

Proposed Draft Recommended International Code of Hygienic Practice for Powdered Formulae for Infants and Young Children

IBFAN Comment at Step 3

INTRODUCTION

Note: International standards use the term breastmilk as one word rather than “breast milk”.

Paragraph 1

First sentence

Change to read:

It is recognized internationally that breastmilk is the normal source of nutrition for infants.

Paragraph 2

First sentence

Change to read:

Powdered formulae covered by this code include: infant formula, follow-up formula, formula for special medical purposes intended for infants and young children, foods for special medical purposes intended for infants and young children and human milk fortifiers.

Delete the next two sentences. They are not necessary.

Paragraph 3

Second sentence

Change to read:

Thus to reduce the risk of infection from intrinsic contamination these products require strict adherence to good hygienic practices during both manufacture and use.

Paragraph 7

First sentence

Change to read:

Enterobacter sakazakii has recently emerged as a pathogen that can cause serious infections and death in infants.

Paragraph 8

Last sentence

Add:

The lack of case reports from developing countries and the lack of capacity to determine the source of infection as intrinsically contaminated PF implies that the incidence of infection may be highly under-reported.

Paragraph 9

Reverse the sentences to read:

Reported fatality rate of *E. sakazakii* infections in infants vary considerably with rates as high as 50 percent reported in one instance. In addition a portion of surviving infants have permanent disabilities such as retardation and other neurological conditions. Although most reported....

It is important to highlight the seriousness of infections.

Paragraph 10

Delete this paragraph.

The information does not contribute to the topic being addressed. The paragraph is redundant and may dilute the impact of critical information and confuse those using the standard to reduce the risk of infection for infants and young children.

Paragraph 11

Sentence 3,

line 4

delete the word “small”.

The size of the outbreak is unknown and this is but one example of potentially many outbreaks. To use the word small minimizes the risk and undermines the fact the results of serious illness and death.

Paragraph 12

Add the following sentence:

It should be noted that sterilized liquid products are not available in many parts of the world and increases the cost of formula feeding by more than 3 fold.

Paragraph 14

Delete the word “prevention” and insert: “**risk reduction**” and change the sentence to read:

The primary responsibility for risk reduction measures must be with the manufacturer. Health care providers and parents must be appropriately warned through product labels to take into consideration the risks to infants both within and beyond the neonatal period.

Paragraph 15

Change to read:

Product **label warnings, independent** consumer programs and staff training at hospitals should **be in full compliance with the International Code of Marketing of Breast-Milk Substitutes and subsequent relevant resolutions of the WHA and** be updated as appropriate to give adequate information to caregivers on **reducing the risks of intrinsically contaminated PF** and to provide adequate **warnings** regarding the health hazards of inappropriate **use,** preparation, **storage** and handling of PF.

SECTION I. – OBJECTIVES

Paragraph 1

Change the sentence to read:

The objective of this Code is to provide practical guidance and recommendations to manufacturers and governments ~~and care givers of infants and young children~~, as appropriate, **on the measures that must be taken in order to reduce the risk of infection, serious illness and death associated with the intrinsic contamination of PF.**

Codex standards are intended for governments and manufacturers of food products for the purpose of regulating food commodities and food products. Codex is not mandated to make recommendations to the general public but to recommend measures to manufacturers, distributors and governments that are designed to protect the health and safety of consumers.

Paragraph 2

Delete this paragraph.

This is not an “objective”, repeats information already stated in the introduction and does not contribute to this section.

Paragraph 3

Replace the term “food chain” to read:

...**manufacturing process, use, preparation, storage and feeding** that can be employed to reduce the risks for infants and young children that are associated with the consumption of **contaminated** PF.

SECTION II. – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

Paragraph 3

Add the following sentence.

The application of this standard shall be in conformity with the International Code of Marketing of Breast-Milk Substitutes and subsequent relevant resolutions of the WHA.

The aim of the International Code and resolutions of the WHA is to protect infant and young child health by ensuring that PF are not used unnecessarily. Information and education about the products use must include adequate warnings on product labels that the product is not sterile and must be prepared according to manufacturers instructions.

2.1.1 ROLES OF GOVERNMENT AND INDUSTRY TO PROTECT CONSUMERS

Paragraph 2

Change to read:

~~Although~~ The primary responsibility for ensuring that PF are **hygienically** produced and suitable for their intended use lies with the manufacturer. There is a continuum of effective control measures that are needed, including the manufacture of ingredients. ~~caregivers of infants and young children to assure the safety and suitability of PF.~~

Paragraph 3

The term **food chain** should be deleted as it is not defined.

Paragraph 4

Bullet 3

Delete the term **food chain** and insert **manufacturing process**.

Bullet 4

Second sentence

Change to read:

Manufacturers are responsible for ensuring that all information on the use and preparation of the product is in conformity with the International Code of Marketing of Breast-Milk Substitutes and subsequent relevant resolutions of the WHA.

Bullet 6

Add "**independent**" and change to read:

Hospitals and institutions should provide effective training by an **independent** health care provider to ensure that PF are prepared, handled and stored properly and according to the manufacturer's instructions and hygienic training provided to them.

This is in conformity with the International Code to reduce the possibility of conflict of interest for those working in infant and young child health.

Paragraph 5 (indented)

Last sentence change to read:

Furthermore adequate **warnings regarding the intrinsic contamination of PF** and consumer and education programs should be implemented.

Paragraph 6

Delete this sentence.

This is a vague comment. If the intent of this paragraph is to make a recommendation about communications between the various parties of the manufacturing and distribution process, then a clear statement should be made.

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENES

Change to read:

OBJECTIVES

Products should bear appropriate **information warnings that PF is not sterile and may contain pathogens that can cause infection, illness and death** to ensure that:

- adequate and accessible information is available to all concerned in the **food chain distribution, retailing, use, storage and preparation**, in particular, retail establishments, caregivers of infants in the home, day care and health-care facilities and health-care professionals to enable them to handle, store, process, prepare and display PF **to reduce the risk of infection**; and
- the lot or batch can be easily identified, and recalled if necessary.

Caregivers of infants in the home, day care and health-care facilities and health-care professionals ~~must should be informed~~ **warned** that the product is not sterile and may be contaminated with bacteria **pathogenic organisms** which can cause serious illness or death. **Labels must provided in clear, concise and in the appropriate language(s) preparation instructions to enable care givers to reduce the risk of infection** and with sufficient information on food hygiene to enable them to:

- make informed ~~choices~~ **decisions** appropriate to the infant; and
- ~~prevent~~ **reduce risk of** contamination and/or growth of foodborne pathogens by, preparing, storing and using PIF according to manufacturers's instructions.

Specific information ~~must should~~ be provided regarding the preparation and handling of PF, for example, that rehydration at 70 C followed by rapid cooling provides an effective way to mitigate risks. For infants at greatest risk, instead of PF, the use of commercially available sterilized liquid products or other infant feeding options **such as pasteurized donor human milk** which have undergone an effective decontamination procedure at the point of use, should be encouraged.

RATIONALE

~~The means of implementation of the~~ Control measures recommended for application beyond manufacturing and distribution are through **warnings regarding lack of sterility and preparation instructions** provided to the user, ~~either~~ through product labelling (and/or separate written information); written procedures (e.g. in professional institutions), **and** through oral instructions and training. For parents means of implementation **must be through product labels in clear and concise language and graphics in appropriate languages on the outside panel of the product packaging.**

Delete the last paragraph and insert the following sentence:

Parents must understand the intrinsic nature of the contamination in order to reduce the risk of illness or death associated with the use of PF.

9.3 LABELLING

Refer to the *General Principles of Food CAC/RCP 1-1969, Rev. 4-2003*). In addition:

The label should contain appropriate instructions regarding the need for proper preparation, handling and storage of reconstituted PF to prevent or minimize bacterial growth. Where literacy may be low, pictograms may be used.

Delete the above sentences and change to read:

Packages must carry clear, conspicuous, easily readable and understandable warnings, in all appropriate languages printed on the outside of the label that cannot be easily removed, which alert all those who prepare formula and who feed infants, that powdered infant formulas are not commercially sterile and may contain pathogens. 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 claims.

9.4 EDUCATION

Change to read:

Health education programs should cover general food hygiene. The development and distribution of educational documents related to PIF to caregivers of infants in the home, day care and health-care facilities and health-care professionals for infants should be encouraged. **All such information and programs 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 PFs.**

These programs should enable i) the understanding of the importance of product information, ii) following any instructions accompanying products, and iii) making informed **decisions**.

Guidelines for the safe preparation, storage and handling of powdered infant formula are being developed by the WHO/FAO and may be used as appropriate. Individual countries are encouraged to provide caregivers and parents with appropriate educational material.

Caregivers of infants in the home, day care and health-care facilities and health-care professionals involved in caring for infants should be aware that PF is not a sterile product and may be contaminated, ~~on occasion~~, with extremely low levels of pathogens that can cause serious illness **or death** (e.g., *Salmonella*, *E. sakazakii*) **.....**

Information/education about necessary hygiene practices in relation to preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized, particularly regarding the relationship between time/temperature control and foodborne illness.

It should be emphasized that the improper handling and storage of reconstituted PF can promote the growth of pathogens (e.g., *Salmonella*, *E. sakazakii*, and possibly other microorganisms such as sporeformers) which may be present initially at low levels.

.....

In situations where the mother cannot breastfeed, **decides** ~~chooses~~ not to breastfeed or when banked human milk is not available, the information provided by WHO/FAO as well as information provided by Annex III **should** be communicated to caregivers of infants in the home, day care and health-care facilities and health-care professionals to increase awareness on the proper preparation, storage, handling and use of reconstituted formula.

SECTION X - TRAINING