

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 4

CX/FH 05/37/4 – Add.2  
February 2005

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-Seventh Session

Buenos Aires, Argentina, March 14 -- 19, 2005

#### PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

Comments submitted by the Islamic Republic of Iran and International Baby Food Action Network  
(IBFAN)

#### IRAN

It seems that the microbiological criteria for other formula such as follow – up formula is not mentioned and it is suggested that the mould , *Staphylococcus aureus* and *Bacillus cereus* must be considered in microbiological analysis .

#### IBFAN

#### INTRODUCTION

First paragraph, first sentence, delete “safely”

First paragraph, last sentence , modify to read “A review of the available scientific information reveals that, intrinsic, in rare cases, contamination (or contamination during the manufacturing process) of powdered infant formula with *Enterobacter sakazakii* and *Salmonella* has been a cause of colonization, serious illness and death in infants.”

Rationale:

1. There is overwhelming evidence that the use of powdered infant formula cannot be classified as “safe”.
  - it is not sterile and may be contaminated with pathogenic bacteria,
  - numerous studies show that infants fed powdered formulas have higher risk of infectious disease, autoimmune disease, lower IQs and lower visual acuity,
  - infants who are formula fed are considered to be immunocompromised because they do not receive the normal immunological transfer from mother to infant via breastmilk
2. The incidence of illness and death caused by contaminated powdered formulas is unknown.
  - cases have only been identified in tertiary care hospitals with laboratory facilities with the capacity to identify and trace the causative organisms to the powdered formula. Reported

cases have been in industrial countries.

- The incidence is likely to be higher in countries where sources of fuel, refrigeration and clean water are scarce or unavailable to the majority. The European Union, speaking at the WHO Executive Board meeting in January 2005, stressed the need for precautionary measures in all geographical regions.
- The World Health Organization estimates that 1.5 million infants die every year because they were not breastfed. A number of these deaths are likely to be related to contaminated powdered formulas.

Second paragraph, first sentence, change beginning of the sentence to read “While **reporting of the incidences**”

Third paragraph, replace it with the following:

**All infants (from 0 to 12 months of age) fed powdered infant formulas are at risk. The group at particular risk is infants (i.e., children <1 year). However, Among infants, those who are immunocompromised and neonates (<28 days) are considered to be at greatest risk, particularly neonates of low birth weight (<2 500 g) and in those situations where the use of infant formulas is considered to be appropriate, for example, for infants of HIV-positive mothers. are also of concern because they may specifically require infant formula and may be more susceptible to infection**<sup>1</sup>.

Rationale: ALL infants fed powdered infant formulas are at risk. The consequences of mortality, sepsis, necrotizing enterocolitis and meningitis may be more serious for those who are newborn - neonates, prematurely born and low-birth weight because of their low capacity to resist the pathogenic *Enterobacter sakazakii*.

## SECTION I. - OBJECTIVES

First paragraph, first sentence, delete “ensure the safety” and substitute “reduce the risk of illness and mortality.

First paragraph, second sentence, delete “fortify” and substitute with “supplement.”

### II.1 SCOPE

First sentence, delete “fortify” and substitute with “supplement.”

### II.3 DEFINITIONS

#### *Human milk fortifier*

Change the definition to read “**a nutrient supplement product that may be added to human milk for feeding low-birth weight and premature infants. ~~It provides enriched nutrition needed by these special babies while still allowing them to receive their mother's milk. It increases the levels of protein, energy, calcium, phosphorus, or other nutrients, producing a diet more suited to the nutritional needs of these infants.~~**”

Rationale: The use of human milk fortifiers remains controversial and is generally not suitable for use in developing countries.

#### *V.2.1 Time and temperature control*

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<sup>1</sup> *Enterobacter sakazakii* and other microorganisms in powder infant formula: meeting report, MRA Series 6. ISBN: 92 4 156262 5 (WHO)

Second paragraph, first sentence and through out the document delete “should” and replace it with “must.”

#### V.7 DOCUMENTATION AND RECORDS

First paragraph, first sentence, after “...the shelf-life of the product” add “ by three years.”

Second paragraph, end of the paragraph, add “for a period of three years.”

Rationale: Record keeping has to be mandatory for a product designed to exclusively feed newborn and special needs infants. There must be a mandatory time for which the records are kept.

### SECTION IX. - PRODUCT INFORMATION AND CONSUMER AWARENESS

#### OBJECTIVES:

Fourth paragraph, modify it to read “Caregivers of infants in the home, day care and health-care facilities and health-care professionals **must should** be informed that the product **is not sterile and may contain pathogenic organisms does not undergo a sterilization process** and **must should** be provided with sufficient information on food hygiene to enable them to:

Third dash, delete “choices” and substitute with “decisions.”

Fourth dash, delete “prevent” and substitute with “reduce.”

Last paragraph, modify the paragraph to read “Specific information, **linked to the warning about lack of sterility must should** be provided regarding the use **and risk** of powdered infant formula for infants at greatest risk.

#### IX.3 LABELLING

Second paragraph, modify it to read:

**Packages Labels must carry have clear, conspicuous, easily readable and understandable warnings, in all appropriate languages printed on them or on a label that cannot be easily removed, should be considered on products, reminding which alert all** those who prepare formula and who feed infants, that powdered infant formulas **are not commercially sterile and may contain pathogens. do not undergo a sterilization process. Therefore, The label must should** contain appropriate information, **linked to this warning** regarding the need for proper preparation, handling and storage of reconstituted powdered infant formula to prevent or minimize bacterial growth. **The above warnings should occupy at least 20%/30% of the surface area of the label.**

**The remaining text and pictorial information on the label should do nothing to minimise the importance of this warning, for example idealise text or images or health or nutrition claims.**

#### IX.4 EDUCATION

After first sentence add the following new sentence.

**All such information must be in compliance with the requirements of the World Health Organization Code of Marketing of Breast-milk Substitutes and relevant resolutions of the World Health Assembly to avoid unnecessary and inappropriate use of powdered infant formulas.**

Second paragraph, after “...may be contaminated ...” change the sentence to read “~~on occasion,~~ with extremely low levels of pathogens that can cause serious illness **or death. Proper handling and storage of reconstituted infant formula helps to minimize the risk. in case of mishandling or improper storage of reconstituted infant formula.**”

First square dot, delete “extremely low levels of”

Third square dot point, second diamond point, Does this imply that one should prepare in batches and refrigerate? Does this contradict advice to prepare, feed immediately after preparation and discard immediately after each feed?

**For health-care providers/professionals and hospitals:**

First square dot point, at the beginning of the sentence add “When banked human milk is unavailable” and delete “feasible.”

Second square dot point, change the last diamond point to read “Keeping a daily **individual infant feeding** record of the product and lot number. **These records must be retained for three years.**

Add a new point to read “**All unused feeds must be discarded immediately after feeding.**”