# codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

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**Agenda Item 4** **CX/FH 08/40/4**
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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON FOOD HYGIENE**

**Fortieth Session**

The Marriot Hotel, Guatemala City, Guatemala

## MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN (ANNEX TO THE CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN)

*Prepared by the Electronic Working Group led by Canada*

The proposed draft **Annex II – Microbiological Criteria for Powdered Follow-up Formula and Formulas for Special Medical Purposes for Young Children** (Annex to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)) is not being circulated for comments at Step 3 due to late arival of the document, therefore there will be no document CX/FH 08/40/4-Add.1 to be discussed at the physical working group which was scheduled to meet on Sunday, 30 November 2008.

Please note that those delegations and observers wishing to consider the document CX/FH 08/40/4 are invited to do so at the meeting scheduled to start at the Hotel Mariot on Sunday, 30 November at 14:00.

**Background**

During the consideration of the proposed draft *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*, the 39th session of the Codex Committee on Food Hygiene (CCFH) had a lengthy discussion in relation to the establishment of a microbiological criterion for *E. sakazakii* in follow-up formula (FUF); however, the Committee could not reach consensus on this aspect.

In order to proceed with the finalization of the document, the Committee agreed to forward the proposed draft *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*, including Annexes I (*Microbiological criteria for powdered infant formula, formula for special medical purposes and human milk fortifiers*) and III (*Guidance for the establishment of monitoring programs for Salmonella, Enterobacter sakazakii and other enterobacteriaceae in high hygiene processing areas and in powdered formula preparation units*) for final adoption by the 31st Session of the Codex Alimentarius Commission at Step 5/8, and to remove FUF from Annex I and consider it in Annex II (*Microbiological Criteria for Powdered Follow-Up Formula and Formula for Special Medical Purposes for Young Children*).

The Committee returned Annex II to Step 2 for further revision by an electronic working group (E-WG) open to all interested parties and led by Canada, and requested additional scientific advice from the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) regarding specifications of *E. sakazakii* (*Cronobacter* spp.) in follow-up formulae. The Committee also agreed that a physical working group would meet the day before the 40th Session of the CCFH to consider the comments received at Step 3 on the proposed draft Annex II and to prepare proposals for consideration by the Committee.

The *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children*[1] was adopted with Annex I and Annex III at the 31st Session of the Codex Alimentarius Commission (Geneva, 30 June – 4 July 2008).

An FAO/WHO technical meeting on *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered FUF was convened (Washington DC, USA, 15-18 July 2008) with the objective of providing the scientific information to inform the decision making process of the CCFH on the need for a microbiological criterion for *E. sakazakii* (*Cronobacter* spp.) in powdered FUF. The preliminary report of the meeting is available at http://www.fao.org/ag/agn/agns/jemra/Sakazaki_FUF_report.pdf

The FAO/WHO expert technical meeting reviewed all the available information in the context of whether or not a microbiological criterion for *E. sakazakii* (*Cronobacter* spp.) should be established for FUF and weighed the scientific evidence for and against. Based on this, the meeting concluded that there was not a clearly defined scientific justification either for or against the establishment of such an international microbiological criterion. However, by presenting the available evidence, the meeting sought to present the data that is currently available and highlight both how it contributes to our knowledge base and could be used for determining alternative risk management options. Furthermore, the limitations of those data, particularly in relation to the narrow spectrum of the global population which it represents, were described in the report of the meeting. In this context, it concluded that the analysis should provide guidance to risk managers as to whether there is any value in establishing a microbiological criterion for FUF.[2]

CCFH members should review the report of the FAO/WHO Expert meeting to inform the discussion at the physical working group meeting on Annex II, scheduled one day prior to the 49th CCFH on the afternoon of November 30, 2008, and at the plenary session.

**Electronic Working Group Report**

An invitation to participate in the E-WG was circulated to all Codex contact points and expressions of interest were received from several member countries and member organizations[3]. The list of participants is provided in Annex I.

In light of the information presented in the FAO/WHO expert meeting report and the conclusion that there was not a clearly defined scientific justification either for or against the establishment of an international microbiological criterion for *E. sakazakii (Cronobacter* spp.) in follow-up formulae (FUF), a proposal was made to E-WG members not to establish such a criterion in Annex II at the present time with a proviso that the Annex could be revised in the future, if further epidemiological evidence became available, as appropriate. WG members were asked to indicate whether they supported or did not support the establishment of a criterion, in light of the information presented in the report of the FAO/WHO expert meeting and to present a scientific rationale for their position. It should be noted that countries are not being asked to decide, in isolation from other risk management options, whether or not a microbiological criterion

[1] CAC/RCP 66-2008.
[2] Chapter 6. FAO/WHO. 2008. *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formulae: preliminary meeting report , available at : http://www.fao.org/ag/agn/agns/jemra/Sakazaki_FUF_report.pdf
[3] E-WG members: Argentina, Australia, Brazil, Canada, China, Cuba, European Community, France, Germany, Ireland, Italy, Jamaica, Japan, the Netherlands, New Zealand, Peru, Switzerland, Thailand, the United Kingdom, the United States of America, European Network for Childbirth Associations (ENCA), International Association of Consumer Food Organizations (IACFO), International Commission on the Microbiological Specifications for Food (ICMSF), International Dairy Federation (IDF), International Lactation Consultants Association (ILCA), International Special Dietary Foods Industries (ISDI), FAO and WHO.

should be established. Also, a number of recommendations were made to E-WG members for their consideration and feedback.

A) The majority of participants did not support the establishment of a microbiological criterion for *E. sakazakii* (*Cronobacte*r spp.) in follow-up formula. The following rationale was presented:

- The expert consultation identified 120 recorded cases of *E.sakazakii* (*Cronobacter* spp.) infections in infants and young children less than 3 years of age. Of these, 6 have occurred in infants 6-11 months of age, 5 of which are known to have consumed powdered infant formulae. These cases have not been conclusively linked to the consumption of the formula (i.e., analysis of factory-sealed cans of powdered formula from lots associated with the cases did not yield *E. sakazakii* (*Cronobacter* spp.); however, no other sources of infection were identified, although it is recognized that environmental testing was not undertaken in all cases. Also, five out of six of these infants were confirmed to have consumed powdered infant formula and not follow-up formula.

- While it is recognized that there is uncertainty in the overall rate of *E. sakazakii* (*Cronobacter* spp.) infections, there is evidence that the incidence of illness decreases with age.

- Among the identified cases, immunodeficiency appears to be associated with either prematurity or disease. The issue of immunodeficiency associated with malnutrition, etc., and the risk from exposure to *E. sakazakii* (*Cronobacter* spp.) remains unresolved, especially for a condition where there is limited or no surveillance in many, if not most countries.

- There is evidence that FUF is consumed by infants <6 months of age; however, this indicates that the product is not used as per the label instructions. The unintended use of the product for infants less than 6 months should be addressed through clearer labelling and advertising and by education of caregivers and healthcare professionals, as to the appropriate uses of the product.

- While there is evidence of consumption of FUF by infants for which it is not intended (i.e., less than six months), there is no reported evidence of this having caused *E. sakazakii* (*Cronobacter* spp.) infection in such infants.

- Microbiological criteria applicable to a product should consider its intended use rather than all its possible uses/misuses. On this basis, the lower risk profile associated with the intended consumer of FUF (based on available data) would support a less stringent measure for FUF as compared to infant formulae. Section 4 of the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997) states that, to fulfil the purposes of a microbiological criterion, consideration should be given to the intended use of the food, among other factors.

- The establishment of microbiological criteria for *E. sakazakii* (*Cronobacter* spp.) in FUF would not be proportionate to the evidence of risk identified in the risk assessment, based on the current, albeit limited, level of available information, and it has not been made evident that it will improve the degree of protection offered to the consumer.

- FUF is intended to be used when the diet of the infant begins to be varied, thus, establishing a criterion for one component of the diet, i.e., FUF, is not scientifically justified. Furthermore, there is a lack of evidence to support FUF as being the most important source of *E. sakazakii* (*Cronobacte*r spp.) in this age group, as compared to weaning foods or the environment.

B) Four member organizations did not agree with the proposal and recommended that a criterion should be established for *E. sakazakii* (*Cronobacte*r spp.) in follow-up formula. The following key rationales were presented:

- There is evidence that FUF is consumed by infants below 6 months of age and the HACCP Annex of the *Recommended International Code of Practice – General Principles of Food Hygiene*(CAC/RCP 1-1969, Rev. 4(2003)) indicates that during hazard identification, evaluation and subsequent operations in designing and applying HACCP systems, consideration must be given to several

factors, including likely end-use of the product, categories of consumers of concern and epidemiological evidence relative to food safety.

- It would be wise to apply a precautionary approach as cases reported to-date may be under-estimated, as infections caused by *E. sakazakii* (*Cronobacte*r spp.) are not notifiable in most jurisdictions.

- The system of voluntary reporting makes community-based outbreaks among older infants less likely to be detected than hospital-based outbreaks among very young infants.

- Infants in developing countries will not have the same immune status as infants in developed countries.

- Consumer education material may not be translated or reach at-risk populations in developing countries

C) Two member countries proposed to add the following text in Annex II:

"*In instances where FUF is manufactured on a production line that is also used to manufacture powdered infant formulae, it may be appropriate to apply the more stringent microbiological criteria specified in Annex I to FUF.* "

The rationale for this proposition is derived from the report of the Expert meeting which notes that microbiological criteria, and therefore hygiene control measures, are more stringent for powdered infant formula than for FUF. In some manufacturing facilities production lines may be shared, i.e., used to manufacture both PIF and FUF. In these situations, the hygiene requirements necessary to ensure compliance with the microbiological criteria for PIF are also applied to FUF.

D) Participants supported the addition of text to Annex II, to emphasize that FUF should only be used for the target population for which it is intended and to highlight the need for further education of caregivers and health care professionals as to the appropriate uses of FUF. One member country proposed to further expand the recommendation, as follows:

"*Competent authorities should understand patterns of use in order to target education to the appropriate groups. If there is evidence of extensive misuse of FUF (i.e., feeding FUF to infants < 6 months of age), then competent authorities should consider applying the more stringent microbiological criteria of Annex I.*

**Recommendations of the E-WG:**

- CCFH members are invited to review Draft Annex II (*Microbiological Criteria for Powdered Follow-Up Formula and Formula for Special Medical Purposes for Young Children*) of the *Code of Hygienic Practice for Powdered Formulae and Young Children* (CAC/RCP 66-2008) and provide comments at Step 3. In doing so, **members are reminded that they should consider draft Annex II in the context of the whole Code and the guidance provided within, and not as a standalone document**. It is also important to keep in mind the information provided in the report of the FAO/WHO Expert meeting on *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formulae. The report is available at: http://www.fao.org/ag/agn/agns/jemra/Sakazaki_FUF_report.pdf

- The majority of E-WG members did not support the establishment of a microbiological criterion for *E. sakazakii* in FUF as a risk management option. The CCFH is invited to endorse this recommendations and Annex II as presented in Appendix II of this document, and to emphasize that other risk management tools are available, including enhanced product labelling and education of caregivers and healthcare professionals. Further, the CCFH should support revision of Annex II should further epidemiological evidence become available to link consumption of FUF with cases of *E. sakazakii* (*Cronobacter* spp.) and thus to support the establishment of such a criterion in FUF.

- The E-WG recommends that the following text be added to Annex II, to emphasize that FUF should be used for the target population for which it is intended and to highlight the need for further education of caregivers and health care professionals as to the appropriate uses of FUF:

"*Follow up formulae should only be used for the target population for which it is intended. There should be increased emphasis on the education of caregivers and healthcare professionals as to the appropriate uses of FUF and improved labelling with respect to the intended consumer*".

- The E-WG proposes that the CCFH consider making the following recommendations to Member Countries and to FAO/WHO:

  - In addition to awareness and education programs about appropriate preparation, handling and storage of powdered formulae, education of caregivers and health care professionals should emphasize the appropriate uses of infant formulae and follow up formulae, i.e., that products should be used for the categories of consumers for which they are intended.

  - That labelling of FUF be enhanced to emphasize the importance of appropriate use of the product.

  - There is a need for better surveillance and reporting of *E. sakazakii* infections as well as the origin of these infections in all age groups (attribution data). Further research should also be encouraged to establish the relationship between age as well as possible specific medical conditions and vulnerability of infants and young children to infection by *E. sakazakii* (*Cronobacter* spp.)

  - The CCFH should consider recommending that *E. sakazakii* (*Cronobacter* spp.) surveillance and reporting systems be improved in member countries.

  - One important finding of the FAO/WHO expert meeting is that many caregivers worldwide fail to follow recommended formula preparation and feeding practices to reduce the risk associated with microbiological contamination of these powdered products. Thus, the CCFH should further emphasize to its members the need for education and training of caregivers and health care professionals at the national level, as recommended in the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008).

  - More specific training should be undertaken by FAO and WHO in developing countries to increase surveillance and improve data collection in foods and the environment, including the development of guidance document and/or training manuals.

  - That FAO/WHO should consider the need to review the "Guidelines on Safe preparation, storage and handling of powdered infant formula"[4] to establish whether these sufficiently cover FUF, as well as information on the need to ensure that the products are used for their intended target populations.

[4] FAO/WHO. 2007. Safe preparation, storage and handling of powdered infant formula: guidelines.

**APPENDIX I**

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**APPENDIX II**

# PROPOSED DRAFT ANNEX II ON MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULA AND FORMULA FOR SPECIAL MEDICAL PURPOSES FOR YOUNG CHILDREN

Microbiological criteria should be established in the context of risk management options and in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-97). Two sets of criteria are provided below, one for pathogens and a second for process hygiene indicators.

Criteria for pathogenic microorganisms

These are to be applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary package is opened.

| **Microorganisms** | **n** | **c** | **m** | **Class Plan** |
|---|---|---|---|---|
| *Salmonella** | 60 | 0 | 0/25 g | 2 |

Where n = number of samples that must conform to the criteria: c = the maximum allowable number of defective sample units in a 2-class plan. m= a microbiological limit which, in a 2-class plan, separates good quality from defective quality.

* The mean concentration detected is 1 cfu in 526g (if the assumed standard deviation is 0.8 and probability of detection is 95%).[5]

The method to be employed for *Salmonella* should be the most recent edition of ISO 6579 or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc.

The criterion above is applied with the underlying assumption that the history of the lot is unknown, and the criterion is being used on a lot-by-lot basis. In those instances where the history of the product is known (e.g., the product is produced under a fully documented HACCP system), alternate sampling criteria involving between-lot process control testing may be feasible. The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected lot from being released for human consumption and (2) determine and correct the root cause of the failure.

Criteria for process hygiene

These are to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of the verification.

The safe production of these products is dependent on maintaining a high level of hygienic control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs, and not by the competent authority. As such these tests are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs.

| **Microorganisms** | **n** | **c** | **m** | **M** | **Class Plan** |
|---|---|---|---|---|---|
| Mesophilic Aerobic Bacteria* | 5 | 2 | 500/g | 5000/g | 3 |
| Enterobacteriaceae** | 10 | 2[6] | 0/10 g | Not Applicable | 2 |

[5] International Commission on Microbiological Specifications for Foods, 2002, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, Kluwer Academic/Plenum Publishers.

[6] This 2 class plan is proposed because a 3 class plan with equivalent performance would not be practical analytically, given the low levels of EB typically occurring when stringent hygiene conditions are maintained.

Where n = number of samples that must conform to the criteria; c = the maximum allowable number of defective sample units in a 2-class plan; m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality, or in a 3-class plan, separates good quality from marginally acceptable quality; M = a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality.

* The criteria for mesophilic aerobic bacteria are reflective of Good Manufacturing Practices and do not include microorganisms that may be intentionally added such as probiotics. Mesophilic aerobic counts provide useful indications on the hygienic status of wet processing steps. Increases beyond the recommended limits are indicative of the build-up of bacteria in equipment such as evaporators or contamination due to leaks in plate-heat exchangers (refer to Annex III).

** The mean concentration detected is 1 cfu in 16g (if the assumed standard deviation is 0.8 and probability of detection is 95%) or 1 cfu in 10g (if the assumed standard deviation is 0.5 and probability of detection is 99%).

The methods to be employed for Mesophilic Aerobic Bacteria and Enterobacteriaceae should be the most recent editions of ISO 4833 and ISO 21528-1/21528-2, respectively, or other validated methods that provide equivalent sensitivity, reproducibility, reliability, etc. The criteria above are intended to be used as a means of achieving ongoing verification of a facility's microbiological hygiene programs. Such indicators tests are most effective when the stringency of the criteria allows deviations to be detected and corrective actions to be taken before limits are exceeded. The typical action to be taken when there is a failure to meet the above criteria would be to determine and correct the root cause of the failure and, as appropriate, review monitoring procedures, including environmental monitoring (Annex III), and review prerequisite programs in particular the hygienic conditions from the drying step up to the packaging step (Enterobacteriaceae) and the process conditions during wet processing (mesophilic aerobes). Continued failures should be accompanied by increased sampling of the product for *Salmonella* and potential re-validation of the control measures.

While these tests were originally developed for lot-by-lot applications where the history of the lot was unknown, their usefulness is much greater when there is a full understanding of the product and the processes used in its manufacture, in which case this can provide a means of verifying correct implementation of specific hygiene measures. Such indicator tests are particularly amenable to alternative process control sampling plans and statistics.

**Labelling and Education**

Follow up formulae should only be used for the target population for which it is intended. There should be increased emphasis on the education of caregivers and healthcare professionals as to the appropriate uses of FUF, in addition to the training and education on the safe preparation, handling and storage (as recommended in Section IX of the main document), and improved labelling with respect to the intended consumer.

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It may seem that peak contaminations in up to 2 samples are tolerated in this microbiological criterion (MC). However, it is assumed that the product is sufficiently homogeneous that high level contaminations will fail the MC. It is further assumed that, in practice, under sufficiently strict hygienic operation, the manufacturer will normally not find positives and that if, occasionally, positives are found the manufacturer will take appropriate actions.

Finding 1 or 2 positives should indicate to the manufacturer a trend toward potential loss of process control and appropriate actions would include further microbial evaluation of the implicated end product (i.e. re-evaluation of the EB content; when EB MC fails, evaluation of product safety using the proposed MCs for *Salmonella* before its release as well as evaluation of the hygiene programme to confirm it is suitable to maintain ongoing hygiene control or to amend the programme such that is suitable to do so).

Finding 3 or more positives should signal to the manufacturer loss of process control and appropriate actions should be the evaluation of product safety using the MC for *Salmonella* before release of the implicated product as well as evaluation of the hygiene programme to amend the programme such that it

is suitable to maintain high hygiene control on an ongoing basis before production is resumed.

The rationale for using 2 class plans for hygiene indicators in particular situations is explained in ICMSF, 2002. Microorganisms in Foods. Book 7. Microbiological Testing in Food Safety Management. Kluwer Academic/Plenum, NY. ISBN 0-306-47262-7.