. 68, *supra*. *Cf.* Mandy B. Belfort, Sheryl L. Rifas-Shiman, Ken P. Kleinman, Lauren B. Guthrie, David C. Bellinger, Elsie M. Taveras, MD, Matthew W. Gillman and Emily Oken, *Infant Feeding and Childhood Cognition at Ages 3 and 7 Years Effects of Breastfeeding Duration and Exclusivity*, JAMA Pediatr (2013), Abstract available at: http://archpedi.jamanetwork.com/article.aspx?articleid=1720224. This study "examined [the] relationships of breastfeeding duration and exclusivity with child cognition at ages 3 and 7 years and…evaluate[d] the extent to which maternal fish intake during lactation modifies associations of infant feeding with later cognition." *Id.* The study found that, "[a]djusting for sociodemographics, maternal intelligence, and home environment…longer breastfeeding duration…*to age 12 months*…was associated with higher Peabody Picture Vocabulary Test score at age 3 years…and with higher intelligence on the Kaufman Brief Intelligence Test at age 7 years…Beneficial effects of breastfeeding on the Wide Range Assessment of Visual Motor Abilities at age 3 years seemed greater for women who consumed 2 or more servings of fish per week" (emphasis added). *Id*. *See also* Nicole Ostrow, *Breastfeeding Boosts Smarts as Babies Grow, Study Finds*, Bloomberg (July 29, 2013), available at: http://www.bloomberg.com/news/2013-07-29/breastfeeding-boosts-smarts-as-

BMS Framework's promotion of exclusive breastfeeding up to 12-24 months of age could achieve its objective of protecting breastfeeding and infant health.

II. Philippine Institutional, Educational, Cultural, Societal, Economic Challenges to Promoting Breastfeeding Overshadow BMS Commercial Marketing Concerns

A 2010 UNICEF review of the breastfeeding programs of six developing countries, five of which, including the Philippines, have enacted infant formula marketing laws modeled after the WHO Code raises additional questions concerning the PH BMS Framework's ability to address infant and young child malnutrition.[461] Although UNICEF continues to proclaim that "[a] strong Code of Marketing, with active monitoring and enforcement, is a critical part of effective national breastfeeding programmes", this report revealed that a number of *other* important "challenges were widespread within the countries reviewed"[462] which substantially eclipse the alleged threat posed to breastfeeding by "commercial pressures" alone.[463] This strongly suggests that the PHDOH's implementation of the PH BMS Framework to severely restrict most breastmilk supplement product advertising and labeling, including by curtailing the use of proprietary trademarks, logos and brand names in such media is misguided. It may even represent a disguised effort to divert public attention away from the PHDOH's inability to adequately address such challenges. As the UNICEF report reveals, these other challenges include: 1) "[l]ack of infant feeding knowledge and skills among caregivers"; 2) "[c]ultural beliefs and practices"; 3) "l]ack of family support"; 4) "[u]nsupportive work environments"; 5) "[u]nsupportive health facility and community-based services"; and 6) "[a]dministrative and political challenges".[464]

Indeed, the United Nations International Labor Organization ("UNILO"[465]) agrees that "unsupportive work environments" present a significant challenge to promoting breastfeeding in the Philippines. It has observed that, since Filipino "women's participation in wage employment has increased over the years…women are likely to be trapped in vulnerable forms of employment [that]…challenge [them]…to effectively balance their work and family life."[466] According to ILO Philippines Director, Lawrence Jeff Johnson, it is because of their "fear of losing their only source of income, [that] working women find it hard to continue exclusive breastfeeding even just until their babies reach six months; some are forced to give up exclusive breastfeeding altogether."[467] The UNICEF report confirms this unfortunate reality. It found that "[e]ven if leave is guaranteed, the workplace itself

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babies-grow-study-finds.html. "After controlling for maternal intelligence, they found that IQ scores for 7 year olds increased by about one-third of a point for every month of breastfeeding. That means a 7-year-old child who was breastfed as a baby for 12 months would score four points higher on intelligence tests than a child who was never breastfed…*The findings also hinted that children's intelligence benefited when their moms ate more fish while breastfeeding* then those who ate less fish, but the results weren't statistically significant" (emphasis added). *Id*.

461 *See* UNICEF New York, *Infant and Young Child Feeding Programme Review - Consolidated Report of Six-Country Review of Breastfeeding Programmes* (April 2010), available at: http://www.unicef.org/nutrition/files/IYCF_review_6_country_consolidated_report_Sept._2010.pdf. This study reviewed the breastfeeding regimes of Bangladesh, Benin, Philippines, Sri Lanka, Uganda and Uzbekistan. "Three of the six countries studied – Sri Lanka, Bangladesh, and the Philippines – passed laws in the 1980s, with Sri Lanka starting the process at the same time the International Code was being developed. All but Uzbekistan now have laws or regulations in place." *Id*., at p. 31.

462 *Id*., at Sec. 3.2, p. 19.

463 *Id*., at p. 20.

464 *Id*., at pp. 19-20.

465 *See* United Nations, International Labour Organization, *About the ILO*, available at: http://www.ilo.org/global/about-the-ilo/lang--en/index.htm.

466 *See* UNICEF Philippines, UN in PH Joins Celebration of World Breastfeeding Week 2013, Joint Press Release by ILO, UNICEF and WHO (Aug. 1, 2013), *supra*.

467 *Id*.

may not accommodate breastfeeding or breastmilk expression upon the mothers' return."[468] In addition, it determined that "maternity…legislation is likely to have had a small effect in countries where the leave is limited to public sector employees."[469]

Concerning the challenge of "unsupportive health facility and community-based services", the UNICEF report found that the work performed by the Philippines on the "Baby-friendly Hospital Initiative (BFHI), launched by WHO and UNICEF in 1992…was initially intense and brought energy and enthusiasm to the breastfeeding movement. But the failure to adequately monitor compliance, provide refresher training, and fully institutionalize the BFHI led to a decline in the compliance with the "Ten Steps."[470] "The major focus placed on BFHI in the Philippines…had a more limited effect because institutional deliveries represent only 38 percent of all deliveries in the Philippines."[471] "[D]ata on percentages of institutional deliveries in the countries studied indicates that…the Philippines…are in particular need of additional strategies to reach the majority of women who deliver at home."[472]

The UNICEF report indicates that the Government of the Philippines has not adequately addressed the challenge of insufficient "infant feeding knowledge and skills among caregivers". It found that that there was limited "[c]apacity building of health care providers [which] was a major component of the programmes reviewed. Capacity building took three forms: in-service training, pre-service education, and professional development courses."[473] The UNICEF report observed that "in many of the countries studied, little was done to analyze the IYCF-related knowledge and skills needed by various health providers and to tailor the courses and clinical practice sessions to their needs. Common challenges mentioned during the country assessments were the high demand for and the cost of in-service training because of high turnover of trained staff."[474] It also found that the absence of good training records made it difficult "to improve counselling and problem solving skills and to follow-up and mentor after training."[475] For example, "[i]n the Philippines there have been periodic recommendations, including in the current IYCF action plan, to strengthen the lactation management and IYCF content in the curricula of medical, nursing, and other health science schools", but little consensus regarding how to convert such theoretical knowledge into practical guidance.[476]

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468 *Id*., at p. 34.
469 *Id*. For this reason, the report recommended further study regarding "[t]he extent to which maternity legislation affected breastfeeding rates in the countries reviewed." *Id*. *See also* Carlos H. Conde, *Breast-feeding: A Philippine Battleground*, New York Times (July 17, 2007), *supra*. (quoting Dr. Nicholas Alipui, the Unicef representative to the Philippines, stating that formula is a convenient fallback for many Filipino mothers who work outside the home).
470 *Id*., at p. 36.
471 *Id*.
472 *Id*., at p. 37.
473 *Id*., at p. 40.
474 *Id*.
475 *Id*. "Those conducting the assessment visits found that good training records were absent, making it difficult to determine who had been trained, the number trained, and the content of the training. No reports of training evaluations were provided. The limited information available on the effectiveness of the training points to a major gap." *Id*.
476 *Id*., at p. 41. "A challenge in all of the countries is to address IYCF in more than a rudimentary way. Pre-service education often focuses on theoretical knowledge, without much practical guidance for dealing with lactation management issues, and the messages are not always harmonized in the different curricula. In many of the educational systems that provide pre-service education for health professionals, the professors and other instructors make the decisions concerning what topics to include in their courses, making it difficult to institute sustainable curriculum reforms." *Id*.

As the UNICEF report reflects, the PHDOH has made some progress addressing the challenge of "community-based promotion and support". For example, the PHDOH has initiated "several community outreach programmes [that] have used a 'negotiation' strategy as part of their IYCF peer counselling approach, with promising results."[477] The PHDOH and breastfeeding activist groups continue to advocate "for the establishment of model breastfeeding communities".[478] Several cities have responded in positive ways. They have "passed ordinances in line with recommended feeding practices", and have also "worked to create breastfeeding rooms, monitor and report Code violations, establish community support groups, train health workers, and prepare peer counsellors to aid pregnant and new mothers with IYCF problems."[479] In addition, several cities have built breastfeeding stations "within many shopping malls and within provincial and city government offices, plantations, and UNICEF itself."[480]

The UNICEF report also shows that efforts in the Philippines to effectively nationalize breastfeeding practices have also fallen flat, despite the PHDOH's promotion, with donor support, of "[e]arly and exclusive breastfeeding…practices" in large communities.[481] Apparently, "[t]he vast majority of the population in…the Philippines…remain untouched by community-based breastfeeding activities", and efforts to scale up [have] been hampered…by lack of coordination between the various partners involved in IYCF."[482]

Moreover, the PHDOH has had its share of "administrative challenges". For example, between 1999 and 2002, the Philippines Government "established 2,220 health and nutrition posts", but was able to fill "only 30 percent" of them. What is more, the report found that "the last training these workers received was about 5 years ago."[483] And, although new programs and initiatives have "provided an opportunity to strengthen and expand" existing Philippines IYCF programs, "leverage resources, and scale up interventions at a more rapid pace", the UNICEF report found that the Philippines continues to suffer from "high staff turnover, poor supervision, missed opportunities, and other weaknesses in [its] health delivery system [that have] limited [the] gains that [otherwise] could have been achieved."[484]

A more recent 2012 UNICEF report reviewing the success of infant and young child feeding ("IYCF") programs in 65 countries[485] reaffirms and further explains these findings. It demonstrates that while the Philippines had achieved a high score ($\geq$9/10)[486] ("very good") in IYCF policy and legislation

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477 *Id*., at p. 46. This type of strategy "involves at least three visits to households with pregnant women, new mothers, or families with malnourished children to: 1) review the situation and current feeding practices, 2) discuss and negotiate with the mother (and her family) to try one or more improved infant feeding practices, and 3) assess what has been tried and what more needs to be done to achieve success." *Id*.
478 *Id*., at p. 47.
479 *Id*.
480 *Id*., at p. 47.
481 *Id*., at p. 53.
482 *Id*., at p. 55. "In many of the countries studied, sustainability of initially successful programmes was hindered by the failure of planners to integrate promising interventions into the health system and make provisions for ongoing government and donor support beyond the life of individual projects. Insufficient coordination among development partners led to unnecessary inefficiencies." *Id*.
483 *Id*., at pp. 44-45.
484 *Id*., at p. 51.
485 *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), available at: available at: http://www.unicef.org/nutrition/files/IYCF_65_country_assessment_report_UNICEF.pdf.
486 *Id*., at p. 14, Figure 1: National level IYCF actions score, p. 15.

because it had developed an IYCF national strategy,[487] it has been unable to convert that policy and law framework into positive tangible positive results on the ground. As the result of scoring substantially lower in several other areas critical to the success of such programs, the Philippines received an "overall IYCF comprehensive actions score" of "fair" (6/10),[488] reflecting a "[l]ow number of key IYCF actions or intervention *implemented*" (emphasis added).[489]

For example, the Philippines scored significantly lower (4/10)[490] ("fair") in "[h]ealth service interventions for IYCF [,which] are one of the key pillars of the overall IYCF policy and strategy."[491] Although the Philippines had initiated a Baby-friendly Hospital Initiative (BFHI) pursuant to which it had certified hospitals/maternity facilities as being compliant with BFHI principles, the report found that it has since failed to recertify any of those institutions.[492] In addition, UNICEF likely found that the Philippines has not adequately "[i]ncorporat[ed] IYCF topics in[to] the basic curriculum of medical and para-medical health professionals…to address the current knowledge gaps."[493] "The four key IYCF documents/references used in updating/developing health professionals' pre-/in-service curricula as captured by the assessment matrix included (i) Global strategy for IYCF 2003; (ii) Revised BFHI material 2009; (iii) Guiding principles for complementary feeding of breastfed child 2001; and (iv) Guiding principles for feeding non-breastfed children 6 to 24 months WHO 2005."[494]

In addition, the Philippines scored even lower (3/10)[495] ("poor") in "community level IYCF actions" consisting of "[c]ommunity level breastfeeding and complementary feeding promotion and support [which] can be effective in improving optimal infant and young child feeding, particularly for those disadvantaged and vulnerable groups with low access to health services."[496] With respect to community-level complementary feeding promotion, UNICEF found that the Philippines does not adequately provide counsel to mothers/caregivers in home preparation of complementary foods or in promoting behavioral change in order to improve complementary feeding practices of children 6-24 months of age.[497] The Philippines also do not provide sufficient complementary food supplements "(e.g. industrially and locally produced fortified foods, micronutrient powders or lipid-based nutrient supplements) to improve complementary feeding of children 6-24 months old."[498]

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487 *Id.*, at p. 12. "[The] Philippines' overall national policy, strategy and plan of actions status appears to be 'good'. The country has adequate number of the building blocks for a comprehensive IYCF strategy." *Id*., at "Section 4: IYCF PROFILES – Philippines", at p. 80.
488 *Id*., at Figure 9: Overall IYCF Comprehensive actions score, p. 47.
489 *Id*.
490 *Id*., at Figure 2: Health service IYCF actions score, p. 22.
491 *Id*., at p. 16.
492 *Id*., at p. 21. "The low rate of certification, in particular recertification, highlights the difficulty of rapidly scaling up the BFHI in the traditional vertical manner and of sustaining the intervention." Id., at p. 20. *See also* "Section 4: IYCF PROFILES – Philippines", at p. 80.
493 *Id*., at p. 16. "Almost all of the countries that responded (43) had an IYCF stand-alone counseling training in-country during 2006-2009. *Very few countries monitored health workers skills routinely or monitored the quality of counseling taking place within the health service level*" (emphasis added). *Id*., at p. 21.
494 *Id*., at fn# 4. The Philippines scored "fair" in "Baby-friendly hospital initiative", "poor" in "IYCF health pre- and in-service training curricula" and "IYCF health service counseling", and "good" in "IYCF health workers capacity Development". For this reason, it scored "fair" in "Overall IYCF health system level actions score." *Id*., at "Section 4: IYCF PROFILES – Philippines", at p. 80.
495 *Id*., at Figure 3: Community level IYCF actions score, p. 26.
496 *Id*., at p. 23. The Philippines scored "poor" in "IYCF community system integration" and "Community monitoring and evaluation", and "fair" in "IYCF community health workers capacity development." For these reasons, it scored "poor" in "Overall IYCF community system level actions score." *Id*., at "Section 4: IYCF PROFILES – Philippines", at p. 80.
497 "Quality counseling of mothers/caregivers and appropriate behavioural change and communication are essential for improving complementary feeding practices among children 6 to 24 months and beyond." *Id*., at p. 31.
498 *Id.*, at p. 32. The average complementary feeding component/interventions action score was 4. This score is ranked as 'fair' and is indicative that actions to strengthen complementary feeding through counseling to caregivers/mothers as well as provision of complementary food supplements are low across countries." *Id*.

The UNICEF report likely rated the Philippines "fair" (4/10)[499] in this subcategory because it also does not offer "social protection measures such as cash transfers or vouchers, and nutrition sensitive measures in the agriculture sector."[500]

The Philippines also scored much lower (3/10)[501] ("poor") in "communication on IYCF actions". UNICEF found that the Philippines does not employ an "effective communication strategy [which] uses a wide mix of channels appropriate to the identified participant groups, which may include interpersonal, group and mass media channels, as well as participatory methods and social marketing…[and]…a plan to implement communication activities at scale and on a continuous basis, rather than just focusing on a one-off event such as World Breastfeeding Week alone."[502] Although the Philippine national level IYCF communication strategy included World Breastfeeding Week, National campaigns and health days, it "did not indicate having ongoing behaviour change and communication activities at the community level."[503]

These multiple findings demonstrate, beyond a reasonable doubt, that the PHDOH's narrow focus on strictly implementing the BMS Framework is misplaced, and that the PHDOH must take numerous steps, above and beyond that framework, in order to promote higher breastfeeding rates in the Philippines for purposes of protecting public health. And, the WHO seems to agree.

During 2012, the WHO emphasized that, in addition to effectively implementing the WHO Code and WHA resolutions, "[n]ecessary actions…to ensure breastfeeding is adequately promoted, protected and supported…include revitalizing the *Baby-Friendly Hospital Initiative*…extending maternity leave…[and helping w]omen before, during and after pregnancy…to correct inappropriate nutrition that leads to low birth weight[504] and stunting,[505] as well as the growing problems of overweight[506] and diabetes."[507] It apparently recognized the widespread deficiencies in such countries' programs. Sadly, UNICEF and FAO data[508] support this WHO call for action. They reflect that the "Philippines has a stunting prevalence rate of 32% among children under 5 years of age; while 22% and 7% are

499 *Id*., at Figure 5: Complementary feeding components/interventions score, p. 33.
500 *Id*., at p. 31. The Philippines scored "poor" in "IYCF counseling of care-givers in relation to home preparation of complementary foods", and "fair" in "Provision of complementary food supplements." For this reason it scored "fair" in "Overall complementary feeding interventions." *Id*., at "Section 4: IYCF PROFILES – Philippines", at p. 81.
501 *Id*., at Figure 4: Communication on IYCF actions score, p. 30.
502 *Id*., at p. 27.
503 *Id*., at pp. 27, fn.7 and 28. While the Philippines scored "good" in "National IYCF behaviour change and communication," it scored "fair" in "IYCF behaviour change and communication channels", and "poor" in "Behaviour change and communication materials on IYCF" and "Monitoring and evaluating the effect of communication on behavior". For these reasons, it scored "poor" in "Overall national level communication on IYCF." *Id*., at "Section 4: IYCF PROFILES – Philippines", at p. 81.
504 "Low birthweight is defined as a weight of less than 2,500 grams at birth." *See* UNICEF, *Improving Child Nutrition: The Achievable Imperative for Global Progress* (April 2013), at p. 7, Box 2, available at: http://www.unicef.org/philippines/Nutrition_Report_final_lo_res_8_April(1).pdf
505 "Stunting reflects chronic undernutrition during the most critical periods of growth and development in early life. It is defined as the percentage of children aged 0 to 59 months whose height for age is below minus two standard deviations (moderate and severe stunting) and minus three standard deviations (severe stunting) from the median of the WHO Child Growth Standards." *Id*.
506 "Overweight is defined as the percentage of children aged 0 to 59 months whose weight for height is above two standard deviations (overweight and obese) or above three standard deviations (obese) from the median of the WHO Child Growth Standards." *Id*.
507 *See* World Health Organization, Regional Office for the Western Pacific 63rd Session, Regional Committee, Provisional Agenda Item 15 - *Nutrition*, WPR/RC63/10 (June 29, 2012), at p. 4, available at: http://www.wpro.who.int/about/regional_committee/63/documents/RC63_10_Item_15_Nutrition_FINAL.pdf.
508 *See* Food and Agriculture Organization, *Nutrition Country Profiles – Philippines* (2001), Executive Summary at p. 3, available at: ftp://ftp.fao.org/ag/agn/nutrition/ncp/phlmap.pdf.

underweight[509] and wasted,[510] respectively."[511] It is one of "[f]ive countries account[ing] for more than half of the global low birthweight burden".[512]

As a more recent UNICEF (2013) report explains, "[p]oor maternal nutrition impairs fetal development and contributes to low birthweight, subsequent stunting and other forms of undernutrition. After birth…inadequate breastfeeding practices such as non-exclusive breastfeeding[,] inappropriate complementary feeding, such as starting at the wrong age[,] and poor access to or use of diverse types of food and inadequate intake of micronutrients…can directly lead to poor growth."[513] According to the report, "[p]oor growth can be aggravated further by frequent incidence of infectious diseases like diarrhea, malaria or infestation with intestinal worms."[514] This report recommends the following three "optimal IYCF practices": 1) breastfeeding initiated within one hour of birth; 2) "exclusive breastfeeding for the first six [6] months of life"; and 3) "continued [partial] breastfeeding up to the age of 2 and beyond, together with safe, age-appropriate feeding of solid, semi-solid and soft food starting at 6 months of age."[515] The UNICEF report, furthermore, reveals that "[u]ndernourished girls have a greater likelihood of becoming undernourished mothers who in turn have a greater chance of giving birth to low birthweight babies, perpetuating an intergenerational cycle. This cycle can be compounded further in young mothers, especially adolescent girls who begin childbearing before attaining adequate growth and development."[516]

FAO data similarly document the extent of adult (pregnant women/unborn child), infant and young child protein-energy and micronutrient malnutrition in the Philippines. In general, the FAO found that approximately "4 million (31.8%) of the preschool population were…underweight-for-age, 3 million (19.8%) adolescents and 5 million (13.2%) adults, including older persons were found to be underweight and chronically energy deficient, respectively."[517] Furthermore, the FAO found that 7.1% of pregnant women and 8.2% of children 6 months to 5 years of age were micronutrient deficient. In particular, it found that 56.6% of infants, 45.7% of lactating women, and 49.1% of male older persons were iron-deficient.[518] The FAO report concluded that, while there appeared to be "enough food to feed the country, many Filipinos continue to go hungry and become malnourished *due to inadequate intake of food and nutrients*. In fact, except for protein, *the typical Filipino diet*

509 "Underweight is a composite form of undernutrition that includes elements of stunting and wasting. It is defined as the percentage of children aged 0 to 59 months whose weight for age is below minus two standard deviations (moderate and severe underweight) and minus three standard deviations (severe underweight) from the median of the WHO Child Growth Standards." *See* UNICEF, *Improving Child Nutrition: The Achievable Imperative for Global Progress* (April 2013), *supra* at p. 7, Box 2.
510 "Wasting reflects acute undernutrition. It is defined as the percentage of children aged 0 to 59 months whose weight for height is below minus two standard deviations (moderate and severe wasting) and minus three standard deviations (severe wasting) from the median of the WHO Child Growth Standards." *Id*.
511 *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), *supra* at "Section 4: IYCF PROFILES – Philippines", at p. 80.
512 *See* UNICEF, *Improving Child Nutrition: The Achievable Imperative for Global Progress* (April 2013), *supra* at p. 16, Fig.16. Approximately .5 million Filipino children suffer from low birthweight. *Id*. The Philippines ranks 9th in worldwide stunting worldwide and accounts for 2% of the world's stunting. *Id*., at "Nutrition Profiles – Philippines", at p. 92.
513 *Id*., at pp. 4-5.
514 *Id*., at p. 5.
515 *Id*., at p. 19.
516 *See* UNICEF, *Improving Child Nutrition: The Achievable Imperative for Global Progress* (April 2013), supra at p. 4.
517 *See* Food and Agriculture Organization, *Nutrition Country Profiles – Philippines* (2001), supra at Executive Summary at p. 3.
518 *Id*.

was found to be grossly inadequate for energy and other nutrients" (emphasis added).[519] These findings suggest that cultural and indigenous capacity factors may be responsible for this outcome. The degree of Filipino malnutrition was further elaborated upon in a recent study jointly authored by representatives of the FAO's Nutrition and Consumer Protection Division, the Philippine Department of Science and Technology's Food and Nutrition Research Institute, the Division of Human Nutrition at Wageningen University in the Netherlands, and the Department of Agricultural Economics at the University of Florence in Italy.[520]

Two more recent Philippine Government-sponsored reports also confirm how malnutrition has continued to plague Filipino children aged 0-5 years. One report documented the significant increase in the proportion of underweight children aged 0-5 years (20.2% to 20.7%) from 2005-2008.[521] The second report reemphasized "the need for the government to be pro-active in addressing the pressing problem on young child malnutrition",[522] considering that, as of 2011, 33.6% of Filipino children 0-5 years were stunted, 20.2% were underweight and 7.3% were wasting.[523]

Apparently, the serious problem of malnutrition in the Philippines is partly attributable to the lack of diversity in the typical diet of Filipino children and adults which, in turn, is partly attributable to the country's "low raw material base of agriculture and fishery" and its low crop productivity. This has adversely "affected the performance of…agri-food manufacturing industries," such as coconut and fruit processing.[524] According to agricultural experts, "[t]here are several culprits for raw material shortages…[including]…the low productivity of such crops…[and] the limited variety of raw materials such as fruits."[525] The Philippine Food Processors and Exporters Organization Inc. has expressed concern that "the continued scarcity of supply of essential raw materials…[w]as directly hampering the export performance of the sector", and that "[t]he country's productivity of many agricultural crops registered yields below global average."[526] Other experts have observed how "[t]he country's low agricultural productivity has raised policy concerns in view of the country's

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519 *Id*.

520 *See* Gina L. Kennedy, Maria Regina Pedro, Chiara Seghieri, Guy Nantel, and Inge Brouwer, *Dietary Diversity Score Is a Useful Indicator of Micronutrient Intake in Non-Breast-Feeding Filipino Children*, Journal of Nutrition (2007), pp. 472-477, available at: http://jn.nutrition.org/content/137/2/472.full.pdf+html. "In the Philippines, 40% of children 6 mo–5 y of age have low or deficient serum retinol levels and 29% of children 1–5 y of age are anemic. The prevalence of low serum retinol and anemia in Filipino children has increased over the past decade. The increase in low serum retinol has occurred despite Department of Health biannual vitamin A capsule supplementation program for young children, most probably as a result of low coverage and poor compliance with biannual doses. *The continuing high prevalence of anemia is attributed to low birth weight, low dietary iron intake, and helminth infections*" (emphasis added). *Id*., at p. 472.

521 *See* Clarita R. Magsadia, Julieta B. Dorado, Rowena V. Viajar, Glenda P. Azana, Chona F. Patalen, and Georgina S. Caraig, *The Effect FNRI Complementary Foods on the Nutritional Status of 6-35 Month Old Children*, Republic of the Philippines, Department Food and Nutrition Research Institute, 38th FNRI Seminar Series Abstracts (2011), at p. 1, available at: http://www.fnri.dost.gov.ph/images/stories/FSS/38thFSS/fnri%20complementary_foods.pdf. (reporting that "[t]he feeding of FNRI-developed complementary foods could contribute in the improvement of the nutritional status of 6-35 months old children after…120 days of feeding intervention") *Id*.

522 *See* Julieta B. Dorado, Rowena V. Viajar, Chona F. Patalen, Emily O. Rongavilla, and Clarita R. Magsadia, *Policy Translation and Advocacy on the Production and Consumption of Complementary Foods*, Republic of the Philippines, Department Food and Nutrition Research Institute (2011) at p. 7, available at: http://www.fnri.dost.gov.ph/images/stories/FSS/38thFSS/policy%20translation_advocacy.pdf.

523 *Id*., at p. 4.

524 *See* Rolando T. Dy, *The Achilles' Heel in Philippine Agri-manufacturing*, Inquirer Business (June 3, 2013), available at: http://business.inquirer.net/124929/the-achilles-heel-in-philippine-agri-manufacturing.

525 *Id*. "By comparison, "Thailand, a leading fruit packer, has a wide variety of raw materials: pineapple, mango, guava, tamarind, longan, lychee, durian, custard apple, rambutan, jackfruit, among others." *Id*.

526 *See* Elisa P. Osorio, *Low Agri Exports Traced to Declining Productivity*, The Philippine Star (Feb. 20, 2012), available at: http://www.philstar.com/business/778931/low-agri-exports-traced-declining-productivity.

growing population, worsening malnutrition, dependence on rice imports, and the widening agricultural trade imbalance."[527] Malnutrition in the Philippines is only made worse by Filipinos' "significant price sensitivity" to food products, which has resulted in other ASEAN nations with food quality and safety problems of their own exporting "large volumes of low price products such as fruit (particularly from China[528]), vegetables, processed foods and dry goods."[529] This makes it more difficult for the PH BMS Framework to protect the health of young children older than 6 months, pregnant women, unborn fetuses and ultimately newborn infants who consume local foods as well as foods imported from such countries as a complement to partial breastfeeding.

No doubt, more needs to be done to further promote breastfeeding. As of 2011, approximately 54% of Filipino infants had initiated early breastfeeding,[530] approximately 34% of Filipino infants were exclusively breastfed greater than 6 (0-5) months,[531] approximately 34% of young Filipino children continued partial breastfeeding until 20 - 23 months, and approximately 58% of children 6 to 9 months are breastfed with complementary food.[532] The PHDOH deserves credit for having established and operated creative programs like the State-run breast milk banks, which are "intensifying collection efforts to boost breastfeeding among poor people and [to] help women

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527 *See* Corazon T. Aragon, Artemio M. Salazar, Antonio Jesus A. Quilloy, and Gideon P. Carnaje, *Policy Issues and Directions for Increasing Agricultural Productivity in the Philippines* (Policy Paper 2), College of Economics and Management, University of the Philippines Los Baños (2013), Abstract available at: http://cem.uplb.edu.ph/index.php/research-extension-training/policypapers/40-policypaperseries1/75-policypaper2#. *See also* Roehlano M. Briones, Francis Quimba, Jonathan B. Bungcayao, Joseph B. Paglingayen, Ivee Libunao and Myrna B. Asuncion, *Realizing the Millennium Development Goals Through Socially Inclusive Macroeconomic Policies: Assessing Development Strategies to Achieve the MDGs in The Republic of the Philippines*, United Nations Department for Social and Economic Affairs (ECOSOC) (March 2011), available at: http://www.un.org/en/development/desa/policy/capacity/output_studies/roa87_study_phi.pdf. ("The government's anti-poverty strategy must focus on agriculture and rural development through asset reforms and (agrarian reform, urban land reform and ancestral domain reform) and investments in productivity improvements and supporting infrastructure, particularly for agriculture.") *Id*., at p. 17.

528 *See, e.g.*, European Commission, Increased Checks on Import of Food of Non-Animal Origin – Overview 2012 (7/29/13), available at: http://ec.europa.eu/food/food/controls/increased_checks/docs/results_ms_border_controls_2012_en.pdf. (EU Member State border authorities documented that approximately 4% of dried noodles imported into the European Union from China tested positive for aluminum, while approximately 62.5% of broccoli, 11.9% of tea leaves, and 9.1% of pomelos imported into the European Union from China tested positive for pesticide residues). *Id.*, at pp. 11, 13-14; Phuc Hau, Fruit Batches from China Found with Harmful Chemicals, Saigon-GP Daily (Sept. 20, 2012), available at: http://www.saigon-gpdaily.com.vn/Health/2012/9/102781/. ("The Ministry of Agriculture and Rural Development announced at a recent meeting that after checking fruits batches imported from China between August 10 and September 10, authorities discovered that fresh plums and pomegranates contained carbendazim and tubeconazole, and fresh grapes contained difenoconazole") *Id*.; Cheung Chi-fai, *Fruit Dumped in Challenge to Food Safety Tests*, South China Morning Post, (Aug. 11, 2012), available at: http://www.scmp.com/article/579342/fruit-dumped-challenge-food-safety-tests. ("Greenpeace activists yesterday dumped hundreds of mainland tangerines and strawberries outside the Centre for Food Safety after they found excessive amounts of pesticides in five samples. The activists cast doubts on the results of the centre's tests last month, which found about 350 fruit samples taken at both retail and wholesale level did not contain excessive amounts of pesticides. The group said its results exposed flaws in the food surveillance system"). *Id*; Jonathan Watts, *Exploding Watermelons Put Spotlight on Chinese Farming Practices*, The Guardian (May 17, 2011), available at: http://www.theguardian.com/world/2011/may/17/exploding-watermelons-chinese-farming. ("Fields of watermelons exploded when he and other agricultural workers in eastern China mistakenly applied forchlorfenuron, a growth accelerator. The incident has become a focus of a Chinese media drive to expose the lax farming practices, shortcuts and excessive use of fertiliser behind a rash of food safety scandals. It follows discoveries of the heavy metal cadmium in rice, toxic melamine in milk, arsenic in soy sauce, bleach in mushrooms, and the detergent borax in pork, added to make it resemble beef"). *Id*.

529 *See* The State of Victoria Department of Primary Industries, *Future Farming: Analysis of the Food Sector in Philippines - Opportunities for Victorian Exporters* (June 2009), at p. 6, available at: http://www.dpi.vic.gov.au/__data/assets/pdf_file/0019/32626/Analysis-of-the-Food-Sector-in-Philippines-Opportunities-for-Victorian-Exporters.pdf.

530 *Id*., at p. 93; *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), *supra* at "Section 4: IYCF PROFILES – Philippines", at p. 80.

531 *See* UNICEF, *Improving Child Nutrition: The Achievable Imperative for Global Progress* (April 2013), *supra* at 20, Fig. 22.

532 *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), *supra* at "Section 4: IYCF PROFILES – Philippines", at p. 80; UNICEF New York, *Infant and Young Child Feeding Programme Review - Consolidated Report of Six-Country Review of Breastfeeding Programmes* (April 2010), *supra* at *Appendix B. IYCF Indicators – Trend Data from the Six Case Study Countries*, p. 68.

return to work immediately after giving birth if they want to."[533] According to Esmeraldo Ilem…head of the…family planning unit [of]…Jose Fabella Memorial hospital, the busiest maternity institution in Manila…'Human milk or breast milk is the best way to make babies healthy in the early stages of life…Sadly…there are many mothers who need to go back to work or do not lactate very well, so this is where our milk comes in.'"[534] As of February 2012, the Dr. Jose Fabella Memorial Hospital (DJFMH) was one of only "three milk banks in the whole of Metro Manila where lactating mothers can donate their milk."[535] The other two were "the Philippine Children's Medical Center (PCMC) and the Philippine General Hospital (PGH).[536] In March 2013, Makati City located within metropolitan Manila opened a PHDOH-approved human milk bank located at the Bangkal Health Center that is operated by "personnel trained under PCMC…a [PH]DOH-accredited training institution on the management and operation of human milk banks."[537] More recently, in August 2013, Quezon City within the Manila metropolis announced the opening of its first breast milk bank. The milk bank will be operated by the city-owned Quezon City General Hospital, pursuant to the ordinance approved by the city council last year, which "seeks the creation of human milk banks in all local government hospitals offering pediatric care."[538]

These accomplishments notwithstanding, the PHDOH appears to have bitten off more than it can chew. The PH BMS Framework has endeavored to incorporate both the WHO Code and the WHO IYCF Strategy in an effort to protect the health of both infants and young children via protection of breastfeeding. Given the recognized benefits of exclusive breastfeeding during the first 6 months of life, the PH BMS Framework's restrictions on the advertising/marketing and labeling of infant formula and follow-up formula intended for infants 0-6 months of age as a breastmilk substitute/replacement could likely achieve that policy objective by protecting infant health via exclusive breastfeeding. Substantial uncertainty remains surrounding the benefits and the likely risks of extending exclusive breastfeeding beyond 6 months, contrary to the WHO recommendation to commence complementary feedings at such time. Therefore, it is unlikely that the PH BMS Framework's restrictions on the advertising/marketing and labeling of follow-up formula intended as bona fide breastmilk *supplements* to complement the partial breastfeeding of infants and young children older than 6-12 months of age will be capable of protecting infant and young children's health by protecting exclusive breastfeeding.

In other words, the following factors make it less likely that the PH BMS Framework's restrictions on the advertising/marketing and labeling of follow-up formula and complementary foods will be able to achieve its objective of protecting the health of infants and young children by protecting exclusive and/or partial breastfeeding: 1) the extremely low agricultural productivity and diary production and the lack of other raw materials such as fresh fruits in the Philippines; 2) the high volume of inexpensive low quality food imports from China; 3) the lack of essential nutrients

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533 *See* IRIN - UN Office for the Coordination of Humanitarian Affairs, *Philippines Banks Breast Milk to Boost Breastfeeding Among Poor People* (Aug. 13, 2012), available at: http://www.irinnews.org/report/96089/philippines-banking-breast-milk-to-save-lives..
534 *Id*.
535 *See* Rem Zamora, *Mothers Know Breast*, ABS-CBNNEWS.COM (2/3/12), available at: http://www.abs-cbnnews.com/lifestyle/02/03/12/slideshow-mothers-know-breast.
536 *Id*.
537 *See* Mike Frialde, *Makati Opens Human Milk Bank*, The Philippine Star (March 4, 2013), available at: http://www.philstar.com/health-and-family/2013/03/04/915719/makati-opens-human-milk-bank.
538 *See* Janvic Mateo, *QC to Set Up Breast Milk Bank*, The Philippine Star (Aug. 10, 2013), available at: http://www.philstar.com/headlines/2013/08/10/1072611/qc-set-breast-milk-bank.

contained in partial breastfeedings beyond 6-12 months; and 4) extensive lawmaker corruption that has blocked the use of earmarked funds for improvement of the healthcare system, particularly to fight child malnutrition.[539] It is also more likely than not that these factors will render the PH BMS Framework unable to significantly contribute to the protection of pregnant women's health which is critical, if not indispensable to ensure the health of the unborn fetus, and the newborn infant.

B. Achievement of the PH BMS Framework Consumer Protection Objective of Preventing Misleading and Confusing Advertising and Labeling is Uncertain

As stated above, to the extent the PH BMS Framework exceeds the WHO Code by restricting and/or prohibiting the advertising and labeling of (and use of trademarks related to) bona fide breastmilk *supplement* products marketed or intended for young children *older than 6-12 months of age* as a complement *to partial breastfeeding*, it is more trade-restrictive than necessary to achieve its policy objectives.

The PHDOH, UNICEF/WHO and breastfeeding activists have alleged that two of their main concerns are that formula companies are employing advertising and labeling to deceive Filipino consumers: 1) by indirectly equating their breastmilk substitute product offerings with breastfeeding;[540] and 2) by indirectly "passing-off" their follow-up formula breastmilk supplement offerings appropriate for infants and young children older than 6-12 months of age as infant formula breastmilk substitute offerings appropriate, in limited circumstances, for infants younger than 6 months of age.[541] The extent to which the PH BMS Framework is capable of addressing these concerns, however, remains highly uncertain. In particular, it is questionable whether the PH BMS Framework is capable of preventing deceptive advertising and labeling by ensuring: 1) that breastmilk supplement products perform as claimed in advertising and labeling, where all health and nutrition claims have been prohibited; and 2) that breastmilk supplement (follow-up formula) products are not advertised or

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539 *See* Anne Marxe D. Umil, *What Change? Child Rights Advocates Lament Ailing Health of Filipino Children*, Bulatat.com (Aug. 15, 2013), available at: http://bulatlat.com/main/2013/08/15/what-change-child-rights-advocates-lament-ailing-health-of-filipino-children/. ("In the midst of scandals about billions worth of pork barrel funds involving lawmakers and 'fake' non-government organizations, more children continue to suffer from malnutrition and deteriorating health. 'We are enraged over the alleged corruption in the use of pork barrel funds, which could have been allocated to social services,' said Kharlo Felipe Manano, acting secretary general of Salinlahi Alliance of Children's Concerns. Salinlahi is an alliance of organizations advocating for children's rights in the Philippines. He added, 'Cases of misappropriation of funds and corruption are very alarming especially in the context of the diminishing government budget for health. The more than P10 billion ($229 million) that was allegedly scammed could have been put to good use by improving the health care system.'") *Id*.

540 *See, e.g.,*Tereasa Cerojano, *Study: Infant Formula Ads Reduce Breast-feeding*, Associated Press (Nov. 2, 2011), available at: http://www.utsandiego.com/news/2011/nov/02/study-infant-formula-ads-reduce-breast-feeding/all/?print. This not unbiased unscientific "household survey" was conducted by six authors, four of whom were WHO employees "led by the organization's medical officer Howard Sobel". *Id*. It concluded that "59.1 percent of the [Filipino] mothers [surveyed] recalled an infant formula advertisement message and one-sixth reported a doctor recommended using formula. Those who recalled an ad message were twice as likely to feed their babies infant formula, while those advised by a doctor where four times as likely to do so." *Id*. *See also* Howard L. Sobel, Alessandro Iellamoa, René R. Rayab, Alexander A. Padillac, Jean-Marc Olivéa, and Soe Nyunt-U, *Is Unimpeded Marketing for Breast Milk Substitutes Responsible for the Decline in Breastfeeding in the Philippines? An Exploratory Survey and Focus Group Analysis*, Social Science & Medicine 73 (2011) at pp. 1445e-1448, available at: http://www2.wpro.who.int/NR/rdonlyres/283E8865-F3DB-453B-B265-5A50399B4E12/0/InfantFormulaMarketingPHL_SocialScienceandMedicine.pdf.

541 *See* World Health Organization, *Information Concerning the Use and Marketing of Follow-up Formula* (July 17, 2013), available at: http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf. "Even though follow-up formula is not necessary, and is unsuitable when used as a breast milk replacement, it is marketed in a way that may cause confusion and have a negative impact on breastfeeding A number of studies strongly suggest a direct correlation between marketing strategies for follow-up formulae, and perception and subsequent use of these products as breast-milk substitutes. In many instances, the packaging, branding and labelling of follow-up formula closely resembles that of infant formula. This leads to confusion as to the purpose of the product, i.e. a perception that follow-up formula is a breast-milk substitute. This may result in its early introduction, thereby undermining exclusive breastfeeding up to six months of age and sustained breastfeeding up to two years or beyond." *Id*., at p. 2.

labeled in a false or misleading manner to give the impression they are (i.e., being "passed-off as") breastmilk substitute (infant formula) products, especially where very few PH BMS Framework provisions actually address the issue of consumer confusion regarding such products.

To recall, RIRR, Rule VI Section 17, Circular 2008-0006, Items V.6-7, and AO 2012-0027, Section 20.a prohibit all breastmilk substitute and breastmilk supplement health and nutrition claims, except those relating to special dietary needs or special medical purposes, based on the presumption they are potentially misleading. By banning all health and nutrition claims on the basis of national breastfeeding protection policy, the PHDOH has effectively assumed all decision making for the Filipino people with respect to such products, and prevented Filipino consumers from gaining an education about such products, thereby denying them their consumer right-to-information.[542] That right includes the right to know about how such products should perform in health and nutrition terms for purposes of identifying false claims and making purchasing decisions.

Circular 2008-0006 only minimally addresses the issue of consumer confusion and the potential passing-off of follow-up formula as infant formula. For example, Circular 2008-0006 Item VI.A.1(i) requires that formula manufacturers designate different products with different product category names in addition to the specific product brand names in order to ensure against such confusion. Infant formula products are to be designated on a label's principal display panel as "Infant Formula", Formula for Special Medical Purposes as "Formula for Special Medical Purposes Intended for Infants", Follow-up Formula as "Milk Supplement".[543] Circular 2008-0006, Item VI.B.9 requires that each container/label's information display panel contain the following messages which do little, if anything to distinguish Infant Formula from Follow-up Formula (Milk Supplements): "The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional"; "The unnecessary and improper use of this product may be dangerous to your child's health".[544]

Similarly, AO 2012-0027 only minimally addresses this issue. For example, AO 2012-0027, Section 21.B.a provides that the primary advertising messages of Milk Supplements must state the following: "The use of milk supplements must only be upon the advice of health professional"; "The unnecessary and improper use of this product may be dangerous to your child's health".[545] AO 2012-0027, Section 21.C provides that the message for advertisements *and labels* of complementary food should state in bold letters: "THIS PRODUCT IS NOT INTENDED FOR BABIES 6 MONTHS OF AGE AND BELOW".[546]

Therefore, the degree to which the PH BMS Framework is capable of achieving its objective of preventing deceptive advertising and labeling practices, especially those which can lead to consumer confusion between follow-up formula and infant formula products, is highly uncertain.

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542 *See*, Republic of the Philippines Department of Trade and Industry, Consumer Welfare and Business Regulation - Consumer Rights, *The Eight Basic Consumer Rights*, available at: http://www.dti.gov.ph/dti/index.php?p=720. The right to information "is the right to be protected against dishonest or misleading advertising or labelling and the right to be given the facts and information needed to make an informed choice." *Id*. See also *Knowledge is Power*, The Manila Times (July 21, 2013), available at: http://www.manilatimes.net/knowledge-is-power/21318.
543 Circular 2008-0006, Item VI.A.1(i).
544 *Id*., at Item VI.B.9(i)-(ii).
545 AO 2012-0027, Sec. 21.B.a.
546 *Id*., at Sec. 21C.

v. Comparing the PH BMS Framework to Readily Available Less Trade-Restrictive Alternatives

Assuming arguendo, that the PH BMS Framework sufficiently contributes to the achievement of its objectives (of promoting public health by promoting breastfeeding and preventing deceptive breastmilk substitute and breastmilk supplement product advertising and labeling practices that mislead or confuse consumers and undermine breastfeeding), it is necessary to consider the availability of less trade-restrictive alternatives.

A. Asia Region BMS Frameworks Are Not Less Trade-Restrictive or Capable of Fulfilling PH BMS Objectives

A comparison of the Philippine BMS Framework with the WHO Code-implementing measures enacted/adopted by other developing countries in Southeast Asia, such as Cambodia, Indonesia, Malaysia, Thailand and Vietnam, reveals a varied collection of laws and a disparate pattern of implementation due to divergent institutional capacities and incapacities resulting in widespread poverty and malnutrition in each of these countries. UNICEF data characterize the Philippines along with Cambodia, Indonesia and Vietnam as 4 of 47 countries that "have enacted legislation or other legal measures encompassing many of the provisions of the International [WHO] Code."[547] The U.S. Central Intelligence Agency ("CIA") ranks the Philippines most closely to Indonesia and Vietnam in terms of national GDP purchasing power and GDP per capita,[548] as do UNICEF ICYF data,[549] with the Philippines and Vietnam having the most extensive and far-reaching ICYF policies and laws that they each have difficulties implementing.

Notwithstanding these similarities, however, there are several reasons why it would not be appropriate to look to Vietnam and Indonesia as potential comparatives against which to measure the availability of a less trade-restrictive alternative to the PH BMS Framework.

First, Vietnam Decree No: 21/2006/ND-CP - *On the Trading In and Use of Nutritious Products for Infants*[550] actually imposes more stringent prohibitions and restrictions on the advertising of breastmilk substitute and breastmilk supplement products than does the PH BMS Framework. For example, Article 2.3 of Vietnam Decree No: 21/2006/ND-CP - *On the Trading In and Use of*

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

548 The CIA World Factbook ranks the Philippines, Indonesia and Vietnam, respectively, 32nd, 16th and 42nd in terms of GDP overall, and 165th, 158th and 170th, respectively, in terms of GDP per capita. *See* Central Intelligence Agency, *The World Factbook*, Country Comparison: GDP (Purchasing Power Parity), available at: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html; Central Intelligence Agency, *The World Factbook*, Country Comparison: GDP Per Capita (PPP), available at: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2004rank.html. The CIA World Factbook ranks Cambodia, Malaysia and Thailand, respectively, 108th, 30th and 25th in terms of GDP overall, and 187th, 78th and 116th, respectively, in terms of GDP per capita. *Id.*

549 UNICEF's recent assessment of country comprehensive infant and young child feeding programs ranks the Philippines closest to Vietnam in terms of national level policy and legislation (9/10 for each), and community level IYCF actions (3/10 for the Philippines and 5/10 for Vietnam). The Philippines was ranked closest to Cambodia, Thailand and Vietnam in terms of IYCF in difficult circumstances (5/10 for the Philippines and 5/10 for Cambodia, Thailand and Vietnam). Otherwise, the Philippines was ranked closest to Indonesia in health services (4/10 for each), communication on IYCF actions (3/10 for each), complementary feeding (4/10 for each), and WHO Code compliance monitoring (4/10 for each). *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), *supra*, at Table 3: IYCF Comprehensive Action Score (All countries), at p. 46.

550 *See* Socialist Republic of Vietnam, The Prime Minister of Government *No: 21/2006/ND-CP, Decree On the Trading In and Use of Nutritious Products for Infants* (Feb. 27, 2006), available at: http://moj.gov.vn/vbpq/en/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=5898.

Nutritious Products for Infants defines the term "infant", contrary to WHO and Codex standards as "children who are from newborn to 24 months old."[551] Pursuant thereto, Article 6 "strictly *prohibit[s]* the advertisement *for milk for under-12 month infants [and] food for under-6 month infants*," (emphasis added)[552] while permitting the "advertisement for milk for infants aged between 12 months and 24 months", subject to certain restrictions,[553] including the submission of advertisement dossiers to the Ministry of Health for review and approval.[554] By comparison, the PH BMS Framework does not outright prohibit advertisements of breastmilk substitute and breastmilk supplement products intended for infants and young children 0-24 months of age. Rather, it requires the submission of advertisement proposals for all such products to the IAC/IAC Secretariat for review and approval.[555] Meanwhile, Articles 10.2(c) and 12.2(a) of Vietnam Decree No. 21 impose relatively lesser restrictions than does the PH BMS Framework on the use of images[556] and trademarks and logos on product labels.[557]

Second, Indonesia's laws on exclusive breastfeeding, while less numerous, are also more stringent in some respects than those of the Philippines. For example, Article 19(e) of Government Regulation GR No. 33/2012,[558] implementing Article 129(2) of Health Law No. 36/2009,[559] prohibits outright "[t]he advertisement of baby formula milk published in mass media, both printed and electronic, and outdoor media," permitting advertising only "in the special printed media on health."[560]

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551 *Id., at* Art. 2.3.
552 *Id.,* at Art. 6.1.
553 *Id*., at Articles 6.2, 4-5.
554 *Id*., at Art. 6.3. *See also* Socialist Republic of Vietnam, The Ministry of Public Health – The Ministry of Trade – The Ministry of Culture and Information – The Committee for Population, Family and Children, *No: 10/2006/TTLT/BYT-BTM-BVHTT-UBDSGDTE, Joint Circular Guiding the Implementation of the Government's Decree no. 21/2006/ND-CP of February 27, 2006, On Trading In and Use of Nutritious Products For Babies* (Aug. 25, 2006), at Sec. III, available at: http://moj.gov.vn/vbpq/en/Lists/Vn%20bn%20php%20lut/View_Detail.aspx?ItemID=5024. In a report apparently prepared in cooperation with UNICEF, activist NGO Alive & Thrive has criticized Decree No. 21 for permitting any advertising for formula products intended for children 12-24 months old, claiming that is inconsistent with the WHO Code, which is INCORRECT. *See* Institute of Social and Medical Studies, *Executive Summary: A Review of the Status of Implementation of Decree 21 and the International Code of Marketing of Breastmilk Substitutes in Vietnam* (July 2011), available at: http://isms.org.vn/img/userfiles/files/Review_Implementation_Decree_21_Exec_Summary.pdf. "Advertising: Decree 21 allows for advertising of milk products for children from 12 to 24 months of age, with some restrictions. *This provision is not in line with the International Code*, which states that there should be no advertising of products within the scope of the Code. This provision is also at odds with the internationally recognized recommendation that breastfeeding to be maintained for up to 24 months or beyond" (emphasis added). *Id*., at p. 3.
555 *See* discussion *supra*.
556 "Although extensive, the Decree's provisions on the labeling of nutrition products for young children do not fully meet the minimum requirements set by the International Code…[O]nly images or photos of infants less than 12 months old are prohibited under Decree 21. This age limit makes it more difficult to determine true violations of the Decree and creates a potential loophole for companies. *This weakness is also found within the International Code*" (emphasis added). *See* Institute of Social and Medical Studies, *Executive Summary: A Review of the Status of Implementation of Decree 21 and the International Code of Marketing of Breastmilk Substitutes in Vietnam*, supra at p. 4.
557 Article 10.2(c) of Vietnam Decree No. 21 effectively provides that formula manufacturers and distributors may not provide to physicians or health workers at healthcare facilities milk samples intended for under-12 month-old infants or food samples intended for under-6-month old infants that display product names or logos. Article 12.2(a) of Vietnam Decree No. 21 provides that physicians and health workers in healthcare facilities may not receive or distribute milk samples intended for under-12 month-old infants and food samples intended for under-6 month-old infants that display product names or logos.
558 *See* Raymond Hutagaol, *Exclusive Breastfeeding – Indonesia*, Leks & Co. (June 2012), available at: http://www.lekslawyer.com/?option=com_content&view=article&id=125:indonesia-law-making-system&catid=38:berita&Itemid=49; http://www.hg.org/article.asp?id=27043. This article indicates the implementation regulation was enacted on March 1, 2012.
559 Article 128(1) of Health Law No. 36/2009, issued on October 13, 2009, ensures that "[e]very child has the right to receive breast milk exclusively from birth for a minimum of 6 (six) months, unless there is a medical indication to the contrary", violation of which Articles 201(1)-(2) subjects to monetary fines, terms of imprisonment and/or revocation of business permits and legal entity status. Article 129(2) of Health Law No. 36/2009 provides that, "Further provisions as referred to in paragraph (1) shall be governed by Government Regulations." *See* Asosiasi Ibu Menyusui Indonesia (AIMI) and Better Work Indonesia, *Law and Regulations on Breastfeeding* (1/13/13) at pp. 2-3, available at: http://betterwork.org/indonesia/wp-content/uploads/20130113_Law-and-Regulation-on-Breastfeeding_English.pdf.
560 *See* Raymond Hutagaol, *Exclusive Breastfeeding – Indonesia*, supra.

Third, while the WHO Code-implementing laws and policies of Indonesia and Vietnam may appear relatively robust, UNICEF and activist NGOs have deemed their implementation by governmental health authorities as less than adequate to address reduced breastfeeding rates and infant and young child malnutrition. According to UNICEF's ICYF data metrics, Vietnam ranked (6/10) overall, only one level above the Philippines (5/10), and Indonesia ranked (3/10) overall, two levels below the Philippines.[561] These rankings roughly correspond to the relative percentages of children 0-5 years of age in each of these three countries who unfortunately continue to suffer from stunting because of ongoing poor governmental implementation of such policy and legislative initiatives and other institutional capacity limitations.[562]

With these shortcomings in mind, it may be more appropriate to consider the mandatory infant formula and follow-on formula regulatory framework of the United Kingdom/England ("the UK BMS Framework") as a readily available less trade-restrictive alternative to the PH BMS Framework. The UK BMS Framework is currently expressed as a national implementation of the regionally applicable regional regulatory framework of the European Union.

B. The UK BMS Framework Offers a Readily Available Less Trade-Restrictive Alternative to the PH BMS Framework

The UK Breastmilk Substitute/Breastmilk Supplement ("BMS") Framework consists of several legal instruments and related guidance documents. The primary statutory instrument is the *Infant Formula and Follow-on Formula (England) Regulations 2007* ("Statutory Instrument ('SI') 2007/3521"),[563] which revoked[564] the *Infant Formula and Follow-on Formula Regulations 1995* ("Statutory Instrument ('SI') 1995/77").[565] In addition, two subsequent statutory instruments amended SI 2007/3521 - the *Infant Formula and Follow-on*[566]*Formula (England) (Amendment)*

561 UNICEF ranked Indonesia in terms of national level policy and legislation (2/10), community level IYCF actions (0/10), IYCF in difficult circumstances (3/10), health services (4/10), communication on IYCF actions (3/10), complementary feeding (4/10), and WHO Code compliance monitoring (4/10). *See* UNICEF, *Infant and Young Child Feeding Programming Status: Results of 2010 - 2011 Assessment of Key Actions for Comprehensive Infant and Young Child Feeding Programmes in 65 Countries* (April 2012), *supra*, at Table 3: IYCF Comprehensive Action Score (All countries), at p. 46.

562 Pursuant to data compiled by UNICEF and the MDG Fund, 34%, 36% and 37%, respectively, of the 0-5 year olds in the Philippines, Vietnam and Indonesia suffered from stunting during the period 2003-2008, while 32%, 31% and 37%, respectively, of the 0-5 year olds in the Philippines, Vietnam and Indonesia suffered from stunting during the period from 2006-2010. *Id*., at pp. 66 and 80. *See also* UNICEF, *Tracking Progress on Child and Maternal Nutrition: A Survival and Development Priority* (Nov. 2009), at p. 10, available at: http://www.childinfo.org/files/Tracking_Progress_on_Child_and_Maternal_Nutrition_EN.pdf; MDG-F Achievement Fund, *Children, Food, Security and Nutrition: Review of MDG-F Joint Programmes, Key Findings and Achievements*, MDG-F Thematic Studies (2013), at Table 1 – MDG-F CFSN Country Indicators at p. 15, available at: http://www.mdgfund.org/sites/default/files/Nutrition_Thematic%20Study.pdf.

563 *See* Government of the United Kingdom, *Statutory Instrument 2007 No. 3521 - The Infant Formula and Follow-on Formula (England) Regulations 2007* (Jan. 11, 2008), at Regulation 21, available at: http://www.legislation.gov.uk/uksi/2007/3521/pdfs/uksi_20073521_en.pdf. SI 2007/3521 applies "in relation to England only." *Id*., at Explanatory Note, par. 1, p. 13.

564 "These regulations revoke the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77) in so far as they apply in relation to England." *Id*., at Explanatory Note, par. 3(gg), p. 14.

565 *See* Government of the United Kingdom, *Statutory Instrument 1995 No. 77 - The Infant Formula and Follow–on Formula Regulations 1995* (March 1, 1995), available at: http://www.legislation.gov.uk/uksi/1995/77/made.

566 The terms "follow-up formula and "follow-on formula are used interchangeably from this point on. According to the USFDA, "[f]ollow-up or follow-on formulas are iron-fortified, cow milk-based or isolated soy protein-based products intended for use by older infants (>6 months) and toddlers consuming solid foods. These formulas are marketed in powdered, liquid concentrate, and liquid ready-to-feed forms." *See* U.S. Food & Drug Administration, *Current Marketing and Use of Powdered Infant Formula in the United States* (2003), at p. 3, available at: http://www.fda.gov/ohrms/dockets/ac/03/briefing/3939b1_tab4c_coversheet.pdf.

Regulations 2008 ("Statutory Instrument ('SI') 2008/2445)")[567] which amended SI 2007/3521 to cover the presentation as well as the labeling and advertising of infant formula and follow-up formula products,[568] and the *Transfer of Functions (Food) Regulations 2011* (Statutory Instrument ('SI') 2011/3012)"), which shifted legal responsibility for implementation of SI 2007/3521, as amended, from the UK Food Standards Agency to the UK Department of Health via the UK Secretary of State for Health.[569] All three of these statutory instruments implement the UK Food Safety Act of 1990, as amended,[570] in part, and EU regulations, in part. The UK BMS Framework also consists of UKDOH Guidance Notes discussed below which, though not legally binding, contain quite persuasive and helpful information to assist in the implementation of these statutory instruments.

I. Infant Formula Marketing Rules

In general, SI 2007/3521, as amended, limits infant formula advertising to only scientific and trade publications, provided the labeling and other requirements[571] corresponding to those set forth in WHO Code Articles 9.1-9.2 are satisfied. SI 2007/3521, as amended, "give[s] effect to [i.e., implements for England, European] Commission Directive 2006/141/EC[572] on infant formulae and follow-on formulae."[573] The UKDOH Guidance Notices accompanying SI 2007/3521 indicate that Directive 2006/141/EC "lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants ["children under the age of 12 months"[574]] in good health in the Community".[575] It also enables "Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing [including advertising], information and responsibilities of health authorities."[576]

Directive 2006/141/EC, Article 2 defines "infant formula" as "intended for particular nutritional use by infants during the first months of life",[577] and "follow-on formula" as intended for…use by infants when appropriate complementary feeding is introduced."[578] Meanwhile, Directive 2006/141/EC

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567 *See* Government of the United Kingdom, *Statutory Instrument 2008 No. 2445 - The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008* (Sept. 16, 2008), available at: http://www.legislation.gov.uk/uksi/2008/2445/pdfs/uksi_20082445_en.pdf.
568 SI 2008/2445, Regulation 2(2).
569 *See* Government of the United Kingdom, *Statutory Instrument 2011 No. 3012 - Transfer of Functions (Food) Regulations 2011* (Dec. 14, 2011), available at: http://faolex.fao.org/docs/pdf/uk109259.pdf.
570 SI 1995/77, and successors SI 2007/3521, SI 2008/2445 and SI 2011/3012 implement the Food Safety Act of 1990 *See* Government of the United Kingdom, *Food Safety Act 1990*, at Chapter 16, available at: http://www.legislation.gov.uk/ukpga/1990/16. Article 53(1) of the Food Safety Act of 1990 defined the term "advertisement" as including "any notice, circular, label, wrapper, invoice or other document, and any public announcement made orally or by any means of producing or transmitting light or sound." *Id*. The term "infant formula" was defined as "a food intended for particular nutritional use by infants in good health during the first four to six months of life, and satisfying by itself the nutritional requirements of such infants." *See* SI 1995/77, *supra* at Regulation 1(2).
571 SI 2007/3521, at Regulations 21(1)(a)-(b); 17(1)(e), (2)-(4); 19; 21(2)-(3).
572 *See* European Commission, *Directive 2006/141/EC (Dec. 22, 2006), on Infant Formulae and Follow-on Formulae and Amending Directive 1999/21/EC*, OJ L 401 of 30.12.2006, at Annex IV, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:401:0001:0033:EN:PDF.
573 SI 2007/3521, Art. 2(1) and Explanatory Note, par. 1, p. 13.
574 Directive 2006/141/EC, at Art. 2(a).
575 *Id*., at Art. 1. *See also* Government of the United Kingdom Department of Health *("UKDOH") Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), at par. 3, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/204314/Infant_formula_guidance_2013_-_final_6_March.pdf.
576 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 3. The WHO Code-implementing provisions of Directive 2006/141/EC concerning, labeling, advertising and promotional information are set forth in Articles 13-15 thereof.
577 Directive 2006/141/EC, Art. 2(c).
578 *Id*., at Art. 2(d).

Article 5 requires that infant formula "suitability for particular nutritional use by infants from birth [must be] established by generally accepted scientific data",[579] while Article 6 requires that follow-on formula "suitability for particular nutritional use by infants *aged over six months* [must be] established by generally accepted scientific data" (emphasis added).[580] This strongly suggests that the UKDOH, like the EU Commission, deems infant formula as suitable for use by infants up to 6 months of age, and follow-on formula as suitable for use by infants over 6 months of age, consistent with WHO Code Article 2 (defining "infant formula") and Annex 3 and Codex STAN 156-1987, and consequently, has interpreted the WHO Code as requiring the separate and distinct treatment of such products. This contrasts markedly with the PH BMS Framework which interprets the WHO Code as covering, and thus, imposing the same treatment on such products.

SI 2007/3521, Regulation 13 requires all infant formula and follow-up formula product labels to be submitted to the UKDOH to secure market authorization of such product(s) in the UK.[581] SI 2007/3521, Regulation 21(a) expressly restricts infant formula advertising to only two distribution channels, and precludes all other advertising of such products. Infant formula advertising can occur only in scientific or manufacturer/wholesaler trade publications ("prior to the retail stage") that are not intended for a general public readership.[582] It also restricts the type of information such advertising may contain, and prohibits the ad from undermining breastfeeding.[583] For example, such advertising "shall only contain information of a scientific and factual nature",[584] and "shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding."[585] In addition, infant formula advertising must contain label-consistent statements regarding breastfeeding superiority and recommending product use contingent on receipt of medical advice.[586] It also requires such advertising to contain appropriate use information that does not discourage breastfeeding, does not contain the words, 'humanized' or 'maternalized', and does not include any infant picture or other picture or text idealizing formula products.[587]

Furthermore, consistent with Article 13(6) of EU Directive 2006/141/EC, SI 2007/3521 permits infant formula advertising and labeling to include health and nutrition claims only if they are listed and expressed "in the first column of Annex IV" of said directive and satisfy the condition(s) specified in the second column of Annex IV in relation to the relevant claim."[588] Section 1 of Annex IV sets forth various permissible nutrition claims, while Section 2 of Annex IV sets forth various permissible health claims, including reduction of disease risk claims.[589]

The UKDOH Guidance Notes accompanying SI 2007/3521 clarify that health or nutrition claims made in relation to infant formula "are regulated pursuant to Regulation 17(4) *wherever they*

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579 *Id*., at Art. 5.
580 *Id*., at Art. 6. *See also* Art. 13(1)(b) ("The labelling shall bear…in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by *infants over the age of six months*") (emphasis added). *Id*.
581 SI 2007/3521, at Regulation 13.
582 SI 2007/3521, at Regulation 21(1)(a).
583 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 54.
584 SI 2007/3521, at Regulation 21(2).
585 *Id*., at Regulation 21(3).
586 *Id*., at Regulations 21(1)(b); 17(1)(e).
587 *Id*., at Regulations 21(1)(b); 17(2)-(3).
588 SI 2007/3521, at Regulations 21(1)(b); 17(4).
589 Directive 2006/141/EC at Annex IV.

appear on the labelling, on a website or in advertising or presentation" (emphasis added),[590] and that "[a]ll other nutrition and health claims in relation to infant formula or its ingredients are therefore prohibited."[591] The term "presentation includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed."[592] The UKDOH Guidance Notes also emphasize how the European Commission (pursuant to Articles 2(1), 2(4) and 2(5) of Regulation 1924/2006/EC[593]) considers advertising and labeling "claims which refer to functionality or an implied effect on health as health claims [that]…cannot be used in relation to infant formula *unless* they are included in Table 2 of Annex IV (emphasis added)."[594] The term "claims" is defined by Article 2(1) to include textual, pictorial, graphic or symbolic representations. In addition, the UKDOH Guidance Notes point out with respect to infant formula advertising, that "nutrition claims cannot be used in conjunction with additional statements, where those additional statements would make the claim a health claim or implied health claim."[595]

Moreover, SI 2007/3521 mandates that infant formula shall be advertised and labeled in a way that "enables consumers to make a clear distinction", and "avoids any risk of confusion", between it and follow-on formula intended for infants older than 4-6 months of age.[596] It is evident that these regulations have linked infant formula advertising restrictions with infant formula labeling restrictions in much the same way that the PH BMS Framework has.

II. Follow-on Formula Marketing Rules

Unlike the PH BMS Framework, SI 2007/3521 does not impose similar restrictions on the advertising of follow-on formula. Follow-on formula advertising need only remain consistent with follow-on formula labeling restrictions requiring appropriate use information that does not discourage breastfeeding or contain the words, 'humanized' or 'maternalized'.[597] The UK BMS Framework endeavors (much more than does the PH BMS Framework) to ensure that follow-on formula is

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590 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 35. The Guidance notes also accompany SI 2008/2445. *Id*., at par. 1.
591 *Id*., at par. 34.
592 SI 2007/3521, at Regulation 20(3); SI 2008/2445, at Regulation 20(3).
593 *See* European Commission, *Regulation (EC) No 1924/2006 of the European Parliament and of the Council, (Dec. 20, 2006) On Nutrition and Health Claims Made on Foods*, OJ L 404, 30.12.2006 available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:404:0009:0025:EN:PDF; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1924:20100302:EN:PDF. These provisions respectively define the terms "nutrition claims" and "health claims", consistent with the definitions contained in applicable Codex guidelines. *See* Codex Alimentarius Commission, *Guidelines on Nutrition and Health Claims* (CAC/GL 23-1997), at Sections 2.1 and 2.2, available at: http://www.codexalimentarius.net/input/download/standards/351/CXG_023e.pdf.
594 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 35. "For example, claims relating to 'prebiotics', such as 'contains prebiotics', are considered health claims because they describe a function and are not permitted." *Id*. *See also* Department of Health (UK), *Letter to Interested Parties - Update from the European Commission's Working Group Meeting on Nutrition and Health Claims* (Jan. 11, 2013), at p. 3, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213362/update-on-the-working-group-meeting-on-nutrition-and-health-claims.pdf ("[N]utrition and health claims used on foods for lower birth weight and pre-term infants…in good health…which are not considered to be foods for special medical purposes (FSMPs)…are subject to the rules in the NHCR and health claims on foods for infants and young children would have to be Article 14(1)(b) claims.") *Id.*
595 *Id*. "For example, 'contains added LCPs' is permitted, whereas 'with LCP care' is not." *Id*.
596 SI 2007/3521, at Regulations 21(1)(b); 19. SI 1995/77 defined the term "follow-on formula" as "a food intended for particular nutritional use by infants in good health who are aged over four months, and constituting the principal liquid element in a progressively diversified diet." *Id*., at Regulation 1(2). This definition also appears in Article 2(d) of Directive 2006/141/EC and is incorporated by reference into SI 2007/3521. *See* SI 2007/3521, at Art. 2(3). This definition anticipates that follow-on formula will be consumed during the period of partial breastfeeding.
597 SI 2007/3521, at Regulations 22; 18(2).

advertised and labeled in a way that "enables consumers to make a clear distinction", and "avoids any risk of confusion", between it and infant formula.[598]

The UKDOH Guidance Notes accompanying SI 2007/3521 set forth a number of very useful recommendations for this purpose. For example, advertising should not "promote a range of formula products by making the brand the focus of the advert, rather than the specific products".[599] In addition, "the specific terms 'infant formula' and 'follow-on formula' should be clearly featured on the packaging, in a font size no smaller than the brand name."[600] Also, "information on labels, such as pictures and blocks of text should differentiate between…infant formula and follow-on formula" to reflect their fundamental differences, as illustrated in Appendix III of the Guidance Notes.[601] Furthermore, "[t]he colour scheme used for infant formula packaging should be clearly different to the colour scheme of follow-on formula packaging", and should not merely be "different shades of the same colour."[602] Moreover, follow-on formula packaging should not include "[n]on-mandatory references to breastmilk or breastfeeding" that can confuse consumers into believing that such product, which "should be used only from six months", is appropriate for "feeding infants from birth."[603] Lastly, companies should take care to ensure that "in-store presentation…of infant formula and follow-on formula…are clearly differentiated in order to avoid any risk of confusion."[604]

Unlike in the case of infant formula, health claims and nutrition claims "made in relation to follow-on formula are controlled by European Regulation (EC) No 1924/2006" which governs the making of such claims with respect to foods.[605] "The Annex to [EC] Regulation 1924/2006 contains the list of permitted nutrition claims which may be used on foods, including follow-on formula, and the criteria for using them,"[606] which list has since been amended (expanded) by EU Regulation No 1047/2012[607] and is broader than the list applicable to infant formula claims. Meanwhile, the list of permitted health claims "other than those referring to the reduction of disease risk and to

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598 *Id*., at Regulations 22 and 19.
599 See *UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 48. For example, "specific products [should not be mentioned only in a footnote or in a picture of a tin of formula within the advertisement." *Id.*
600 *Id*., par. 50.
601 *Id*., at par. 51 and Appendix III.
602 *Id*., at par. 51.
603 *Id*.
604 *Id*., at par. 53. For example, follow-on formula "'shelf-talkers' (attachments that add a company's logo or sales message to the edge of a shelf) and other in-store promotional devices…must not be used in the vicinity of infant formula." *Id.* And, if possible, follow-on formula "should be located at a different part of the store to infant formula" or, at the very least, follow-on formula "should be clearly separated in physical location" from infant formula. *Id*.
605 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 40. *See also* European Commission, *Guidance on the Implementation of Regulation No 1924/2006 on Nutrition and Health Claims Made on Foods – Conclusions of the Standing Committee on the Food Chain and Animal Health* (Dec. 14, 2007), at p. 4, available at: http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf ("The only permitted claims for infant formulae are listed in Annex IV of Directive 2006/141/EC…As no similar provision is laid down for follow-on formulae, nutrition and health claims made on such products are governed by Regulation (EC) N°1924/2006."). *Id.*
606 *Id*., at par. 43. "The European Commission guidance classifies health claims made on follow-on formula as claims referring to children's development and health. Only health claims for which an application for authorisation was submitted by 19th January 2008 can be used on follow-on formula during the transitional period. The transitional period lasts until the Commission's Standing Committee reach a decision on the application." *Id*.
607 *See* European Commission, *Regulation (EU) No 1047/2012 of 8 November 2012 Amending Regulation (EC) No 1924/2006 With Regard to the List of Nutrition Claims*, OJ L 310 9.11.2012, at Annex, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:310:0036:0037:EN:PDF.

children's development and health" ("Regulation 1924/2006, Article 13 claims"[608]) is contained in EC Regulation No 432/2012.[609] Such health claims include those relating to "the role of a nutrient or other substance in growth, development and the functions of the body" – functionality claims, which do not require European Food Safety Authority ("EFSA"[610]) authorization under Regulation 1924/2006, Article 15.[611] On the other hand, disease risk claims ("Regulation 1924/2006, Article 14 claims"[612]) are subject to EFSA authorization.[613]

The UKDOH Guidance Notes accompanying SI 2007/3521 also indicate that, "[c]laims about follow-on formula which the [UK] Advertising Standards Authority (UKASA) [, an industry-funded self-regulatory entity,[614]] ha[s] found to be unsubstantiated should not be used in advertising."[615] The UKDOH Guidance Notes advise "manufacturers…[to] consider such judgments when developing their labelling, websites and other promotional materials."[616] "Since September 2010…[t]he Advertising Standards Authority ([UK]ASA) regulates advertising across all media…includ[ing,]…advertisers' own marketing communications on their own websites and in other non-paid-for space under their control, such as social networking sites like Facebook and Twitter."[617] UKASA Code violations and noncompliance are subject to the imposition of various sanctions. These include adverse publicity and business reputation loss,[618] and referral to legal authorities for prosecution under various consumer protection and false advertising laws.[619] For example, legal sanctions may be imposed upon summary conviction for false or misleading

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608 *See* European Commission, *Guidance on the Implementation of Regulation No 1924/2006 on Nutrition and Health Claims Made on Foods – Conclusions of the Standing Committee on the Food Chain and Animal Health* (Dec. 14, 2007), at Sec. III.2, available at: http://ec.europa.eu/food/food/labellingnutrition/claims/guidance_claim_14-12-07.pdf.

609 *See* European Commission, *Regulation (EC) No 432/2012 Establishing a List of Permitted Health Claims Made on Foods, Other Than Those Referring to the Reduction of Disease Risk and to Children's Development and Health* (May 16, 2012), OJ L 136 25.5.2012 at Annex, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:EN:PDF.

610 EC Regulation 1924/2006, Art. 2(7).

611 *Id*., at Articles 13(1) and 13(3).

612 *See* European Commission, *Guidance on the Implementation of Regulation No 1924/2006 on Nutrition and Health Claims Made on Foods – Conclusions of the Standing Committee on the Food Chain and Animal Health* (Dec. 14, 2007), *supra* at Sec. III.2.

613 EC Regulation 1924/2006, Article 14.1.

614 *See* Advertising Standards Authority, *About ASA*, available at: http://www.asa.org.uk/About-ASA.aspx. ("The Advertising Standards Authority is the UK's independent regulator of advertising across all media. We apply the Advertising Codes, which are written by the Committees of Advertising Practice. Our work includes acting on complaints and proactively checking the media to take action against misleading, harmful or offensive advertisements."). *Id*. *See* Advertising Standards Authority, *About Regulation*, available at: http://www.asa.org.uk/About-ASA/About-regulation.aspx. ("The UK advertising regulatory system is a mixture of self-regulation for non-broadcast advertising and co-regulation for broadcast advertising…[T]he system is paid for by the industry, which also writes the rules, but those rules are independently enforced by the ASA. For TV and radio advertising, we regulate under a contract from Ofcom. The UK Advertising Codes are written by two industry committees: the Committee of Advertising Practice writes the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing and the Broadcast Committee of Advertising Practice (BCAP) writes the UK Code of Broadcast Advertising…Even though many steps are taken to ensure ads are in line with the Codes before they are aired or published, consumers have the right to complain about ads they have seen, which they believe to be misleading, harmful or offensive. The ASA can act on just one complaint. We don't play a numbers game: our concern is whether the Codes have been breached… If we have judged an ad to be in breach of the Codes, then the ad must be withdrawn or amended. The vast majority of advertisers comply with the ASA's rulings and they act quickly to amend or withdraw an ad that breaks the Codes. We have a range of effective sanctions at our disposal to act against the few who do not and ensure they comply with the rules.") *Id*.

615 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 46.

616 *Id.*

617 *Id*., at Appendix II - *Guidance On Website Information Relating to Infant formula, Follow-on Formula and Infant Feeding*, p. 27.

618 *See* Advertising Standards Authority, *Sanctions*, available at: http://www.asa.org.uk/Industry-advertisers/Sanctions.aspx ("[S] some of the sanctions at our disposal can be very detrimental to those who choose not to comply. One of the most persuasive is bad publicity – an advertiser's reputation can be badly damaged if it is seen to be flouting the rules designed to protect consumers.") *Id*.

619 *See* Advertising Standards Authority, *Non-Broadcast Sanctions*, available at: http://www.asa.org.uk/Industry-advertisers/Sanctions/Non-broadcast.aspx ("For misleading or unfair advertising, if an advertiser refuses to comply with the ASA, then the ASA Chief Executive is able to refer the advertiser to the Office of Fair Trading for legal proceedings under the Consumer Protection from Unfair Trading Regulations 2008 [("CPRs")] or the Business Protection from Misleading Marketing Regulations 2008 [("BPRs")].")

advertising of food products in contravention of the provisions of the *Consumer Protection from Unfair Trading Regulations 2008* and/or the *Business Protection from Misleading Marketing Regulations 2008*.[620] Such sanctions may consist of fines of up to £5000 (USD$7,753.50) for a single offence, in addition to or in lieu of a prison term of up to two years.[621]

III. Enforcement of Infant Formula and Follow-on Formula Marketing Rules

SI 2007/3521, Articles 28(1)-(2)[622] and 29(e), (g), (h) and (i)[623] contain enforcement provisions which authorize judicial imposition of criminal fines of up to £5,000 (USD$7,753.50) and/or up to two years imprisonment for a single offence following a manufacturer's, distributor's or advertising marketing firm's summary conviction in proceedings initiated by the UK Department of Health ("UKDOH") under Section 35 of the Food Safety Act of 1990, as amended.[624] Significantly, these include Article 3 violations of infant formula and follow-on formula marketing authorization rules triggered by violations of infant formula and/or follow-on formula labeling requirements (e.g., Articles 17 and 18) and/or violation of Article 19 avoidance of infant formula/follow-on formula labeling risk-of-confusion requirements, each of which is aimed at preventing infant formula and follow-up formula labeling practices from undermining breastfeeding. These fines also apply to violations of Article 21(1) infant formula advertising requirements and Article 22 follow-on formula advertising requirements, especially those triggered by violation of Articles 17(1)(e), 17(2)-(3)), 17(4) (relating to health and nutrition claims), 18(2) (restricting advertising information to a scientific and factual nature and precluding it from implying or creating a belief that bottlefeeding is equivalent or superior to breast feeding) and 19 (requiring that infant formula and follow-on formula labeling ensure against confusion).

In addition, such fines may be imposed for violations of Article 22 follow-on formula advertising requirements triggered by violations of applicable Article 18(2) follow-on formula labeling

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620 "2.1 The…(CPRs) introduce a general prohibition on traders in all sectors engaging in unfair commercial (mainly marketing and selling) practices against consumers…2.3 The…(BPRs) prohibit misleading business-to-business advertising and set out the conditions under which comparative advertisements…are permitted. The BPRs are intended to…protect[] businesses as well as consumers." *See* Government of the United Kingdom, *Explanatory Memorandum to The Consumer Protection From Unfair Trading Regulations 2008, 2008 No. 1277 ("CPRs") and The Business Protection From Misleading Marketing Regulations 2008 ("BPRs"), 2008 No. 1276*, available at: http://www.legislation.gov.uk/uksi/2008/1277/memorandum/contents.

621 Section 13 of the CPRs provides that "[a] person guilty of an offence under regulation 8, 9, 10, 11 or 12", and Section 7 of the BPRs provides that "[a] person guilty of an offence under regulation 6", "shall be liable - (a) on summary conviction, to a fine not exceeding the statutory maximum [£ 5000 or USD$7,753.50]; or (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or both." *See* Government of the United Kingdom, *The Consumer Protection From Unfair Trading Regulations 2008, Statutory Instrument ("SI") 2008 No. 1277 ("CPRs")*, available at: http://www.legislation.gov.uk/uksi/2008/1277/contents/made. SI 2008/1277 implemented Directive 2005/29/EC - the "Unfair Commercial Practices Directive (UCPD)" into UK law. *See also* Government of the United Kingdom, *The Business Protection From Misleading Marketing Regulations 2008 ("BPRs"), Statutory Instrument ("SI") 2008 No. 1276*, available at: http://www.legislation.gov.uk/ukdsi/2008/9780110811475/contents. SI 2008/1276 implemented Directive 2006/114/EC – the "the Directive on Misleading and Comparative Advertising" into UK law.

622 *See UKDOH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 (as amended)* (March 2013), *supra* at par. 81; SI 2007/3521, Art. 28(1). Article 28(1) specifically provides that any person "guilty of an offence… shall be liable on summary [criminal] conviction to a fine not exceeding level 5 on the standard scale." *Id*. A "level" 5 offence is defined in Article 37 of the Criminal Justice Act 1982. *See* Commonwealth of the United Kingdom, *Criminal Justice Act 1982*, 1982 CHAPTER 48 (Oct. 28, 1982), as amended, at Article 37, available at: http://www.legislation.gov.uk/ukpga/1982/48#commentary-c1933859.

623 SI 2007/3521, Articles 29 (e), (g), (h) and (i). "The following provisions of the [Food Safety] Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations…(e) section 33(1) (obstruction etc. of officers)…(g) section 35(1) (punishment of offences)(c), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e); (h) section 35(2) and (3)(d), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f); (i) section 36 (offences by bodies corporate)."

624 *See* Government of the United Kingdom, *Food Safety Act 1990*, at Section 35 – Punishable Offences, available at: http://www.legislation.gov.uk/ukpga/1990/16/section/35.

requirements and/or Article 19 avoidance of infant formula/follow-on formula labeling risk-of-confusion requirements. Furthermore, such fines also apply to violations of Article 23 infant formula promotion restrictions and to Article 24 dissemination of infant feeding informational/educational materials restrictions. Clearly, the UK BMS Framework's enforcement mechanism addresses practically the same kinds of violations that the PH BMS Framework does in an effort to prevent the undermining or discouraging of breastfeeding, and imposes relatively comparatively greater criminal fines in lieu of a prison sentence than does the PH BMS Framework. Presumably, the UKDOH also imposes administrative fines as well, similar to the PHDOH BFAD/FDA.

IV. Future UK BMS Framework Trends

When evaluating the UK BMS Framework as a possible alternative to the PH BMS Framework, the Philippine Government should review new EU Regulation No. 609/2013,[625] commonly known as the Regulation on "Foods for Specific Groups".[626] The UK BMS Framework will eventually be updated to implement Regulation No. 609/2013 in July 2016 at which point EU Directive 2006/141/EC will be repealed and superseded.[627] This new regulation applies to infant formula, follow-on formula and a host of complementary baby and cereal-based foods.[628] Legal authorization to place such products into the EU market can only be ensured by compliance with all of the Regulation's provisions.[629] These include Articles 9(5), 10, 11 and 12 which cover infant formula, follow-on formula, baby and cereal-based foods and are guided by application of the precautionary principle.[630]

Article 9(5) generally requires that product labeling shall not be misleading or otherwise attribute to such foods the property of preventing or curing human disease, or otherwise imply it.[631] Articles 10(1)-(2) require that infant formula/follow-on formula advertising, labeling and presentation "not discourage breastfeeding", and "not include pictures of infants, or other pictures or text which may idealise the use of such formulae."[632] Articles 11(1)(c)-(f) empower the European Commission, until July 20, 2015, to adopt certain "delegated acts" to facilitate proper implementation of the Regulation. In other words, the Commission is authorized to promulgate acts imposing specific requirements for infant formula, follow-on formula and complementary foods notification, labeling, advertising, and presentation, including the authorization of health and nutrition claims,[633] specific

625 *See* European Commission, *Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 On Food Intended For Infants and Young Children, Food For Special Medical Purposes, and Total Diet Replacement For Weight Control and Repealing Council Directive 92/52/EEC*, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181 29.6.2013, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:181:0035:0056:EN:PDF. *See also* UNICEF UK, *European Parliament Agrees [to] New Rules on Formula Labelling*, The Baby Friendly Initiative (June 12, 2013), available at: http://www.unicef.org.uk/BabyFriendly/News-and-Research/News/European-Parliament-agrees-new-rules-on-formula-labelling/.

626 *See* Government of the United Kingdom, Department of Health, *Letter to Interested Parties: European Parliament Agreement to Legislation on 'Foods for Specific Groups'* (June 12, 2013), available at: https://www.gov.uk/government/publications/eu-regulation-on-foods-for-specific-groups; https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/211049/Foods_for_Specific_Groups_12_June_2013.pdf.

627 This regulation will apply to infant formula, follow-up formula, baby foods and cereal-based foods beginning on July 20, 2016, and shall repeal and supersede Directive 2006/141/EC governing the UK Framework on the date of application of the delegated acts referred to in Article 11(1)(c), (e) and (f). *Id*., at Articles 20(4) and 22.

628 *Id*., at Articles 1(a)-(b), 2(a)-(f).

629 *Id*., at Art. 4.

630 *Id*., at Art. 5.

631 *Id*., at Art. 9(5).

632 *Id*., at Arts. 10(1)-(2).

633 *Id*., at Art. 11(1)(c)-(d).

requirements concerning the promotional and commercial practices relating exclusively to infant formula,[634] and requirements concerning information to be provided for infant and young child feeding to ensure adequate information on appropriate feeding practices.[635] Lastly, Article 12 empowers the European Commission to consider the necessity of promulgating special provisions to cover milk-based drinks and similar products (i.e., intended for young children, taking into account the nutritional requirements of young children, the role of such products in their diet, and the nutritional benefits of such products relative to a normal diet for a child who is being weaned.[636]

In sum, the UK BMS Framework imposes advertising, labeling and packaging restrictions and prohibitions which can satisfy PH BMS Framework policy objectives. First, they ensure that infant formula products intended for infants 0-6 months of age are marketed only in science and trade publications, and that only scientifically substantiated health and nutrition claims made with respect to follow-on formula are permitted, to prevent against discouragement of breastfeeding among the general public. Second, they ensure that follow-on formula products intended for infants 6-12 months of age and older are clearly distinguishable from infant formula products in the marketplace to prevent against consumer confusion that can lead to follow-on formula being passed off as infant formula.

vi. Assessing the Risks that Non-Fulfillment of PH BMS Framework Legitimate Objectives Would Create Due to Adoption of the Reasonably Available Less Trade-Restrictive UK BMS Framework

A. Despite Differences Between UK and PH BMS Frameworks Many Similarities

As previously discussed, the UK BMS Framework offers a reasonably available less-trade restrictive regulatory alternative to the PH BMS Framework that would be capable of largely achieving Philippine Government public health and consumer protection objectives, with little risk of nonfulfillment. The UK BMS Framework's product scope and coverage are currently narrower than that of the PH BMS Framework because it focuses only on infant formula and follow-on formula, and not on complementary foods.*[637] For this reason, the UK BMS Framework has, thus far, posed fewer impediments to trade in breastmilk supplement products (follow-on formula and complementary foods) than has the PH BMS Framework. However, the UK, as an EU Member State, must eventually implement new EU Commission Regulation No. 609/2013 which will somewhat lessen the gap in product scope and coverage that now exists between these two frameworks, since the new regulation will cover various aspects of the marketing of infant formula, follow-on formula

634 *Id*., at Art. 11(1)(e).
635 *Id.*, at Art. 11(1)(f).
636 *Id*., at Art. 12; Preamble, par. 31.
637 *The UK Framework has been described for purposes of this analysis as *not* including solid complementary food products such as cereal-based foods and baby foods, which are covered by separate regulations. *See* Government of the United Kingdom, *Statutory Instrument 2003 No. 3207 - The Processed Cereal-Based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003*, available at: http://www.legislation.gov.uk/uksi/2003/3207/contents/made, as amended by *Statutory Instrument 2007 No. 2591 – The Food for Particulary Nutritional Uses (Misc. Amendments) (England) Regulations 2007*, available at: http://www.legislation.gov.uk/uksi/2007/2591/contents/made, implementing *Commission Directive 2006/125/EC on Processed Cereal-Based Foods and Baby Foods for Infants and Young Children*, OJ NO. L339, available at: http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21101a_en.htm. However, with the enactment of EU Commission Regulation 609/2013 which supersedes Commission Directive 2006/125/EC (see Regulation 609/2013 at Articles 20(4)-(5)), the marketing of cereal-based foods and baby foods will be covered at the EU regional level together with infant formula and follow-on formula. The UK can be expected to eventually amend SI 2007/3521 and SI 2003/3207 to bring all of these products under the same instrument for purposes of implementing Commission Regulation 639/2012 at the national level.

and complementary food products. Irrespective of the current gap between these frameworks, it is notable how they address many of the same issues to ensure the protection of public health via breastfeeding consistent with the WHO Code, and the protection of consumers from deceptive advertising, labeling and packaging practices that can result inappropriate use of follow-on formula.

For example, with respect to protection of public health via breastfeeding, SI 2007/3521, Regulations 17(1)(e) and 21(3), 18(1)(a)(iii)-(iv), 21(b) and 22, UKDOH Guidance Notes pars. 27 and 54, and EC Directive 2006/141/EC, Articles 13(4)(a)-(b) and 14(1) of the UK BMS Framework require infant formula and follow-on formula labeling and advertisement statements that ensure superiority of breastfeeding and physician advice before use, in much the same way that Milk Code Section 190(b)(ii), RIRR, Rules V, Sections 13, 15(a), VII Section 26, Circular 2008-0006, Items VI.A.3(i)-(ii) and B.9.(i), and AO 2012-0027, Sections 19.1.6, 21A.a, 21B.a of the PH BMS Framework do. In addition, SI 2007/3521, Regulations 17(2)(a)-(b) and 18(2)(a)-(b), 21(b), UKDOH Guidance Notes pars. 3, 28 and 58, and EC Directive 2006/141/EC, Article 13(3) and 13(8)(b) of the UK BMS Framework require that infant formula labeling and advertising statements do not discourage breastfeeding and do not contain the terms “humanised”, “maternalised”, “adapted”, in much the same way that Milk Code Sections 10(a) and 10(d), RIRR, Rule V Sections 13 and 15(b), and AO 2012-0027, Sections 19.1.1 and 19.1.2 of the PH BMS Framework do. Furthermore, to prevent the idealization of breastmilk substitutes and the undermining of breastfeeding, SI 2007/3521, Regulations 17(3)(a)-(b), 18(2)(a), 21(b) and 22, UKDOH Guidance Notes pars. 28-31 and 58-60, and EC Directive 2006/141/EC, Articles 13(5) and 13(8)(b) of the UK BMS Framework prohibit non-mandatory text or pictures in infant formula and follow-on formula labels and advertisements from making reference to ‘breastmilk’, ‘breastfeeding, ‘moving on from breastfeeeding’, or ‘closer to/inspired by breastmilk’, in much the same way that Milk Code Section 10(c), RIRR, Rule V Sections 15(a) and 15(c), and AO 2012-0027, Sections 19.1.1, 19.1.3 and 19A.1.7.10(a)-(c), (e), (h), (j)-(k) and (n) of the PH BMS Framework do.

With respect to consumer protection, SI 2007/3521, Regulations 17(1)(a)-(d), 18(1)(a)(i) and (b)-(d), 18(3)(a)-(b), 21(b) and 22, UKDOH Guidance Notes pars. 15, 24-26 and 38, EC Directive 2006/141/EC, Articles 7(1)-(2), Annexes I-III and VI-VII, and new EU Regulation No. 609/2013 of the UK BMS Framework address for infant formula and follow-on formula labeling purposes suitability for use, appropriate use and preparation, energy values (including cow’s milk protein source), mineral composition, and warning against health hazard information issues, in much the same way that RIRR, Rule VII Sections 25-28 and AO 2006-0008, Items VI.A.1(i)-(iv) and B.1-B.4, B.9(ii) of the PH BMs Framework do. However, SI 2007/3521, Regulations 19 and 22, UKDOH Guidance Notes pars. 48, 50-51, 53 and Appendix III of the UK BMS Framework require much more to ensure suitability for use and appropriate use of follow-on products relative to infant formula products than does Circular 2008-0006, Item VI.A.1(i) of the PH BMS Framework, by requiring that follow-on formula be advertised and labeled in a way that “enables consumers to make a clear distinction”, and “avoids any risk of confusion”, between it and infant formula.

With respect to the protection of public health via breastfeeding and consumer protection, SI 2007/3521 and UKDOH Guidance Notes par. 46 and Appendix II of the UK BMS Framework, like AO 2007-0012, Section 11.3 of the PH BMS Framework, effectively call for the pre-regulatory review of proposed infant formula and follow-up formula advertising materials at the industry (self-

regulatory) level by the UK Advertising Standards Authority ("UKASA") and the PH Advertising Standards Council ("PHASC"), respectively. In addition, both the UKASA and PHASC provide a complaints filing procedure whereby consumers and industry competitors may submit grievances for investigation concerning observed false or misleading company advertising practices, with respect to which each body must issue a determination/decision following their investigation thereof. Both the UKASA and the PHASC also provide mechanisms to ensure the enforcement of their decisions in the event of company noncompliance. These can include the imposition of advertising cease-and-desist orders, recalls-of-clearance, prospective advertising bans, and adverse publicity and loss of business reputation. The UKASA can also refer noncompliant companies to legal authorities for prosecution under various consumer protection and false advertising laws, and the PHASC can impose considerable monetary fines.

In the interest of protecting public health via breastfeeding and consumer protection, both the UK and PH BMS Frameworks impose further monitoring of infant formula, follow-up formula and/or complementary food advertising materials/practices at the regulatory level by the relevant federal authorities. In the UK, SI 2007/3521, Regulation 13 requires all proposed infant formula product labels to be submitted to the UKDOH for review in order to secure market authorization of such product(s). While, in the UK, there is no regulatory review of proposed infant formula or follow-on formula product-related advertising materials once the UKASA has undertaken its own review thereof, the UKDOH and/or the Office of Fair Trading ("OFT") will investigate false and misleading food advertising complaints filed by civil society, industry competitors or members of the public and pursue enforcement of UK Framework compliance where necessary. Meanwhile, in the Philippines, pursuant to Milk Code Sections 12(a)(1)-(2), RIRR, Rule V Sections 12-15, and Rule X, Sections 36-38, and AO 2012-0027, Sections 8-9, 11, 15 and 17 of the PH BMS Framework, the IAC and the BFAD/FDA-dominated IAC Secretariat review proposed infant formula, follow-up formula and complementary food product advertising after the PHASC has already done so. In addition, pursuant to Milk Code Sections 10(a)-(f), RIRR, Rule VII Sections 26-28 and AO 2006-0008, the BFAD/FDA reviews all infant formula, follow-up formula and complementary food product labels. And, pursuant to Milk Code Section 12(b)(2), RIRR, Rule X Sections 36-37 and 39, the PH DOH and BFAD/FDA monitor PH BMS Framework compliance and investigate false or misleading advertising complaints filed by civil society, governmental agencies and/or members of the public., and pursue enforcement of PH BMS Framework compliance where necessary.

Both the UK and PH BMS Frameworks impose various fines and penalties to enforce compliance with relevant laws and regulations. For example, pursuant to Sections 28 and 29 of SI 2007/3521, Section 35 of the UK Food Safety Act of 1990 of the UK BMS Framework, the UKDOH can pursue the imposition of criminal fines and terms of imprisonment of officers and/or directors of infant formula/follow-up formula and/or complementary food manufacturers, distributors and/or advertising agents upon their summary conviction for false or misleading advertising or labeling practices. Pursuant to Section 13 of SI 2008/1276, and Section 7 of SI 2008/1276 which supplement the UK BMS Framework, the OFT of the UKDTI can pursue similar criminal fines and terms of imprisonment. Meanwhile, pursuant to Milk Code Sections 12(b) and 13(a)-(b), RIRR, Rule X Sections 36-37 and 39, Rule XI Section 40, and Rule XII Sections 44-45, 47, 49-50, and AO 2012-0027, Section 11.3 of the PH BMS Framework, the PHDOH BFAD/FDA can issue cease-and-desist orders, revoke business permits and professional licenses, and impose fines directly on company

officers and directors, and the PHDOJ upon conviction can impose criminal fines and prison sentences on officers and directors of manufacturers, distributors and their agents. In addition, pursuant to Chapter III, Article 164(e) of RA 7394 and AO 1 which supplement the PH BMS Framework, the PHDTI can impose its own administrative fines for false or misleading advertising practices.

B. Adoption of the UK BMS Framework in the Philippines Poses Little Risk of Nonfulfillment of PH BMS Framework Objectives Since Cultural Differences Account for Relatively Lower UK Breastfeeding Rate

Considering all of the similarities between these two frameworks, it is therefore manifestly inaccurate for the UNICEF and breastfeeding activists to allege that the UK Framework is "not as robust as the [WHO] Code and [provides]…companies…[with non-difficult]…ways around the law".[638] It is also untrue that "the [WHO] Code considers follow-on formula (i.e. milk intended for babies over six months) as a breastmilk substitute."[639] Much to the contrary, as previously discussed,[640] WHO Code Annex 3 clearly states that "the [C]ode's references to products used as partial or total replacements of breast milk are *not* intended to apply to complementary foods unless these foods *are actually marketed - as breast-milk substitutes*" (emphasis added) – i.e., "as being suitable for the partial or total replacement of breast milk" (emphasis added).[641] In other words, the WHO Code is best understood as *not* covering liquid and solid infant and young children's food products, including follow-up formula and complementary foods, if they are marketed, represented or intended to *supplement* partial breastfeeding for infants older than 6-12 months of age.

Recognition of this fact, leads to the real reason why UK breastfeeding rates are relatively low, "[d]espite [the] concerted efforts of health professionals and policy initiatives",[642] including

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638 *See* UNICEF United Kingdom, *A Guide for Health Workers to Working Within the International Code of Marketing of Breastmilk Substitutes – The Baby-Friendly Initiative* (March 2013), at p. 6, available at: http://www.unicef.org.uk/Documents/Baby_Friendly/Guidance/guide_int_code_health_professionals.pdf.

639 *Id*.

640 *See* Part III.3.b.iii.A, *supra*.

641 *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law (Part 2 of 3)*, LexisNexis Emerging Issues 7048 (Aug. 2013), *supra* at Part II.6.d.i.A.

642 *See* Lisa Then, *Breastfeeding Babies in Public – Why So Rare?*, Public Policy Blog at Southampton (July 4, 2013), available at: http://publicpolicy.southampton.ac.uk/public-breastfeeding/ ("Despite concerted efforts of health professionals and policy initiatives, our rates of breastfeeding at six-months lag behind those of many European nations. We lag behind commonwealth countries with roughly comparable maternity leave like Canada, Australia and New Zealand. We even lag behind the US which has no statuary paid maternity leave and average lengths of leave are months shorter. In other words, although UK women take longer maternity leaves than their US counterparts, they stop breastfeeding sooner. Why is this the case? What happens in the first six months after birth– when most women are still on maternity leave – to make them stop breastfeeding before the (recommended) six month mark? We understand the bio-physical difficulties women can experience, and the importance of support, information and practical guidance. But one aspect we don't understand well enough is women's' experiences trying to integrate breastfeeding with the rest of their lives in the weeks and months post-birth… Research suggests that about half of all UK women who have breastfeed in public have had at least one negative experience, including being asked to leave a restaurant or café.") *Id*. *See also* Kate Boyer, *Affect, Corporeality and the Limits of Belonging: Breastfeeding in Public in the Contemporary UK*, Health & Place 18 (2012) 552–560, available at: http://ac.els-cdn.com/S135382921200024X/1-s2.0-S135382921200024X-main.pdf?_tid=aae7042a-19cd-11e3-8530-00000aab0f6c&acdnat=1378785867_f9436baa92eafcdbca0a6a24e238f7a9 ("[D]espite being promoted by policy, breastfeeding women are marked and marginalized in the public sphere in the UK through a process of intersubjective affective practice…I propose that breastfeeding women are expected toact so as to maintain public comfort (i.e., the comfort of others) or risk censure; and that this schema is further sustained in the way that breastfeeding is 'provisioned for' in the built environment in the form of lactation rooms. I suggest that these spaces, practices, and affects can serve to constrain women in the UK from breastfeeding in public, and that an analysis of them helps explain why UK breastfeeding duration rates are so low when viewed in a global comparative context… This work has two implications for health policy. The first is that women's ability to breastfeed in public plays a role in increasing duration rates. And the second is that the work of making breastfeeding in public easier is ultimately a matter of cultural change. The government can help activate such change by directing funding

enactment of the UK Equality Act which prohibits discrimination against women who are publicly breastfeeding.[643] Apparently, negative social/cultural attitudes in the UK towards the appropriateness of public breastfeeding have continued to discourage women from breastfeeding outside the privacy of their own homes.[644] Unremarkably, this is a fact of life that women in the Philippines have also encountered, notwithstanding all of the breastfeeding measures the Philippine Government has enacted at the insistence of UNICEF and breastfeeding activists.[645]

Thus, it can no longer be ignored that the lower than desired Philippine breastfeeding rate is largely attributable to the various institutional and infrastructural incapacities previously discussed in this analysis, in addition to lingering negative social/cultural attitudes about the appropriateness of public breastfeeding in the Philippines. In light of all these *non*-industry factors, it is arguable that the adoption of the less-resource-intensive UK BMS Framework in the Philippines would pose little

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towards programmes that shake-up and challenge prevailing social norms: i.e., that seek to make breastfeeding in public less strange."). *Id*., at pp. 553 and 559; L. Condon, C. Rhodes, S. Warren, J. Withall and A. Tapp, *'But Is It a Normal Thing?' Teenage Mothers' Experiences of Breastfeeding Promotion and Support*, Health Education Journal (March 2013), vol. 72 no. 2 156-162, published online March 2012, available at: http://hej.sagepub.com/content/72/2/156; http://eprints.uwe.ac.uk/16500/3/v7%20with%20title%20page%20'a%20normal%20thing'.pdf ("The social barriers to continuing breastfeeding are insufficiently recognized and addressed by health professionals. It is likely that teenage mothers would breastfeed for longer if they perceived that breastfeeding was a normal way to feed baby in their social milieu.") *Id*., at p. 2.

643 *See* Government of the United Kingdom, *Equality Act of 2010*, c. 15 Part 2 Chapter 2, Sec. 17(3)-(4), available at: http://www.legislation.gov.uk/ukpga/2010/15/section/17 ("A person (A) discriminates against a woman if, in the period of 26 weeks beginning with the day on which she gives birth, A treats her unfavourably because she has given birth…[which] includes, in particular, a reference to treating her unfavourably because she is breast-feeding"). *Id*.; Government of the United Kingdom, *Equality Act 2010, 2010 c. 15 - Explanatory Notes, Commentary on Sections Part 2 Chapter 2 Section 17*, at par. 74, available at: http://www.legislation.gov.uk/ukpga/2010/15/notes/division/3/2/2/5 ("Examples - A café owner must not ask a woman to leave his café because she is breast-feeding her baby.") *Id*.; Government of the United Kingdom, National Health Service, *Breastfeeding in Public*, available at: http://www.nhs.uk/conditions/pregnancy-and-baby/pages/breastfeeding-in-public.aspx#close ("Know your rights. You shouldn't ever be made to feel uncomfortable about breastfeeding in public. In fact, the Equality Act 2010 has made it illegal for anyone to ask a breastfeeding woman to leave a public place such as a cafe, shop or public transport") *Id*.

644 *Id*. *See also* Daily Mail Reporter, *Lifeguard Demands Mother, 20, Stops Breastfeeding Her Son at Public Swimming Pool Because She is Breaking the Ban on Food and Drink*, UK Mail Online (July 17, 2013), available at: http://www.dailymail.co.uk/news/article-2367012/Lifeguard-demands-mother-20-stops-breastfeeding-son-public-swimming-pool-breaking-ban-food-drink.html ("The 20-year-old hairdresser said she started feeding nine month-old Riley in the whirlpool bath to calm his nerves on his first visit to the baths. She said: 'I noticed I was being watched by a female member of staff. She then told a male colleague who came to me and said, 'You are not allowed to feed inside the pool area'. 'I told them I knew my rights that it was against the law to stop me feeding, and they didn't say anything else but it made everybody stare at me. I felt annoyed and intimidated'") *Id*.; Sophie Borland, *Breastfeeding Boom in UK as Well-off Older Mothers Lead the Way*, UK Mail Online (Nov. 20, 2012), available at: http://www.dailymail.co.uk/health/article-2236014/Breastfeeding-boom-UK-older-mothers-lead-way.html ("Louise Silverton, director for midwifery at the Royal College of Midwives said…'Furthermore, there needs to be a sea change in public attitudes towards breastfeeding in public places and more needs to be done to increase the visibility of breast-feeding and its acceptability in public.'") *Id*.; Lisa Watts, *If the Aim is to Increase Breastfeeding Rates, Mums Should be Supported, Not Scolded*, The Independent (Oct. 18, 2012), available at: http://www.independent.co.uk/voices/comment/if-the-aim-is-to-increase-breastfeeding-rates-mums-should-be-supported-not-scolded-8215242.html ("Feeding in public is still an issue - if not the major issue - which puts mothers off breastfeeding.").

645 *See* Kate Delos Reyes, *Do People Judge Moms When They Breastfeed in Public?*, Yahoo SHE Philippines (Aug. 30, 2013), available at: http://ph.she.yahoo.com/is-it-shameful-to-breastfeed-in-public---034123184.html ("Breastfeeding in public is gradually becoming more common in recent years. Filipino mothers recently held a breastfeeding mob to increase awareness about the benefits of breast milk and breastfeeding. Malls and other public establishments have also responded to national laws by putting up breastfeeding stations in key areas of their buildings…However, breastfeeding mothers admit that they have received mixed reactions when they nurse their child outside their homes…Some people are still uncomfortable seeing a breastfeeding mother and child even if it is one of the most natural ways to nurture a child…There are also stories of women who do not breastfeed in public because their husbands discourage them from doing so. Instead, they bring expressed milk or formula milk in bottles when they go out with their babies."); GMA News Online, *Mommy 'Mob' Urges Increased Support for Breastfeeding*, Yahoo News Philippines (Aug. 5, 2013), available at: http://ph.news.yahoo.com/mommy-mob-urges-increased-support-breastfeeding-065719262.html ("The event, held in the middle of World Breastfeeding Week (August 1 to 7), was held not just to encourage more women to breastfeed their children, but to urge the government and the private sector to support breastfeeding through actions such as instituting longer maternity leaves and putting up breastfeeding stations in the workplace."); Rina Jimenez-David, *Latching On*, Philippine Daily Inquirer (Aug. 1, 2013), available at: http://opinion.inquirer.net/57913/latching-on ("But that's small potatoes compared to the harassment and public embarrassment that other breastfeeding mothers experience. One told me that when she started breastfeeding her bawling child while aboard a jeepney, the rest of the passengers turned away while one old lady reprimanded her: 'Hija, that's not something you do in public.' Other mothers breastfeeding their babies inside malls have been told off by security guards to do their 'thing' in more private spaces. That is, until shopping malls opened nursing rooms in their premises, billing it as part of their "corporate social responsibility" program.").

risk that the objectives of the PH BMS Framework (protecting public health via breastfeeding and protecting consumers via prevention of deceptive advertising practices) would go unfulfilled.

IV. Conclusion

1. Recap

This article has assessed the WTO-compatibility of the Philippines (PH) BMS Framework, which regulates the labeling, advertising and other marketing and promotion of foreign and domestic imported and manufactured breastmilk substitute and breastmilk supplement ("BMS") products intended for use by infants and young children 0-24 months of age or beyond, and has concluded that it violates the WTO Technical Barriers to Trade ("TBT") Agreement.

The TBT Agreement applies because the various separate but integrally related mandatory legal instruments promulgated exclusively by the executive branch of the Philippine Government that comprise the PH BMS Framework satisfy the requirements of a technical regulation consistent with TBT Annex I.1 and related jurisprudence and adversely affect international trade in BMS products. These instruments include an executive order, agency administrative orders, an agency circular and agency memoranda, *but no legislation*.

TBT Article 2.4 requires that WTO Members use relevant international standards, or relevant parts thereof, where they exist, as the basis for their technical regulations, except when they are insufficient to fulfill the legitimate objectives pursued. WTO Member developing country, such as the Philippines, may be eligible for an exemption from TBT Article 2.4 if it can demonstrate that a relevant international standard which exists is nonetheless inappropriate to its development needs, consistent with TBT Article 12.4.

Although the PH BMS Framework is partly based on the WHO International Code of Marketing of Breast-milk Substitutes ("WHO Code") which can be considered a relevant international standard within the meaning of TBT Article 2.4, various PH BMS Framework provisions relating to product scope and coverage, informational materials, product labeling, advertising and promotion, and the use of intellectual property go far beyond the letter and spirit of the WHO Code. Even if the Philippine Government could demonstrate either that the WHO Code is insufficient to fulfill its legitimate policy objectives or its special and differential development needs, however, it must still comply with the requirements of TBT Article 2.2.

TBT Article 2.2 obliges WTO Members to ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. This means that technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective taking account of the risks non-fulfillment would create. The PH BMS Framework, however, fails to meet the requirements of TBT Article 2.2. While the PH BMS Framework's objectives of protecting public health via breastfeeding, and protecting consumers against deceptive BMS product advertising and labeling practices that can ultimately discourage breastfeeding qualify as legitimate policy objectives, the PH BMS Framework's labeling,

advertising, intellectual property and enforcement provisions are more trade-restrictive than necessary to achieve these policy objectives.

There are exogenous factors unrelated to the commercial marketing of BMS products that raise serious questions regarding the degree to which the PH BMS Framework's policy objective of protecting breastfeeding for infants and young children up to 24 months of age and beyond can be achieved. For example, the health benefits and risks surrounding exclusive breastfeeding beyond 6 months of age is at best uncertain as revealed by the caveated science that underlies a growing number of studies. In addition, the Philippines has been unable to implement the laws/regulations it already has on the books due to national, regional and local political, administrative, institutional, environmental, educational, and behavioral impediments. Philippine infants and young children also continue to suffer from malnutrition and stunting due to culturally insufficient diets attributable to a lack of indigenous raw food materials and to infrastructural and technological incapacities resulting in inadequate domestic agricultural and dairy food production and the importation of inexpensive substandard and nutrition-poor food products from other developing Asian countries, particularly China. Such shortcomings have led to an increased reliance on foreign producers of milk products, mainly powdered milks and their ingredients, including whey powder used in the local production of infant formula and follow-up formula.

In addition, the degree to which the PH BMS Framework is capable of achieving its objective of preventing deceptive advertising and labeling practices, is highly uncertain. By banning all health and nutrition labeling and advertising claims to ensure that consumers are not mislead about the inferiority BMS products relative to breastfeeding, the PHDOH has effectively engaged in scientific censorship and denied Filipinos their consumer right-to-information. That right includes the right to know about how BMS products should perform in health and nutrition terms for purposes of identifying truly false and misleading claims, and determining if and when they should use such products. And, by failing to adequately address how infant formula and follow-up formula products are to be distinguished in labeling, advertising and product packaging materials, such as by requiring identical messages on the labels of both types of products, the PH BMS Framework does little to ensure against consumer confusion regarding such products that could prevent follow-up formula from being inappropriately passed-off as infant formula in the Philippine marketplace.

The UK BMS Framework provides a reasonably available less-trade restrictive alternative that imposes advertising, labeling and packaging restrictions and prohibitions on the marketing of infant formula and follow-on formula which could achieve the PH BMS Framework's policy objectives at the Philippine Government's chosen level of protection with little risk of nonfulfillment. First, they ensure that infant formula products intended for infants 0-6 months of age are marketed only in science and trade publications, and that only scientifically substantiated health and nutrition claims made with respect to follow-on formula are permitted, to prevent against discouragement of breastfeeding among the general public. Second, they ensure that follow-on formula products intended for infants 6-12 months of age and older are clearly distinguishable from infant formula products in the marketplace to prevent against consumer confusion that can lead to follow-on formula being inappropriately passed-off as infant formula.

There is little risk that the Philippine Government's adoption of the UK BMS Framework in lieu of the PH BMS Framework will result in the latter's policy objectives going unfulfilled. Although the UK BMS Framework's product scope and coverage are currently narrower than that of the PH BMS Framework, it is notable how these frameworks address many of the same issues to ensure the protection of public health via breastfeeding consistent with the WHO Code, and the protection of consumers from deceptive advertising, labeling and packaging practices that can result in inappropriate use of follow-on formula. And, future anticipated regulatory changes in the EU which the UK must implement will further reduce any differences between them. Despite disingenuous UNICEF and breastfeeding activist efforts to mischaracterize the UK BMS Framework as less robust than the WHO Code and as the cause of the UK's relatively lower breastfeeding rates, the facts reveal otherwise. Negative social/cultural attitudes in the UK towards the appropriateness of public breastfeeding have continued to discourage women from breastfeeding outside the privacy of their own homes. Unremarkably, women in a modernizing Philippines have also encountered such cultural resistance, notwithstanding all of the pro-breastfeeding measures the Philippine Government has enacted.

2. Looking Forward

Perhaps sensing that the executive branch dictates that have coalesced into the Philippine BMS Framework do not reflect the will of the Filipino people, members of the 14th,[646] 15th, [647] and current 16th [648] Philippine Congresses have proposed various pieces of legislation in an effort to codify into law what they think are the framework's most salient elements. Given the proclivity of legislators to recycle and/or enhance portions of prior session bills that have languished in committee, a brief survey of such proposed legislation follows.

The least trade-restrictive of these bills is House Bill No. 3525, entitled, "An Act to Regulate the Trade, Marketing, Advertising and Promotions of Infant Formula of 2010", which was introduced on October 14, 2010, as a re-filed version of consolidated predecessor House Bill 3179 previously filed during the 14th Congress.[649] Consistent with the WHO Code and the UK BMS Framework, this bill aimed to impose a ban "on advertisements and promotions of breastmilk substitute, infant formula and complementary food products…intended for children from 0-6 months old and [to] promote breastfeeding for the first *(6)* months of an infant" (emphasis in original).[650] It would have permitted the "[a]dvertising and promotion of follow-on formula, growing-up milk or milk supplements…intended for children over six *(6)* months of age",[651] provided they do not discourage breastfeeding, and would have subjected any claims of false, misleading or deceptive advertising made with respect to such products to review under the Consumers Act of the Philippines (RA

646 The 14th session of the Philippine Congress commenced on July 23, 2007 and ended on June 4, 2010. See *14th Congress of the Philippines*, Wikipedia, available at: http://en.wikipedia.org/wiki/14th_Congress_of_the_Philippines.
647 The 15th session of the Philippine Congress commenced on June 26, 2010 and ended on June 6, 2013. See *15th Congress of the Philippines*, Wikipedia, available at: http://en.wikipedia.org/wiki/15th_Congress_of_the_Philippines.
648 The 16th session of the Philippine Congress commenced on July 22, 2013. See *16th Congress of the Philippines*, Wikipedia, available at: http://en.wikipedia.org/wiki/16th_Congress_of_the_Philippines.
649 *See* Republic of the Philippines, House of Representatives Fifteenth Congress First Regular Session, *House Bill No. 3525 - An Act to Regulate the Trade, Marketing, Advertising and Promotions of Infant Formula, and For Other Purposes,* available at: http://www.congress.gov.ph/download/basic_15/HB03525.pdf. See *Legislative History of NO. HB03525*, at: http://www.congress.gov.ph/legis/search/hist_show.php?congress=15&save=1&journal=&switch=0&bill_no=HB03525.
650 *Id*., at Explanatory Note.
651 *Id*., at Sections 11 and 13.

7394).[652] In addition, it would have subjected the proposed sales promotion of breastmilk supplement products to review by the PHDOH and BFAD/FDA, pursuant to the review and appeals procedures provided for under such statute.[653] *Inter alia*, it would have provided for the creation of the IAC the purpose of which would be to develop regulations to ensure the implementation of said Act and company compliance therewith, through development of cooperative monitoring mechanisms and imposition of civil and criminal sanctions.[654]

House Bill No. 3527, entitled the "Breastfeeding Act of 2010", was introduced on October 14, 2010.[655] Aside from House Bill No. 3525, it, too, is the least trade-restrictive of all the bills proposed to date. Consistent with the WHO Code and the UK BMS Framework, this bill set forth a number of initiatives promoting exclusive breastfeeding in the Philippines "from birth to six months of age,"[656] in public health institutions,[657] the workplace[658] and in public spaces,[659] and through breastfeeding education.[660] In addition, it would have prohibited the advertising and promotion of "breastmilk substitutes, infant formula and complementary foods…intended for infants 0-6 months,"[661] but "allowed…[a]dvertising…[and promotion of such] products [if]…intended for infants 6-12 months…upon review and approval of the IAC,"[662] provided it did not undermine breastfeeding.[663] It would have also prohibited infant formula, breastmilk substitutes and complementary food product labeling from undermining breastfeeding and idealizing infant formula.[664] Furthermore, this bill would have permitted "[h]ealth and nutritional claims for [such] products…as long as it [was] based on scientific and factual information upon review and approval by the IAC", and "prohibited…[f]alse or misleading information or claims."[665]

House Bill No. 3396, entitled "Milk Code 2", was introduced on September 29, 2010.[666] Far in excess of the WHO Code and the Philippine Supreme Court decision, and consistent with the PH BMS Framework, the bill would have banned the direct and indirect advertising, promotion, marketing and/or sponsorship of infant formula, follow-up formula and complementary food products[667] - "[d]esignated products intended for infants and young children up to three (3) years of age...[including those that] tend to convey subliminal messages or impressions that undermine or compete with breastmilk and breastfeeding, and/or exaggerate the benefits and value of

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652 *Id*., at Sec. 11.
653 *Id*.
654 *Id*., at Sections 19-20.
655 *See* Republic of the Philippines, House of Representatives Fifteenth Congress First Regular Session, *House Bill No. 3527 – An Act Providing for the Promotion of Breastfeeding Practices and Instituting Measures Therefor and for Other Purposes*, available at: http://www.congress.gov.ph/download/basic_15/HB03527.pdf. See *Legislative History of NO. HB03527*, available at: http://www.congress.gov.ph/legis/search/hist_show.php?congress=15&save=1&journal=&switch=0&bill_no=HB03527.
656 *Id*., at Chap. I, Sec. 2, Chap. V, Chap. VII.
657 *Id*., at Chap. III, Sec. 6; Chap. IV.
658 *Id*., at Chap. III, Sec. 8-9.
659 *Id*., at Chap. III, Sections 5, 7
660 *Id*., at Chap. VI.
661 *Id*., at Chap. IX, Sections 27, 28(a) and 29(a)(1).
662 *Id*., at Chap. IX, Sections 27, 28(b) and 29(a)(2).
663 *Id*., at Chap. IX, Sec. 30.
664 *Id*., at Chap. IX, Sec. 39.
665 *Id*., at Chap. IX, Sec. 31(a)-(b).
666 *See* Republic of the Philippines, House of Representatives Fifteenth Congress First Regular Session, *House Bill No. 3396 – An Act to Protect, Promote and Support Proper Infant and Young Child Feeding by Regulating the Marketing of Certain Foods for Infants and Young Children*, available at: http://www.congress.gov.ph/download/basic_15/HB03396.pdf. See *Legislative History of NO. HB03396*, available at: http://www.congress.gov.ph/legis/search/hist_show.php?congress=15&save=1&journal=&switch=0&bill_no=HB03396.
667 *Id*., at Chap. I, Sections 5(c), (g), (l) and (t).

Designated products."[668] Said bill would have prohibited all health and nutrition claims in advertisements, sales promotions, marketing and sponsorships, as well as on product labels.[669]

House Bill No. 3537, entitled "The Breastfeeding Practices Act of 2010", was introduced on October 15, 2010.[670] Broadly consistent with the WHO Code, the 2007 Philippine Supreme Court decision and the UK BMS Framework, it would have "prohibit[ed] the advertisement [and sales promotion of] infant formula and other products [including complementary foods intended] for infants 0-12 months"[671] and permitted the advertising and sales promotion of BMS products intended for "a young child one (1) year of age up to three (3) years of age…upon review and approval of the IAC."[672] In addition, it would have adopted various initiatives promoting and protecting breastfeeding[673]and breastfeeding education,[674] in public health institutions,[675] the workplace,[676] and public spaces.[677] *Inter alia*, it would have also "allowed…[h]ealth and nutritional claims for [BMS] products…as long as [they] are based on scientific and factual information upon review and approval by the IAC",[678] while prohibiting "false or misleading information", and information or claims "in [an] advertising concept…[that]…make the product appear to be as good or equal to breastmilk or breastfeeding."[679] Apparently, HB No. 3537 so alarmed the UNICEF/WHO and the PHDOH[680] and the international breastfeeding activist community[681] that they launched an all-out

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668 *Id*., at Chap. V, Sec. 13(b).
669 *Id*., at Chap. V, Sections 13(f) and 16(b).
670 *See* Republic of the Philippines, House of Representatives Fifteenth Congress First Regular Session, *House Bill No. 3537 – An Act to Promote a Comprehensive Program for Breastfeeding Practices in the Philippines*, available at: http://www.congress.gov.ph/download/basic_15/HB03537.pdf. See *Legislative History of NO. HBO3537*, available at: http://www.congress.gov.ph/legis/search/hist_show.php?congress=15&save=1&journal=&switch=0&bill_no=HB03537.
671 *Id*., at Explanatory Note; Art. IX, Sections 27, 28(a), 29(a)(1).
672 *Id*., at Art IX, Sections 27, 28(b), 29(a)(2).
673 *Id.,* at Articles V and VI.
674 *Id.,* at Art. VIII, Sections 22-24 and 26.
675 *Id.,* at Art. III, Sec. 5; Art. IV.
676 *Id.,* at Art. III, Sections 8 and 10.
677 *Id.,* at Art. III, Sections 7 and 9.
678 *Id*., at Art. IX, Sec. 31(a).
679 *Id*., at Art. IX, Sections 31(b)-(c).
680 *See* World Health Organization Western Pacific Region, *WHO Expresses Alarm Over Bill on Breastfeeding in the Philippines*, Press Release (Sept. 1, 2012), available at: http://www.wpro.who.int/mediacentre/releases/2012/20120912/en/. ("The Department of Health (DOH) and international partners the World Health Organization (WHO) and United Children's Fund (UNICEF) today jointly expressed alarm over a new legislation that threatens to… substantially change the contents of the current Milk Code of 1986 (Executive Order No. 51), the Expanded Breastfeeding Act of 2009 (Republic Act No. 10028), and the Revised Implementing Rules & Regulations of both…The draft consolidated House Bill (HB) is entitled, 'An Act Promoting a Comprehensive Program on Breastfeeding Practices and regulating the Trade, Marketing and promotions of Certain Foods for Infants and Children.' The draft bill is *in substitution of HB Nos. 3525, 3527, 3396, and 3537*…The salient features of the new bill are: *narrowing the application of the Milk Code only to artificial feeding products, such as formula milk, for the 0 to 6 months instead of the current 0 to 36 months*…") (emphasis added). *Id*.
681 *See* Inquirer Lifestyle, *Save the Children: Don't Dilute Breastfeeding Provisions of Milk Code*, INQUIRER.net (Oct. 13, 2012), available at: http://lifestyle.inquirer.net/71208/save-the-children-dont-dilute-breastfeeding-provisions-of-milk-code. ("Save the Children has advised lawmakers and aspiring candidates in the upcoming congressional elections in May 2013 'not to tamper with provisions in the Milk Code, which promote breastfeeding over milk substitutes.' The 'Milk Code'…was commended in 2009 by the Committee on the Rights of the Child in its Concluding Observations on the Philippines' implementation of the United Nations Conventions on the Rights of the Child (UNCRC)…Last June, *breastmilk advocates including Save the Children were alarmed* by attempts to dilute the Milk Code. An unnumbered House Bill entitled 'An Act Promoting a Comprehensive Program on Breastfeeding Practices and Regulating the Trade, Marketing and Promotions of Certain Foods for Infants and Children' is being circulated among members of the House of Representatives. The bill is currently under Congress deliberations. The bill limits the application of the Milk Code to infant formula for infants, age 0 to 6 months *instead of 0 to 36 months*…The proposal likewise lifts several restrictions by the existing law on milk companies, particularly on their advertising, promotional and marketing practices…'In the Philippines, breastfed babies are at least 6 times more likely to survive in the early months of life than non-breastfed children,' says Anna Lindenfors, Country Director of Save the Children in the Philippines") (emphasis added). *Id*. *See also* Sacha Passi *Big Business is Threatening the Philippines' Progressive Breastfeeding Culture*, Southeast Asia Globe (Dec. 25, 2012), available at: http://sea-globe.com/mothers-milk/. ("'Infant formula companies have a vested interest in babies not being breastfed and that is financial profit for their shareholders. Their motives are focused on product sales and not on infant health,' said Dr Jennifer James, a nursing and midwifery expert at Royal Melbourne Institute of Technology of University…The introduction of the Executive Order No. 51 – also known as the Milk Code – marks the Philippines as the only

emotion-driven anti-business public relations assault on the bill, replete with misinformation and election day voting threats, in an effort to help the PHDOH defeat it.

Lastly, as of this writing, new House Bill No. 0015, entitled, the "Breastfeeding Promotion and Breastmilk Substitute Regulation", was introduced on or about August 7, 2013. According to the Philippine House of Representatives press release, "a lawmaker has filed a measure which prohibits the advertisement for infant formula and other milk products for infants 0-24 months of age to encourage breastfeeding in the country."[682] This bill, which is hardly consistent with the WHO Code or the UK BMS Framework, also "mandates the adoption of rooming-in in health institutions, establishment of human milk banks and setting up of lactation facilities in work places", as well as "the implementation of [breastfeeding] educational programs."[683] In addition, the bill "imposes a penalty of not less than 6 years imprisonment or a fine of not less than P2,000,000 [USD$45,610] or both on violators of the proposed act."[684]

Such competing legislation clearly reflects the ongoing policy debate in the Philippines regarding how best to balance the need to ensure public health and consumer protection with the need to facilitate international trade. For as long as this national vetting process shall continue, it is expected that the Philippine Government, including its legislature, will be mindful of the country's obligation to remain compliant with its international WTO (TBT and TRIPS) obligations.

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country in the region to implement legislation that substantially includes all provisions of the WHO's international code, developed to ensure that women and children have clear and unbiased information about the benefits of breastfeeding…'The Milk Code is the backbone of breastfeeding protection, promotion and support efforts in the Philippines,' said Mike Brady, Campaigns Coordinator for Baby Milk Action. 'It also aims to ensure that health workers, parents and carers receive accurate, independent information about breast milk substitutes if necessary.' *Under the Milk Code guidelines for breastfeeding, substitutes for children under the age of 36 months cannot be advertised*…'Although breastfeeding practices in the Philippines increased in 2011 and are relatively high in Southeast Asia compared to other countries, we are afraid that these rates will go down and slow because of the aggressiveness of these multinational milk companies,' said Madella Santiago, executive director of the Association for the Rights of Children in Southeast Asia (ARCSEA). The concern is not unfounded, with the milk formula industry aggressively fighting to protect advertising rights for as long as the regulations have been in place. After losing a Supreme Court battle to block the implementation of the Milk Code in 2007, multinational milk formula companies have been lobbying Congress to amend the code under a consolidated bill that combines previous proposals…'The most vulnerable group is the infants and young children from 0-36 months, who will be put at great risks of dying or even [becoming] developmentally disadvantaged – both physically and mentally – before they reach their fifth birthday,' said Cora Acosta, *from WHO in the Philippines*. The passing of the proposed bill by the House of Representatives was postponed in September after the Joint Committee on Health and Trade requested that all legislators present further amendments before it was reconsidered by Congress") (emphasis added). *Id*; Maria Aleta Nieva Nishimori, Breastfeeding Advocates Block 'Monster Bill', ABS-CBNnews.com (7/31/12), available at: http://www.abs-cbnnews.com/lifestyle/07/31/12/breastfeeding-advocates-block-monster-bill. ("Advocates and supporters of breastfeeding have come together to prevent the passage of a measure which they referred to as a 'monster bill'…'An Act Promoting Comprehensive Program on Breastfeeding Practices in the Philippines,' which was filed before the House of Representatives, states that breastfeeding employees will no longer be compensated when they express milk during work hours…*Breastfeeding advocates are also against the advertising of milk formula and allowing health and nutritional claims* of milk companies. According to Fernandez, legalizing these ads for babies above six months will affect breastfeeding mothers") (emphasis added). *Id*.

682 *See* Republic of the Philippines, House of Representatives 16th Congress, *Ban on Ads for Infant Milk Formula Pushed*, Press Release (Aug. 7, 2013), available at: http://www.congress.gov.ph/press/details.php?pressid=7184.

683 *Id*.

684 *Id*.

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