CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 6.2, 6.21, 8 **CRD30**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Forty-fourth Session

Dresden, Germany

(Comments by IBFAN)

AGENDA ITEM 6.2 PROPOSALS FOR NEW WORK/EMERGING ISSUES

(REPLIES TO CL 2024/52-NFSDU)

IBFAN is of the opinion that the proposal does not meet the recommendations of the WHO Guidelines for Complementary Feeding of Infants and Young Children 6 – 23 months*.

The introduction of a new range of commercial complementary feeding products to be marketed from the age of 6 to 36 months will be in contradiction of optimal infant and young child complementary feeding. At the age of six months pureed and mashed foods that are spoon fed or fed from pouches are not appropriate and contrary to the development of life-long healthy eating habits. Responsive, child directed complementary feeding with a dietary diversity of eggs, fish, meat, fresh fruits and vegetables and, legumes etc. is a critical time for developing food tastes and preferences, a time of learning about the feel, taste, colours, aroma and texture of real foods.

The proliferation of complementary food products, fortified with industrial nutrients to compensate for processing losses and now frequently packaged in plastic pouches from which a child can suck mashed and watered-down ingredients denies this critical phase of development of learning about food and developing life-long food preferences.

The recently updated WHO Guidelines * makes the following recommendations for optimal complementary feeding practices:

1. Continued breastfeeding
2. Animal milks for those not breastfeeding after 6 months
3. Age of introduction at 6 months
4. Dietary diversity – animal sourced foods, fruits and vegetables, pulses nuts and seeds (frequently especially when animal foods are limited)
5. Avoid unhealthy foods and beverages – no foods high in sugar, salt, trans-fat, no sugar-sweetened or sweeteners beverages, limit 100% fruit juice.
6. Some children may benefit from nutrient supplements or fortification – should not be “stand – alone” never replace optimal feeding practices
7. Responsive feeding – child directed and cue based

**WHO Guideline for complementary feeding of infants and young children 6–23 months of age. Geneva: World Health Organization; 2023.*

IBFAN is opposed to the proposal to develop a formulated complementary foods standard to replace the 3 current Codex standards for foods for infants and young children 6 to 36 months of age into one globally harmonized standard for complementary food products.

The Codex Standard for Canned Baby Foods Stan 73-1981 is not fit for purpose and should be revoked.

For the Codex Standard for Cereal Based Foods for Infants and Young Children Stan 74-1981 we are calling for a prohibition on added sugars and other sweeteners.

The proposal aims to develop complementary food products consisting of the basic food groups as individual food products or combination food group products.

The rationale proposed for the new work uses the data that in low and middle-income countries 2 out of 3 children are “not able to be fed a diet diverse in daily animal-source foods, daily fruits and vegetables, and adequate pulses, nut and seeds” to justify the proposed new work for a complementary food products standard.

IBFAN questions how commercial complementary food products can address the needs of families in low and middle-income countries who may lack the economic resources to access animal sourced foods, fruits and vegetables, pulses nuts and seeds. Will processed complementary food products, possibly fortified with industrial nutrients be the global response to lack of access to affordable healthy foods?

We do not consider that a global standard could ever address the needs of families in low and middle-income countries who may lack the economic resources to access animal sourced foods, fruits and vegetables, pulses nuts and seeds. Given that the products covered would invariably be extensively processed and fortified with industrial nutrients, additives and sweeteners, yet sold back to LICs as 'value-added' we consider that the new standard being proposed by the USA would be likely to undermine, rather than improve access to affordable healthy foods.

IBFAN is of the opinion that the development of regulations for complementary food products be left to national governments. At national governmental level economic, cultural and the nutritional status of children 6 to 23 months of age can be considered to best address complementary feeding needs and implement the WHO Guidelines for Complementary Feeding of Infants and Young Children 6 – 23 months.

AGENDA ITEM 6.21 DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND FOOD SUPPLEMENTS

IBFAN is opposed to the use of microorganisms as probiotic additives for foods and food supplements for infants and young children.

1. Lack of substantive evidence

The promotion of infant formulas claiming to have probiotic effect is false and misleading. The addition of Lactobacilli species to a product that has negative impact on the gut microbiome and is a reductionist approach that cannot replicate the complex, synergistic and uniquely specific protective microbiome of a breastfeeding infant.

Cochrane reviews on the use of probiotics as preventive interventions note that none of the studies that meet inclusion criteria provided high-quality evidence for any outcome (Do probiotics help to treat acute infectious diarrhoea? | Cochrane, Probiotics for prevention of necrotising enterocolitis in very preterm or very low birth weight infants | Cochrane, Probiotics to prevent infantile colic | Cochrane).

Studies claiming no risk generally did not compare results to breastfed infants.

2. Safety of powdered infant formula products with added probiotics

IBFAN notes that the following standards permit the addition of lactic acid cultures as optional additives:

The Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants 3.2.3 states that "Only L(+)lactic acid producing cultures may be used in Formulas for Special Medical Purposes for infants if shown to be safe and appropriate for use in these *vulnerable populations*.

The Standard for Follow-up Formula for Older Infants and Products for Young Children

3.2.3 (+) lactic acid-producing cultures

Only L(+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L (+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.

The standard also notes that" It is recommended that the product covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CXC 1-1969), and other relevant Codex texts such as the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CXC 66-2008).

Additionally the preamble of the Standard recommends that "The application of this Standard should be consistent with national/regional 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, as per the national/regional context. Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries.".

The inherent risks of contamination by *Cronobacter* and *Salmonella* species during the industrial production of powdered infant formulas is a continuous threat to the lives and health of infants. Recalls of contaminated products are frequent with unknown numbers of infants infected resulting in serious health outcomes such as sepsis, necrotizing colitis, meningitis and even death.

IBFAN is exceedingly concerned that the addition of lactic acid cultures is stopping the formula producing industries from implementing the WHO/FAO recommendation of reconstituting powdered infant formula at 70C. We note that lactic acid bacteria are destroyed at approximately 48C. Hence implementing the safety

measure of reconstitution at 70C to ensure the elimination of the highly pathogenic *Cronobacter* species would also eliminate the purported "benefit" of the probiotic lactic acid cultures, clearly not meeting the Codex requirement of "achieving the intended effect", and rendering such claims fraudulent.

IBFAN strongly objects to the addition of probiotics to powdered infant formulas. This is a serious safety risk and disregards the life-saving preparation recommendations of *WHO/FAO Safe Preparation, Storage and Handling of Powdered Infant Formula: Guidelines, 2007.*

3. Negative impact of formula feeding, including those with probiotic additives, on the gut microbiome

- For the breastfeeding infant, human milk oligosaccharides, promote growth of bifidobacterium and inhibit growth of pathogenic organisms,
- Formula fed infants have higher levels of pro-inflammatory classes of bacteria,
- Breastfeeding supports the growth of protective bacteria – *Bifidobacterium* species. (this does not occur when grown on formula FOS, GOS and inulin with *B.lactis*)
- Breastmilk specific immune constituents such as IgA adhere to the intestinal cell wall and prevents invasion by undesirable bacteria,
- Breastmilk reduces pro-inflammatory cytokines and release anti-inflammatory cytokines,
- Breastfeeding inhibits transfer of gram-negative toxins by increasing the production of short chain fatty acids – this also reduces gut inflammation,
- Breastfed gut pH is much lower than formula due to higher acetate production by the Bifidobacteria – even one bottle reduces the amount of acetate produced and this continues for several weeks. Even small amounts of formula shifts unfavourably this perfect microbial ecological and complex system of protection.
- Formula feeding increased levels of harmful bacteria - Clostridia, Proteus (not detected in the breastfed infants), and caused alterations in gut microbial ecology leading to increased mucosal inflamation, autoimmunity, and allergic disorders

The gut microbiome of breastfeeding infants has critical health protective and optimal growth importance.

Recent research demonstrates the importance of exclusive breastfeeding and when interfered with by the introduction of infant formulas during the first six months of life, the infant gut microbiome is altered by increasing the microbe diversity species that have negative impact on the immune system development and increases the risk of negative health outcomes such as increased risk of asthma (Shenhav, L et al. Microbial colonization programs are structured by breastfeeding and guide healthy respiratory development. Cell.187(19): 5431-5452, 2024)

4. Permeable gut of premature, neonatal and young infants

Full gut closure can take up to 6 months, although generally it is the most rapid during the first month. For the breastfeeding infant, the antibodies (IgA) coat the permeable gut to protect against invasive constituents. Feeding formulas with probiotic microorganisms or treatment with probiotic products risks the development of sepsis during the critical months of gut closure development without the protection of breastmilk antibodies.

Premature infant's gut permeability can influence gut colonization and the risk of necrotizing enterocolitis (NEC). The introduction of cow's milk formulas and the use of probiotics as a yet unproven protection against NEC increases the potential for increased microbial colonization and the risk of septic infection.

The USA Food and Drug Administration (FDA) issued warning, dated September 29, 2023: *Risk of Invasive Disease in Premature Infants Given Probiotics Formulated to Contain Live Bacteria or Yeast* in response to the death of a premature infant fed the Evivo probiotic formulation containing live *Bifidobacterium longum* subsp.*infantis*.

"The FDA is warning that preterm infants who are given probiotics are at risk of invasive, potentially fatal disease caused by bacteria or fungi contained in probiotics."

Additional concerns:

Indigenous fermented food products

Traditional and cultural food products using microbial cultures, such as cheeses, cultured milks etc., made with traditional methods of fermentation are important sources of food for billions globally - how will regulations impact on such cultural food production practices?

The method of production of probiotics

Will bioengineered microorganisms be permitted as food additives? Will the substrates for the production of probiotic microorganisms be bioengineered? What will be the risk of production contaminants ending up in the proposed products?

Prioritization of impact on trade

The rationale for the proposed new work on probiotics is heavily weighted towards trade priorities. The discussion paper CX/NSFDU 24/44/6 Add.1 July 2024 Appendix 1, notes that the need and relevance to address the lack of harmonization is required to facilitate international and regional trade. Hence the need for countries to develop "regulations which are harmonized globally". The prioritization of the proposed harmonized guidelines criteria for impact on health of the target group is listed as "*medium positive",* however the impact on trade practices and global impact on trade to be "*high positive".*

Public health priority needs are described in general terms without a clear rationale of consumer benefit and based on "potential" for health benefits and reduction of "consumer health risks".

Ethics of feeding trials on vulnerable populations

IBFAN is opposed to feeding trials for optional ingredients using premature, low-birthweight infants, full-term infants and young children subjects. This is a vulnerable population that needs special protection. Research with infants is by nature research with a vulnerable population and as such special protection is needed for this population and special ethical reviews are needed and can only be done if the research cannot be done on an adult population.

Probiotics term as a health claim

There is considerable concern that the term "probiotics" is in itself a health claim. This has led to exploitation of the term and used as a marketing device to create an idealized and glamorized understanding of foods and supplements with microbial additives.

Elisabeth Sterken, IBFAN Codex Working Group

AGENDA ITEM 8 DISCUSSION PAPER ON USE OF FRUCTANS, BETA-CAROTENE, LYCOPENE IN STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS (CXS 72-1981)

IBFAN is opposed to the addition of synthetic oligosaccharides to infant formulas.
There is insufficient research demonstrating health advantages for the addition of synthetic oligosaccharides to infant formulas and formulas for special medical purposes intended for infants.
IBFAN is of the opinion that if an ingredient is permitted to be added to infant formulas, it must be demonstrated to be safe and have a high certainty evidence of benefit, verified by rigorous independent science. If that ingredient demonstrates a well-defined benefit it should be a mandatory ingredient and therefore be listed on the Nutrient Content panel of the product label.

General Comments

- The use of optional ingredients as additives to infant formulas are used as marketing tools with unsubstantiated claims, deceiving consumers to accept these products as having similar outcomes as breastfeeding infants.
- Nutrition and health claims must not be permitted for any product ingredients or additives in feeding products for infants and young children.
- Moreover, feeding trials using formulas containing optional ingredients, synthetic oligosaccharides, beta-carotene or lycopene do not use breastfeeding infants as controls and do not compare outcomes to breastfeeding infants. Outcomes are compared to formulas without the intervention.
- Feeding trials with premature, low-birth and full-term infants to construct alleged advantages for optional ingredients raises serious ethical concerns.
- The method of production of synthetic oligosaccharides is of concern, such as oligosaccharide synthesis production using recombinant *E. coli* or other biotechnological production methods. Is there research on the risk of carry-over contaminants from using bioengineered pathogentic organisms?

IBFAN fully agrees with the statement of the *Commission for Nutrition of the German Society for Child and Adolescent Medicine**, although not seeing any safety concerns has acknowledged the following:

The few studies on infants available to date do not allow any reliable conclusions to be drawn about clinically relevant advantages of synthetic oligosaccharide additives.

"Preferential use of infant formulas with synthetic oligosaccharide additives is therefore not recommended on the basis of currently available data.

The use of terms such as 'human milk oligosaccharides' and abbreviations such as "HMO" in promoting infant and follow-on formula represents an unacceptable idealization, which suggests a non-existent similarity with human milk and can thus undermine the priority of breastfeeding promotion.

The Committee on Nutrition urges infant formula manufacturers to end the current unacceptable idealized promotion of infant formula. It calls on supervisory authorities to stop possible violations of the existing legal restrictions on the marketing of infant formula.

Pediatricians should inform families that synthetic oligosaccharides in infant formula do not match the complex composition of oligosaccharides found in human milk."

> **Buhrer C. et al. Infant formulas with synthetic oligosaccharides and respective marketing practices: Position Statement of the German Society for Child and Adolescent medicine e.V. (DGKJ), Commission for Nutrition. Mol Cell Pediatr. Dec 9:14, 2022.*

Human milk contains close to 200 individual oligosaccharides. These are genetically unique between mother and her child. No two mothers produce the same oligosaccharides. It is impossible to replicate the complex synergistic and varied functions of human milk oligosaccharides by adding 2 or 3 synthetic oligosaccharides to an inert formula product to provide "functional benefit to infants similar to those provided by human milk.".

The baby food industries must cease to refer to synthetic oligosaccharides and 'human milk oligosaccharides. This is highly deceptive and false, misleading parents by implying that these are human milk sourced with

human milk benefits when they are sourced from genetically modified microorganisms and are not similar in structure to those genetically specific between a breastfeeding mother and her child.