# INTERVENTIONS AT WTO AND CODEX RELATED TO NATIONAL IMPLEMENTATION OF THE WHO INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES

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#### Overview

This policy brief describes interventions at the World Trade Organization (WTO) and in related Codex Alimentarius Commission standard-setting, both preceding and following the weakening of provisions of Thailand's national Milk Code designed to support breastfeeding. The brief also describes parallel lobbying of the US government, the leader in some of these interventions, where the positions weigh the relative importance of the Codex Alimentarius versus World Health Organization (WHO) recommendations as international standards in World Trade Organization Technical Barriers to Trade (TBT) Committee processes.

- 1. In response to questioning by New Zealand and the United States, Thailand notified the WTO in 2015 of its intention to adopt legal provisions for "Controlling the Marketing Promotion on Food for Infant and Young Children" in alignment with the WHO International Code of Marketing of Breast-Milk Substitutes.
- 2. The United States and other countries interjected repeatedly at meetings of the World Trade Organization TBT Committee in 2016-2017 that Thailand's proposed legislation deviated from Codex standards and that the WHO Code is not recognized as an international standard.
  - The Codex Standard on Follow-Up Formula is a less restrictive standard than the WHO Code (including its subsequent resolutions) and WHO implementation guidance.
  - In particular, the WHO Code and implementation guidance prohibits the marketing of Follow-Up Formula (manufactured for children aged 12-36 months) in a way that the packaging, branding and advertising would have the effect of promoting sales of products for infants aged 0-12 months. This is called cross-marketing or cross-promotion. There is peer-reviewed evidence that this approach to marketing confuses consumers in way that can undermine infant nutrition. (See Russ, Baker, et al. 2021 for description.)
  - The WTO's public archives describe complaints focusing on Thailand's proposed provisions restricting marketing of formula products manufactured for children aged 12-36 months, mode of enforcement, and severity of penalties.
  - The United States rejected WHO guidance as relevant to standards during the November 2016 WTO TBT Committee meeting. The minutes report:

Thailand was asked to explain how the provisions regarding nutrition and health claims reflected the Codex Guidelines... The US reiterated that the WHO's Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not an international standard according to the criteria established by this Committee and asked whether Thailand also recognized this fact. (G/TBT/M/70)

3. Complaints not resolved in WTO committees may result in costly legal battles and punitive tariffs.

- Following interventions in the WTO TBT Committee by Australia, Canada, the European Union, New Zealand, and the United States, Thailand weakened its restrictions on marketing of followup formula in the final version of its domestic legislation, passed in 2017.
- Upon this notification, the United States expressed approval of the weakening of the domestic law at the WTO TBT Committee meeting in June 2017. The minutes report:

The representative of the <u>United States</u> strongly supported the public health objective of increasing breast feeding, and her delegation acknowledged receipt of the revision to the measure, which included a welcome modification, allowing advertising of food for young children. (<u>G/TBT/M/72</u>)

- 4. A review and revision of the Codex Standard for Follow-Up Formula began in 2017. The United States has protested language that would explicitly acknowledge national determination of whether to restrict marketing of follow-up formula in a manner similar to formula for infants aged 0-12months as a measure to prevent cross-promotion.
  - In 2019, the United States argued to delete the key text in the standard (a footnote) that would provide legal protection from trade complaints in the WTO TBT Committee for countries regulating follow-up formula in a manner similar to products for infants aged 0-12 age months to prevent cross-promotion. The footnote continues to be subject to possible deletion.
  - This occurred a year after the committee charged with revising the standard rejected a proposal
    to include language explicitly prohibiting cross-promotion in the marketing of follow-up
    formula.
- 5. Peer-reviewed research shows that conflicts with Thailand over its Milk Code occurred in parallel to the emergence in 2016 to heavy lobbying activity by affiliates of a cross-industry coalition in the United States that elevates Codex standards and criticizes WHO policies and processes, in particular due to the stronger protocols used to mitigate conflicts of interest in WHO processes. (Russ, Baker, Kang, and McCoy 2022)
  - Affiliates of this coalition have lobbied the US federal government on United States positions toward WHO guidance on infant nutrition since 2016, as well as US appropriations to WHO since 2018.
  - Industry associations criticizing WHO policies on infant and young child nutrition and lobbying on the Codex standard are among the founding members of this coalition.
  - Specific mention of WHO guidance and processes being inferior to Codex standards and processes is a theme of affiliates' lobbying, including on issues related to infant and young child nutrition. WHO protocols to mitigate conflicts of interest have been targeted as problematic.

#### References

Russ, Katheryn, Phillip Baker, Michaela Byrd, Manho Kang, Rizki Nauli Siregar, Hammad Zahid, and David McCoy. 2021. International Journal of Heath Policy Management 10(12): 983-997. DOI: 10.34172/IJHPM.2021.109

Russ, Katheryn, Phillip Baker, Manho Kang, and David McCoy. 2022. Corporate Lobbying on U.S. Positions Toward the World Health Organization: Evidence of Intensification and Cross-Industry Coordination." Global Health Governance 17(1): 37-83.

#### BIO

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### APPENDIX: EXCERPTS FROM RELATED MEETING MINUTES, DELEGATION COMMENTS, AND MEETING SUMMARY DOCUMENTS

I. November 2015: The United States and New Zealand ask Thailand about its Milk Code at the World Trade Organization Trade Policy Review of Thailand, November 2015 Meeting; Thailand replies that it is expanding regulation to be consistent with the WHO International Code of Marketing of Breastmilk Substitutes (Minutes)

Note: The US specifically asks Thailand here if it plans to implement regulations aligning with the WHO International Code of Marketing of Breast-Milk Substitutes, Thailand replied yes.

#### 3.2.6.2.1 Food standards-setting framework

Paragraph 3.58. of the Secretariat Report <u>WT/TPR/S/326</u> states "Food safety control measures include hazard prevention, inspections and surveillance on imports and domestic production apparently based on the risk analysis principle and scientific evidence."

Question: Could Thailand please advise whether it is considering any changes to the legislative Act for "Controlling the Marketing Promotion on Food for Infant and Young Children and other Related Products" (commonly known as "The Milk Code") and if so, what are those changes? Will any changes be in line with international standards, in particular the World Health Organisation's "International Code of Marketing of Breast-Milk Substitutes"? Please provide a copy of the latest draft milk code governing the sale of infant formula and nutritional products and identify any amendments that Thailand is considering more generally to its milk code. Also, please clarify when Thailand intends to finalize this code, as well as the process of stakeholder consultation. In instances where the draft deviates from the international guidance, please provide the scientific rationales to support and justify those deviations.

([Response to] New Zealand, US) The current Thai laws does not specifically cover marketing of food for infant and young children. Therefore, the Milk Code was drafted to address the issue and was approved by the cabinet on December 1, 2015. The Draft is consistent with the MFN and National Treatment under the WTO GATT 1957, since the Milk Code will apply to both domestic and imported products. As for the details on marketing restrictions, it is consistent with the International Code of Marketing of Breast-Milk Substitutes, which is an international standard of advice, as well as the WHA 54.2 resolution on Infant and young child nutrition. The stakeholder consultation process has been conducted on May 18, 2015. The consultation involves over 600 participants from the public sector, private companies, milk powder manufacturers, doctors, NGOs, etc. The draft of the Milk Code can be obtained by request from the Department of Health.

II. The United States argues at WTO Technical Barriers to Trade (TBT) Committee Meetings that Thailand must follow Codex standards for regulating the marketing of infant formula, rather than WHO guidance.

Note: The United States declared that the WHO's implementation guidance for the International Code of Marketing of Breast-Milk Substitutes and subsequent resolutions is not recognized by the TBT Committee as an international standard.

II.A. June 2016 WTO Technical Barriers to Trade Meeting: G/TBT/M/69

From the minutes:

# 3.2.3.44 Thailand - Milk Code - Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE, G/TBT/N/THA/471 (IMS ID 503)

3.345. The representative of the <u>United States</u> said that, while her delegation strongly supported efforts to ensure that the marketing of infant and follow-up formulas would not negatively impact breast feeding, it nonetheless remained concerned with the following aspects of the Thai measure at issue. With respect to the use of international standards, she noted that there were several Codex Alimentarius standards that were relevant to this measure, including one for infant formula and formulas for special medical purposes intended for infants. There were, more specifically, standards for follow-up formula, canned baby foods and processed cereal-based foods for infants and young children, as well as the Codex Guidelines for nutrition and health claims. In this respect, she asked Thailand to explain how it had considered these existing standards, and why it had deviated from them in certain areas. She also expressed her delegation's view that, conversely, the new WHO guidance on ending the inappropriate promotion of foods for infants and young children<sup>20</sup> was not an international standard in accordance with the criteria established by the TBT Committee. She additionally noted, in this respect, that in the US the adherence to the application of the 1981 WHO's *International Code of Marketing of Breast-milk Substitutes* was voluntary. In the US, this International Code was also complemented by some more codes developed by leading US medical professional societies on the marketing of these products.

3.346. The US also had questions about whether the regulatory approach outlined in the Thai draft measure could be more trade restrictive than necessary. She requested Thailand to provide the scientific explanation for its complete ban on the marketing and advertising of infant and follow-up formula for babies up to 36 months of age. More specifically, the US asked Thailand to provide the scientific explanation of how a ban on health claims and trademark information on labels would contribute to the accomplishment of the desired goal of increasing and sustaining breastfeeding in Thailand's specific context. She also asked for available information on any assessment Thailand made with respect to the potential regulatory impacts of the proposed measure. Additionally, she noted that the draft provided for the punishment of violations of its advertising and marketing requirements under the Thai criminal code, including the imposition of prison time for certain offences. She then asked Thailand to provide the reasoning behind imposing such criminal penalties as well as any additional detail with respect to the procedures for prosecution.

3.347. Finally, the US requested Thailand to allow for sufficient time, both after the publication of the final rule and before implementation and enforcement of the regulation, so that industry would be able to come into compliance with the new requirements. In this respect, she also asked Thailand to confirm if it was indeed planning to provide for a 180-day transition period following ratification.

3.348. The representative of <u>Australia</u> noted that the Thai draft measure proposed measures that had similarities to new WHO guidance on ending the inappropriate promotion of foods for infants and young children, welcomed by WHO members, including Australia, at the World Health Assembly last month.<sup>21</sup> He explained that in Australia the marketing of infant formulas was conducted under the auspices of a

voluntary, self-regulatory Code of Conduct between manufacturers and importers of infant formula. This Code of Conduct applied to the marketing and promotion of formulas for infants up to 12 months of age only. Australia recognised, however, that countries regulate marketing of infant formulas in different ways so as to suit their own national circumstances. As a reliable supplier of high quality dairy products to Thailand, Australia would encourage Thailand to develop and implement standards for the marketing of food for infants and young children in a manner that would be as trade facilitating as possible. In this respect, Australia was concerned about the allowance for unspecified Ministerial requirements on marketing products under the legislation. Australia also asked Thailand for clarification on whether the proposed regulations would exclude nutritional labelling on products. Australia also requested more time for exporters, importers and manufacturers to adapt to Thailand's new regulation. Finally, he underscored Australia's belief in promoting harmonization with relevant Codex standards in this area.

3.349. The representative of the <u>European Union</u> expressed his delegation's concerns with this draft regulation, in particular, as regards certain definitions, which would either deviate from the relevant Codex Alimentarius standards, or whish, in some cases, would seem redundant. The EU also asked Thailand to explain more clearly the rationale for setting out certain restrictions in the proposed measure. Finally, the EU asked Thailand to reply to the written comments submitted to it in February 2016.

3.350. The representative of <u>New Zealand</u> noted that Thailand was an important export market for New Zealand products, including in particular infant formula products. She said that she looked forward to an update as to how comments her delegation had already sent to Thailand bilaterally had been taken into account.

#### II.B. November 2016 WTO Technical Barriers to Trade Meeting: G/TBT/M/70

#### From the minutes:

# 2.2.3.39 Thailand — Milk Code - Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE (IMS ID 503)

2.275. The representative of the <u>United States</u>, whilst strongly supporting the public health objective of promoting breast feeding, expressed continued concern regarding Thailand's proposed measure. Her delegation was of the understanding that a new draft of the measure would be notified and requested a timeframe for this notification. She asked how the revised draft, "Marketing Control on Food for Infants and Young Children Act", would interact with the Thai Food Law and the Thai Food Labelling Regulation and whether either of these measures would need to be revised in order to enforce the Marketing Control Act. Recalling the various Codex standards relevant to this measure, including the Standard on Infant Formula and Formulas for Special Medical Purposes Intended for Infants, Standard on Follow-up Formula, Canned Baby Foods, and Processed Cereal-based Foods for Infants and Young Children, as well as the Codex Guidelines for Nutrition and Health Claims, her delegation asked Thailand how it had considered these standards and any deviations therefrom in certain areas.

2.276. Regarding the un-notified draft entitled "Draft Marketing Control on Food for Infants and Young Children Act BE", the US asked Thailand to clarify if they were defining supplementary or complementary foods. She noted that Section 15.2 in the un-notified draft stated that importers must provide warnings against inappropriate preparation or use of the Food for Infants and Young Children and in this regard asked what inappropriate use was, and what types of warnings would be required. In particular, the US was concerned that the new draft did not appear to take into account the Codex Guidelines for Nutrition and Health Claims [CAC/GL 23], although resolution WHA 63.23 on Infant and Young Child Nutrition, noted in the draft Thai Code, referenced the Codex. Thailand was asked to explain how the provisions regarding nutrition and health claims reflected the Codex Guidelines.

- 2.277. The US reiterated that the WHO's Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not an international standard according to the criteria established by this Committee and asked whether Thailand also recognized this fact. She reminded Members that in the US, adherence to the application of the WHO's International Code of Marketing of Breast-Milk Substitutes was voluntary, and complemented by similar codes developed by leading US medical professional societies on the marketing of those products. Her delegation expressed hope for deeper technical engagement with Thailand on how to achieve its health objectives without unnecessarily impacting trade in products appropriate for infants and young children and requested that a reasonable interval for implementation be provided after notification of this measure to the TBT Committee.
- 2.278. The representative of the <u>European Union</u> joined the US in its interest in this measure and thanked Thailand for the reply to written comments. She reminded the Thai authorities of the need to ensure that the draft Milk Code was aligned with relevant international standards and therefore the need to take into consideration the ongoing revision taking place within the Codex Alimentarius of the Standard on Follow-up Formula. She also recalled that, as stated in Article 2.2 of the TBT Agreement, the Thai draft Milk Code should not be more trade restrictive than necessary. Further, and in accordance with Article 2.12 of the TBT Agreement, Thailand was urged to allow for a reasonable interval of time between the publication and enforcement of the measure, in order to allow time for producers in exporting Members to adapt their products or methods of production to the Thai requirements. She noted that her delegation would be following closely the developments on the draft, in order to ensure that its concerns were taken into account, and looked forward to receiving information on the timing for its adoption.
- 2.279. The representative of <u>Australia</u>, whilst recognizing Thailand's right to take measures to address a legitimate public health concern, said that as a supplier of high quality dairy products to Thailand, his delegation encouraged them to implement standards for the marketing of food for infants and young children in a manner that was as trade facilitating as possible. His delegation supported transparent and flexible implementation of regulations to minimize disruptions to trade and which would provide opportunities to allow traders to comply with new regulations.
- 2.280. The representative of New Zealand said that her delegation was of the understanding that the draft legislation had been revised and requested that the revised draft be promulgated to give Members adequate opportunity to comment. Recalling New Zealand's continued concerns about the intended application of the draft legislation and its potential impact on trade, she said whilst the draft regulation pertained to infant formula, follow-up formula and growing up milk, her delegation sought clarification on the application of the draft regulation to other food products consumed by young children defined in the act as between 12 months and 3 years. Additionally, clarification was sought on the product labelling restrictions for food products covered by the draft legislation.

#### II.C. March 2017 WTO Technical Barriers to Trade Committee Meeting: G/TBT/M/71

#### From the minutes:

- 2.2.4.31 Thailand Milk Code Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE <u>G/TBT/N/THA/471</u>, <u>G/TBT/N/THA/471/Rev.1</u> (IMS ID 503)
- 2.212. The representative of the <u>United States</u> said that while the US fully supported public health objectives that aimed at increasing levels of breastfeeding, concerns remained with Thailand's proposed measure. The US had submitted comments to the TBT Enquiry Point in January which highlighted several Codex standards relevant to the measure, including the Standard on Infant Formula and Formulas for Special Medical Purposes Intended for Infants, Standard on Follow-up Formula, Canned Baby Foods, and Processed Cereal-based Foods for Infants and Young Children, as well as the Codex Guidelines for

Nutrition and Health Claims. She asked if Thailand had considered these standards and to explain any deviations from them. Given that the new draft did not take into account Guidelines for Nutrition and Health Claims even though those standards in particular were referenced in WHA 63.23 on Infant Nutrition, she requested an explanation of how the provisions regarding nutrition and health claims reflected Codex Guidelines. The US reminded Thailand that the WHO's Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children was not an international standard according to the criteria established by the TBT Committee. The US adherence to the application of the WHO's International Code of Marketing of Breast-Milk Substitutes was voluntary, and complemented by similar codes developed by leading US medical professional societies on the marketing of these products. The US proposed deeper technical engagement with Thailand on how to achieve this health objective without unnecessarily impacting trade in products appropriate for infants and young children. She also invited Thailand to explain how the revised draft code would interact with the Food Law and the Food Labelling Regulation and whether they might be superseded by the Milk Code.

- 2.213. The representative of the <u>European Union</u> said her delegation continued to follow with interest the new draft Milk Code. She reminded Thailand of the need to ensure that the draft Milk Code was aligned with relevant international standards and, therefore, the need to take into consideration the ongoing revision taking place within the Codex Alimentarius of the Standard on Follow-up Formula. The Thai draft Milk Code should not be more trade restrictive than necessary so as to not violate Articles 2.2 of the TBT Agreement, and in accordance with Article 2.12, Thailand should allow for a reasonable interval between the publication and enforcement of the measure. The EU was closely following the developments on the draft, so as to ensure that its concerns were taken into account, and asked for information on the timing for its adoption.
- 2.214. The representative of <u>Australia</u> said that his delegation recognized the rights of Members to take measures necessary to protect public health and understood Thailand's efforts to address a legitimate public health concern. As a reliable supplier of high quality dairy products to Thailand, Australia encouraged Thailand to implement the measure in a trade facilitating manner where the transparent implementation of regulations minimized disruptions to trade and provided opportunities to allow producers and manufacturers to comply with new regulations.
- 2.215. The representative of <u>Canada</u> said that while supporting Thailand's public health objective of promoting breast feeding, his delegation supported the concerns expressed by the US, the EU and others related to the sole use of guidance from the WHO in developing technical regulations. In this context, Canada reminded the Committee that the TBT Agreement strongly encouraged Members to base their measures on international standards. Canada encouraged Thailand to consider the standard on infant formula and formulas for special medical purposes intended for infants, the standard on follow-up formula, canned baby foods, and processed cereal-based foods for infants and young children, as well as the Codex guidelines for nutrition and health claims in the development and implementation of relevant measures.
- 2.216. The representative of <u>New Zealand</u> thanked Thailand for notifying the draft measure to the TBT Committee. New Zealand had submitted comments through the WTO process, and had also engaged bilaterally with Thailand on the issue. While supporting the objective of promoting breast-feeding, New Zealand continued to have concerns about the intended application of the draft legislation, and its potential impact on trade. New Zealand looked forward to further engagement with Thailand and updates on the development of this legislation.
- 2.217. The representative of <u>Thailand</u> reiterated that breast feeding offered substantial and lifelong benefits to infants. The rate of exclusive breastfeeding in Thailand was among the lowest in the world. Several factors contributed to this phenomenon including sales promotion of milk formula for infants and young children. Therefore, there was a strong need for a regulation that controlled marketing promotion of milk products that were specifically marketed for infants and young children. Thailand had been using

Codex as its guide to develop its quality and safety standards for food including milk products. However, some issues were not sufficiently covered by Codex, and therefore other internationally recognized guidelines had been used, while ensuring that their application did not contradict Codex. Although this regulation concerned control of marketing promotion, this regulation still allowed health and nutrition claims of milk products as long as they were not misleading. The draft Act did not prohibit industry from showing health and nutrition claims on the labels. Furthermore, in general the draft Act did not prohibit the use of trademarks, brand names, logos, and symbols of products. In line with other existing food-related laws in Thailand, exaggerated claims and misleading advertisements were criminal offenses and punishable by law. Thailand was a firm believer in free trade and would not do anything that restricted trade unnecessarily. Comments and support from other Members was welcome in helping Thailand achieve the target of having a 50% breastfeeding uptake by 2025.

III. The Thai Milk Code was passed before the revision of the Codex Standard on Follow-Up Formula was finalized. The United States Government publicly welcomed and described the weakening of the Thai law through removal of restrictions on marketing of formula to young children aged 12-36 months.

#### III.A. June 2017 WTO Technical Barriers to Trade Meeting

# 3.2.4.27 Thailand — Milk Code - Draft Act on Controlling to the Marketing Promotion on Food for Infant and Young Children and Other Related Products BE, <u>G/TBT/N/THA/471</u>, <u>G/TBT/N/THA/471/Rev.1</u> (IMS ID 503)

3.172. The representative of the <u>United States</u> strongly supported the public health objective of increasing breast feeding, and her delegation acknowledged receipt of the revision to the measure, which included a welcome modification, allowing advertising of food for young children. Both the US government and the US industry planned to submit comments on the revised measure through Thailand's Enquiry Point. The US understood the Committee on the Control of Marketing of Infant and Young Child food had been granted substantial authority, including developing a system for monitoring the marketing of foods for infants, young children and supplementary food for infants and providing advice to the Ministry of Public Health to ensure compliance with the measure. She mentioned that the US comments would address questions on the broad definition of foods for young children and the Marketing Committee's work to ensure compliance with the measure. Her delegation welcomed any comments or feedback from Thailand on the scope of the Marketing Committee's work.

# III.B. United States Trade Representative's Office. <u>2018 National Trade Estimate Report on Foreign</u> Trade Barriers (p.437).

#### From the report:

In December 2015, following repeated requests from the United States, Thailand notified to the WTO its draft Marketing Control of Food for Infant and Young Child and Related Products ("Milk Code"). The Milk Code proposed to restrict the use of trademarked brand names, packaging, symbols -- and educational, promotional, and marketing activities -- for modified milk for infants, follow-up formula for infants and young children, and supplemental foods for infants. The restrictions would have covered infants and young children up to 36 months of age. In April 2017, the National Legislative Assembly passed a revised version of the Milk Code, which removed the advertising restrictions for products for young children from older than 12 months up to 36 months of age, but maintained other marketing restrictions on foods for young children, as well

as other restrictive penalties for violating the Milk Code. In late January 2018, Thailand issued several draft regulations under the Milk Code dealing mainly with advertising and marketing. These regulations were notified to the WTO and Thailand provided 60 days for comment. Throughout this process, the United States has engaged extensively with Thailand both bilaterally and at the WTO and continues to monitor developments, particularly any potential regulations relating to restrictions on products for young children.

III.C. United States Department of Agriculture <u>Foreign Agricultural Service Global Agricultural Information Network Report Number TH7048</u>. This contains full and detailed redlines (edits) of the original version, indicating exactly which aspects were revised. From the report:

The approved legislation differs from the original draft legislation proposed by the Ministry of Public Health in the following ways:

- The approved legislation has separate definitions for infants and young children as well as separate definitions for food for infants, food for young children, and supplementary food for infants.
- The approved legislation limits the prohibition on advertising to just food for infants and supplementary food for infants. Advertising for food for young children is now permitted as long it does not cause the public to believe the product is for infants or cause the public to believe that the product was suitable for feeding infants.
- The approved legislation reduces the maximum criminal penalty of imprisonment from 3 years to 1 year and the maximum fine from 300,000 baht to 100,000 baht for violations of the advertising prohibitions.

# IV. Parallel efforts to modify draft standard during the Codex NFSDU Review of the Codex Standard for Follow-Up Formula, which began in 2017

Note: The Codex Standard for Follow-Up Formula applies to products for infants age 6-36 months and did not mention regulation of marketing of these products in a manner similar to restrictions on marketing of products manufactured for infants age 0-12 months. This omission means doing so makes a country's national regulation more strict than the Codex standard, which leaves it open to the charges observed in II.A-C above that regulation is unnecessarily "trade-restrictive" or not "science-based." The following illustrates what happened in response to efforts to bring the Codex standard into alignment with the WHO code in this respect.

# IV.A. United States argues to remove reference to the WHO Code of Marketing of Breast-Milk Substitutes in the preamble to the Codex Standard for Follow-up Formula

This was a series of debates at CCNFSDU. See for example CX/NFSDU 18/40/5 (especially CX/NFSDU 18/40/5-Add.1). The Executive Committee was asked for a judgment. While it declined to make a specific determination, it said that references must "have a scientific basis, and have been developed through a transparent process." United States industry lobbies contend that WHO guidance on a range of products including infant formula is not science-based and that WHO policy processes are not transparent, as an

argument to elevate Codex standards over WHO guidance, so the Executive Committee's choice of words is significant.

Here is an example of a large lobbying group's position statement using the "science-based" language relevant to this context:

The WHO should not lobby national governments to implement the Guidance [on adhering to the WHO International Code of Marketing of Breastmilk Substitutes], nor should the WHO undermine science-based international standards by seeking to incorporate the Guidance into development of the Codex standard on follow-up formula. (Russ, Baker, Kang, and McCoy 2022, p.60)

#### Here is a quote on transparency:

The WHO process, which is not transparent and tends to be more staff-led than member-driven, is quite different from that followed under Codex. It is critical that each body retain its unique mandate and independence moving forward. (Russ, Baker, Kang, and McCoy 2022, p.60)

# IV.B. Mexico issued a call to the WTO TRIPS Council cautioning against efforts to insert language prohibiting cross-promotion into the Codex Standard on Follow-Up Formula (IP/C/W/660)

- 2. At the 40th Session of the CCNFSDU, held from 26 to 30 November 2018, the proposed draft revised Standard for follow-up formula (hereinafter "the proposed draft") was discussed. It was agreed to submit its labelling provisions for endorsement by the Codex Committee on Food Labelling (CCFL) at its 45th Session, which would be held from 13 to 17 May 2019 in Ottawa, Canada. One of the issues that was discussed was the labelling provision contained in Section A, paragraph 9.6.4., of the proposed draft, which refers to "cross promotion".
- 3. The provision reads:
- 9.6.4. Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes, and to enable consumers to make a clear distinction between them, in particular as to the text, images and colours used. Cross promotion between products is not permitted in product labelling. (Emphasis added)
- 5. Subsequently, at the 42nd Session of the Codex Alimentarius Commission held in Geneva, Switzerland, from 8 to 12 July 2019, comments in favour of the endorsement of the proposed draft were made. The Commission decided to endorse the text of the proposed draft, but stressed that the concept of "cross promotion", described at the end of paragraph 9.6.4., should continue to be examined in the CCNFSDU Committee, especially in light of its possible incompatibility with international obligations under the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).
- 6. The concept of "cross promotion" in paragraph 9.6.4. of the draft Standard for follow-up formula (CXS 156-1987) will be further discussed at the 41st Session of the CCNFSDU to be held in Düsseldorf, Germany from 24 to 29 November 2019.
- 10. A single undertaking may produce "infant formula, follow-up formula for older infants, (name of product) for young children, and formula for special medical purposes". Consequently, the prohibition on "cross promotion" between product categories in product labels or labelling could be interpreted (in the absence of clarification on the scope of that definition) as a prohibition on the use of the same trademark for different categories of products, or it may possible to use the same trademark, but in a different way (e.g. through variations in colour), to avoid the appearance of "cross promotion". This could undermine

the capability of a trademark to distinguish the products of one undertaking from those of other undertakings, as stated in Article 20 of the TRIPS Agreement.

- 11. Although Article 17 of the TRIPS Agreement provides for exceptions to the rights conferred by a trademark, a prohibition on "cross promotion" must be examined to determine whether it could be justified under this Article, as it provides that such exceptions must take account of the legitimate interests of the owner of the trademark and of third parties.
- 13. Mexico recommends analysing the definition of "cross promotion", as well as the implications for TRIPS Council members of including the prohibition on "cross promotion" between categories of follow-up formula for infants in an international Codex Alimentarius standard, without having due clarification of the scope of this prohibition or its possible effects.
- 14. Mexico supports pursuing the discussion on the prohibition on "cross promotion" between categories of follow-up formula for infants in the various Codex Alimentarius bodies, and recommends that the WTO, as an intergovernmental organization with observer status in this international standardization body, take note of the concern that this concept's lack of clarity could generate for its Members.

#### V. Continuing efforts to prevent strengthening of domestic restrictions on cross-marketing

The United States argued to remove the footnote that eventually becomes the sole language in the draft revision of the Codex Standard for Follow-up Formula that would allow countries to regulate marketing of follow-up formula (for ages 12-36 months) in ways similar to formula for younger infants to prevent cross-promotion in adherence to the WHO Code. Mexico put out a call for the WTO to intervene in Codex discussions of cross-promotion.

V.A. In the <u>U.S. Delegate's Report on the 41<sup>st</sup> Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)</u>, the US Delegate notes acknowledgement of national determination regarding regulation of marketing of follow-up formula during the Review of the Standard for Follow-Up Formula. Follow-up formula here is referred to as "[name of product]" due to ongoing debate over labelling:

The Committee agreed to forward the proposed draft scope, definition, and labeling section for the [name of product] for young children to the Codex Alimentarius Commission (CAC) for adoption at Step 5 (allowing for another round of comments and review by the CCNFSDU at its next session), and to forward the labeling provisions to CCFL for endorsement. The draft standard is silent on the issue of whether these products may be considered breast milk substitutes (BMS), but includes a footnote noting that some countries regulate them as BMS. (p.1, second bullet point)

- V.B. November 2019: The United States argues to remove the footnote in the draft Codex Standard on Follow-Up Formula that would protect national determination of whether to regulate marketing follow-up formula in line with the WHO International Code of Marketing from trade complaints at the WTO like those seen in Section II above. (REP20/NFSDU\_rev)
- 60. ... Footnote: In some countries these products are regulated as breast-milk substitutes.
- 62. The United States of America expressed its reservation with respect to the footnote to the product definition (section 2.1.1), noting that the use of footnotes, when it is difficult to reach consensus, has proven to be problematic in other committees, and given that a footnote does not reflect a conclusion by

Codex but simply states that some countries regulate these products in a certain way at this time. In the US view, the Committee had made many significant revisions to the existing standard; Codex Standards should be forward looking and global in nature.