

# CODEx ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 15

CX/AFRICA 19/23/CRD9

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME FAO/WHO COORDINATING COMMITTEE FOR AFRICA

Twenty-third Session

Nairobi, Kenya, 2 - 6 September 2019

### PROPOSAL FOR NEW WORK CONCERNING

#### **A REGIONAL STANDARD FOR THE LABELLING AND ADVERTISING OF BREASTMILK SUBSTITUTES AND OTHER PRODUCTS THE PROMOTION OF WHICH UNDERMINES BREASTFEEDING AND IS CONTRARY TO THE *INTERNATIONAL CODE OF MARKETING OF BREASTMILK SUBSTITUTES* AND SUBSEQUENT RELEVANT RESOLUTIONS OF THE WORLD HEALTH ASSEMBLY**

*(Prepared by International Baby Food Action Network (IBFAN))*

IBFAN proposes that the FAO/WHO COORDINATING COMMITTEE FOR AFRICA undertake new work to fully align regional Codex labelling and advertising guidance with the World Health Organization *International Codex of Marketing of Breast-milk Substitutes* and subsequent relevant resolutions of the World Health Assembly.

In particular, the current Codex *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants*<sup>1</sup> includes some guidance to Codex member states to ensure that labelling does not include nutrient and health claims as prohibited by the Guidelines for Nutrition and Health Claims, and includes requirements for important preparation instructions and a clear statement about the importance of breastfeeding for normal growth and development (acknowledgement that breastfeeding is superior to formula-feeding). However, these global Codex labelling standards do not:

- specifically address the importance of labels noting that powdered formula must be heated to a minimum of 70°C to eliminate the risk of intrinsic microbial contamination, such as *Enterobacter sakazakii*, and *Salmonella*<sup>2</sup> posing serious health risks that cannot be completely eliminated in the manufacture of powdered formula;
- expressly stipulate that labelling standards extend to advertising, a neglected standard-setting area for Codex that a legal opinion by Codex FAO Legal Counsel determined is within the mandate of the Codex Alimentarius Commission<sup>3</sup>

1 STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS CODEX STAN 72-1981 Formerly CAC/RS 72-1972. Adopted as a worldwide Standard in 1981. Amendment: 1983, 1985, 1987, 2011, 2015 and 2016. Revision: 2007. Available at: [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BStan%2B72-1981%252FCXS\\_072e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCODEX%2BStan%2B72-1981%252FCXS_072e.pdf)

<sup>2</sup> [Standard for Infant Formula and Formulas for Special Medical Purposes](#) Intended for Infants Codex STAN 72-1981 Formerly CAC/RS 72-1972. Adopted as a worldwide Standard in 1981. Amendment: 1983, 1985, 1987, 2011, 2015 and 2016. Revision: 2007.

<sup>3</sup> A 1984 legal opinion provided by the FAO/WHO legal counsel to the Committee and cited in the Government of Canada's 2006 discussion paper. (Government of Canada. [Discussion Paper on Advertising](#). Codex Committee on Food Labelling. CX/FL 06/34/10 citing the FAO/WHO legal opinion published at CX/FL 85/7, in particular:

*In 1984 document "Advertising' in the Mandate of the Codex Alimentarius Commission and its Subsidiary Bodies" the Legal Counsels of FAO and WHO stated in paragraph 18: "Advertising" is not specifically referred to in the Statutes of the Codex Alimentarius Commission, whose mandate is the implementation of a program designed to protect the health of consumers and to ensure fair practices in the food trade. However, to carry out such a mandate, the Commission is implicitly authorized to deal with matters which are necessarily incidental and ancillary to the very substance of such mandate."*

In 1976, at its 11th session, the Commission issued a Statement on Infant Feeding that said, "it is necessary to encourage breastfeeding by all possible means in order to prevent that the decline in breastfeeding, which seems to be actually occurring, does not lead to artificial methods of infant feeding which could be inadequate or could have an adverse effect on the health of the infant." Codex Alimentarius Commission. Codex Alimentarius Commission. Statement on Infant Feeding, CAC/MISC-2-1976. 1976. [http://www.codexalimentarius.net/download/standards/301/CXA\\_002e.pdf](http://www.codexalimentarius.net/download/standards/301/CXA_002e.pdf)

- authorize governments to prescribe label formatting rules to ensure that label warnings highlight:
  - that breastfeeding is superior to formula feeding and that formula feeding can pose acute negative health outcomes;
  - that improper preparation and storage pose safety hazards;
  - the financial costs of not breastfeeding;
  - that no idealising pictures or text such a “humanized,” images or graphics of babies and mothers or cross-promotions via other foods be permitted.

*(Formula companies have strong commercial incentives to de-emphasize such notices and mask the risks of the use of the product.);*

- include all the restrictions on the advertising and promotion of foods and related products for infants and young children in the *International Code of Marketing of Breast-milk Substitutes* (and subsequent relevant resolutions of the World Health Assembly), or
- expressly authorize national authorities to require labelling statements to indicate that:
  - providing free samples of formula and related products is contrary to public health norms,
  - conflicts of interest in health care systems must be avoided,
  - it is considered unethical for health workers, medical doctors, dietitians, and health care institutions to promote breastmilk substitutes and related products, and
  - it is considered unethical for manufacturers and distributors of breastmilk substitutes and related products to communicate directly with parents of infants and young children or use sales incentives to promote such products in any way.

The 2018 edition of the Codex *Procedural Manual* notes that Article 1 of the *Statute of the Codex Alimentarius Commission* identifies the first propose of Codex as:

*(a) protecting the health of the consumers and ensuring fair practices in the food trade;*<sup>4</sup>

The *Procedural Manual* direction regarding risk management stresses that health is the primary objective:

*27. While recognizing the dual purposes of the Codex Alimentarius are protecting the health of consumers and ensuring fair practices in the food trade, Codex decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.*<sup>5</sup>

The *Procedural Manual* sets out the following five general criteria to consider for the Committees when commencing new work. In our view, as explained below, beginning work to fully align Codex regional standards with the WHO *Code* and WHA resolutions meets all of the criteria.

**(a) Diversification of national legislations and apparent resultant or potential impediments to international trade.** According to a global UNICEF survey of U.N. Member States, while approximately 40% of nations have fully implemented the *International Code of Marketing of Breastmilk Substitutes*, only six countries have implemented comprehensive monitoring programs to ensure that regulations are being followed. Furthermore, according to a collection of national surveys of six-month exclusive breastfeeding rates compiled by UNICEF, only two African countries come within 20 percentage points of the what *The Lancet* considers to be optimal rates of six-month exclusive breastfeeding (90%<sup>6</sup>): Rwanda (87%) and Zambia (72%).

**(b) Scope of work and establishment of priorities between the various sections of the work.** Barring unforeseen barriers to consensus, a regional standard could be finalized in 2-6 years depending on whether the CCAFRICA meetings are aided by intersession Electronic Working Groups.

**(c) Work already undertaken by other international organizations in this field and/or suggested by the**

<sup>4</sup> See page 4.

<sup>5</sup> The *Procedural Manual* at page 128.

<sup>6</sup> Cesar G Victora, Rajiv Bahl, Aluísio J D Barros, Giovanny V A França, Susan Horton, Julia Krusevec, Simon Murch, Mari Jeeva Sankar, Neff Walker, Nigel C Rollins for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. *The Lancet*. Vol 387 January 30, 2016 at 476. Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)01024-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext)

**relevant international intergovernmental body(ies).** This proposal is an effort to encourage implementation of the World Health Organization's guidance in a standard-setting body that is recognized as authoritative by the World Trade Organization to address a global health risk to children resulting in harm that is most acutely suffered by African babies relating to the marketing practices and exports of applicable products from companies that are largely based in Europe. The World Health Organization (a Codex parent organization) and UNICEF are standard bearers for the scientific and political consensus on the need to promote breastfeeding by, in part, controlling the labelling, promotion, and advertising of breast-milk substitutes and related products. The need for this has also been emphasized by political accords of the United Nations and the African Union, including the Political Declaration on the United Nations High-Level Meeting on Universal Health Coverage and the African Union support for a continental Nutrition Accountability Scorecard in 2019 (including 5 indicators related to breastfeeding).<sup>7</sup> Likewise, the Political Declaration of the United Nations High-Level Meeting on the Prevention and Control of Noncommunicable Disease of the 2018, attended by 52 heads of state, recognized that:

*"children who are given the opportunity to grow and develop in a healthy environment that is responsive to their needs, including breastfeeding...can greatly reduce the risk of non-communicable diseases in adulthood;"<sup>8</sup>*

Codex has a ready-made procedure for elaborating standards that are recognized as authoritative by the World Trade Organization for resolving trade disputes. While a binding treaty on the marketing of food and nutrition might also create some protections and incentives for national governments to implement laws to protect children and mothers from advertising of breastmilk substitutes, this is still too hypothetical to protect mothers and children in the near future. For instance, in 2018, the United Nations Secretary General's Independent Accountability Panel called on UN member States to:

*"undertake consultations to design and commit to a comprehensive international binding convention, with the support of the WHO, other UN agencies, civil society, and parliamentarians...[to]...Establish minimum legal requirements to guide governments in their development of national food and beverage regulations. [and] Bring together existing international standards—including the International Code of Marketing of Breast-milk Substitutes—as well as guidelines on marketing to children and adolescents. It should be modelled after the Framework Convention on Tobacco Control (FCTC), which was adopted and ratified by governments in record time. As with the FCTC drafting process, rent-seeking interests should be excluded from the negotiations."<sup>9</sup>*

**(d) Amenability of the subject of the proposal to standardization.** Protecting, promoting, and supporting breastfeeding is amenable to a standard approach as evidenced from the 37-year-old effort by the WHO to promote such an approach, and the gradual efforts by many countries to domestically implement that guidance, perhaps discouraged only by concern that authorizing authority from Codex falls short of the WHO standard. The Codex Commission describes itself as a science-based decision-making body,<sup>10</sup> and the "Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses" in the Committee's *Procedural Manual* stipulate that:

*33. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, FAO and WHO are acknowledged as the primary source of nutritional risk assessment advice to Codex*

<sup>7</sup> Dr. Akinwumi Adesina, President of the African Development Bank (AfDB) commended creation of the Scorecard and stressed the need to shift the debate from nutrition as a social development issue to one that shapes economic growth and development of African countries. "The greatest contributor to economic growth is not physical infrastructure but brain power." He called on all partners present to invest in developing Africa's grey matter infrastructure by investing in better nutrition for its children who are the future of the continent. The AU Commission support expresses the highest level of political support and the most specifically relevant issue of breastfeeding in the region. This support is especially notable considering that the vast majority of infant formula, the principle commercial product that undermined this objective, originates from outside the region: Europe.

<sup>8</sup> United Nations General Assembly. Political declaration of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases. October 10, 2018. A/RES/73/2 at paragraph 12. Available at: [https://www.un.org/en/ga/search/view\\_doc.asp?symbol=A/RES/73/2](https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2)

<sup>9</sup> United Nations Secretary-General's Independent Accountability Panel for Every Woman, Every Child, Every Adolescent (IAP), *Private Sector: Who is Accountable?* (New York: United Nations, 2018) at 8, 25, 46, 51, 54, and 64 online: < [http://iapreport.org/img/pdf/IAP18001\\_REPORT\\_B\\_020\\_WEB.pdf](http://iapreport.org/img/pdf/IAP18001_REPORT_B_020_WEB.pdf)>.

<sup>10</sup> The Codex Commission website states: "Codex standards are based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO." Codex Alimentarius Commission, *About Codex Alimentarius*, (Rome: Codex, 2018): <<http://www.fao.org/fao-who-codexalimentarius/about-codex/en/>>.

Alimentarius. [emphasis added]

Regulations to protect, support and promote breastfeeding are especially well-suited to the 54 African member states where many have inadequate resources and infrastructure for medical and pharmaceutical therapies for infections and other illnesses caused by sub-optimal breastfeeding. The Codex Coordinating Committee for Africa could also simply propose to dynamically incorporate-by-reference the WHO *International Code of Marketing of Breast-milk Substitutes* and subsequent relevant resolutions of the World Health Assembly, thereby sparing Committee resources in re-stating WHO guidance in Codex format. Doing so accords well with the Codex approach. The Codex Committee on Food Labelling is composed mainly of members states from regions that export breastmilk substitutes (chiefly the EU) or have safe public drinking water supplies and widely available robust health care services that are equipped for treating pediatric infections.

**(e) Consideration of the global magnitude of the problem or issue.** Like the criteria for commencing new work as established by the [Codex Committee on Food Hygiene](#) (CCFH) 2013 (approved by the Codex Commission in July 2014), addressing public health risks should be a key factor in deciding whether to take on new work. The CCFH developed a method for quantifying food safety risk to help with priority-setting. In 2016, *The Lancet* again confirmed the critical importance of breastfeeding. Better breastfeeding practices could prevent the deaths of 823,000 children per year (mainly by preventing approximately half of all diarrhea episodes and one-third of infections). Of the total worldwide deaths, 311,000 (38%) are estimated to occur in Africa where approximately 16% of the world's population lives.<sup>11</sup> Breastfeeding has also been found to help prevent malocclusion, increase intelligence, and probably help reduce the risk of maternal overweight. And, optimal breast-feeding can also prevent 20,000 breast cancer deaths in mothers worldwide each year and generate economic savings of US \$300 billion.<sup>12</sup>

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11 This total was not disaggregated regionally, the World Health Organization did estimate regional and global totals in WHO. Global Health Risks: Mortality and burden of disease attributable to selected major risks. Geneva: WHO, 2009. P. 50, table A3 "Table A3: Attributable mortality by risk factor and income group in WHO regions, estimates for 2004." Available at: [https://www.who.int/healthinfo/global\\_burden\\_disease/GlobalHealthRisks\\_report\\_full.pdf](https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf)

12 Cesar G Victora, Rajiv Bahl, Aluísio J D Barros, Giovanny V A França, Susan Horton, Julia Krusevec, Simon Murch, Mari Jeeva Sankar, Neff Walker, Nigel C Rollins for The Lancet Breastfeeding Series Group. Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effects. *The Lancet*. Vol 387 January 30, 2016 Available at: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(15\)01024-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(15)01024-7/fulltext) estimated that 823,000 children die from suboptimal breastfeeding. This total was not disaggregated regionally, the World Health Organization did estimate regional and global totals in 2004, finding that nearly 38% of global deaths occurred in Africa. See WHO. Global Health Risks: Mortality and burden of disease attributable to selected major risks. Geneva: WHO, 2009. P. 50, table A3 "Table A3: Attributable mortality by risk factor and income group in WHO regions, estimates for 2004." Available at: [https://www.who.int/healthinfo/global\\_burden\\_disease/GlobalHealthRisks\\_report\\_full.pdf](https://www.who.int/healthinfo/global_burden_disease/GlobalHealthRisks_report_full.pdf)