codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FH 07/39/4-Add.1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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COMMENTS ON THE

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR POWDERED FORMULAE FOR INFANTS AND YOUNG CHILDREN AT STEP 3

SUBMITTED BY:

Brazil, Costa Rica, Islamic Republic of Iran, Mexico, Peru, Philippines, United States of America, International Baby Food Action Network (IBFAN), International Dairy Federation (IDF), International Lactation Consultant Association (ILCA), International Special Dietary Foods Industries (ISDI),

GENERAL COMMENTS

BRAZIL

Brazil congratulates the drafting group led by Canada for the advances obtained and the efforts to grant an objective approach to the document. Continuing the revision of the document, the alterations in the items described below are suggested.

ISLAMIC REPUBLIC OF IRAN

Generally speaking the draft Code, including the different annexes, is supported as developed so far by the WG and the decisions taken to clearly define the scope of the document, according to the recommendations of the CCFH (USA, 2006): "Powdered formulae for special medical purposes for infants and young children, intended to partially replace or supplement breast-milk, infant formula or follow-up formula".

Infant cereals are thus excluded from the scope of the revised draft and this approach is supported as this product category is completely different (as regards different processing technologies, etc.)

The Code is exclusively focused on the control of microbiological hazards, *Salmonella* and *E. sakazakii*, and other hazards such as allergens have been excluded. While we acknowledge the importance of the management of all significant hazards, this decision which allows to streamline the scope and purpose of the whole document, is supported..

MEXICO

We congratulate the technical group for their work on the development of this document, which in general we regard as complete.

It must be clearly understood that the products covered by the document are those developed exclusively to meet nutritional purposes and not linked to therapeutic purposes, particularly those intended for medical purposes, since even from the title its context may be misunderstood.

We consider it advisable to retain the follow-up formulae intended for infants up to 12 months of age in Annex I, until the information needed to define the specific risk for this population is obtained. The above is in agreement with the information provided in the introduction of the document regarding the fact that in FAO/WHO expert meetings it was identified that all infants <12 months of age are considered the population at particular risk for Enterobacter sakazakii infections.

With this idea in mind, we believe it to be advisable to transfer all the formulae for children intended for medical purposes to Annex I, due to their susceptibility and based on the uncertainty relative to the risk for this type of population identified in the background section of the same document.

PERU

Peru appreciates the opportunity to express its views on this text, subject to discussion.

In general, we are in agreement with the document in question. However, we would like to present a comment about the information included in Section IX regarding **Product Information and Consumer Awareness**

PHILIPPINES

The Philippines supports the elaboration of a Draft Code of Hygienic Practice for Powdered Formulae for Infants and Young Children because of the reported high incidences of infection in infants from this product due to poor manufacturing environment, preparation equipment, and preparation hygiene. (FAO/WHO Expert Meeting on Enterobacter sakazakii and other microorganisms in powdered infant formula, WHO, Geneva, 2-5 February 2004).

UNITED STATES OF AMERICA

The United States appreciates the work of Canada and the members of the working group in developing this proposed draft Code. The working group is to be commended for the progress it has achieved. The United States believes the document adequately and appropriately addresses the major aspects of powdered formula safety and offers the following comments in the hope that they will strengthen the document.

IDF

IDF would like to congratulate the chair of the CCFH Drafting Group for the work undertaken and for facilitating the revision the document. We believe that the document has improved and that only few issues are left to be resolved.

We would like to put forward the following comments for consideration by the Committee

Our main concern is to ensure that the Code of Hygienic Practice throughout reflects the general view of the working group, that a range of preparation and handling options are available, and which has been documented by the two JEMRA reports. The FAO/WHO guidelines (2007) focus on a particular subset of the risk management options (e.g. including 70^{o}C). Countries and PF manufacturers may, in accordance with the information provided by the JEMRA reports, wish to develop their own guidelines or instructions based on the national situation e.g. quality of PF and consumer knowledge.

ISDI

ISDI would like to thank Canada for having chaired the ad-hoc WG in Ottawa and having given to the industry of foods intended for infants and young children the opportunity to share its expertise of the sector with the several countries that participated.

ISDI would like to congratulate Canada for having been able to efficiently drive the working group and having obtained a clear and more achieved document to be discussed in the plenary session of the CCFH in November 2007 and hopefully put forward to the Codex Commission for adoption at Step 5.

E. sakazakii criterion application to products categories

Background information

At the 2007 CCFH ad-hoc WG Meeting held in Canada, after a lengthy discussion, it was finally agreed that the *E. sakazakii* criterion would be proposed to be extended to any powder formulae up to 12 months of age; including therefore powdered infant formulae[1], powdered formulae for medical purposes intended for infants[1] both used as the sole source of nutrition, as well as powdered follow-up-formulae[2] and formula for special medical purposes for infants and young children[3] both not used as the sole source of nutrition for infants (= up to 12 months).

When concluding the meeting, some delegations however reserved their position on this proposal, as they felt that a criterion for follow-up-formulae was not needed.

ISDI does not understand this unnecessary stringency for products only fed to infants above 4/6 months i.e. follow-up-formulae, especially in light of the fact that those infants will be fed at the same time with other foods intended for infants and young children as well as with the family food for which no criteria for *E. sakazakii* has been laid down.

EFSA Risk assessment and European legislation

To our knowledge, up to date, only one region has taken actions to control *E. sakazakii* in infant food: the European Union (EU), representing 27 countries.

Prior to drafting its legislation, the European Commission usually asks for a scientific opinion from the European Food Safety Authority (EFSA); in this particular case, the request was made twice.

The first EFSA opinion[4] adopted on 9th September 2004 shows that *E. sakazakii* has caused illness in all age groups, but that by far the majority of cases are seen in infants less than 4-6 weeks of age, especially pre-term, underweight, immunocompromised babies.

This risk assessment led to the Regulation No 2073/2005[5] that gives release microbiological criteria for *Salmonella* and *E. sakazakii* as well as process hygiene indicators for Enterobacteriaceae (EB) in infant formulae and formulae for special medical purposes for infants less than 6 months; the EB criterion when exceeded will trigger improvement in production hygiene.

The second opinion[6] adopted on 24th January 2007 generated in the EU a revision of the above Regulation. The modified text, very likely to be formally adopted in October 2007 by the Standing Committee for Food and Animal Health (SCFCoAH) after the consultation of the European Parliament and European Council adjusts the criteria for *E. sakazakii*, *Salmonella* and EB for infant formulae and formulae for special medical purposes for infants less than 6 months and adds criteria for *Salmonella* and EB for follow-on-formulae.

However, based on the EFSA risk assessment, no criterion for *E. sakazakii* has been set for any powdered products that will be fed either to infants above 6 months or to young children, e.g. follow-on-formulae.

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[1] CODEX STAN 72-108 rev. 1.2007
[2] CODEX STAN 156-1987, amended 1989
[3] CODEX STAN 180-1991
[4] EFSA-Q-2003-111 - EFSA Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to the microbiological risks in infant formula and follow-on formula - EFSA Journal. 2004, 113, 1-35
[5] Commission Regulation 2073/2005 of 15 November 2005 on microbiological criteria for foodstuff
[6] EFSA-Q-2006-078 - EFSA opinion on microbiological risks in infant formulae and follow-on-formulae with regard to Enterobacteriaceae as indicators

Consumer understanding of the different products categories

A recent government-sponsored survey from the UK, where separate regulatory standards exist for infant and follow on formulae, found that *"the vast majority of mothers do not introduce follow-on milk before six months as recommended."*[7]

Manufacturing process perspective

While most follow-up formulae are manufactured in the same facilities as infant formulae, manufacturers do use different ingredients in follow-up formulae compared to infant formulae as well as appropriate production sequencing is applied to properly segregate the different product types.

ISDI Comments

ISDI believes that the EFSA risk assessment does form a solid basis for the decision to set only an *E. sakazakii* criterion for those products intended for the infants at greatest risk for *E. sakazakii* who are neonates and infants under 2 months of age.

ISDI is of the opinion that in this particular case, Codex should seriously take into account a legislation as developed in the European Union, in place since 1 January 2006 and that has proven to be efficient.

Indeed, in this region, all the products intended for infants and young children as defined by Codex are on the market, contrary to other parts of the world. It is therefore a good example of a wide usage of the variety of products as defined by Codex.

Conclusion

As a conclusion, ISDI would like to reiterate its position that a microbiological criterion for *E. sakazakii* is not relevant for follow-up-formulae.

It therefore requests that follow-up-formulae up to 12 months are moved from Annex I to Annex II and that the necessary texts changes are made (see section 2. of the ISDI comments).

Comments on the 'not sterile' statement

The use of statements such as 'not sterile' on labels can be misinterpreted by consumers, causing them to panic and subsequently reduce their ability to follow manufacturers' instructions.

According to a consumer research commissioned by the UK Food Safety Authority (FSA), the phrase not sterile *"failed to communicate the nature and level of risk as most did not think it meant potentially harmful but actually harmful."*[8]

The recommended language provides strong responsibility messages and therefore is likely to result in increased compliance as per the findings of the UK FSA report, which noted consumers are more apt to follow such directions as compared to inflammatory statements that may cause panic and confusion.

Conclusion

As a conclusion, ISDI requests that the example *'e.g. that PF is not sterile'* be deleted (see section 2. of the ISDI comments) from the para. 6 of section 9.3, considering that the rest of the paragraph gives to manufacturers and governments sufficient and clear guidance on the necessary information to be provided.

Although ISDI perfectly understands that this sentence is only given as an example, it foresees that some national governments may consider it as a recommendation or even as a mandatory statement.

[7] UK NHS 2005 Infant Feeding Survey published May 14 2007 available at http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/infant-feeding/infant-feeding-survey-2005.

[8] UK FSA 2006 (COI and FSA Powdered Infant Formula Qualitative Research) available at http://www.food.gov.uk/science/surveys/infantformula.

INTRODUCTION

SECOND PARAGRAPH

ILCA

In the below quoted bullet points defining "powdered formulae" we miss a clearer definition to the product composed of follow on formula and cereals . Please include the following definition 2.1.2. from the CODEX standard for cereal based foods for infants and young children) which reads as follow: Cereals with an added high protein food which are or have to be prepared for consumption with water or appropriate protein-free liquid

The second bullet point will read then:

Follow-up formulae which are used in combination with other foods as part of the weaning diet of older infants and young children; ***including Cereals with an added high protein food which are or have to be prepared for consumption with water or appropriate protein-free liquid (2.1.2. from the CODEX standard for cereal based foods for infants and young children****)*

Rationale: they have been shown to contain E sakazakii

SEVENTH PARAGRAPH

IBFAN

First sentence, after "6" add "reported"

Rationale: *It is more accurate to state "****reported****" outbreaks to avoid the assumption that there are only 6 outbreaks.*

EIGTH PARAGRAPH

IBFAN

First sentence, modify it to read: "*Enterobacter sakazakii* has recently emerged as an ***intrinsic*** pathogen of infant~~s~~ ***formulae***."

NOTE: The World Health Organization's Inter-agency Task Team (IATT) on the Prevention of HIV in Pregnant Women, Mothers, and their Infant, Dec 2006, noted that:

- *Exclusive breastfeeding for up to six months was associated with a three to four fold decreased risk of transmission of HIV compared to non-exclusive breastfeeding,*
- *Artificial feeding showed no advantage over breastfeeding for 3 to 6 months in stopping HIV infection and death,*
- *Early cessation of breastfeeding (before 6 months) was associated with an increased risk of infant morbidity (especially diarrhoea) and mortality in children who's mothers were HIV positive,*
- *Breastfeeding of HIV-infected infants beyond 6 months was associated with improved survival compared to stopping breastfeeding,*
- *The outbreak of diarrhoea which claimed the lives of 470 Botswanan infants earlier this year was noted as an example of the dangers of combating MTCT with artificial feeding. Botswanan health officials had been distributing formula to stop MTCT through breastfeeding and the infants became infected after floods led to contaminated water in the region.*

PARAGRAPH 11

IBFAN

Delete in its entirety.

Rationale: The above paragraph should be deleted since this document deals only with the intrinsic contamination of PIF with E. sakazakii. The above paragraph is redundant.

PARAGRAPH 12

IBFAN

First sentence, after "link with" insert "***the intrinsic contamination of"***

Rationale: The added text helps to clarify the intent of the statement.

14 WHO, HIV and infant feeding: framework for priority action. Geneva: World Health Organization, 2003

PARAGRAPH 13

First sentence

COSTARICA, ISDI

For infants at greatest risk, **e.g., in neonatal intensive care settings,** ~~instead of PF, the use of~~ **a** commercially ~~available~~ steril~~eized~~ liquid **infant formula must be used if available unless the attending physician recommends otherwise.** ~~products or other equivalent infant feeding options which have undergone~~ **If a non-commercially sterile feeding option is chosen,** an effective point of use decontamination procedure~~, should be encouraged~~ **must be used**.

Modify sentence as noted.

Rationale: The paragraph should be stronger regarding the use of commercially sterile liquid formulas, if available.

UNITED STATES OF AMERICA

This paragraph should be modified as indicated below to more directly convey the risk.

For infants at greatest risk, e.g., in neonatal intensive care settings, commercially available liquid infant formula must be used if available unless the attending physician recommends otherwise. If a non-commercially sterile feeding option is chosen, an effective point-of-use decontamination procedure must be used.

IBFAN

Modify the paragraph to read: "For infants at greatest risk, ***breastfeeding is the safest and optimal means to feed infants. When replacement feeds are medically indicated, and when donor human milk is unavailable,*** instead of PF, the use of commercially available sterilized liquid products or equivalent infant feeding options which have undergone an effective point of use decontamination procedure, ~~should be encouraged~~.***may be considered***.

Rationale: When donor human milk is unavailable as the priority replacement feeding, the use of commercial sterile formula is only one option available to parents and care givers and therefore may be considered as a choice in a range of replacement feeding option.

ILCA

Insert the highlighted text to read: "*For infants at greatest risk, instead of PF,* ***breastfeeding is the safest and optimal means to feed infants. When breastfeeding, breastmilk or donor breastmilk are not available and replacement feeds are medically indicated****, the use of commercially available sterilized liquid products or other equivalent infant feeding options which have undergone an effective point of use decontamination procedure, should be encouraged."*

Rationale: all options should be made clear here

ISDI

Modify the sentence as noted.

"For infants at greatest risk, **e.g., in neonatal intensive care settings,** ~~instead of PF, the use of~~ **a** commercially ~~available~~ steril~~ized~~ liquid **infant formula must be used if available unless the attending physician recommends otherwise.** ~~products or other equivalent infant feeding options which have undergone~~ **If a non-commercially sterile feeding option is chosen,** an effective point of use decontamination procedure should be ~~encouraged~~ **considered**."

Rationale: The paragraph should be stronger regarding the use of commercially sterile liquid formulas, if available.

PARAGRAPH 14

UNITED STATES OF AMERICA

1st sentence, item 2, at this point it is not certain that contamination during drying can be ruled out so the sentence should be revised to read:

"…in the steps during or following drying,…"

PARAGRAPH S 15 AND 16

ISLAMIC REPUBLIC OF IRAN

In the last 2 paragraphs: it is suggested to add, for emphasis, the *types of units/centres delivering health services,* the text to read as follows:

Prevention efforts must be multi-faceted, directed at manufacturers, *units/centres delivering health services, such as nurseries, baby clinics, hospitals, health centres, infirmaries, etc.,* as well as home settings, and take into consideration the risk to infants both within and beyond the neonatal period.

Product labelling, consumer education programs and staff training at *nurseries, baby clinics, hospitals, health centres, infirmaries, etc.,* as well as home settings, should be updated as appropriate to provide adequate information to caregivers on the safe use of the product and to provide caution regarding the health hazards of inappropriate preparation and handling of PF.

ILCA

Paragraph 15: **infant care givers** should be included in the prevention efforts and listed here.

PARAGRAPH S 16

IBFAN

Delete the word ***safe*** and insert the word ***use after inappropriate***

SECTION II. – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

FIRST PARAGRAPH

ILCA

Second sentence, insert: **Cereals with an added high protein food (for instance follow-on formula)** which are or have to be prepared for consumption with water or appropriate protein-free liquid

Rationale: These products need to be inserted as they have been shown to be contaminated with E sakazakii.

IBFAN

First sentence, after "…milk substitute," add "when medically indicated and/or when donor human milk is unavailable." And delete rest of the sentence.

Second sentence, delete the following text; "…and ~~***which serve as the sole source of nutrition***~~, human milk fortifiers and powdered formulae for special medical purposes for infants and young children ~~***intended to partially replace or supplement breast milk***~~, .."

Rationale: The term when medically indicated should be used since the use of infant formula should only be in consultation with a health care provider to ensure the appropriate use of infant formula in replacement feeding.

SECOND PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

At the end of the paragraph add the following; " ***Also refer to the following WHO document:*** *WHO (1981). International Code of Marketing of Breast Milk Substitutes. WHO, Geneva."*

2.1.2 ROLES OF GOVERNMENTS, INDUSTRY, AND CONSUMERS

SECOND PARAGRAPH

COSTA RICA, ISDI

After "manufacturers of ingredients" add the following text "**and primary packaging components**"

Rationale: Primary packaging can harbor some bioburden so must be carefully controlled to minimize significant microbiological contamination.

UNITED STATES OF AMERICA

Add additional words highlighted below concerning packaging manufacturers and components.

Although the primary responsibility lies with the manufacturer for ensuring that PF manufactured are safe and suitable for their intended use, there is a continuum of effective control measures that need to be performed by other parties, including manufacturers of ingredients **and packaging materials** and caregivers of infants and young children, to assure the safety and suitability of PF.

IBFAN

End of the paragraph, delete the words: *" the safety and suitability" and add "***that the risks associated with the use of intrinsically contaminated PF are minimized."**

ILCA

End of the paragraph, replace the words: *"to assure the safety" by "to minimize the risks and assure…"*

THIRD PARAGRAPH

ILCA

At the end Include a reference in the text to the 2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula.

IBFAN

Last sentence, modify the start of the sentence to read "~~**however, the**~~ ***C***aregivers should also ***be made aware*** ~~**have an understanding …"**~~

FOURTH PARAGRAPH

1ST BULLET

COSTA RICA, ISDI

After the first sentence add the following new sentence: **"Producers and manufacturers of primary packaging components should also apply the appropriate practices."**

RATIONALE**:** Primary packaging can harbor some bioburden so must be carefully controlled to minimize significant microbiological contamination

ISLAMIC REPUBLIC OF IRAN

At the end of bullets 1 and 2 and, in general, wherever GHP is mentioned, add*Good Laboratory Practices (GLP).*

2ND BULLET

UNITED STATES OF AMERICA

The first sentence should be modified to read: **"Manufacturers of ingredients and packaging materials should utilize good manufacturing and good hygienic practices and have HACCP systems implemented."**

3RD BULLETT

ISLAMIC REPUBLIC OF IRAN

Also mention *SQA*, when speaking about the manufacturer implementing controls…..This is because suppliers are/should be considered, after all, one of the stakeholders

4TH BULLETT

ILCA

Insert: on the labelling and/or packaging following the 2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula. To read:

- *Manufacturers should provide accurate and understandable* ***information on the labelling and/or packaging following the 2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula,*** *to enable the subsequent person(s) in the food chain, including the final user/caregiver, to use the product appropriately.*

6TH BULLETT

ILCA

Change 6th bullet point to read:

- *Hospitals and institutions should establish hygienically designed rooms designated for preparation of formulae and good hygienic practices* ***based on the 2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula****. (e.g., HACCP, labelling of prepared food, hygiene and cleaning instructions, temperature control, , etc.), and should provide effective training* ***by independent professionals free from conflict of interest*** *to their caregivers of infants and to other caregivers.*

7TH AND 8TH BULLET

IDF

The references to the FAO/WHO guidelines and manufacturers' instructions (foot note no. 16) should be removed. These are covered in more detail in the later text (section 9.3).

LAST BULLETT

IBFAN

Last sentence, modify it to read; "Furthermore, ***an independent party should provide consumer guidance and consumer education programmes about proper preparation,storage and handlingopf PF.***

~~**adequate consumer guidance and consumer education programs should be provided.**~~

ILCA

Add at the end of the last bullet point; "**by trained professionals free from conflict of interest."**

2.2 DEIFINITIONS

ILCA

Insert another definition: Cereals with an added high protein food which are or have to be prepared for consumption with water or appropriate protein-free liquid.

This is the definition 2.1.2. from the CODEX standard for cereal based foods for infants and young children. As these products are prepared with powdered follow-on formula they have to be included here.

Powdered formulae

IBFAN

After "intended for infants..." , modify the sentence to read; " ~~**as sole source of nutrition**~~, human milk fortifiers, and formulae for special medical purposes for infants and young children, ~~**intended to partially replace or supplement breast milk**~~, infant formulae"

Formula for special medical purposes intended for infants

IBFAN

After "… (CODEX STAN 180-1991" delete rest of the sentence.

Formula for special medical purposes for infants and young children (not sole source of nutrition)

IBFAN

After "… (CODEX STAN 180-1991)" delete rest of the sentence.

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES

4.1.2 Equipment

SECOND PARAGRAPH

BRAZIL

It is suggested to exclude the expression "*whenever possible*", to confer more clarity to the text and considering the ability of *Salmonella spp.* e *E. sakazakii* to persist on surface of the equipments for long periods:

4.3.1 General

SECOND PARAGRAPH

ILCA

Delete the last sentence, as unavoidable harbourage sites not accessible to cleaning, cannot be easily inspected, this weakening by keeping this sentence in should not be tolerated.

SECTION V - CONTROL OF OPERATION

5.2.2.2 Intermediate Storage

FIRST PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

In the last sentence of the first paragraph replace "high" with "*higher"*

SECOND PARAGRAPH

BRAZIL

It is proposed to include the phrase "*if there is no loss in nutrient contents*" in the end of the paragraph, once the use of high temperatures in powdered formulae can provoke inactivation of nutrients, especially vitamins and/or inactivation of active ingredients, as use of probiotics and other technological innovations as enzymes addition and active proteins:

Microbiological cross contamination

THIRD PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Second sentence, after "Where possible,: delete the word "*packaged"*

5.3 INCOMING MATERIAL REQUIREMENTS

SECOND PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Mention also ***SQA***, when speaking about manufacturers selecting suppliers.

5.7 DOCUMENTATION AND RECORDS

ILCA

Second paragraph, change the last sentence to read; *Documentation must be sufficient and available for product traceability in the event that a recall may prove necessary.*

5.8 RECALL PROCEDURES

IBFAN

NOTE: Because of the serious health consequences associated with infection caused by Salmonella and E. sakazakii, it is vital that recall procedures be established specifically for these products.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

GENERAL COMMENTS

PERU

With regard to paragraphs 2, 3, 6, 7, we agree with the Working Group about the need for appropriate information for consumers and users, which may be communicated by different means, that allows for understanding of the importance of hygienic preventive measures during processing, reconstitution, handling, and use of the PFs.

ISDI

ISDI is strongly opposed to any labelling statement that would frighten the consumer and would not focus on urging parents to respect the manufacturers' instructions for the reconstitution of the powder.

ISDI also believes that negative warning labels may also lead the parents to feed their infants with other products that would not meet their nutritional requirements; this is perfectly reflected in the text as drafted in section 9.3 para. 6: '*When considering the wording of such information, consideration should also be given to any potential risk of caregivers being inadvertently encouraged to use inappropriate alternatives to powdered infant formulae (e.g., milk powder).'*

ISDI believes that the rest of the para. 6 is very clear to ensure that the labelling will give appropriate and clear messages to the parents: *'The label should include information to make clear the potential risks of inappropriate preparation, handling and use […]* especially in light of the recommendation to validate such indication with the national governments: '*Industry and national governments should be encouraged to validate the label to ensure that the intended messages are understood.'*

ISLAMIC REPUBLIC OF IRAN

The approach by the WG focusing on the need for the implementation of combined control measures, i.e. from manufacturing to the use of the formulae, and not an exclusive focus on single steps of the food chain, is fully supported.

THIRD PARAGRAPH

ILCA

1st sentence, …..a small number of servings, **delete the word small** and replace by "certain." The word small is not giving an accurate figure of the fact that 1 tin out of 4 is intrinsically contaminated with harmfull bacteria. **Insert the word intrinsically** to read:

Even when products have been manufactured according to this Code, a **certain** number of servings may **intrinsically** contain pathogenic microorganisms.

IBFAN

1st sentence, "…..a small number of servings", **delete the word small** and replace by "substantial"

2nd sentence, delete the word "Additional" and replace by "Further"

Last sentence, after "…formula are" add "also"

Rationale: The number of servings should be a scientific determination and can readily be clarified and calculated on the basis of the microbiological criteria presented in Annex I and Annex II. A more specific statement is warranted here.

FOURTH PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Sentence 1, to read: Clear instructions for the appropriate preparation, handling and use of PF should be *available/included.*

Sentence 4, to read: *As far as possible, servings should be prepared one a time, i.e., just sufficient for one feeding and, in any case*, leftover formula should be discarded.

This addition is suggested, because research and general observation show that mothers/care-givers tend to prepare several servings in one go, since it take less time and effort. Leftovers are not always stored properly (as regards temperature, etc.) and are spoiled/contaminated

ILCA

Insert the following sentence at the end: The ***2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formul are the adequate document for this information.***

IBFAN

Modify the paragraph to read; "All health care professionals and caregivers should be informed ***at point of sale*** that powdered formulae are not sterile and that the ***FAO/WHO Guidelines: Safe preparation, storage and handling of powdered infant formula (2007)***[16] ~~**the use of Good Hygienic Practices during reconstitution, handling, and feeding, including appropriate storage**~~ is essential to minimize the risk of ***PI*** borne illness, primarily due to *E. sakazakii and Salmonella."*

FIFTH PARAGRAPH

BRAZIL

First sentence, after "should be" it is suggested to add, "*included in the label.*" T he proposed sentence is incomplete.

COSTA RICA

First sentence, after "should be" modify the text to read **"Communicated to parents and caregivers by health care professionals and displayed on product labels."**

Rationale: Health care professionals should educate parents and caregivers as to the proper handling of PF.

ISLAMIC REPUBLIC OF IRAN

End of the last sentence, give reference in brackets: (reference toRreport/web page).

UNITED STATES OF AMERICA

The first sentence is incomplete and should be modified to read: **"Clear instructions for the appropriate preparation, handling and use of PF should be provided to health care professionals and caregivers."**

IDF

6th sentence

Paragraph 5 is a key paragraph to convey the findings of the report of the 2006 FAO/WHO expert meeting on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula.

It is important that this paragraph is phrased in a way that enables the full use of all appropriate scenarios addressed by the report.

This can be obtained by redrafting this paragraph as follows (additions underlined, removals ~~stricken out~~):

> *"Clear instructions for the appropriate preparation, handling and use of PF should be communicated to the caregiver. Various combinations of hygienic measures can achieve significant risk reduction and are addressed in the report of the 2006 FAO/WHO expert meeting on* Enterobacter sakazakii *and* Salmonella *in powdered infant formula[11] and can be used according to the risk reduction strategy chosen. For example, one risk reduction strategy includes feeding the formula immediately after reconstitution and rapid cooling to the appropriate feeding temperature is one practical approach to minimize risk. In this case, (i) the ~~The~~ feeding time should be minimized and should not exceed two hours, (ii) leftover ~~Leftover~~ formula should be discarded, and (iii) any ~~Any~~ formula prepared for later use should be refrigerated immediately following reconstitution and used within 24 hours. Various other risk reduction strategies for the preparation, storage and handling are provided in the guidelines of the FAO/WHO on the safe preparation, storage and handling of powdered infant formula (2007)16 which are based on the report of the 2006 FAO/WHO expert meeting on* Enterobacter sakazakii *and* Salmonella *in powdered infant formula[11], or can be derived from ~~as well as in~~ the report itself."*

IBFAN

1st sentence, finish the unfinished sentence, after "should be" add "***provided on the label of the product"***

ILCA

1st sentence, finish the unfinished sentence **by adding** after "should be"***: provided on the label of the product in line with the2007 WHO/FAO Guidelines: Safe preparation, storage and handling of powdered infant formula.***

ISDI

First sentence, complete the sentence as noted. "Clear instructions for the appropriate preparation, handling and use of PF should be **communicated to parents and caregivers by health care professionals and displayed on product labels**. […]"

Rationale: Health care professionals should educate parents and caregivers as to the proper handling of PF.

SIXTH PARAGRAPH

PERU

Also, we agree with the option of considering different alternatives to the PFs' reconstitution temperature (>70°C) proposed by the FAO/WHO, taking into consideration the information included in the Risk Assessment FAO/WHO (2004) document about that point, due to the fact that this recommendation would not lead to a significant global risk reduction if it is not consistently applied by the users, something that has a high probability of occurring in various countries.

ILCA

This paragraph should be deleted.

Rationale: Confidence in microbiological quality is an unscientific approach. Heat-labile ingredients cannot be a reason to change risk management.

IBFAN

Delete this paragraph in its entirety.

Rationale: The above paragraph should be deleted as it creates confusion and allows a huge loophole to avoid labelling and effective preparation instructions to reduce risk, which is to reconstitute at 70 degrees centigrade. At whose disretion are the decisions made to use other risk reduction management which are scientifically shown to be less effective?

SEVENTH PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Add the text in brackets ; *Control measures should be communicated to different stakeholders* ***(and/or separate additional written information),*** *written procedures (e.g., in professional institutions) and/or through oral instructions and/or training. These instructions, if adhered to, would help manage the risk associated with the product."*

Such additional information, which can be provided through different means to users and consumers, will help greatly the stakeholders to understand the importance of preventive hygiene measures at each step of the food chain and the responsibilities of each stakeholder.

This new/modified section is of particular importance as it removes the sole and unique approach of reconstitution of the products at >70°C as supported by FAO/WHO and IBFAN, as well as by certain national authorities in some countries.

In this context it is again necessary to consider the whole chain and the fact that infant formulae manufactured according to the most stringent hygiene requirements are safe products. Exclusive reconstitution at >70°C would not reflect this approach and negate all efforts made by industry to comply with stringent requirements. It should also be understood that, as shown in the FAO/WHO risk assessment (2004), such a recommendation would not lead to a significant global reduction of the risk if not applied systematically by users – which is very likely to occur, as several countries and/or organizations, including paediatricians' associations, do not advocate such a reconstitution method.

In addition, a requirement for exclusive reconstitution at >70°C would render the currently proposed microbiological criteria (i.e. for ready-to-feed products) questionable, as much more lenient criteria (i.e. for products to be heated before consumption) would be perfectly sufficient in such a case (in line with Codex Alimentarius guidelines on the establishment of microbiological criteria for foods).

IBFAN

First sentence, after "(which may include separate written information)," add "***independent"***

ILCA

Written information and written procedures should be established free from commercial influence. Insert to read: *Control measures should be communicated to different stakeholders through appropriate product labelling (which may include separate written information* **free from commercial influence***, independent written procedures* **free from commercial influence** *(e.g., in professional institutions) and/or through oral instructions and/or training. These instructions, if adhered to, would help manage the risk associated with the product.*

NINTH PARAGRAPH

IBFAN

After "regarding" add "the appropriate use and"

TENTH PARAGRAPH

IBFAN

Modify the paragraph to read: "For infants at greatest risk ***who may require replacement feeding, when medically indicated and when donor human milk is unavailable,*** ~~**feasible**~~, commercially available sterilized liquid products or other equivalent infant feeding options which have undergone an effective point of use decontamination procedure ~~**should** *may*~~ be used.~~ **instead of PF.**~~

Rationale: ***When donor human milk is unavailable as the priority replacement feeding, the use of commercial sterile formula is only one option available to parents and care givers and therefore may be considered as a choice in a range of replacement feeding option.***

ILCA

Insert to read: *For infants at greatest risk,* ***requiring medically indicated replacement feeding and when breastmilk or banked donor milk is not available****, commercially available sterilized liquid products or other equivalent infant feeding options which have undergone an effective point of use decontamination procedure should be used instead of PF.*

9.3 LABELLING

ISLAMIC REPUBLIC OF IRAN

The WG suggestion as to make the labelling of infant formulae more informative is particularly welcome here, since the sole warning "*not sterile*" would not provide sufficient information to the consumer.

As a general point, it might be said that the wording of the paragraph is such that it may provides sufficient flexibility in defining the content of label for products, taking into consideration different elements, such as understanding of the consumers, cultural characteristics, etc., and to avoid the risk of consumers using alternative products (such as milk powder) just because they are not labelled as "not sterile".

The text as proposed avoids also further discussions on labelling of other ingredients used in the context of the preparation of infant formulae, such as water, additions to the infant formulae, the preparation environment, etc.

THIRD PARAGRAPH

IBFAN, ILCA

Change the paragraph to read: "Where literacy is low, pictograms ~~may be useful~~ **should be used in addition to written instructions."**

ISDI

Move the sentence from §3 to §6.

Rationale: The use of pictograms could be a good example of measures taken by the industry to ensure that the intended message on the label is understood. Therefore it would be better valued if placed in context in §6 than alone in §3.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

Paragraph 4, A footnote should be added to provide the complete citation for the International Code of Marketing of Breast-Milk Substitutes (1981).

IBFAN, ILCA

At the end of the paragraph, ***add "… and subsequent relevant resolutions of the WHA".***

FIFTH PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Last sentence, modify to read "The importance of *preparing one serving at a time and* discarding leftovers should be emphasized."

ILCA

Replace "nipples" by "teats"

SIXTH PARAGRAPH

COSTA RICA, PHILIPPINES

First sentence, delete the following text; ",e.g., the PF is not sterile"

Rationale: The use of statements such as "not sterile" on labels can be misinterpreted by consumers, causing them to panic and subsequently reduce their ability to follow instructions. Philippines adds that a consumer research study commissioned by the UK Food Safety Authority (FSA)[1] indicated that the phrase "not sterile" failed to communicate the nature and level of risk as most did not think it meant potentially harmful but actually harmful.

ISLAMIC REPUBLIC OF IRAN

First sentence, after "risk" add "/*hazards"*

MEXICO

First sentence, the wording used for the example included in item **9.3 Labelling,** regarding the information to be included on the label, where it says that failure to follow manufacturers' instructions on the product may cause serious illness, this could be a source of negative information for the consumer. Therefore, we propose deleting it or revising its wording.

UNITED STATES OF AMERICA

1st sentence. The United States continues to be concerned with the average consumer's understanding of identification of PF as a non-sterile product. Initial investigations suggest that this type of labelling may actually result in consumer seeking less desirable alternatives. Accordingly, the United States recommends that the 1st sentence be revised to read:

> "The label should include information to make clear the potential risks of inappropriate preparation, handling and use, ~~**e.g., that PF is not sterile**~~ and that failure to follow manufacturers' instructions may cause serious illness."

IDF

Remove the example "*e.g. that PF is not sterile and that failure to follow manufacturers instructions may cause serious illness*."

The example is not necessary here as the points are duly covered in Section IX, paragraph 4 and in section 9.4, paragraph 4.

Also the remainder of paragraph 6 encourages validation of messages for consumers, as different messages will be appropriate in different countries. If the examples remain in the labelling section then they may be interpreted as the message that must be on a label, therefore validation of the message is of little value.

ISDI

Delete the text as noted and reword the first two sentences to read; "The label should include information to make clear the potential risks of inappropriate preparation, handling and use,~~ e.g., that PF is not sterile~~ and that

failure to follow manufacturers' instructions may cause serious illness. Industry and national governments **should work together** ~~be encouraged to validate the label~~ to ensure that the intended messages are understood **for example, through the use of pictograms and appropriate and balanced terminology."**

Rationale: Infant formula is used by a diverse population with differing levels of literacy, numeracy and scientific knowledge. Therefore ISDI strongly believes that all labels should use terminology and messaging that can be clearly and unambiguously understood by all consumers.

IBFAN

Third sentence, after "…the wording of such information" add the following: "*, that breastfeeding is the safe and optimal way to feed infants as well"*

9.4 EDUCATION

SECOND PARAGRAPH

IBFAN

Modify the paragraph to read:

Independent ~~**The**~~ development and distribution of educational documents related to the preparation, handling and use of PF to ***inform*** all caregivers on ***reducing the risks associated with intrinsically contaminated PI products*** should be encouraged. These programs should enable one to i) understand the importance ***of the lack of sterility of these*** product**s** i~~**nformation**~~, ii) follow instructions accompanying products, and iii) make informed choices after discussing with professional caregivers, as needed.

NOTE: Education and information provided to care givers should be free from conflicts of interest and be provided by independent sources.

ILCA

Add to read:

The development and distribution of educational documents related to the preparation, handling and use of PF to **inform** all caregivers **on reducing the risks associated with potentially contaminated PF** products should be encouraged **and free from commercial influence.** These programs should enable one to i) **understand the importance of lack of sterility of PF products,** ii) follow instructions accompanying products, and iii) make informed choices after discussing with professional caregivers, as needed.

THIRD PARAGRAPH

IBFAN

Modify to read: Infants and young children who are not breastfed ***or who are unable to receive donor human milk, require replacement feeding . One option option for replacement is PI.*** When PF is used, national governments are encouraged to provide all caregivers with ***independently produced*** appropriate educational material. The guidelines for the safe preparation, storage and handling of powdered infant formula developed by the FAO/WHO16 ~~**may**~~ ***should*** be used.

ILCA

Insert to read: *Infants and young children who are not breastfed* ***and for whom no donor breastmilk is available****, require - replacement feeding. When PF is used, national governments are encouraged to provide all caregivers with appropriate educational material* ***produced free from conflict of interest****. The guidelines for the safe preparation, storage and handling of powdered infant formula developed by the FAO/WHO****Error! Bookmark not defined. should*** *be used.*

IDF

3rd sentence

Include text (underlined in the following) that put more emphasis on other appropriate risk management strategies.

"The guidelines for the safe preparation, storage and handling of powdered infant formula developed by the FAO/WHO may be used. Likewise, alternative guidelines or other clear instructions may be developed and used. This could include, for instance, instructions for the appropriate preparation, handling and use of PF when the risk reduction strategy chosen is based upon feeding the formula immediately after reconstitution and rapid cooling to the appropriate feeding temperature"

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

1st sentence should be revised to read: "All caregivers should be informed of the potential risks associated with the inappropriate preparation, handling, and use of PF which may result in serious illness."

ISDI

First sentence, at the end of the sentence add "**if the product is not properly handled**."

Rationale: ISDI believes that it is important to give the correct message to the caregiver. Would the product be handled properly, then it will not cause any serious illness to the baby

FIFTH PARAGRAPH

COSTA RICA

Modify the seventh sentence to read "Thus, **reconstituted powdered formula should be fed immediately when possible and** ~~it should be~~ kept refrigerated **at 2-4°C for no more than 24 hours** ~~if not used immediately following preparation~~. Delete the seveth sentence "~~Refrigerated storage should not exceed 24 hours following reconstitution.~~"

Parents and caregivers should be educated on the proper handling and storage of powdered formula, including feeding reconstituted powdered formula immediately and storing at 2-4°C for no more than 24 hours.

UNITED STATES OF AMERICA

Modify the sentences 6, 7 and 8 highlighted below to more specifically detail the safe storage temperature for reconstituted PF.

It is important to stress the fact that reconstituted formula may allow the growth of microorganisms, **and temperature abuse may lead to foodborne illness. "Reconstituted powdered formula should be fed immediately (within 1 hour) when possible or kept refrigerated at 2-4°C for no more than 24 hours. Reconstituted PF should be refrigerated promptly in containers and volumes that allow the reconstituted PF to cool rapidly."**

IBFAN

1st sentence, after "…due to the potential for" add "additional"

2nd sentence, after "..PF will" delete greatly and add "also"

3rd sentence, modify to read: "Appropriate preparation and handling, according ***WHO/FAO Guidelines and*** ~~**to**~~ manufacturer's instructions reduces the risk of illness and, when appropriate, these ~~**should**~~ ***may also*** be emphasized by national governments."

4th sentence, after "...bottled water is not" add "***suitable for reconstitution of PI and not*** "

Fifth sentence, beginning of the sentence insert "***Independent"***

Ninth sentence, modify the sentence to read: Temperature abuse ~~**may**~~ ***will*** lead to ***growth of organisms in the product and lead to infection and*** ~~**food- borne**~~ ***illness.***

ISDI

Modify the text (sentences 7 and 8) as noted: "Thus, **reconstituted powdered formula should be fed immediately when possible and** ~~it should be~~ kept refrigerated **immediately after preparation at not more than 4°C for no more than 24 hours** ~~if not used immediately following preparation~~. ~~Refrigerated storage should not exceed 24 hours following reconstitution~~"

Rationale: Parents and caregivers should be educated on the proper handling and storage of powdered formula, including feeding reconstituted powdered formula immediately and storing at not more than 4°C for no more than 24 hours.

SIXTH PARAGRAPH

IDF

1st sentence

Remove the example "*e.g. that PF is not sterile and that failure to follow manufacturers instructions may cause serious illness*."

The example is not necessary here as the points are duly covered in Section IX, paragraph 4 and in section 9.4, paragraph 4.

Also the remainder of paragraph 6 encourages validation of messages for consumers, as different messages will be appropriate in different countries. If the examples remain in the labelling section then they may be interpreted as the message that must be on a label, therefore validation of the message is of little value.

ILCA

Insert to read : *Stringent hygienic preparation and storage conditions should be emphasized due to the potential for* ***additional*** *contamination of the product from various sources, e.g., equipment, utensils, the preparation environment, other ingredients/foods. Likewise, the water used to rehydrate PF will greatly impact the safety of the product. Appropriate preparation and handling, according to* ***WHO/FAO Guidelines and*** *manufacturer's instructions reduces the risk of illness and, when appropriate, these should also be emphasized by national governments. Additionally, experience has indicated that all caregivers need to be periodically reminded that bottled water is not a sterile product unless specifically indicated as such on the product. Information/education* ***free from conflict of interest*** *about the need to follow good hygiene practices during preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized.*

SECTION X - TRAINING

SECOND PARAGRAPH

IDF

Include explanatory text (underlined in the following) that put more emphasis on the fact that the FAO/WHO Guidelines provide information relevant to preparation and handling even if 70°C water is not being advocated in the training.

"Refer to the FAO/WHO guidelines for the safe preparation, storage and handling of powdered infant formula (2007), noting that the guidelines are relevant to a range of preparation and handling options."

ANNEX I

MICROBIOLOGICAL CRITERIA FOR POWDERED FORMULAE FOR INFANTS

TITLE

ISDI

Delete *'follow-up formula up to 12 months'* and add 'intended for infants'; the modified title is modified as follows:

"**MICROBIOLOGICAL CRITERIA FOR POWDERED INFANT FORMULA, ~~FOLLOW-UP FORMULA UP TO 12 MONTHS~~, FORMULA FOR SPECIAL MEDICAL PURPOSES[23] INTENDED FOR INFANTS AND HUMAN MILK FORTIFIERS"**

Rationale: for deleting *'follow-up formula up to 12 months'* see Section 1.1 of the ISDI comments.

Products intended for young children are not covered by this Annex and therefore it should be clearly stated.

ISLAMIC REPUBLIC OF IRAN

The microbiological criteria outlined in the two annexes (as summarised below) have been the object of very long discussions and represent a consensus between the members of the Working Group. The difficulty resided in finding a solution to fit and combine criteria taking into consideration the definition of infant (up 12 months), the different definitions (or absence of definition) of infant/follow-up formulae in different countries or regions and Codex Alimentarius, as well as the epidemiological situations with regards to outbreaks.

If the proposed criteria are questioned or not accepted during the upcoming CCFH meeting in India, then this may significantly delay the progress in finalising the revised Code.

Another point: *E. sakazakii* is considered a risk factor for infants, i.e., up to 12 months old. Now, testing for it is recommended for follow-up formulae (intended to be consumed by infants>6months old) in Annex I, but not in Annex II.

The question is: How would the authority/officer responsible for the control of this product know whether the product is going to be consumed by infants (<12 months) or by young children (>12 months)? (Will he/she know this through, say, the label, or how???....) It is depending on the answer to this question that the authority/officer will decide whether to test for E. sakazakii or not.

Annex I (up to 12 months):

E. sakazakii: n = 30, c = 0, m = 0 (in 10g)

Salmonella: n = 60, c = 0, m = 0 (in 25g)

Aerobic mesophilic counts: n = 5, c = 2, m = 500, M = 5000

Enterobacteriaceae: n = 10, c = 2, m = 0 (in 10g)

PHILIPPINES

We recommend provision of titles to the untitled tables on microbiological criteria for pathogenic organisms and criteria for process hygiene found in ANNEX I, as follows:

Table 1. add the title ….."Microbiological criteria for pathogenic organisms in powdered infant formula for infants up to 12 months."

Table 2. , add the title….."Microbiological criteria for process hygiene in powdered infant formula for infants up to 12 months."

ISDI

As a conclusion, ISDI would like to reiterate its position that a microbiological criterion for *E. sakazakii* is not relevant for follow-up-formulae. It therefore requests that follow-up-formulae up to 12 months are moved from Annex I to Annex II and that the necessary texts changes are made (see section 2. of the ISDI comments).

Rationale: Products intended for young children are not covered by this Annex and therefore it should be clearly stated

Criteria for pathogenic organisms

LAST PARAGRAPH

UNITED STATES OF AMERICA

3rd sentence. Modify sentence to read: **"…**be to (1) prevent the affected lot from being released for human consumption, **(2) recall the product if it has been released for human consumption, and (3) determine…"**

CRITERIA FOR PROCESS HYGIENE

SECOND PARAGRAPH

ILCA

First sentence; delete "safe" and replace to read: ***To reduce the risk of infection*** *the 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..*

Rationale: This is in line with the second sentence on page 25 which reads: *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*

Table

BRAZIL

It is proposed to modify, in the table below, the c value to Enterobacteriaceae, considering that in a two class plan, c=0 and the maximum acceptable number is absent or modify the Enterobacteriaceae to a three class plan:

Microorganisms	n	c	m	M	Class Plan
Mesophilic Aerobic Bacteria*	5	2	500/g	5000/g	3
Enterobacteriaceae**	10	~~2~~ **0**	0/10 g	NA	2

ANNEX II

PHILIPPINES

We recommend provision of titles to the untitled tables on microbiological criteria for pathogenic organisms and criteria for process hygiene found in ANNEX II, as follows:

Table 1. ..add the title.. "Microbiological criteria for pathogenic organisms in powdered infant formula for young children."

Table 2. ..add the title …"Microbiological criteria for process hygiene in powdered infant formula for young children."

Criteria for pathogenic microorganisms

ISDI

During the CCFH ad-hoc WG meeting, the following criterion for *Salmonella* for Annex II was agreed and this was reflected in the document gathering the outcome of the discussions and shared with the members of the ad-hoc WG by Canada in June 2007 as follows:

Microorganisms	**n**	**c**	**m**	**M**	**Class Plan**
*Salmonella**	30	0	0/25 g	N/A	2

In the document as presented by Codex in CX/FH 07/39/4, this criterion has been changed: the sampling plan with n=30 for *Salmonella* that was proposed has been transformed into a sampling plan with n=60.

ISDI does not understand the reasons why the WG consensus has finally not been reflected in the Codex document and seeks for clarification on that change.

ISLAMIC REPUBLIC OF IRAN

Annex II (from 12 months):

Salmonella: n = 60, c = 0, m = 0 (in 25g)

Aerobic mesophilic counts and Enterobacteriaceae: as in Annex I.

The rationale with respect to some of the comments or oppositions to certain elements on which the proposed criteria (Annexes I and II)have been based are as follows:

(1) Epidemiological considerations

(a) The majority of reported cases have occurred in infants < 6 months and there is therefore no discussion about the relevance of *E. sakazakii* for infant formulae. It is also clear that no relevant cases are reported for infants >12 months and that therefore the criteria for *E. sakazakii* are not justified for products consumed by young children (i.e. >12 months).

(b) However, according to the expert report of the FAO/WHO (2006; Table 2), isolated cases have been reported for infants up to 10 months (e.g. Reina *et al.*, 1989; Noriega *et al.*, 1990; Tekkok *et al.*, 1996). A few additional cases seem to have occurred in the United States (unpublished data, information from the American delegation and US FDA). For this reason, and considering the uncertainty related to risk assessments, it seems justified, from a risk management perspective and as a precautionary measure, to include the criterion for *E. sakazakii* for products consumed up to 12 months.

(c) Surveys performed in the United Kingdom have shown that a small but significant percentage of infants below 6 months are nevertheless fed h follow-up formulae (Bolling *et al.*, 2007). While this is not the intended use of these product categories, extending the criterion for *E. sakazakii* up to 12 months would allow to address this potential issue. Similar situations are likely to occur in other countries.

(2) Hygiene considerations

The Codex proposal seems contradictory to the EC criteria, but at the European level, tightened requirements for Enterobacteriaceae as well as for follow-up formulae have recently been adopted. This is indicative of a clear wish of the EC to enhance the hygiene control measures during the manufacture not only of infant formulae but also of follow-up formulae. As such, the hygiene requirements for the two product categories would not be different at all and thus be reflected in compliance for *E. sakazakii* of follow-up formulae as well.

(3) Other considerations

The absence of recommendations in Codex Alimentarius to get a wider consensus would open the door to prolonged discussions probably without really reaching a conclusion and thus delaying the finalization of the Code, which is a high priority of Codex. Alimentarius. This could also very well lead to the establishment of very different criteria in different parts of the world (in particular, based on the different definitions of follow-up formulae), which may ultimately result in t difficulties in management at the level of manufacturers.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

3rd sentence. Modify sentence to read:

"…be to (1) prevent the affected lot from being released for human consumption, **(2) recall the product if it has been released for human consumption, and (3) determine…"**

CRITERIA FOR PROCESS HYGIENE

Table

BRAZIL

It is proposed to modify, in the table below, the c value to Enterobacteriaceae, considering that in a two class plan, c=0 and the maximum acceptable number is absent or modify the Enterobacteriaceae to a three class plan:

Microorganisms	**n**	**c**	**m**	**M**	**Class Plan**
Mesophilic Aerobic Bacteria*	5	2	500/g	5000/g	3
Enterobacteriaceae**	10	~~2~~ **0**	0/10 g	NA	2

ANNEX III

GUIDANCE FOR THE ESTABLISHMENT OF SURVEILLANCE PROGRAMS FOR *SALMONELLA*, *ENTEROBACTER SAKAZAKII* AND OTHER ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS AND IN POWDERED FORMULA PREPARATION UNITS

1. GUIDANCE FOR THE ESTABLISHMENT OF AN ENVIRONMENTAL SURVEILLANCE AND PROCESS CONTROL PROGRAM IN HIGH HYGIENE PROCESSING AREAS

PARAGRAPH 1

ISLAMIC REPUBLIC OF IRAN

The last sentence reads as follows:

Although it was recognized that there is no demonstrated correlation to date between counts of EB and E. sakazakii/Salmonella, it may be reasonably anticipated that a reduction in the levels of the EB in the environment would correspondingly lead to lower levels of EB (including E. sakazakii and Salmonella) in the finished product. In view of the limitations of end product testing alone, it is important to have an environmental surveillance program for these products, particularly since contamination has led to several recognized outbreaks.

The reasoning is rather weak. If there is no evidence, is it justified to make such a definite assumption? Or should this area be highlighted as an area for further research before final conclusions and appropriate recommendations can be made?

2. MICROBIOLOGICAL SURVEILLANCE IN POWDERED PREPARATION UNITS

FIRST PARAGRAPH

ILCA

First sentence, at the end of the sentence add ***"and in child caring facilities"***.

THIRD PARAGRAPH

UNITED STATES OF AMERICA

Microbiological Surveillance in Powdered Infant Formula Preparation Units, 3rd paragraph:

The paragraph reads "Microbiological surveillance of powdered formula storage, preparation areas and surfaces in direct contact with the product (e.g., utensils) represents an essential element of the quality assurance program." Environmental monitoring in this type of a facility is a unique concept, but could be appropriate. However, it is not clear why storage areas are included in this section where they have not been in the previous section, which focuses on the high hygiene areas where contamination might take place, with no mention of storage. We recommend that storage be removed as area for microbiological surveillance.

Editorial Comments

IBFAN, ILCA

Introduction, first sentence, we want to suggest to change breast milk to breastmilk which is the widely accepted scientific spelling and should be considered for this document.

Last sentence page 10 [could not be located in the document]

Delete "s" in WHO Global Strategy for Infants and Young Child Feeding, to read WHO Global Strategy for Infant and Young Child Feeding.