codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/FH 06/38/7 – 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

Australia, New Zealand, Philippines, United States of America, International Commission on Microbiological Criteria for Foods, (ICMSF), International Dairy Federation (IDF), Confederation of the European Food and Drink Industries (CIAA), International Dietary Foods Industry (ISDI),

GENERAL COMMENTS

AUSTRALIA

Australia supports the general content of the Proposed Draft Revision of the International Code of Hygienic Practice for Powdered Formulae for Infants and Young Children**.**

The Working Group recommendation to restrict the scope of the Code of Hygienic Practice to infants less than 12 months of age is supported, including one annex for infants.

Australia queries the reference to 'performance objectives' throughout Annex III as there is ongoing debate on the usage of these concepts.

Australia believes that Annex 3 should be retained for further development

NEW ZEALAND

New Zealand believes that the current draft Code is an improved document that addresses some, but not all, of the issues raised by the Codex Committee on Food Hygiene (CCFH) and various international and national bodies. However, there are still significant issues that require clarification.

New Zealand believes that, wherever possible, the various components of this draft Code should be risk-based. This is particularly significant in such areas as recognition of varying population susceptibilities and microbiological criteria, as proposed in Annex I.

New Zealand is disappointed that the proposed draft does not follow the instructions given at the 37th session of CCFH that the relevant code would contain two annexes: Annex A addressing powdered formula for "infants at greatest risk" with a focus on *Enterobacter sakazakii* and *Salmonella enterica*; and Annex B, addressing all powdered products for infants and young children (CCFH Alinorm 05/28/13 Clause 47). However New Zealand would not wish to see further progression of this important code delayed. These concerns can well be addressed through the development of separate annexes that could progress at different rates through the Codex process.

Application of *E. sakazakii* criteria

New Zealand believes that the *E. sakazakii* criteria should apply to powdered infant formula (as defined by Codex) and other products, e.g. breast milk fortifier, intended for infants less than six months of age, rather than to infants and young children. This would be consistent with the findings of the 2006 FAO/WHO Expert Consultation report which identified "the infants at greatest risk" group as being infants less than two months of age.

Recommendations in the text regarding the use of 70°C water in the preparation of Powdered Formula.

New Zealand believes that the Code should not contain specific recommendations concerning preparation of Powdered Formulae at 70°C. Such advice should not be given until there is sufficient evidence and information to demonstrate that any non microbiological risks associated with this strategy (e.g. reduction in nutritional value of the formula) are identified and either eliminated or managed to an acceptable level.
More specific comment on this issue is provided later in this submission.

Clarification of the validated microbiocidal control points (e.g. pasteurisation) and drying processes in relation to environmental hygiene management and controls

New Zealand is concerned that, throughout the text of the document, there may be confusion regarding the environmental hygiene zones operating within the processing plant. Strict hygiene and segregation controls should apply to all processing areas after the microbiocidal CCP (e.g. heat treatment) with additional measures relating to the dry nature of the environment of, and after the drier and that this needs to be clearly stated so as to avoid confusion. An example of this occurs in the second paragraph of Section 5.2.2 Specific Process Steps where it is stated that
"…… steps should be taken to avoid recontamination of the product during dry product handling, following the thermal processing steps that would ensure elimination of S. enterica and E. sakazakii."
Recommendation 2

New Zealand strongly disagrees with the view offered in Recommendation 2 that the scope should be restricted to powdered formula for infants, i.e. persons less than twelve months of age, and including one annex for infants.

New Zealand supports the development of an Annex A for Microbiological criteria for powdered formulae for "infants at greatest risk" as requested by the 37th session of CCFH.

PHILIPPINES

The Philippines fully support the Recommendation 2 of the CCFH Ad-Hoc Working Group (WG) that is to restrict the scope of the Code of Hygienic Practices. We believe that the scope of the document should only focus on infant formulae as defined by Codex as Infant Formulae.

We fully support the development of recommendations for preparation, handling and storage of powdered Infant Formulae. Manufacturers have to follow Good Manufacturing Practices (GMP) and Good Hygienic Practices (GHP) to ensure the safety of the prepared formula but it is also critical to stress the importance of proper preparation, handling, and storage of prepared powdered formula at homes or in institutions to ensure the safety of the infants.
We also would like to emphasize the need for accuracy and clarity when setting those recommendations and to express its concern with regards to any recommendation that would lead to generate risks for caregivers, mothers or infants. As an example, reconstituting formulae at very high temperatures may cause scalding of the person preparing the formula or possibly even the infant. Additionally, the product quality may be decreased by high temperature.

We would also like to draw the attention to the report of the first FAO/WHO expert meeting in 2004 indicating that if the recommendation of reconstituting at a temperature of 70°C is not strictly followed by all users, then the overall risk mitigation would be dramatically decreased. Considering the position, for example, of European Association of Pediatricians (ESPGHAN) or of the French Food Safety Authority against such a way of reconstitution, it is important that alternatives are clearly spelled out – as is the case in Annex III. However, as mentioned below we believe the Annex III needs to be further discussed and worked out to make it a more "user friendly" and practical guidance.

UNITED STATES OF AMERICA

The United States appreciates Canada hosting the working group meeting in Ottawa and the excellent progress that has been made in revising the outdated “International Code of Hygienic Practices for Foods for Infants and Young Children.” We offer following recommendations that we feel will further strengthen the revised document.

The Delegation of the United States would also like to volunteer for the sub-working group on labeling of powdered infant formulae. Due several members having to leave just prior to the end of the working group meeting, the United States Delegation did not have the opportunity to volunteer for this sub-working group. The United States have extensive expertise and experience in assessing consumer responses and their level of understanding of information and guidance. As such we would like to volunteer to be included in this sub-working group.

ICMSF

The scope of the guidelines is powdered formulae for infants and for young children. However, it is not always clear whether the guidance provided applies to both types of formulae or not. The ICMSF would be in favour of keeping to the current scope but improve the text to ensure clarity is provided on the application of the guidance to either type of formulae.

IDF

It is important that the Committee is aware of the risk involved in the drafting of the Code, which currently follows the old-fashioned approach (harmonizing one “correct” way of controlling the hazards). This is not in line with the draft Principles and Guidelines for the Conduct of Microbiological Risk Management currently at Step 6/7. As shown by the risk assessments and illustrated in Annex III, numerous combinations of control measures and levels in PIF exist that will achieve equivalent outcomes in terms of relative risk reduction. Therefore, we highly recommend the establishment of a

FSO for *E. sakazakii* for reconstituted products intended for the vulnerable group of infants (either nationally or internationally). This will be an enormous help to public authorities and industry in designing appropriate guidelines to end users based on local patterns, local accessibility to hygienic measures and local skills and education levels.

The intention to follow the structure of the General Principles of Food Hygiene negatively impacts the flow of information and guidance provided by this Code. It is awkward that the most important part of the food chain is addressed in an Annex to the Code (Annex III). Annexes should primarily be used to offer additional details and not key guidance.

The CCFH should consider, in this particular case, to deviate from the strict adherence to this general approach and allow for a more logic and user-friendly format.

ISDI AND CIAA

ISDI fully supports recommendation 2 of the CCFH ad-hoc WG to clarify the scope of the Code of Hygienic Practice. ISDI believes that the scope of the document should focus only on formulae used as a sole source of nutrition for infants, defined by Codex as Infant Formulae.

ISDI fully supports the development of recommendations for preparation, handling and storage of powdered Infant Formulae. Manufacturers follow GMP (Good Manufacturing Practices) and GHP (Good Hygienic Practices) to ensure the safety of the prepared formula but it is also critical to stress the importance of proper preparation, handling and storage of prepared powdered infant formula at homes or in institutions to ensure the safety of the infants.

In addition, ISDI would like to stress the need for accuracy and clarity when setting those recommendations and to express its concern regarding any recommendation that could generate risks for caregivers, parents or infants. As an example, reconstituting formulae at very high temperatures may cause scalding of the person preparing the formula or possibly even the infant. Additionally, product quality may be decreased by high temperatures. We would also like to draw the attention to the report of the first FAO/WHO expert meeting in 2004 indicating that if the recommendation to reconstitute at a temperature of 70°C is not strictly followed by all users, then the overall risk mitigation would be dramatically decreased. Considering the position, for example, of ESPGHAN (European association of Pediatricians) or of the French Food Safety Authority against such a method of reconstitution, it is important that alternatives are clearly spelled out – as is the case in Annex III. However, as mentioned below, we believe the Annex III needs to be further discussed and developed to make it a more "user-friendly" and practical guide.

ISDI would like to thank the chairs of the CCFH ad-hoc WG for the progresses made on the document but still believes that modifications to be introduced in the Code are significant and are not restricted to editorial modifications i.e.:

- Restriction of the scope of the entire Code
- Simplification of the Annex III
- Definition of clear scenarios in Annex III

It is doubtful that such modifications can be discussed in detail at CCFH due to time constraints. As a consequence, ISDI suggests that a third ad-hoc WG is convened to consider and propose the necessary changes to the Committee so that the document can be advanced at a further stage for discussions in plenary in 2007.

Rationale: In the context of focusing the scope, as suggested by the ad-hoc WG and in the aim to line up the draft Code of Hygienic Practice with the products definitions developed in other Codex Standards[1], 'infant formulae' would be the correct wording.

BACKGROUND

SECOND PARAGRAPH

ICMSF

The bottom paragraph refers to Annexes A and B, the former for formulae for infants and the latter on products for infants and young children. Under "recommendations" on pg 2, it may be considered to explain that the WG has chosen to adopt a different set of annexes (I to IV with an appendix A to Annex III) with different contents as the reader might be confused.

RECOMMENDATIONS:

Item 2

NEW ZEALAND

New Zealand strongly disagrees with the view offered in Recommendation 2 that the scope should be restricted to powdered formula for infants, i.e. persons less than twelve months of age, and including one annex for infants. New Zealand supports the development of an Annex A for Microbiological criteria for powdered formulae for "infants at greatest risk" as requested by the 37th session of CCFH.

UNTED STAES OF AMERICA

The United States agrees that the document should be restricted in scope to infants, i.e., persons less than 12 months of age and only one annex should be included. It should be noted that if the scope is going to be restricted to infants that there are numerous instances in the document where young children are referenced. For the sake of clarity, these should be removed.

IDF

The recommendation of the WG Chair states that it is due to concerns of slowing the process that did not result in Codex Working Group following the CCFH direction to prepare two annexes on Microbiological Criteria (current Annex I) - one addressing powdered formulae for "infants at greatest risk" with a focus on *E. sakazakii* and *Salmonella*, and a second Annex addressing all (other) powdered products for infants and young children.

We recommend the following approach to overcome this difficulty:

- The scope of the current Annex I is restricted to products targeted (intended for) consumer groups that include infants less than 2 months of age, even when these infants are not the only consumers of the products.
- A second Annex (to be developed) should then address products for other infants and young children, where the targeted consumers do not include infants at greatest risk. Development of this second Annex could proceed at a different rate and not hinder the development of the Code.

An alternative to this approach would be to limit the scope of the whole Code, including its Annexes, to products that are intended as the sole source of nutrition of infants.

[1] Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Alinorm 06/29/26 – Appendix IV (A))

TITLE

PHILLIPNES, ISDI AND CIAA

After "..Powdered" add "Infant" and delete "For Infant and Young Children".

Rationale by Phillippenes: In the context of reducing the Scope, as suggested by the Ad-Hoc WG and in the aim to line up the draft Code of Hygienic Practice with the products definitions developed in other Codex Standards[2], 'infant formulae' would be the correct wording. As also mentioned in the Recommendations 2 of the Ad Hoc WG, there is an absence of scientific data for powdered formula for young children and so it is difficult to address the recommendations of the CCFH to include the young children in the scope.

INTRODUCTION

SECOND PARAGRAPH

UNITED STATES OF AMERICA

Modify sentence #1 to read '…foods for medical purposes for infants ~~and young children~~ and …'

Modify sentence #2 to read : '~~Some of t~~These products are …'

In sentence #3, the example used needs to be verified. It is our understanding that follow-up formulae are formulated to serve as a sole source of nutrients for these infants.

FOURTH PARAGRAPH

UNITED STATES OF AMERICA

Modify sentence #1 to read "….with PF consumption ~~either~~ epidemiologically ~~or~~ and microbiologically.

FIFTH PARAGRAPH

UNITED STATES OF AMERICA

Last sentence, mmodify it to read "~~However,~~ It has been established that infants are more…"

TENTH PARAGRAPH

UNITED STATES OF AMERICA

Beginning with this paragraph "While PIF…." Need to do a global change from PIF to PF.

PARAGRAPH 11

NEW ZEALAND

Para 11, sentence 1, delete "setting"

PHILLIPNES, ISDI AND CIAA

Delete the paragraph.

Rationale: We believe that referring to outbreaks that would have occurred in 2004 is inappropriate for the future since this Code of Practice is to be used for years. It would be better to only refer to the FAO/WHO expert consultations, as already made in previous paragraphs.

UNITED STATES OF AMERICA

Beginning with sentence #4, delete remainder of the paragraph. These are examples of only two of several outbreaks. As written, this section gives the impression that these are the only two known outbreaks. Recommend deleting the following sentences and instead cite the FAO/WHO report.

[2] Draft Revised Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Alinorm 06/29/26 – Appendix IV (A))

Delete the paragraph.

PARAGRAPH 12

UNITED STATES OF AMERICA

Sentence 1, modify sentence to read "…infant feeding options which include ~~have undergone~~ an effective point-of-use…"

PARAGRAPH 13

IDF

The last sentence, we recommend a rewording to address the possibility of contamination of product in the factory and from other environments once a package is opened.

> *"Thus, PF may be contaminated by* E. sakazakii *from the manufacturing environment before or during packaging and also from other environments after the package is opened."*

PARAGRAPH 14

IDF

The wording "beyond the neonatal period" is not very specific. This should refer to infants < 2 months of age, as specified in the second risk assessment as the group at greatest risk.

SECTION I. – OBJECTIVES

FIRST PARAGRAPH

PHILLIPPENES

Delete "young children" and modify the acronym "PF" to "PIF" through out the document.

SECOND PARAGRAPH

PHILLIPPENES

Simplify the first sentence to read; "P**I**F are specifically manufactured and **intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants**, paragraph to reflect definition of infant formula."

SECTION II. – SCOPE, USE AND DEFINITIONS

2.1 SCOPE

FIRST PARAGRAPH

PHILLIPPENES

Modify the first sentence to read; "This Code covers the production, preparation and use of products available in powdered form, referred to as Powdered **Infant** Formula (P**I**F) for the purpose of this document, and specifically manufactured to **be and intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants."** Delete the second sentence

Rationale: In line with restriction of the scope, the objectives need to be revised accordingly.

2.1.2 ROLES OF GOVERNMENTS, INDUSTRY, AND CONSUMERS

FIRST PARAGRAPH

ICMSF

States that intended users of the document include "caregivers", which might be parents. Better refer to "professional caregivers".

FIFTH PARAGRAPH

UNITED STATAES OF AMERICA

Sentence 4, it is unclear in this sentence who is being advised to establish effective consumer education programs.

SECOND-TO-LAST PARAGRAPH

NEW ZEALAND

New Zealand believes that competent authorities do not implement the code as such, but rather assure its implementation. The paragraph should therefore read,

"To assure effective implementation of this Code, competent authorities should …"

In the third sentence of the same paragraph, control programmes should include more than auditing relevant documentation. Other appropriate activities are inspection, sampling and analysis, and checks on hygiene. Suggested wording is:
"Control programmes should include such activities as inspection, sampling and analysis, hygiene checks and auditing relevant documentation that shows…"

This section should also mention the role of competent authorities in providing guidance with reference to and as described in Annex III, 1.1. A proposed amendment to the last sentence of the second to last paragraph is:

"Furthermore, adequate consumer guidance should be provided (various control measures are detailed in Annex III) and adequate consumer education programmes should be implemented."

PHILLIPPENES

Add an 8th bullet point to read:

- Parents who cannot breastfeed and who have chosen to feed infant formula to their newborn infant should receive instructions regarding the proper preparation, storage, and handling of infant formula, especially powdered infant formula. Training should be provided before the parents leave the hospital after the baby's birth.

Rationale: Training of persons handling and storing infant formula including parents and caregivers is important to ensure that the prescribed highest level of safety and nutritional value for the reconstituted product is maintained. Proper handling and storage are important to reduce the risk.

ISDI AND CIAA

Add an 8th bullet point.

- Health care professionals should provide effective training to consumers (parents and other caregivers of infants) to ensure that PIF are prepared handled and stored properly and according to the manufacturer's instructions.

Rationale: Parents who have chosen to feed infant formula to their newborn infant should receive instructions regarding the proper preparation, storage, and handling of infant formula, especially powdered infant formula. Health care professionals should provide this training before the parents leave the hospital after the baby's birth. Such training was standard hospital practice years ago and should be reinstated to ensure parents receive such education, when appropriate.

2.2 USE

PHILLIPNES, ISDI AND CIAA

We believe that a reference/presentation of the Annex IV on Guidance on microbiological surveillance in infant formula preparation units in health care settings should be added to this section as it has been made for the Annex III.

2. 3 DEFINITIONS

Infants at greatest risks

UNITED STATES OF AMERICA

Since "neonates" are included in the group "infants < 2 months of age", this definition could be simplified by using "infants < 2 months of age, particularly pre-term, low birth weight and immunocompromised infants.

ICMSF

This definition seems to separate "neonates" as a separate group from "infants < 2month of age" while they are included in the latter group. Would it therefore not be better to define "infants at greatest risk" as "infants <2 month of age, including neonates (<28 days), particularly pre-term, low birthweight and immunocompromised infants"

IDF

The definition is somewhat confusing, since the last group (infants < 2 months age) seems to include all the foregoing groups.

Young Children

PHILLIPPENES

Delete definition for **"Young Children".**

UNITED STATES OF AMERICA

Since young children are not within the proposed scope of this document, it is unclear whether there is a need for this definition.

Powdered formula

PHILLIPPENES

Modify the definition to read; "*Powdered **infant** formula* – for the purpose of this Code of Practice includes all types of powdered formula for infants ~~and young children,~~ including: powdered infant formula, follow-up formula, formula for Special Medical Purposes intended for infants, food for special medical purposes, and human milk fortifiers~~, but excluding cereal-based products~~."

Rationale: "Powdered Formula" is not a standard Codex term. As noted above, the Scope of this Code of Practice should be limited to Infant Formula as defined by Codex.

ISDI AND CIAA

Delete the definition of "Powdered Formula" and include the definition of "Infant Formula".

> ***Infant formula*** **- breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding** as defined in the Codex Standard for Infant Formula, Codex STAN 72-1981 (amended 1983, 1985, 1987), currently under revision at step 6 by the CCNFSDU).

Rationale: "Powdered Formula" is not a standard Codex term. As noted above, the scope of this Code of Practice should be limited to Infant Formula as defined by Codex. As a consequence to the focus of the scope, every time 'PF' is noted, it should be replaced by 'PIF'.

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES

UNITED STATES OF AMERICA

In the text box, final bullet, modify bullet to read "…spread of *Salmonella* ~~but in~~ and particularly ~~of~~ *E. sakazakii*.

SECTION V - CONTROL OF OPERATION

5.2.1 Time and Temperature Control

FIRST PARAGRAPH

NEW ZEALAND

New Zealand proposes that the first paragraph be amended as follows:

"Refer to the General Principles of Food Hygiene (CAC/RCP 1 -1969, Rev. 4-2003) When milk and milk products are used in the manufacturing process such processing should meet the requirements of the Code of Hygienic Practice for milk and Milk Products (CAC/RCP 57-2004. In addition :……..)"

5.2.2 Specific process steps

FIRST PARAGRAPH

AUSTALIA

The 2nd sentence in the 1st paragraph "The process used should ensure that the appropriate levels of nutritional components….." is already addressed in Section 2.1 and should not be repeated. Issues in a Code of Hygienic Practice should only relate to food safety.

5.2.2.7 Packaging

UNITED STATES OF AMERICA

This section could benefit from a more detailed description of the conditions that are required to ensure that contamination is not introduced during the filling operation. For example, some mention limiting access to the packaging room by unnecessary personnel, the use of filtered over-pressure air to exclude airborne contamination, the use of container inverters and air jets to eliminate foreign objects from containers before filling and the need to prevent food allergen cross-contact between soy and milk-

based PIF products, etc.

5.2.3 Microbiological and other specifications

SECOND PARAGRAPH

UNITED STATES OF AMERICA

Sentence 3. Modify sentence to '~~These~~ Verification activities should include, as appropriate, ~~can be supplemented, as necessary, by~~ microbiological testing…'

LAST PARAGRAPH

NEW ZEALAND

New Zealand would like to see all the components of corrective action emphasised, including product disposition. This paragraph should be reworded as follows:
"When monitoring of control measures or verification results demonstrate deviations, appropriate corrective action (including restoration of control, product disposition and prevention of reoccurrence) should be taken."

Additionally re-ordering of this whole section with the present first paragraph becoming the final would also assist. This would conclude the section with references to the later sections in the document where this material is located and provide a more suitable conclusion to the section, whereas the earlier material provides an appropriate introduction to the section.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

6.5 MONITORING EFFECTIVENESS

SECOND PARAGRAPH

PHILLIPPNES, ISDI AND CIAA

In first sentence, after "… process hygiene," add "***Salmonella***".

Rationale (phillippnes): *Salmonella* is a very important pathogen to monitor especially in Infant Formula. Addition of *Salmonella* on the first statement should also be aligned with the second statement.

Rationale(ISDI and CIAA): This section is very much focused on IF and E. sakazakii and does not take into consideration specificities of Salmonella which cannot be managed in the same way, i.e. management measures due to the fact that it is ubiquitous while Salmonella is not of E. sakazakii requires more stringent.

UNITED STATES OF AMERICA

Although the revised wording in this draft is an improvement, microbiological monitoring is more commonly a verification activity. Perhaps we should be discussing supervisory and management oversight/monitoring of critical cleaning operations, ensuring that the processing temperatures/times were adequate, that the filling equipment was functioning as intended, and that pre-start-up SOPs were followed, etc. as monitoring activities and address the role of environmental microbiological testing in a separate paragraph discussing verification activities.
Before "…and *E. sakazakii…*", add 'Salmonella"

SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

SECOND OBJECTIVE

NEW ZEALAND

Boxed text – paragraph 2, beginning "Caregivers of infants…" there is inconsistency with the phrase:
"….and may be contaminated with bacteria which can cause serious illness or death if the product is not prepared as per the label instructions and/or is mishandled…"
being square bracketed in this paragraph but the following phrase in section 9.4: Education, paragraph three, is not square bracketed:
"….and may be contaminated with extremely low levels of pathogens that can cause serious illness…"

This inconsistency should be addressed by the removal of the square brackets in Section IX – boxed text, paragraph 2.

PHILLIPPENES

Delete the text under square brackets.
Rationale: Said statement may cause unnecessary "fear" to mothers who are not yet properly educated that infant formula is safe when proper preparation and handling are applied.

IDF

The square bracket information should be deleted, as it is not necessary to the objectives section.

ISDI AND CIAA

Delete the text and the square brackets; replace it with the text "**and requires correct preparation and handling to reduce the risk of illness."** Start the next sentence with "**Caregivers**" and delete "and."
Rationale: The suggested revised text provides practical information that will be more helpful for the users.

THIRD OBJECTIVE

NEW ZEALAND

Boxed text – paragraph 3, which begins "Specific information…" New Zealand suggests that the example of 70°C should be removed from this sentence
This would remove any potential for the 70°C option to be considered the recommended option.
New Zealand proposes that the second sentence of this paragraph:
"*For infants of greatest risk, instead of PF, the use of commercially available sterilized liquid products or other infant feeding options which have undergone an effective decontamination procedure at the point of use should be encouraged..."*
should be a paragraph on its own to emphasise its importance.

PHILLIPPENES

Delete the second part of the first sentence ", for example …risks" and replace it by "**Appropriate scenarios are specified in Annex III".**

Rationale: Although we support the need to give advices on the preparation of the formula, we do not agree to suggest any example of reconstitution in that section and would prefer to make reference to the Annex III which has been created to specifically address the issues of the scenarios to be followed.

IDF

The example of rehydration at 70^{o}C should be removed. The following paragraph (para. 4) already includes the necessary wording and a reference to Annex III, which also address this particular

approach. The use of the 70°C example here could be misinterpreted as this being a control option with more weight than others. It does not recognize that there are approaches that also may provide sufficient protection and that the use of 70°C reconstitution water is associated with alternate risks (e.g. scalding). It should also be noted that in the report of the first FAO/WHO expert meeting the risk model showed that if the hot reconstitution was not applied by 100% of the users, the overall risk mitigation would drop very rapidly to levels not very much different from the approach based on "room temperature/immediate consumption". However, should the water temperature by ignorance or failure drop to below 50 °C (takes 10-15 minutes in a domestic boiler), the relative risk will increase.

The second sentence should be a stand-alone paragraph as this is a separate and important point.

ISDI AND CIAA

Delete the second part of the first sentence ", for example …risks" and replace it by "**suitable scenarios are available in Annex III".**

Rationale: Although ISDI fully supports the need to give advice on the preparation of the formula, this section should not include examples of reconstitution, but should reference that examples are fully covered in Annex III, which deals specifically with the various reconstitution scenarios that can be followed.

9.3 LABELLING

NEW ZEALAND

New Zealand supports the revised content of these sections of the Code.
Specifically we believe the phrase:
"…the label should contain appropriate instructions…."
should remain in Section 9.3.

We strongly support the concept that labelling instructions be "appropriate" rather than being prescribed by this Code. This approach allows for the development of messages and presentation suitable for national needs when determining the appropriate labelling to communicate the issues discussed in Section 9.4: Education

PHILLIPPENES, ISDI, CIAA

At the end of first sentence add "(see Annex VI)."

Rationale: We believe that the Code should clearly state the information that is critical to the consumer and that should therefore be included in the communication to the consumers. We propose the attachment in this document to be added as an Annex VI to the Code.

ANNEX

Information to be made available to consumers [2] in accordance with national recommendations

1. Ensure that the working surface where the feed is to be prepared is clean.
2. Wash hands.
3. Sterilize all utensils used for or in the preparation of the feed in accordance with the manufacturer's instructions.

[2] Manufacturers may adapt the wording as long as the information given allows the same level of understanding and safety of the users.

4. Preparation of the water, in accordance with the risk assessment to ensure the safety.
5. Measure the required amount of water in the pre-sterilized feeding bottle.
6. Using the scoop provided add the correct amount of powder to the water in the bottle. Make sure that the scoop does not get wet during this process and do not put it down on the working surface. Replace the scoop in the container, using the special holding device if present.
7. Replace the lid on the powder container.
8. Place the presterilized cap/seal on the bottle and shake well.
9. Cool immediately under cold running water, it should be tepid for feeding immediately but as cool as possible if storing under refrigeration.
10. For immediate feeding replace the cap/seal with a presterilized nipple/teat unit, and test the temperature by shaking a few drops on the back of the hand. It should be lukewarm.
11. Once feeding is completed, empty the bottle, never save unfinished feeds, and wash the bottle and teat unit thoroughly and dry before storing.
12. If preparing in advance, store the bottle with the cap/seal in place in the coldest part of the refrigerator (away from the door).
13. To warm for feeding, place the bottle in hot water and swirl the contents. If the water is hot enough this should only take a few minutes. Remove the cap/seal and replace with a pre-sterilized nipple/teat. Test the temperature by shaking a few drops on the back of the hand. It should be lukewarm.
14. Ensure that all stored feeds are used within the time specified by the manufacturers' instructions.
15. Always store the container of powder in a cool dry place, and replace the lid immediately after measuring out the powder. Do not place the lid on a damp or wet surface. Use the contents of the time within the time recommended by the manufacturer.

9.4 Education

NEW ZEALAND

We also believe that caregivers,
"should be aware that PF is not a sterile product and may be contaminated…"
should remain in Section 9.4.

THIRD PARAGRAPH

PHILLIPPENES, ISDI AND CIAA

First sentence, delete part of the text and add the text in bold.

> 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 PIF is not a sterile product~~ **informed that PIF, the environment and the materials/equipment used to prepare formula are not sterile** and may be contaminated, on occasion, with extremely low levels of **potentially harmful** ~~pathogens~~ **microorganisms** that can cause serious illness (e.g., *Salmonella, E. sakasakii*).

Rationale: This section is aimed at home caregivers, we suggest it would be more informative and more understandable to inform them that powdered infant formula may be contaminated, on occasion, with extremely low levels of "potentially harmful microorganisms" instead of pathogens.
Those health education programs should give a clear and understandable definition of sterility and non-sterility. Infant formula, like many other foods is not supposed to be sterile; the proposed wording is in line with the beginning of the section on Labeling.

ANNEX I

MICROBIOLOGICAL CRITERIA FOR POWDERED FORMULAE FOR INFANTS

GENERAL COMMENTS

AUSTRALIA

Australia notes that the scope of the Code of Hygienic Practice is still to be resolved. This will influence the applicability of microbiological criteria to powdered formula products and therefore Australia reserves comment on this issue.

NEW ZEALAND

New Zealand re-iterates its view that the Code's structure should follow the CCFH instruction (CCFH Alinorm 05/28/13 Clause 47) in that:

"The Committee agreed that the Code would include two annexes: Annex A addressing powdered formula for "infants at greatest risk" (as defined by the FAO/WHO Expert meeting) and with a focus on Enterobacter sakazakii and Salmonella enterica; and Annex B, addressing all powdered products for infants (i.e. a person of not more than twelve months) and young children. (i.e. persons from the age of 12 months up to three years) with a focus on E.sakazakii, Salmonella and other micro organisms "

ICMSF

The scope of Annex I currently is powdered formulae for infants. As the scope of the code applies to powdered formulae for both infants and young children it may not be clear whether microbiological criteria are recommended for powdered formulae for young children.

The ICMSF would propose to widen the scope of Annex I to include powdered formulae for young children. The following considerations on the recommendation for microbiological criteria should be added then (see ICMSF recommended criteria under comments under Table for Microbiological Criteria.)

IDF

The criteria in this Annex should apply only to products intended for infants at greatest risk. It should also be noted that the current Codex Principles for the Establishment and Application of Microbiological Criteria: only address MC that are applied for testing of individual batches to determine whether the batch in question is acceptable or not acceptable do not address the use of MC as part of verification procedures that verify the effectiveness of HACCP/GHP systems.

Consequently, the performance studies of different sampling plans, which was included in the risk assessment and consequently used in support of the draft MC, relate only to batch testing and not for routine verification procedures. As MC are almost entirely applied by industry as part of verification procedures to verify HACCP/GHP systems, the "real" performance may very well be much higher than foreseen in the risk assessment.

TITLE

PHILLIPINES

We would like to reserve our position on the title of the Annex I as long as the scope of the Code of Practice is not clarified. On the interim, the working group proposed that the microbiological criteria

below intended for 0-12 months to emphasize the microorganisms of importance. The microbiological limits may change if the CCFH decides to separate standards for 0-6 and 6-12 month infants

ISDI AND CIAA

ISDI would like to reserve its position on the title of the Annex I as long as the scope of the Code of Practice is not clarified.

FIRST PARAGRAPH

NEW ZEALAND

New Zealand believes that it is important that the basis for the establishment of any criteria and their function should be clearly understood, as well as validated where necessary.

In pursuit of this view New Zealand suggests the following modification:

"General principles:
Microbiological criteria should be established in the context of risk management options. It is important that the basis for the microbiological criteria that are established is clearly understood so that they are applied according to their intended use and an appropriate regulatory response to non-compliance can be applied.

A number of factors (known and unknown) will have an impact on the level of pathogenic micro-organisms found in reconstituted powdered infant formula., Measures should be taken during manufacturing (particularly post-drying) to minimise contamination by pathogenic micro-organisms. Microbiological criteria may be applied as statistical process control tools as part of these measures.

Microbiological criteria

The following microbiological criteria should be applied to the finished product. Negative sampling results for pathogens indicate that their presence in the product is likely to be minimal. Where results demonstrate deviations from specifications, appropriate corrective actions based on risks to the consumer should be taken."

PHILLIPPENES, ISDI AND CIAA

Delete the second and third sentence.

Rationale: The second and third sentences of the first paragraph are unnecessary as they deal with control of pathogen contamination and this is dealt with within the Code itself including Annex II. As they stand sentences are also misleading – the presence of the relevant microorganisms in the finished product is not only due to the presence in the powders but also due to hygiene problems in hospitals. According to the first FAO/WHO report at least 20% of the cases account for this issue.

MICROBIOLOGICAL CRITERIA (TABLE)

NEW ZEALAND

New Zealand proposes that the table should define the age-group that each microbiological criterion applies to. Specifically we submit that it is appropriate that the *E. sakazakii* criterion apply only to products destined for infants at greatest risk.
We ask for clarification as to the basis of the microbiological criteria in order to establish:

- The specific purpose of the criteria

Establishment of an appropriate regulatory response to non compliance;

Identification as being risk-based only if a link is established between application of the criteria and the likely outcome in terms of human health i.e. the level of consumer protection afforded.

New Zealand suggest that the square bracketed Enterobacteriacae and the Mesophilic Aerobic Bacteria criteria be removed from this table and that emphasis be given to the use of these criteria as environmental and process monitoring tools in Annex II. The remaining table would then be:

Micro organisms	N	C	m	M	Class Plan
Enterobacter sakazakii	[30]	0	0/10 g	N/A	2
Salmonella	60	0	0/25 g	N/A	2

If Mesophilic Aerobic Bacteria stays within the table, then the criteria level should be scientifically justified. If this table is to retain a scope for infants, we suggest that test methods used for Mesophilic Aerobic Bacteria in PF containing probiotics may require careful consideration (see * footnote)

Asterisked Notes to the Table

First note (*):
New Zealand suggests that the second sentence be deleted because it does not add to the sense of the document and does not reflect the need for a risk based approach to the revision of this criterion.

Second note (**):
New Zealand suggests that the words "and would achieve a reasonable level of risk reduction while not unduly burdening the industry" should be removed because they do not add to the sense of the document and may create the misconception that ensuring that the Industry is not unduly burdened is a primary driver for the revision of the Code.

Suggested rewording of the sentence would be:

"The number of samples allocated for E sakazakii takes into account the outputs of the preliminary risk assessment."

PHILLIPPINES

CODEX PROPOSED TEXT + PROPOSED CHANGES						**COMMENTS**
Microorganisms	n	c	m	M	Class Plan	
Mesophilic Aerobic Bacteria** * **	5	2	500/g	5000/g	3	Delete "*****", "******", "*******". Delete "**[** and **]**".
~~[~~Enterobacteriaceae~~]~~	10	0	0/10g	NA	2	
Enterobacter sakazakii** ** **	30	0	0/10g	NA	2	
Salmonella** *** **	60	0	0/25g	NA	2	
Bacillus cereus	5	2	10	100	3	

Staphylococcus aureus	5	1	0	10	3	These should be included in the monitoring plan for finished goods.[5]

Rationale: Testing for Enterobacteriaceae should be mandatory because this is a good indicator of hygienic control in factory production lines. Presence or absence of other Enterobacteriaceae Category "B" organisms can also be covered when testing is done for Enterobacteriaceae.[6]

UNITED STATES OF AMERICA

Table in paragraph 2. Recommend that this table be divided into two tables, one for the criteria for hygiene (mesophilic aerobic bacteria and Enterobacteriaceae) and the other for pathogens, (S*almonella* and E. sakazakii). The table should be appropriately labeled to ensure the reader understands the difference in their use and importance.

ICMSF

ICMSF recommends the following changes to the table of microbiological criteria:

- Table headings: "N" should be "n" and "C" should be "c".
- The value for "c" for Enterobacteriaceae should be 2, as proposed during the working group meeting. "NA" should be "N/A" and specified in the table legend ("N/A" = not applicable)
- It may advantageous to separate the criteria intended for safety from those for hygiene indicators in two tables in order to underline the important difference in utility , i.e. show criteria for mesophilic aerobic bacteria and for Enterobacteriacea in a separate table from *Enterobacter sakazakii* and *Salmonella* spp.
- In the table's legend, the ** refers to "the preliminary risk assessment" but it may not be clear that this refers to the Joint FAO/WHO Technical Meeting on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula of 16-20 January 2006, Rome, Italy. A footnote could help clarify.
- ***. Add "Both technical meetings concluded that the"… current requirements…. /Plenum Publishers). ICMSF recommends adding after this "In this case, samples may be pooled, which means that 60*25 g random samples may be pooled before the enrichment."
- Change "determination" to "determinations" in the last line of the legend to the Table.

It would be beneficial for the reader to understand the rationale for the proposed microbiological criteria. This text could be added to Annex I (positioned under Table and legend) for this purpose: The following explains the rationale for recommending these particular microbiological criteria:

- The current standard for Salmonella (n=60, c=0, m= 0/25g) was considered adequate by both FAO/WHO technical meetings. The criteria for *Enterobacter sakazakii* previously proposed by the ICMSF would be effective at detecting a mean concentration of around 1 cell in 100g of product and would provide a roughly two-fold reduction in relative risk based on the preliminary risk assessment (FAO/WHO technical meeting, Rome, 2006). This was considered to be a reasonable balance between the ability of a sampling plan to effectively reduce risk and the practicalities of being able to still manufacture the product. The data submitted by ISDI/Industry was examined to see if there was a consistent ratio of Enterobacteriaceae (EB) to *Enterobacter sakazakii* (ES). The data were from different commercial operations and were collected using different methods of sampling and detection and did not show a consistent ratio for EB/ES. As there is not a consistent and reliable ratio between EB/ES, the use of a criterion for EB as an indicator for ES without

[5] BFAD Bureau Circular No. 01-A 2004. Guidelines for the Assessment of Microbiological Quality of Processed Foods. February 2004.
[6] Joint FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula, Geneva, 2-5 February 2004.

testing for ES was not recommended. The criteria for EB should therefore be considered to be a measure of process hygiene.

- It would be more usual to recommend the use of a three class plan for an indicator organism. However, given the importance of maintaining stringent hygiene conditions in infant formula manufacture a two class plan was recommended. The performance of a number of three class plans was previously considered but concluded not to be practical because of the small difference between m and M. A number of two class plans with different positive results being allowed (c values) were considered. A plan allowing two positives (c=2) in 10, 10g samples was proposed. This plan would allow a mean concentration of around 1 EB per 10g of product to be reliably detected and was regarded as being a good indicator for process hygiene.

Considering the guidance of Codex on when and where microbiological criteria are useful tools and after reviewing the scientific and epidemiological information, the ICMSF proposes the following microbiological criteria for powdered formulae for young children:

Microbiological criteria recommended regarding acceptability of end product in view of consumer safety

Microorganisms	**n**	**c**	**m**	**M**	**Class Plan**
Salmonella spp.	60	0	0/25g	n.a.[1]	2

[1]: n.a. = not applicable

Microbiological criteria recommended as indicators of product and process hygiene

Microorganisms	**n**	**c**	**m**	**M**	**Class Plan**
Mesophilic aerobic bacteria	5	2	1000/g	10000/g	3
Enterobacteriaceae	10	2	0/g	n.a.[1]	2

[1]: n.a. = not applicable

IDF

MC for hygienic indicators (mesophilic aerobic bacteria & Enterobacteriaceae)
The suggested MC for Mesophilic Aerobic Bacteria and the Enterobacteriaceae are intended for environmental and process monitoring purposes (of general hygiene measures) and would be more appropriately dealt with in Annex II (Guidance for the establishment of environmental monitoring).

Further, as the current Codex Principles for the Establishment and Application of MC for Foods (CAC/GL 21 – 1997) do not address the use of MC for verification of hygienic control measures, but only MC for use as acceptance/rejection of individual lots of (end) products, it is not appropriate to label them as MC as currently understood by these Codex Guidelines. A term as ”action criteria” or

”guideline levels” that trigger specific action in respect of hygiene measures rather than product rejection would be more appropriate.
When relocating these MC in Annex II, the corrective measures in case of exceeding the MC should not be non-acceptance of the batch but reinforcement of the performances of control measures, reviewing the HACCP plan and/or GHP-measures controlling the levels.

Finally, to be consistent with their use as hygienic indicators it is appropriate to specify both criteria/levels for these two groups of microorganisms as Class 3 Plans.

MC for Mesophilic aerobic bacteria
As hygiene indicators, we do not see any justification for reducing the level/criterion for Mesophilic Aerobic Bacteria, in particular, if a criterion for Enterobacteriaceae is added. Therefore, we recommend retention of the current Class 3 Plan n=5; c=2; m = 1000 cfu/g and M = 10000 cfu/g.

MC for Enterobacteriaceae
Further work is needed on the microbiological specification for Enterobacteriacea.
The proposed 2 class plan (n=10, c=0 m=0(or absent)/10g) for Enterobacteriaceae would enable detection when present at a per 100g level. This is more stringent than is necessary (and perhaps consistently possible) for this hygiene indicator.

An appropriate Class 3 Plan for Enterobacteriaceae could be , for example n=10; c=2; m = 0 cfu/10g and M = absent in 1g. This sampling plan only differs from the other in that 2 of the samples can have Enterobacteriaceae present in 10g provided none of the 10 samples have Enterobacteriaceae present in 1g. However, the ICMSF 3 class plan calculator can't be used for this plan, because in this case (such large sample sizes) it is impractical to use a count method.

Estimating levels of Enterobacteriaceae in PF using an MPN approach is a practical approach for larger sample sizes. The estimated counts for some combinations of positive tubes are given below for a 10 x 10g, 10 x 1g MPN:

Number of positive tubes

10g	***1g***	***MPN/g***
4	0	0.045
3	0	0.032
3	1	0.043
2	0	0.02
2	1	0.03
2	2	0.041
2	3	0.051
1	0	0.0095
1	1	0.019
1	2	0.029
1	3	0.039
1	4	0.049
0	0	<0.0091
0	1	0.0091
0	2	0.018
0	3	0.028

0 4 0.037
0 5 0.047

If EB is present at the 1/50g level, then it is expected that 2 of the 10g tubes would be positive, and if EB is present at the 1/105g, then it is expected that 1 of the 10g tubes would be positive. For the Annex, action levels would need to be defined, for example, >0.02 MPN/g using a 10 x 10g and 10 x 1g tube test.

There are a variety of options (tubes numbers and sample sizes) available when using an MPN approach, however at this point we have only investigated an example similar to the sample plans explored so far - more suitable/better variations might be something to investigate further in the future if there is the opportunity (for example, for 5 x 10 g [1 positive) and 5 x 1 g (0 positive) tubes the estimate is also 0.02 MPN/g, though understandably the 95% CI alters from that for the 10 tube tests).
MC for *Enterobacter sakazakii*

The Committee should be aware of the fact that the current ISO/IDF method for the determination of *E. sakazakii* has not been subject to validation and that the method is still not perfect. Testing results may therefore not be fully reliable

Footnotes
The footnotes include information intended for CCFH and should be removed prior to final adoption of this Code

ISDI AND CIAA

ISDI would like to reserve its position about microbiological criteria as long as the scope of the Code of Practice is not clarified.

ANNEX II

GUIDANCE FOR THE ESTABLISHMENT OF AN ENVIRONMENTAL MONITORING PROGRAM FOR *SALMONELLA, E. SAKAZAKII* AND ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS

IDF

For the reasons stated in our comments to Annex I, microbiological specifications for hygiene indicators should be located in this Annex.

SIXTH PARAGRAPH

UNITED STATES OF AMERICA, IDF AND ICMSF

Note that factors go up from "a" to "f", not to "i".

(a) Type of product and process/operation

FIRST PARAGRAPH

UNITED STATES OF AMERICA

Second sentence, this sentence is confusing. It is unclear what is meant by this sentence since the FAO/WHO report considered all of the products covered by this code as "high risk" products in regard to infants. Are we trying to indicate that Salmonella is a problem in many foods whereas E. sakazakii is a problem only with PF. Is so, there is no need to make broad statements about Salmonella when both Salmonella and E. sakazakii are relevant to the products included in the scope of this code.

(b) Types of samples

ISDI AND CIAA

Delete the first sentence and replace it by "Environment samples consist of non contact food surface samples, as external parts of equipments, floors surrounding the line, pipeline and platforms. Line samples are those collected from inside the equipment or contact food surface."

Rationale: Samples taken from direct food contact surface are considered 'line Samples'. 'Environment samples' are those collected from outside the equipment, at the surrounding environment. Occurrences of *E. sakazakii* or *Salmonella* have different meanings according to the site where sample is taken. If the occurrence is in Environment, the risk is potential, but if in Line, the risk is direct. In consequence the corrective and preventive actions can be different.

(c) Target organisms

UNITED STATES OF AMERICA

This is a misstatement of fact based on the FAO/WHO report and the sentence should be deleted.

(d) Sampling locations and number of samples

(f) Sampling tools and techniques

ISDI AND CIAA

In the second sentence replace "…humidified" sponges' by "dry swabs".

Rationale: this utensil seems more adapted to this type of sampling.

Annex III

CONTROL MEASURES DURING THE RECONSTITUTION, STORAGE, HANDLING AND USE OF RECONSTITUTED POWDERED FORMULAE

GENERAL COMMENT

AUSTRALIA

Australia has provided detailed comments on Annex III to the Working Group.

However, Australia considers that this Annex requires further work. Annex III contains a large amount of information which is too complex and confusing for its intended audience, in particular care givers.

NEW ZEALAND

New Zealand believes that this annex presents a considerable amount of valuable work. However, because of its extent, we consider that it could be viewed as daunting and would benefit from more in-depth discussion and further development. (see initial general comment)
Examples of areas which could benefit from further work include:

- The storage of reconstituted infant formula – there needs to be a clear message in this area.
- The annex should include consideration of non -food safety issues.
- Further clarification with regard to control measure selection.

Additionally New Zealand suggests that the annex material should relate to the ongoing WHO work on the safe preparation, storage and use of powdered infant formula.

The term "PIF" is used throughout this Annex, but the title refers to Powdered Formulae (PF). This is confusing so we suggest that the abbreviated term PF be consistently used throughout the document when referring to general powders.

PHILLIPPINES

Annex III should be kept as simple and concise as Annex II covering the surveillance activities in an industrial setting. We feel that additional review and reformulation of this annex is necessary to make it a simple and straight-forward element of the document. More complex technical and scientific explanation should be taken out. Some information contained in the Annex III, especially in the flow chart (Fig.1) is not adequate, e.g.:
- The inclusion of the "multiple feeding" arrow. This practice is not recommended to be made and therefore should not appear in a general flow chart.
- The timescale to introduce the water. Water has to be introduced in the bottle before the powder and not after, if not the mixing will not be efficiently made.
- The "ingredients" arrow. This practice is not recommended at home and not a systematic practice in hospitals, institutions and therefore should not appear in a general flow chart.

UNITED STATES OF AMERICA

The United States Delegation lists below a series of comments related to Annex III. However, the Delegation feels that this Annex would benefit from discussion at CCFH about the Committee's expectations related to the scope and level of detail required of the Annex. The level of detail is more than would be normally found in an annex of Codex code of hygienic practice. The United States Delegation recommends that this annex be substantially condensed with much of the more technical

aspects being captured in a FAO/WHO technical report. This report could be appropriately cited in the current annex.

ICMSF

We feel that the Annex should illustrate to risk managers that the risk assessment has shown that several risk management options may exist in particular situations but that they may exert different levels of intervention or control, depending on the option and the situation. It would also be an opportunity to show that the adherence to recommendations is crucial. Annex III contains a lot of detailed technical information relating to risk management options. This may make it difficult for risk managers to appreciate the value of the outcomes of the risk assessment and the suitability of the various risk management options discussed in their context. Rather than providing Tables and Figures from which readers have to deduce relevant detail, it might be more useful to develop an interpreted summary of the results by giving examples of risk management options to mitigate the risk. A very suitable list of examples has been developed in the first FAO/WHO technical meeting that took place in Geneva, 2004:

Examples of risk management options following from the microbiological risk assessment study:

- **Reducing the concentration/prevalence of intrinsic contamination of powdered infant formula by *E. sakazakii*.**
    - Employing a supplier assurance scheme and monitoring for raw materials, especially for ingredients not undergoing an additional heat treatment prior to mixing.
    - The main source of contamination is the manufacturing environment, hence reducing the level of *Enterobacteriaceae* in the production environment will also reduce the concentration/prevalence of contamination in the finished product. Key aspects include an effective separation of wet and dry processing operations and an effective management programme of plant hygiene including an environmental monitoring programme within a HACCP plan.
    - Monitoring and testing of the concentration and prevalence of *Enterobacteriaceae* in finished products by industry.
    - A tightening of the current microbiological specifications for powdered infant formula.
- **Reducing the level of contamination through a heating step of the reconstituted powdered infant formula prior to use.**
    - Where feasible, the use of commercially available sterilized liquid products as a replacement to powdered formula, especially for high risk groups.
    - Employing an effective point-of-use pasteurisation step following formula reconstitution (e.g. a number of hospitals use a commercial steamer in their formula preparation area)
    - The use of hot water 70-90^{o}C during the reconstitution of powder. A number of powders clump when very high temperature water is used.
- **Minimise the chance of contamination of reconstituted formula during preparation.**
    - Ensure use of good hygienic practice in the preparation area either through guidelines if in a hospital, or labelling and education if in the home. This should include the prevention of cross contamination from the environment and equipment (e.g., blenders) used during preparation.
- **Minimize the growth of *E. sakazakii* following reconstitution prior to consumption.**
    - Ensuring rapid cooling of reconstituted product and storage below 10^{o}C if not for immediate use.
    - Minimising the length of time between reconstitution and consumption.

Such a list may be very illustrative to risk managers regarding the outputs that can be developed by the microbiological risk assessment. Please note that at this point it is not possible for us to provide, next to the example, a sense of the magnitude of impact for the options which, in our opinion, would be

very worthwhile to inform risk managers. This detail can be calculated on the basis of the microbiological risk assessment developed for the second FAO/WHO technical meeting in Rome, 2006.

IDF

The Annex contains very valuable information and is an attempt to bridge risk assessment information with risk management guidance. It is quite long and complex and would benefit from more editing. To accomplish this particular task, we recommend that is referred to a physical working group.

Annex III should provide several combinations of measures that provide sufficient health protection. These combinations should, as necessary, be targeted specific end-user skills in homes and institutions & hospitals, and at least provide guidelines based upon a combination of non-heated reconstitution with cold water and immediate feeding, and a combination of reconstitution at 60-65 °C and large scale reconstitution and storage.

ISDI AND CIAA

ISDI believes that Annex III needs significant modifications to be clearer. Therefore ISDI suggests it is entirely reviewed to be more focussed on the scenarios and adapted to the audience.

In addition, ISDI stresses the fact that some information contained in the Annex III, especially in the flow chart (Fig.1) is not adequate, e.g.:

- The inclusion of the "multiple feeding" arrow. This practice is not recommended to be made and therefore should not appear in a general flow chart.

- The timescale to introduce the water. Water has to be introduced in the bottle before the powder and not after, if not the mixing will not be efficiently made.

- The "ingredients" arrow. This practice is not recommended at home and not a systematic practice in hospitals, institutions and therefore should not appear in a general flow chart.

1. INTRODUCTION

SECOND PARAGRAPH

UNITED STATES OF AMERICA

Recommend deleting the 1st through 3rd sentences and attaching the 4th sentence onto the first paragraph. Then modify that sentence to read "…a small number of servings will likely be contaminated at the point immediately after reconstitution…."

ICMSF

Third sentence, levels of *E. sakazakii* expressed are mean concentrations, not mean log concentrations and replace "<" by "≤" in all three instances.

THIRD PARAGRAPH

UNITED STATES OF AMERICA

Recommend deleting paragraph 3 in its entirety.

ICMSF

First sentence, the level of *E. sakazakii* referred to in the sentence is the mean concentration, not the mean log concentration.

1.1 Purpose and scope of this Annex

IDF

Annex III is focusing on the control and reduction of *E. sakazakii*. Consequently, the scope should reflect that the Annex is specifically intended for PF intended for infants at greatest risk.

FIRST PARAGRAPH

UNITED STATES OF AMERICA

Final sentence, recommend modifying the second example in parentheses to "cleanliness of preparation areas" rather than "facility maintenance."

SECOND PARAGRAPH

NEW ZEALAND

New Zealand believes that this paragraph could further clarify the purpose of the Annex and suggest rewording as follows:
"The information in this Annex is intended for consideration when:

- PF manufacturers establish…
- Professional caregivers establish…
- Competent authorities give guidance…"

IDF

In the last sentence, replace "*a small number of servings will be initially contaminated*" with "*a small number of servings could be initially contaminated*"

LAST PARAGRAPH

ICMSF

Consider changing "parents" to "caregivers in home situations".

1.2 PROCESS DESCRIPTION

IDF

The arrow in Fig. 1 between "3. reconstitution" and "water" should be reversed

2. AVAILABLE CONTROL MEASURES

ICMSF

The text provided in this section gives a useful description of the range of control measures that might be considered, depending on the particular situation, in the preparation of reconstituted formulae. However, there a several points that require attention:

1. It is not clear whether this Annex is for powdered infant formulae only (as indicated on pg 25) or also for formula prepared for young children. Children are referred to once in this Annex (pg 35 first line).
2. Throughout the section the phrases "control objectives" and "control measure options" are used in an underlined form. Are these new terms proposed by the WG or even new "metrics"?
3. While Appendix A to Annex III occasionally gives the reader a sense of the level of control (i.e. reduction or limitation to growth) over the hazard, it does not so in many others. It would be important for the target audience of the Annex (as listed on pg 25) to understand that different control measures exert a different level of control and what the differences are between control measures. It is understood that the levels of control by the various control measures described can be calculated using the model that was made available to the Joint FAO/WHO Technical Meeting on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula took place in Rome, Italy, January 16-20, 2006. For the purpose of review of control measures and selection of suitable options by sufficiently experienced parties, it would be required

that the model is made publicly available. To make it a valuable and effective tool for risk assessors, it should be accompanied by an adequate description of the model inputs and the mathematical handling (including key assumptions). The former is important for risk managers as well, but they would in addition require an understanding of the criteria that the working group applied regarding the magnitude of hazard control required (e.g. allowing no growth or minimising possible growth to a particular level) to avoid contamination of reconstituted powdered infant formula to reach concentrations that are deemed unsafe.

Steps 1 & 2: Storage & portioning of PIF

FIRST BULLET

UNITED STATES OF AMERICA

Add 'and limiting access to PF' at the end of the sentence, and add a new bullet: "Avoid reintroducing a 'wetted' utensil into the container of PF."

Step 3: Reconstitution

FIRST BULLET

IDF

Considering the information provided in Appendix A as regards the control measure "use of potable tap water", there is no need to list this measure here.

SECOND BULLET

UNITED STATES OF AMERICA

Should we list a range of temps for the cold water? Consumers should be educated that bottled water is not a sterile product.

BULLETED POINTS 4 AND 5

NEW ZEALAND

With regards to the suggestion that infant formula may be reconstituted at 70°C, New Zealand has the following specific concerns**:**
The practicalities and "re-education" implications of changing from currently accepted advice to caregivers.

Occupational health and personal safety concerns (scalding). We are particularly concerned that this proposal increases the risk of scalding to many, so as to reduce the rare but severe impact risk of *E sakazakii* infection. We have concerns over the citing of references under footnote 28, which are based on adult exposures (re-constituters) rather than infants (consumers).

The nutritional impact on heating product to 70°C is virtually unexplored in the scientific literature. We note that the footnote 29 suggests CCNFSDU advice may be needed. The practicality of 70°C verification, if this option was ever to be used in the home environment (though we note that this is not recommended at this stage in the document).

ICMSF

Overlooking the various bullet points under step 3, the reader could get the impression that the objectives for the step could be equally well achieved by reconstituting PIF using cold water, water at 70°C or water at 65-70°C. Quantitative insight in the level of control exerted by the various options is needed or at least a reference to Appendix A for more details (best already before step 1&2 so that it is valid for all steps discussed).
Fifth bullet/second line, ends with ", and". Is there text missing here or does the text under the next bullet need to be added?

LAST PARAGRAPH

NEW ZEALAND

New Zealand believes that the basis for the recommendation of 6 log reductions should be referenced. Note this is also mentioned in Appendix A, Step 3 Table.

Step 4: Cooling

UNITED STATES OF AMERICA

At the end of section, add a new sentence, "When cooling multiple bottles, care should be taken to ensure adequate spacing exists between the bottles so that adequate cool air flows to each bottle can be achieved."

Step 5: Storage

FIRST PARAGRAPH

NEW ZEALAND

New Zealand suggests that it is misleading to state that typical storage times are 2-30 hours. We presume this range is derived from the survey described in paragraph 4.2.1 of the 2006 FAO/WHO document but it does not identify differences between institutional and domestic practices.

Additionally we submit that this section should commence with a statement such as:
"Where possible prepared formula should not be stored but used as close as possible to feeding time and if stored, storage should be no longer than 24 hours".

It is important to clearly state that storage of prepared formula is not a preferred option as it provides an opportunity for microbial growth.

UNITED STATES OF AMERICA

First sentence: Recommend specifying a maximum storage time of 24 hours.
Add new last sentence: "Hospital wards should have a monitoring system in which reconstituted formula is dated and discarded according to a schedule."

Step 6: Feeding

UNITED STATES OF AMERICA

Last bullet. Recommend modifying the last bullet to read: "Discarding of leftovers after feeding and formula that is taken out of the refrigerator but not used."

Step 7: Cleaning and Sterilization of bottles etc

UNITED STATES OF AMERICA

This step should include cleaning and disinfection of the prep area and any utensils used in the rehydration and dispensing of formula.

3.1 Control strategy considerations

SECOND PARAGRAPH

ITEM 1

ICMSF

Is "log concentration" correct? In the further text "concentrations" are mentioned?

UNITED STATES OF AMERICA

Number 1: The specific PO or MC established for the PF will have little or no significance in terms of expectations of the level of control achieved at this stage of consumption.

ITEM 2

UNITED STATES OF AMERICA

Number 2: Modify sentence to read: "The willingness of the institution to prioritize the hygienic reconstitution, storage and use of PF. The higher the priority, the more resources (human, economic) that can be allocated."

THIRD PARAGRAPH

FIRST BULLET

Replace the "and" at the end of the bullet with an "or."

3.2 Examples of appropriate combinations on control measures according to the "design approach"

SECOND PARAGRAPH

UNITED STATES OF AMERICA

First sentence: modify to read "These control measures will be implemented by the user via instructions (e.g., product labeling, separate information,…." Second sentence: Delete in its entirety. First bullet: Add the word "hazard" before the word "control".

Second bullet: Change the word "ensured" to "enabled."

Add new last sentence in section: "It is the responsibility of the caregiver to ensure that these instructions are adequately and consistently followed."

3.2.1 Design Approach Strategy

SECOND BULLETT

ICMSF

Replace "<" by "≤" for the POs quoted. It should be clarified, possibly, whether such a PO already has been established somewhere?

TABLE 2

ICMSF

Header mentions "PIF ~ PO of max 10^{-5} cfu/g. This is not consistent with the statement on pg 24, last line that infant formula complying with the MC for *E. sakazakii* specified in Annex I would contain mean concentrations up to 10^{-3}-10^{-4}. When this is intentional, the rationale may need clarification.

3.2.2 Design Approach Strategy: Reducing the levels of E. Sakazakki (and Samonella)

ICMSF

This section seems to apply only for "infants at greatest risk" so only for reconstituted PIF to be fed to (according to the definitions section) "neonates (<28days), particularly pre-term, low birthweight and immunocompromised infants, and infants <2 months of age". Is this correct?

Second bullet point. Reconsider this statement. A PO should designate a level of a pathogen that provides or contributes to an FSO/ALOP, and it is difficult to understand that a PO for *E. sakazakii* of "> 10^{-3} cfu/g" would qualify for that. Also, under 3.2.1. (pg 30) it is stated that the "design strategy" approach is advisable

for PIF with *E. sakazakii* of < 10^{-3} cfu/g, while here it seems advised for PO >10^{-3} cfu/g. Maybe the level "> 10^{-3} cfu/g" is not indicating a PO?

LAST PARAGRAPH. TABLES 3 AND 4

UNITED STATES OF AMERICA

Tables 3 and 4 do not contain information on cooling time, storage time, and feeding times as Tables 1 and 2 do.

ICMSF

Tables 3 and 4. First column. Time to achieve <6 log reductions". Replace "<" by ">" or still better "≥" as it should be read as "time to achieve a reduction of 6 log or more

IDF

Typos in Table 3 and 4: Should state *"> 6 log reductions"*

3.3 Examples of appropriate combination of control measures according to the "default approach"

FIRST PARAGRAPH

UNITED STATES OF AMERICA

First sentence, modify sentence to read "…skills of the caregiver and the level of hygiene in the preparation procedure…."

IDF

The tables require reformatting – difficult to read.

3.3.1 Default approach strategy: Minimizing increase in levels of E. sakazakii

UNITED STATES OF AMERICA

Under **Scenario 1**, sterilizing tubes and pumps immediately prior to use may not be practical, and modify: "Warm quickly the bottle under hot tap water" to "Warm the bottle quickly under hot tap water."

3.3.2 Default approach strategy: Reducing the levels of E. sakazakii

ICMSF

3.3.1 and 3.3.2: these tables are unclear without adequate explanatory notes.

3.3.5 CLEANING OF BOTTLES, ETC.

LAST PARAGRAPH

ICMSF

States that flushing reduces contamination "slightly"; this may indicate to readers that it is not a very important control measure while it is very important to flush. Flushing may not reduce existing contamination and biofilm formation, but it prevents these problems to become very large.

3.4 Handling of alternate risks

FIRST BULLET

UNITED STATES OF AMERICA

In footnote on Risk of Scalding, it says the human pain threshold is 41-42 C, so we should recommend the temperature be adjusted to < 40 C, rather than < 43 C.

SECOND BULLET

UNITED STATES OF AMERICA

Reconsider this bullet on spores, particularly *B. cereus*—the FAO/WHO panel listed it as a Group C microorganism. If we control the risk of growth of *Salmonella* and *E. sakazakii* there should be little concern for spore germination and outgrowth.

THIRD BULLET

UNITED STATES OF AMERICA

This would only be relevant for PF designed to be reheated at high temperatures and for which there are appropriate instructions. This is not a control measure that can be handled by a caregiver.

3.5.1 Facilities

Domestic caregivers

SECOND BULLET

UNITED STATES OF AMERICA

Add 'and utensils' after 'work surface' and add 'and appropriately sanitized' at the end of the sentence.

3.5.2 Water for reconstitution, if not hot

FIRST BULLET

UNITED STATES OF AMERICA

First indented bullet should read: "The cold water should run for at least 30 seconds…"

SECOND BULLET

UNITED STATES OF AMERICA

Second bullet about boiling should be indented to clearly indicate that tap water should be boiled.

3.5.4 Personal hygiene

SECOND BULLET

UNITED STATES OF AMERICA

Add 'or hand sanitizers' at the end of the sentence.
Second bullet under "Additionally for professional caregivers": Add 'or more often depending upon duties' at the end.

3.5.5 Cleaning of bottles, etc.

UNITED STATES OF AMERICA

Add new first bullet that reads "Single use bottles and teats should not be reused."

Third bullet, Recent research indicates that bottles brushes are an important reservoir for *E sakazakii*.

Fourth bullet, There is ongoing concern about the use of microwaves for heating bottles.

LAST PARAGRAPH

UNITED STATES OF AMERICA

Testing for appropriate indicators is unlikely to happen at a sufficient frequency to make it a practical means of reducing risk. At best, this could be a verification tool for the effectiveness of the flushing procedure.

Appendix A of Annex III: Details on Step Control Measure Options

ICMSF

In some instances control measures seem to impact on *E. sakazakii* only and in some also on *Salmonella*, though the latter sometimes is stated in parentheses. Also, the data provided in tables 1-4 and the figures seem not to refer to *Salmonella*. Is this intentional and correct?

Fig A. The trace for the 64°C data is not clear, nor the label on the x-axis

Appendix A mentions "JEMRA II" or "Decision Analysis, JEMRA II" in several tables; such references may need clarification.

STEPS 1 & 2: CONTROL …PORTIONING

UNITED STATES OF AMERICA

Add "monitor expiration dates" in the Steps 1 & 2 Table.

ICMSF

First control measure option. Keeping the container tightly closed does not prevent "growth" it prevents "increase" by (re)contamination.

Tables 1 and 2: Table headings do not clarify content well. The level of growth that can be accepted should be specified.

STEPS 3 & 4:

ICMSF

Tables 3 and 4: Table heading need to be clarified by adequate legend text. The unit given is "seconds" but it needs to be checked whether this is correct. Could it be minutes in cases? (see for example step 3 p39, last control measure option; 12-13 log/min, or 6 logs in 0.5 min). The calculations in these tables depend on all kind of factors like bottle size, cooling environment, etc. Consequently, they cannot be given without adequate clarifications and/or referencing. The remark referred to by the asterix is very relevant and should be given a more pronounced place.

FIGURES A, B, AND C

ICMSF

The figures are not well legible. They could better be translated in better interpretable language, for instance: "Reconstitution at 70°C reduces potential contaminant practically to zero. Reconstitution at 65°C reduces contaminations largely during cooling, while reconstitution at 63°C gives minimal reductions.

FIGURE E

ICMSF

Fig. E. Why is the y-axis blacked out?

ANNEX IV

UNITED STATES OF AMERICA

This annex is similar to Annex II and could benefit by following the same format. Much of the same content is there; however, it is easier to identify in Annex II because of the subheadings. It may be beneficial to consolidate these annexes.

Editorial Comments Submitted by New Zealand

Introduction
Para 1, line 2: delete comma
Para 3, line 3: "requires"
Para 11, line 2: delete "setting"
Section 2.1
Para 1, line 2: "Formulae"
Footnote 10: Should this be consistent with footnote 9?
Section 4.1.2: This would be clearer if worded: "… accumulation of product residues will takes place … lead to bacterial growth…"
Section 4.2.1
Para 4, line 4: "and then back again"
Section 5.2.4
Last para, last line: there is no footnote 1.
Section IX
Rationale, para 2, line 1: delete hyphen.
Annex III, Introduction
Para 2: The word "initially" in the second-to-last line should be deleted, as it is covered by "at the point immediately after reconstitution".
Annex III, section 1.1
First bullet, line 2: "and/or to determine when…"
Annex III, section 1.2
Figure 1: reverse the arrow for water.
Annex III, section 1.3.1
Para 2, line 4: insert a comma between "refrigerator" and "storage."
Annex III, section 3.2
Tables 1 and 2: The second and third side headings would be clearer if worded, "Storage temp. (refrigerator or ambient) " and "Storage time".
Tables 3 and 4: ["Time to achieve < 6 log reductions" seems wrong. Should the symbol be ≥?]