CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 10 **CRD15**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fifty-fifth Session

Nashville, Tennessee, United States of America

15 - 19 December 2025

Other business and future work New work/Forward workplan (Proposals in reply to CL 2024/64-FH)

(Comments of India, Kenya, Republic of Korea, Thailand, IBFAN)

India

1. India appreciates the proposal for new work submitted by Singapore and China on the development of a Code of hygienic practice for manufacturing of cell-based foods. However, we hereby submit that a mutually agreed codex definition of the cell-based foods is essential before the development of any other work on cell-based foods. We propose that a definition of the cell-based foods to be approved by the Codex first before initiating further work in this area.

2. India acknowledges the scientific rationale presented in the new work proposal submitted by Chile on the revision of Code of Practice for the Processing and Handling of Quick Frozen Foods (CXC 8-1976). However, under Indian conditions, maintaining frozen poultry and pork at −18 °C remains essential to ensure microbiological safety and quality. India's tropical climate, characterized by high ambient temperatures and humidity, significantly increases the thermal load on cold-chain systems. Even minor deviations during storage, transportation or retail handling can rapidly raise product temperatures above critical thresholds. Scientific evidence indicates that pathogen survival is higher and lipid oxidation proceeds faster as storage temperature approaches −12 °C, resulting in increased risk when the operational set-point is relaxed to −15 °C. The Chilean dossier itself acknowledges reduced shelf life and more rapid quality deterioration at −15 °C.

   Retail environments, including wet markets transitioning to chilled/frozen systems, often lack continuous temperature monitoring or validated HACCP-based controls. Under these circumstances, the −18 °C benchmark provides a critical safety buffer, absorbing unavoidable fluctuations while still maintaining product temperature well below the zone where microbial activity or enzymatic degradation accelerates.

   Therefore, India supports the Codex review process but recommends retaining −18 °C as the minimum temperature requirement for frozen poultry and pork to ensure robust consumer protection and maintain product integrity throughout the cold chain.

Kenya

Kenya appreciates the work done by the PWG chaired by USA in collating and preparing new work/forward workplan as submitted by members considering the forward workplan.

Kenya supports and will take-up key roles in the implementation of the proposed Workplan for the Future Alignment of CCFH Texts with CXC 1-1969.

In addition, following the recent work by the CCFL, Kenya supports and will actively participate in the revision of CXC 80- 2020 Code of Practice on Food Allergen Management for Food Business Operators.

Republic of Korea

1. DISCUSSION PAPER FOR NEW WORK ON THE DEVELOPMENT OF CODE OF HYGIENIC PRACTICE FOR MANUFACTURING OF CELL-BASED FOODS

- Korea supports initiating work on developing Code of hygiene practice for manufacturing of cell-based foods within CCFH.

2. PROPOSAL FOR REVISION OF CODE OF PRACTICE FOR THE PROCESSING AND HANDLING OF QUICK FROZEN FOODS (CXC 8-1976)

- Raising the temperature could affect both quality and safety, and more evidence would be needed to support such a change. Therefore, keeping the –18 °C standard is the most practical and reasonable at this time. It will be important to continue monitoring international standards and any emerging needs for safety data. If sufficient scientific evidence becomes available in the future, the standard may be reconsidered.

Thailand

Thailand would like to thank the United States of America in preparing the document. We would like to provide general comment for the following new work proposals:

Code of Hygienic Practice for Manufacturing of Cell-Based Foods

Thailand does not object the new work on Code of Hygienic Practice for Manufacturing of Cell-Based Foods as it is part of new food sources and production system. Apart from FAO/WHO publication on Food Safety Aspects of Cell-Based Food, further work specifically on validated control measures for significant hazards at specific process step should be explored. In our opinion, process steps for this type of food are completely different compared to CXC 1-1969.

Revision of the Code of Practice for the Processing and Handling of Quick Frozen Foods (CXC 8-1976)

Thailand does not object the new work on the Code of Practice for the Processing and Handling of Quick Frozen Foods related to the change of freezing temperature from -18 ^{o}C to -15 ^{o}C. However, we think that further scientific information, specifically on quality and shelf life is required as the CXC 8-1976 is applied to all foods. If adequate scientific data is provided, the proposed change may be applied to all types of food.

Furthermore, we note that the CXC 8-1976 is a Code of Practice which contains both recommendations on food safety and quality. However, quality aspect might not fall under the terms of reference of CCFH.

IBFAN

IBFAN is requesting the CCFH55 to address the serious contamination of powdered infant formulas (PIF) with Clostridium botulinum spores, a potential risk for serious illness in infants. IBFAN is requesting the CCFH55 to start work to review and update the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP 66/2008.

IBFAN is greatly concerned about the current outbreak of infant botulism resulting from Clostridium botulinum spores contaminating powdered infant formula manufactured by ByHeart. To date there are 39 confirmed cases and over 70 are under investigation in the US. The company distributes its PIF via on-line platforms and is thus available in countries where the product is not registered for use.

Infant botulism is a serious condition that can lead to paralysis and even death, and must be treated as quickly as possible. Botulism Immune Globulin (referred to as BabyBig) administered intravenously is the single treatment for infants under one year of age and is only available in the US. Access to the BabyBig treatment outside of the US is available only on ‘a case-by-case evaluation basis.’ International requests must go through an onerous process requiring the affected infant’s attending physician to contact an on-call BabyBig physician for approval; after which a letter of authorization from the importing country’s Medicine Regulatory Authority must be issued; payment made; customs cleared; all with a required international courier account and more.

Needless to say, access to treatment for infants diagnosed with botulism outside of the US, is likely to be a costly and time consuming process that will be unavailable for the many and too late for an effective treatment.

The global marketing, both digital and direct as well as the use of on-line platforms has resulted in contaminated products which are often unregulated, available for purchase by parents in third countries. Thus, exacerbating the risk of infant illness. Moreover the Codex Code of Ethics in International trade and Food Aid forbids the international trade of any food (including re-exported food) which is unsafe, unsuitable, poisonous, harmful or otherwise injurious to health or “is labelled or presented in a manner that is false, misleading or deceptive.”

US Food and Drug inspection documents of the production facilities of the C. botulinum contaminated PIF (although with some redaction) released in late November, reveal systemic violations of hygienic controls. These include:

- receiving and releasing X ingredient used in infant formula powder that was not held under conditions that prevent adulteration
- not taking action to eliminate rodent issues
- not monitoring floor conditions adequately
- approval and release of an ingredient that was not manufactured, packaged, labelled or held under conditions that prevent adulteration,
- did not remove pest from plant to protect against contamination,
- did not maintain the manufacturing building in clean and sanitary condition

The heat resistant Clostridium botulinum spores, which are ubiquitous, and which require high temperatures, time and pressure to eliminate cannot be applied to powdered infant formula without negative impact on the nutritional requirement of the products that “should meet the nutritional specifications of applicable Codex standards”. Nor is it feasible for parents and care givers to apply measure for the elimination C. botulinum spores.

IBFAN is concerned that manufacturing facilities for PIF are not meeting hygienic requirements to minimize microbial contamination - Cronobacter and Salmonella species have a history of frequent recalls due to contamination of PIF. Since measures required to eliminate C. botulinum spores, are not feasible for PIF, manufacturing facilities and procedures need to be reviewed and updated to eliminate this serious and all too frequent risk infant illness. Additionally, governments must ensure with adequate inspections and surveillance of production facilities, that they meet all hygienic practices and standards during all phases of the manufacturing process.

IBFAN notes that the Code of Hygienic Practice on Powdered Formulae for Infants and Young Children CAC/RCP 66/2008 was developed in response to outbreaks of Enterobacter sakazakii (now reclassified as Cronobacter sakazakii) and Salmonella species. Since its development, outbreaks of other contaminants have necessitated product recalls and warnings to parent. This includes Bacillus cereus, also a spore forming and toxin producing bacterium, and now the more serious C. botulinum. Hence the need for a review and revision of the Code of Hygienic Practice for powdered infant formula for infants and young children.

IBFAN is requesting the CCFH55 to address this urgent need to reduce the risk of C botulinum spores in powdered infant formula, a potential cause of serious illness in infants, and review and update the Code of Hygienic Practice of Powdered Formulae for Infants and Young Children CAC/RCP 66/2008.