CODEX ALIMENTARIUS COMMISSION

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Agenda Items 4, 6 **NFSDU/43 CRD24**

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Comments by IBFAN

AGENDA ITEM 4: REVIEW OF THE STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)

IBFAN Comment on the Structure and the Preamble of the proposed draft standard for Follow-Up Formula

IBFAN is of the opinion that the standard has not been completed. There remain unresolved areas of the standard, such as sodium levels for drinks for young children, methods of analysis for sweetness and the lack of consensus on the use of flavourings in drinks for young children.

IBFAN is strongly opposed to Option 1.b: This option proposes the creation of two separate standards for Follow-Up Formula and Drinks for Young Children. Both products are recognized as breastmilk substitutes by the International Code of Marketing of Breast-milk Substitutes and World Health Assembly Resolution 69.9 (2016). Separating them into two standards based on age targeting, creates regulatory and consumer confusion and risk both misuse and needless use.

IBFAN considers that Option 1.d: one standard, sub-divided into four sections covering Infant Formula, Formulas for Special Medical Purposes, Follow-up Formula and Drinks for Young Children would facilitate more efficient and simplified law-making. As New Zealand has identified in Table 1, numerous provisions are common to ALL FOUR categories. In 2006, CCNFSDU decided to bring Formula for Special Medical Purposes and Infant Formula under one standard precisely because of the similarity of product categories – despite the strong lobby of the baby food industry to have two standards.

IBFAN's second choice is **Option 1a.** one standard in two parts, covering Follow-up Formula and Part B for Drinks for Young Children. However, if this is the preferred option, we advocate that each standard contain a footnote to the title referencing the paired/corresponding/associated Codex standard and recommending that governments address products in both standards in national legislation or regulations so that at national level, all four categories should be covered under one national standard.

Rationale:

1. There is no justification for separating the two categories into two separate standards and to do so risks inconsistent and weaker safeguards needed to protect maternal, infant and young child health. Keeping the products under one standard with a clear overarching preamble will facilitate the simpler and clearer legislation needed to safeguard this vulnerable population and prevent inappropriate use.
2. As a global recommendation by the World Health Organization breastfeeding for the second year of life is optimal. Hence regardless of how an infant or young child is fed, Follow-Up Formula and Drinks for Young Children, both function – inappropriately – as breastmilk substitutes during the critical time of rapid growth and development when breastfeeding is recommended.

3. IBFAN notes that the **product definitions in the draft revised standard** for both categories serve the same purpose, albeit for different age groups.
    - Follow-Up Formula is defined as a breastmilk substitute: “Follow-up formula for older infants means a product, manufactured for use as a breastmilk substitute, as a liquid part of a diet for older infants when progressively diversified complementary feeding is introduced.”
    - Drinks for Young Children is defined as a “product manufactured for use as a liquid part of the diversified diet of young children” with an important footnote that acknowledges the steps taken by many countries to ensure regulation that will prevent harmful marketing: ”In some countries these products are regulated as breast-milk substitutes”, as recommended by the World Health Assembly.
4. The International Code of Marketing of Breast-milk Substitutes (1981) and subsequent WHA Resolutions are specifically mentioned in the Code of Ethics for International Trade CAC/RCP 20-1979 which in para: 4.4 states: “National authorities should be aware of their obligations under the International Health Regulations (2005) …. They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed.”
5. WHA Resolution 69.9 (2016) specifically **“WELCOMES with appreciation the technical guidance on ending the inappropriate promotion of foods for infants and young children;”** and “URGES Member States1,2,3 in accordance with national context; to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children**, including, in particular, implementation of the guidance recommendations** while taking into account existing legislation and policies, as well as international obligations, and CALLS UPON manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion**, as set forth in the guidance recommendations..”**
6. Recommendation 2 of the Guidance states that **“Products that function as breast-milk substitutes should not be promoted**. A breast-milk substitute should be understood to include any milks (or products that could be used to replace milk, such as fortified soy milk, in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products.
7. Since World Health Assembly 39.28 categorically states that these products **are not necessary** a separate standard status wrongfully implies they are needed and are safe products

IBFAN strongly supports the inclusion of a Preamble.

If these products are to be allowed onto the market, it is essential that there is a Preamble that outlines where they can most safely ‘fit’ into the national regulatory context. A Preamble will help ensure that the Codex mandate of protecting consumer health is realized and help ensure policy coherence between Codex and World Health Assembly recommendations that safeguard maternal and child health.

The Preamble can alert governments to the unique infant and young child nutritional and immunological contributions provided by breastfeeding and the serious long-term risks of these sweetened, artificially flavoured ultra processed products during a critical stage of children’s growth and development. The health and nutrition risks of these products are shown in a considerable body of peer-reviewed evidence. This evidence has informed the global consensus that the marketing of these products must be in full compliance with WHA recommendations.

Lack of Policy Coherence between Codex Standards and WHA Recommendations and weak ambiguous Codex text has led to numerous challenges at the WTO Technical Barriers to Trade Committee when national governments have attempted to adopt legislation to control the marketing of follow-on formulas.[1]

These challenges are well documented, including in the recently published 2023 Lancet Breastfeeding series.[2] They have a chilling effect on health policies and national governments will know that complaints not resolved in WTO committees may result in costly legal battles and punitive tariffs. Peer-reviewed research has also documented the emergence in 2016 of intense cross-industry lobbying activity. A specific theme of this lobbying has been to elevate Codex standards, criticize WHO policies and processes (including WHO's stronger conflicts of interest processes[3] especially on issues related to infant and young child nutrition.

If the Chair's Recommendation for a Preamble (NFSDU/43 CRD2) is taken up IBFAN proposes the following small additions:

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with REVERSE ORDER: Drink for Young Children, or Product for Young Children, or alternatively Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients.

The application of this Standard should be consistent with national health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, DELETE: ~~as per the national context~~], relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions that were considered in the development of this Standard and provide further guidance to countries in ending the inappropriate promotion of these products and misleading practice of cross-promotion.

ADD: Follow-up Formula and Drinks for Young Children are not necessary. Energy and nutrient dense family foods with continued breastfeeding for young children can provide the essential complementary feeding to meet the nutrient requirements for older infants and young children.

Notes:

Milk-related FAQs - **What are the benefits of giving human milk to children over 1 year of age?** https://www.firststepsnutrition.org/milks-marketed-for-children https://www.firststepsnutrition.org/faq-page

Global recommendations support continued breastfeeding into the second year of life and WHO guidance recommends all infants are breastfed for up to 2 years and beyond (WHO, 2003). The rationale for encouraging continued consumption of a milk in young children beyond 1 year of age is based on a combination of meeting energy needs (proportionally driven by the fat content), calcium requirements for bone deposition and the other nutrients that mammalian milk provides. However, in

[1] Russ K, Baker P, Byrd M, et al. What you don't know about the Codex can hurt you: how trade policy trumps global health governance in infant and young child nutrition. International Journal of Health Policy and Management 2021; **10**(12): 983-97. Baker et al. Globalization and Health (2021) 17:58. Advocacy at Work During the Codex Committee on Food Labelling Meeting
INTERVENTIONS AT WTO AND CODEX RELATED TO NATIONAL IMPLEMENTATION OF THE WHO INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES.
Katheryn Russ* Baker, P., Smith, J. P., Garde, A., Grummer-Strawn, L. M., Wood, B., Sen, G., Hastings, G., Pérez-Escamilla, R., Ling, C. Y., Rollins, N., & McCoy, D. (2023). The political economy of infant and young child *feeding: Confronting corporate power, overcoming structural barriers, and accelerating progress*. *The Lancet*, *401*(10375), 503–524. https://doi.org/10.1016/S0140-6736(22)01933-X

[2] All papers of *Lancet Series* are available at https://www.thelancet.com/series/breastfeeding-2023
https://www.thelancet.com/action/showPdf?pii=S0140-6736%2822%2901933-X

[3] Russ, Baker, Kang, and McCoy 2022

contrast to animal milks, breastmilk can offer not only nutritional benefits but significant health benefits to both mother and child. That said, whilst there is no shortage of evidence for the benefits of

breastfeeding during the first year of life, there are relatively few studies that attempt to quantify the benefits of breastfeeding children over 1 year of age. Nevertheless, those that do support the idea that breastfeeding continues to provide nutrition and immunological protection, is beneficial for IQ and subsequent achievement, provides some protection against overweight and obesity later in life, and offers emotional benefits for as long as it continues. Some benefits continue to be felt beyond the period of breastfeeding (Lopez et al, 2021; NHS, 2020, Grummer-Strawn et al, 2004).

Nutrition Breastmilk composition changes over time to meet the needs of the growing child so that whilst the volume consumed may decrease, an appropriate level of nutrients remains present and immunological protection is not compromised (LLL, 2010). Studies looking at the composition of breastmilk into the second year of lactation have reported a large degree of stability in the macronutrient content with only a small reduction in protein. Mineral elements stay largely stable, although after two years, some studies report a reduction in calcium and zinc content. Four hundred millilitres of mature breastmilk can meet the following percentage of daily nutrient requirements for a 1-2 year old child: 32% energy. 36% protein 58% vitami 53% vitamin C

Immunological protection. Some studies in breastmilk composition in the second year of life report increasing concentrations of the antimicrobial protein lysozyme (Perrin et al, 2017; Hennart et al, 1991; Prentice et al,1984). Perrin at al also reported increasing concentrations of immunoglobin A (IgA) and lactoferrin (Perrin et al, 2017). These breastmilk proteins provide responsive and protective immunity (Breakey et al, 2015) and support the development of a beneficial gut microflora (Mastromarino et al, 2014). The secretion of antimicrobial proteins differs between mothers and this may mask changes over time and may help to explain differences between studies (Perrin et al, 2017; Lewis-Jones et al, 1985). More consistently, results of a systematic review and meta-analysis indicate that breastfeeding protects against acute otitis media until 2 years of age, and protection is greater for breastfeeding of longer duration (Bowatte et al, 2015).

IQ and general ability Research on the relationship between cognitive achievement (i.e. IQ scores and school grades) and breastfeeding has shown the greatest gains for those children breastfed the longest. Some studies show that participants who were breastfed for 12 months or more score higher on IQ and general ability tests than those with shorter durations of breastfeeding (Victora et al, 2015; Lopez et al, 2021). The positive influence on IQ as a result of breastfeeding may also impact upon long-term earnings and productivity. One large retrospective cohort study reported that participants who were breastfed for 12 months or more had higher IQ scores, more years of education, and higher monthly incomes than did those who were breastfed for less than 1 month (Victora et al, 2015).

Overweight and obesity It is becoming widely accepted that breastfeeding protects against overweight (Victora et al, 2016). Analysis of 2015-2017 surveillance data collected in 22 European countries reported that, compared to children who were breastfed for at least 6 months, the odds of living with obesity were significantly higher among children never breastfed or breastfed for less than 6 months. Several studies have reported that longer durations of breastfeeding are associated with a lower risk of obesity in later life (Qiao et al, 2020; Zheng et al, 2020; Rito et al, 2019; Horta et al, 2015). A dose response relationship between breastfeeding and protection against overweight and obesity has been reported by several studies (Qiao et al, 2020; Grummer-Strawn and Mei, 2004) and those that have included a breastfeeding duration category of 12 months + have reported significant reductions in risk for overweight and obesity in later childhood. When comparing those who were breastfed for at least 12 months with those who were never breastfed, Von Kreis et al reported a 57% reduction in the odds of being overweight in a subset of over 9,300 Bavarian 5- and 6-year-olds (Von Kries et al, 1999). When comparing those who were breastfed for more than 12 months to those breastfed for less than 6 months, Liese et al reported a 20% reduction in odds of being overweight among children between 9 and 10 years of age (Liese et al, 2001). A much larger national analysis of longitudinal data drawn from the US Centers for Disease Control and Prevention Pediatric Surveillance System reported a 51% reduced risk of obesity for white non-Hispanic children who were breastfed for more than 12 months compared to those never breastfed (Grummer-Strawn and Mei, 2004).

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AGENDA ITEM 6: TECHNOLOGICAL JUSTIFICATION FOR SEVERAL FOOD ADDITIVES

PART 1

(i) the technological justification for the use of certain food additives in foods complying with The Standard for Infant Formula and Formulas for Special Medical Purposes (CXS 72-1981); and

1. the technological justification for the use of the following food additives for use in foods complying with CXS 72-1981:
    i. low acyl clarified gellan gum (INS 418)
    ii. ascorbyl palmitate (INS 304)
    iii. mixed tocopherol concentrates (INS 307b)
    iv. phosphates (INS 339(i), 339(ii) and 339(iii) and INS 340(i), 340(ii) and 340(iii

The use of food additives for infant formula (IF) and formula for special medical purposes (FSMP) is to suspend a matrix of chemical micronutrients and macro nutrients derived from food substances to give it the appearance and consistency of a milk product. Although the technical justification used by the food industry is to deliver nutrients in an acceptable manner, the use of these additives to expand product marketing and the critical lack of consideration of the health impact of the more than 25 permissible additives (CXS 72-1981) in these products is not addressed.

1. It should be noted that IF and SMP products are approved for feeding infants exclusively from birth, low-birth-weight, premature and those with special medical needs. This means feed after feed exclusively for the first six months of life and promoted for consumption for up to 24 months or more. It is the **lack** of independent scientific evidence of the safety of the exclusive consumption of these additives during vulnerable ages of growth and development that is of primary concern.
2. The negative impacts of formula feeding are well documented on both short- and long-term health and development such as growth, immune system, microbiome, brain/neurological development, metabolic priming and premature death. Increasingly studies on the health impact of food additives are demonstrating negative effects on renal, cardiovascular and gut health.
3. The justification of ***"history of apparent safe use"*** and other vague and meaningless terms currently used to validate other vague inclusions such as "guidance upper levels" when scientific data on the safety of ingredients and additives is lacking must be prohibited in Codex Standards. The justification of **"history of apparent safe use"** in the Standard for IF and FSMP (CODEX STAN 72 – 1981, Para 3.1.3 Footnote 1 in Annex II, and the Review of the Standard

for Follow-up Formula, Sections A (Footnote 1 to Para 3.1. and B Footnote 2 to para 3.1.3) needs to be reviewed and replaced with adequate independent scientific reviewAdditives and manipulation of ingredients such as hydrolyzation of whey proteins are also used as marketing devices. For example, hydrolyzation requires certain additives to emulsify and stabilize the peptides and the addition of amino acids. The use of additives to create products has expanded into addressing normal infant and young child behaviours.Products with trademarked names exploit these behaviours with names such as "total comfort", "sensitive", "pure bliss".

4. The **WHO[1] How the marketing of formula milk influences our decisions on infant feeding** reports that the formula industry promoted products to address normal infant and young child behaviours:

    a. **"Specialized Milks and Comfort Milks** include formula products that can be promoted for specific medical conditions,e.g. lactose intolerance or allergy. Additionally, there are products marketed as comfort milks to address specific infant behaviours such as fussiness, poor sleep or hungry, where the formulation of the milks has been modified, for example the balance of whey or casein protein. There has been a rise in marketing for specialized and comfort milks that make bold claims to solve common infant ailments and behaviours such as colic, reflux and crying, despite insufficient evidence that they are effective"…[and]…"raise awareness of a problem, or convince potential customers that they have a problem which can be solved by purchasing a product". (2-8)

5. The lack of research on the safety for infants of the proposed food additives necessitates close scrutiny of the research that is available – in this case on the impact on adult populations. Research[9] on the health impacts of phosphate additives available from adult epidemiological studies shows that phosphate levels in the general population has risen linked to increased consumption of processed foods with phosphate additives. Elevated serum phosphate levels are correlated with mortality of those with chronic renal failure and with cardiovascular morbidity in the general population.
6. Research[10] on the impact of additives on the gut microbiome demonstrates negative impact. The gut microbiome as an immunological organ protects against inflammation of the mucous gut membrane and protects its permeability. For infants, the gut microbiome is critical for their immune system development. Evidence now suggests that food additives can disturb gut homeostasis, and contribute to tissue-damaging inflammatory responses.
7. The use of food additives to extend shelf life for IF and SMP is not a technical justification but an economic one. Increasing the health risks for infants and those with special medical needs based on shelf life is unacceptable and contrary to the mandate of Codex to protect consumer health.
8. IBFAN does not accept the expanded use of additives for IF and SMP products. It is unethical to research the health impact of the proposed additives on infant and young child populations. The health risks and documented impact in animal and adult studies demonstrates that there are health risks and one must conclude that these would be even greater in this vulnerable population.
9. IBFAN wishes to note and concurs with the JECFA principle: *"Baby foods should be prepared without food additives whenever possible. Where the use of food additives becomes necessary in baby foods, great caution should be exercised regarding both the choice of additive and its level of use." (Annex 3 of TRS488): "Proposals for the inclusion of an additive in Codex standards for foods intended for infants below 12 weeks of age require a separate evaluation by JECFA since food additives used in foods for this population the toxicological investigations should be more extensive and include evidence of safety to young animals...(REP11)/FA para 43)."*

PART II

Codex members and observers are invited to submit comments on plan/programme for the consideration of the remaining food additives

1. IBFAN is of the opinion that any plan to consider the remaining additives should prioritize the reduction of the number of additives in these products and to prioritize the health impact of additives as a primary consideration to protect consumer health as mandated

2. The synergistic impact of additives on the health of infants must be considered, including the carry-over chemicals such as heavy metals that may contaminate additives such as gellan gum.

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