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ISDI proposal for the 'redrafting' of the Proposed Draft Recommended International Code of Hygienic Practice for Powdered Formulae for Infants and Young Children at step 3

ISDI PROPOSALS FOR TEXT CHANGES	ISDI PROPOSALS FOR TEXT PLACES & ISDI JUSTIFICATIONS
INTRODUCTION It is recognized internationally that breast milk is the best source of nutrition for infants. However, there are instances where breast milk may be insufficient or not available and thus, may need to be supplemented or replaced. In those instances, one of the dietary options is the use of powdered infant formulae.	Core document
Powdered formulae (infant formula, follow-up formula, formula for special medical purposes intended for infants, ~~foods for special medical purposes for infants and young children~~ and human milk fortifiers) are foods intended for infants and young children. Some of these products, either alone or in combination with breast milk in the case of breast-milk fortifiers, are designed to serve as the sole source of nutrition for infants. Other products, e.g., follow-up formula, may be used in combination with other foods as part of the diet of older infants and young children. For the purposes of this document, these products will be referred to collectively as powdered formulae (PF). These products are also to be distinguished from ready-to-feed liquid formulae that have been commercially sterilized.	Core document Delete all along the text any reference to foods for special medical purposes for infants and young children Rationale: Paragraph 159 of the 2006 CCFH Report (Alinorm 07/30/13) states "the Committee noted that the Scope of the new Code would focus only on powdered formulae." This specification excludes foods for special medical purposes for infants and young children, thus all references to foods for special medical purposes for infants and young children should be removed from the Code.
As a dehydrated product, it is not possible using current technology to produce powdered formulae that are devoid of low levels of microorganisms, i.e., the product cannot be sterilized. Thus, the microbiological safety of these products require strict adherence to good hygienic practices during both manufacture and use.	Core document

Two FAO/WHO "meetings of experts" on the microbiological safety of powdered infant formula (PIF)[4,5] considered cases of illnesses in infants associated with PF consumption either epidemiologically or microbiologically. They identified three categories of microorganisms based on the strength of evidence of a causal association between their presence in PF and illness in infants: A) microorganisms with a clear evidence of causality, namely, *Salmonella enterica* and *Enterobacter sakazakii*; B) microorganisms for which the causality is plausible but not yet demonstrated, i.e., they are well established causes of illness in infants and have been found in PF, but contaminated formula has not been convincingly shown, either epidemiologically or microbiologically, to be the vehicle and source of infection, e.g., other Enterobacteriaceae; and C) microorganisms for which causality is less plausible or not yet demonstrated, including microorganisms, which despite causing illness in infants, have not been identified in PF, or microorganisms which have been identified in PF but have not been implicated as causing such illness in infants, including *Bacillus cereus, Clostridium difficile, C. perfringens, C. botulinum, Staphylococcus aureus* and *Listeria monocytogenes.*	Core document
Salmonella is a well-known long-standing foodborne human pathogen. The incidence of salmonellosis among infants, originating from various sources, was reported to be more than eight times greater than the incidence across all ages in the United States of America (CDC, 2004). It is unclear whether the increased rate among infants results from greater susceptibility, or whether infants are more likely than persons in other age groups to seek medical care or have stool cultures performed for symptoms of salmonellosis. However, infants are more likely to experience severe illness or death from salmonellosis, and infants with immunocompromising conditions are particularly vulnerable.	Core document
At least 6 outbreaks of salmonellosis involving approximately 250 infants have been associated with PF between 1985 and 2005. Most of these outbreaks involved unusual *Salmonella* serotypes, which likely aided in recognition of those outbreaks. It is recognized that outbreaks and sporadic cases of salmonellosis due to powdered infant formula are likely to be under-reported. **However, the European Food Safety Authority (EFSA) recently noted in *The EFSA Journal* that, "Given the large number of servings consumed by infants worldwide who cannot be, or are not directly, breastfed, the number of cases of illnesses due to *E. sakazakii* and *Salmonella* in powdered infant formulae, is very low."[1]**	Core document Add language in bold. Rationale: This recent and viable information is important to note when putting the amount of *Salmonella* and *E. sakazakii* outbreaks into context.
EFSA also noted recently that, "While *E. sakazakii* is a common contaminant in foods, it is not an important pathogen in terms of incidence of health consequences."[1] *Enterobacter sakazakii* has recently emerged as a pathogen of infants. The FAO/WHO expert consultations have identified infants as the population at particular risk for *E. sakazakii* infections. Among infants, those at greatest risk are neonates (<28 days), particularly pre-term, low-birthweight (<2500 g), and immunocompromised infants, and those less than 2 months of age.[1,7] Infants of HIV positive mothers are also at risk, because they may specifically require infant formula and they may be more susceptible to infection[2,8].	Core document Add language in bold. Rationale: This is also important information to share when assessing the risk of *E. sakazakii*.
Infections from *E. sakazakii* have been documented as both sporadic cases and outbreaks. While the incidence of these *E. sakazakii* infections in infants appears to be low, the consequences can be severe. The primary manifestations of *E.*	Core document

[1] *The EFSA Journal* (2007) 444, 1-14 "Review of the opinion on microbiological risks in infant formulae and follow-on formulae with regard to *Enterobacteriaceae* as indicators".

sakazakii infection in infants, i.e., meningitis and bacteraemia, tend to vary with age. *E. sakazakii* meningitis tends to develop in infants during the neonatal period, while *E. sakazakii* bacteraemia tends to develop in premature infants outside of the neonatal period with most cases occurring in infants less than 2 months of age. However, infants with immunocompromising conditions have developed bacteraemia as late as 10 months of age and previously healthy infants have also developed invasive disease outside the neonatal period. Infections have occurred in both hospital and outpatient settings. It was noted that as older infants generally live at home in the community, infections in such infants may be more likely to be under-reported.	
Although most reported cases have involved infants, a small number of cases have also described infections in children (these have not been linked to PF though) and adults (6 of the 8 adults were >70 years). Reported fatality rates of *E. sakazakii* infections in infants vary considerably with rates as high as 50 percent reported in at least one instance. In addition, a portion of surviving infants have permanent disabilities such as retardation and other neurological conditions.	Core document
While PIF was established as the source of *E. sakazakii* in some of the cases, in many cases it was neither epidemiologically nor microbiologically implicated as the source of infection. However, in such cases, no other source of infection has been epidemiologically or microbiologically implicated. *E. sakazakii* is widely found in the environment, so older infants, children and adults would be exposed to this organism from a range of sources.	Core document
~~The outbreaks of *E. sakazakii* infections have led to the link with PIF, especially in the context of neonatal intensive care setting. *E. sakazakii* is known to be present at low concentration in a proportion of PIF. While the microorganism has been detected in other types of food and environmental settings, only PIF has been linked to outbreaks of disease. For example, in 2004, a small outbreak occurred in New Zealand which was linked to PIF used in a nursery. Subsequently, a premature infant died after contracting *E. sakazakii* meningitis. A follow-up investigation in the neonatal intensive care unit (NICU) found that four other babies had been colonised with the organism. Another outbreak due to *E. sakazakii* occurred in France in 2004. A total of nine cases were reported, with two deaths. Syndromes included fatal meningitis (2), conjunctivitis (1), hemorrhagic colitis (1) and colonization (5). All infants were premature and under 2000g (low birth weight), except for the infant with colitis who weighed 3250g and was born at 37 weeks of gestation.~~	Delete the paragraph. Rationale: ISDI believes 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.
For infants at greatest risk, instead of PF, 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.	Core document
There are three routes by which *E. sakazakii* can enter PF: 1) through the ingredients added in dry mixing operations during the manufacturing of PF, 2) through contamination of the formula from the processing environment in the steps following the drying, and 3) through contamination of the formula as it is being reconstituted by the caregiver prior to feeding. *E. sakazakii* may be found in many environments such as food factories, hospitals, institutions, day-care facilities and homes. Thus, the organism may gain access into the processing line and product since current technology cannot completely eliminate this possibility.	Core document

Prevention efforts must be multi-faceted, directed at manufacturers, health-care providers as well as home settings, and take into consideration the risk to infants both within and beyond the neonatal period.	Core document
Product labelling, consumer education programs and staff training at hospitals 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.	Core document
SECTION I. – OBJECTIVES The objective of this Code is to provide practical guidance and recommendations to governments, industry and caregivers of infants and young children, as appropriate, on the hygienic manufacture of PF and on the subsequent hygienic preparation, handling and use of reconstituted formulae.	Core document
PF are specifically manufactured and **can be in some instances** presented to be used ~~either~~ as breast-milk substitutes, to modify prepared breast-milk substitutes or to fortify human milk, and include infant formula, follow-up formula, formula for special medical purposes intended for infants, ~~foods for special medical purposes (intended for infants and young children)~~[9] and human milk fortifiers. In some instances, PF may represent the sole source of nutrition for infants.	Core document Reword the first sentence and delete all along the text any reference to foods for special medical purposes for infants and young children. Rationale: Rewording the first sentence allows for more clarity of the sentence. As noted above, the scope of the Code is to be limited only to powdered formulae (Alinorm 07/30/13, paragraph 159).
The Code supplements the *Recommended Code of Practice: General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003) and the *Codex Code of Hygienic Practices for Milk and Milk Products* (CAC/RCP 57-2004), with an emphasis on the control of microbiological hazards, in particular *Salmonella* and *E. sakazakii*. The Code identifies relevant control measures at the various steps in the food chain that can be employed to reduce the risks for infants and young children that are associated with the consumption of PF.	Core document
SECTION II. – SCOPE, USE AND DEFINITIONS **2.1 SCOPE** This Code covers the production, preparation and use of products available in powdered form, referred to as Powdered Formula (PF) for the purpose of this document, and specifically manufactured to be used for infants and young children ~~either~~ as a breast milk substitute, to modify prepared breast milk substitutes or fortify human milk. Products included are infant formula, follow-up formula, formula for special medical purposes intended for infants, ~~foods for special medical purposes~~ and human milk fortifiers.	Core document Delete 'either' Rationale: Allows for more clarity of the sentence. Delete all along the text any reference to foods for special medical purposes for infants and young children
The nutritional specifications of these products are beyond the scope of this document. Products should meet the nutritional specifications of the applicable Codex standards[10].	Core document

2.1.2 ROLES OF GOVERNMENTS, INDUSTRY, AND CONSUMERS[11] Intended users of the document include national governments, manufacturers, and caregivers to infants and young children.	Core document
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 caregivers of infants and young children, to assure the safety and suitability of PF.	Core document
The interrelationship and impact of one segment of the food chain on another segment is important to ensure that potential gaps in the continuum are dealt with through communication and interaction between the suppliers of ingredients, the manufacturer, the distributor and the caregivers. While it is principally the responsibility of the manufacturer to conduct the hazard analysis within the context of developing a control system based on HACCP or other equivalent systems and thus to identify and control hazards associated with the incoming ingredients, the caregivers should also have an understanding of the hazards associated with PF, so as to assist in minimizing risks associated with the hazards involved.	Core document
To achieve an effective continuum for the purpose of reducing risk the various parties should pay attention, in particular, to the following responsibilities.	Core document
- Producers and manufacturers of raw materials should ensure that good agricultural, hygienic and animal husbandry practices are employed at the farm level. These practices should be adapted, as appropriate, to any specific safety-related needs specified and communicated by the manufacturer.	Core document
- Manufacturers of ingredients should utilize good manufacturing and good hygienic practices and have HACCP systems implemented. Any needs for additional measures communicated by the PF manufacturer and that are needed to control hazards in PF should be implemented.	Core document
- Manufacturers of PF should utilize good manufacturing and good hygienic practices, especially those presented in this Code. Any needs for additional measures with regard to controlling hazards earlier in the food chain should be effectively communicated to suppliers to enable them to adapt their operations to meet these measures. Likewise, the manufacturer may have to implement controls or adapt their manufacturing processes based on the ability of the ingredients supplier to minimize or prevent hazards associated with the ingredients. Such additional needs should be supported by an adequate hazard analysis and should, where appropriate, take into consideration technological limitations during processing and/or market demands.	Core document
- Manufacturers should provide accurate and understandable information to enable the subsequent person(s) in the food chain, including the final consumer/caregiver, to use the product appropriately. This includes the additional measures to control hazards in the formulae during and after reconstitution.	Core document

- Distributors, transporters and retailers should assure that PF under their control are handled and stored properly and according to the manufacturers' instructions.	Core document
- Hospitals and institutions should provide effective training to their caregivers of infants.	Core document
- Caregivers of infants should ensure that PF are prepared handled and stored properly and according to the manufacturer's instructions and hygienic training provided to them[12].	Core document
- **Health care professionals should provide effective training to consumers (parents and other caregivers of infants) to ensure that PF are prepared handled and stored properly and according to the manufacturer's instructions.**	Core document Add an 8th bullet point. 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. According to recent research carried out on behalf of the UK Food Standards Agency[2], health care professionals play a critical role in educating consumers about appropriate preparation and handling of powdered formula.
In order to effectively implement this Code, competent authorities should have in place legislative framework (e.g., acts, regulations, guidelines and requirements), an adequate infrastructure and properly trained inspectors and personnel. For food import and export control systems, reference should be made to the Codex *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* (CAC/GL 26-1997). Control programs should focus on auditing relevant documentation that shows that each participant along the chain has met their individual responsibilities to ensure that the end products meet established food safety objectives and/or related objectives and criteria. Furthermore, adequate consumer education programs should be implemented.	Core document
It is important that clear communications and interactions exist between all parties to help assure that best practices are employed, that problems are identified and	Core document

[2] COI and FSA. "Powdered Infant Formula Qualitative Research – Final Report." April 2006.

resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.	
2.2 USE This document follows the format of the Codex *Recommended International Code of Practice – General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). The provisions in this document are supplemental to and must be used in conjunction with the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003), including its Annex on *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application*, and the Code of *Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).	Core document ISDI believes 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 IDF Annex III.
This document also addresses steps that are beyond manufacturing and distribution and therefore also beyond the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). ~~These steps (reconstitution, handling, storage and feeding are addressed in Annex III, as an extension of Section IX.~~	Core document This paragraph needs for some adaptation since the IDF Annex III on reconstitution will not be part by itself of the code anymore.
2.3 DEFINITIONS ***Infant* –** a person not more than 12 months of age[13].	Core document
***Infants at greatest risks* –** neonates (<28days), particularly pre-term, low birthweight and immunocompromised infants, and infants <2 months of age[14].	Core document
Young Children – persons from the age of more than 12 months up to the age of three years (36 months)[15].	Core document
Human milk fortifier* –** (also referred to as ***Human milk complement in some countries) product that may be added to human milk to provide additional nutrients for feeding low-birth weight and premature infants.	Core document
***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), under review and sent for adoption at step 8 by the CAC)).**	Core document Add the Codex definition of Infant formula.
***Formula for special medical purposes intended for infants* means a substitute for human milk or infant formula that complies with Section 2, Description, of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX STAN 180-1991) and is specially manufactured to satisfy, by itself, the special nutritional requirements of infants with specific disorders, diseases or medical conditions during the first months of life up to the introduction of appropriate complementary feeding (under review for adoption at step 8 by the CAC).**	Core document Add the Codex definition of Formula for Special Medical Purposes Intended for Infants.
***Follow-up-formula* - means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children as defined in the Codex Standard for follow-up formula (CODEX STAN 156-1987 (amended 1989)).**	Core document Add the Codex definition of Follow-up-formula.

***Powdered 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, ~~foods for special medical purposes~~, and human milk fortifiers, but excluding **processed** cereal-based products **for infants and young children and foods for special medical purposes.**	Core document Precise that the products covered by the term Powdered formula are only intended to infants and young children. Add a clear exclusion of foods for special medical purposes like it is done for processed cereal-based foods Correct the expression 'processed cereal-based foods' to be in line with the Codex standard.
***Wet-mix process* –** manufacturing process by which all constituents of the infant formula are handled in a liquid phase, heat-treated, concentrated by evaporation, homogenized and then dried.	Core document
***Dry-mix process* –** manufacturing process by which all constituents of the infant formula are processed dry and blended to obtain the desired final formula.	Core document
***Combined process* –** manufacturing process by which some of the constituents of the infant formula are wet processed and dried and other ingredients are added in a dry form after the heat treatment.	Core document
SECTION III – PRIMARY PRODUCTION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES **Objectives:** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Facilities and equipment should be designed, constructed and laid out to prevent entry of *Salmonella* and additional *E. sakazakii* into high hygiene areas and to minimize their establishment or growth in harbourage sites.	Core document
Rationale: - The entry of *Salmonella* and *E. sakazakii* in high hygiene areas of establishments manufacturing PF is favoured by an inadequate separation of wet and dry areas and/or by poor control over the traffic of employees, equipment and goods.	Core document
- The establishment of *Salmonella* in harbourage sites is favoured by appropriate conditions such as the presence of water and the occurrence of sites or structures preventing their rapid elimination through appropriate cleaning procedures.	Core document
- The increase of *E. sakazakii*, usually already part of the normal microbial flora of such high hygiene areas, is favoured by the presence of water, even in minute quantities as can be found, for example, in condensation	Core document

spots.	
- The application of wet cleaning procedures has been linked to the occurrence and spread of *Salmonella* but in particular of *E. sakazakii*.	Core document
4.1 LOCATION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.1.1 Establishments Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.1.2 Equipment Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Whenever possible, equipment should be designed, placed and installed in a manner that facilitates access for effective cleaning, thus avoiding the occurrence of sites where accumulation of residues will takes place. Such residues may, in the case of the presence of water, lead to growth and the formation of a harbourage site, thus increasing the risk of recontamination.	Core document
4.2 PREMISES AND ROOMS Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.2.1 Design and layout Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Dry processing areas where all necessary operations are performed, from the drying up to the filling and hermetic closure of containers, are considered as high hygiene areas. The internal design and layout of establishments manufacturing PF need to be such as to ensure the strict physical separation of wet processing areas from the dry processing areas where post-process recontamination from the environment could occur.	Core document
To be effective, the physical separation, known as zoning, needs to be complemented by appropriate measures such as maintaining positive air pressure to prevent entry of unfiltered air in high hygiene areas.	Core document
The access to high hygiene areas needs to be restricted and controlled through measures designed to avoid or minimize the entry of the relevant pathogens. This is achieved through appropriately designed interfaces such as locks for the personnel, for incoming materials (e.g., ingredients used in dry-mixing operations or packaging material), for equipment requiring to be transported out and the back again (e.g., for maintenance and/or wet cleaning). Filtration systems for the air used in the building or for the transport of ingredients or product are also part of this zoning principle and need to be designed and installed accordingly.	Core document

Condensation on non-food contact surfaces should be prevented in high hygiene areas.	Core document
4.2.2 Internal structures and fittings Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Structures within establishments manufacturing PF should be soundly built of durable materials and easy to maintain, clean and, where appropriate, easy to disinfect. The requirements need to be adapted to the conditions encountered in the different areas (wet and dry) of the establishment as outlined in Section 4.2.1. Particular attention is required in the dry high hygiene area in order to avoid the creation of inaccessible hollow sites favouring the accumulation of dust and product residues which may, in the presence of water, lead to the formation of a harbourage site.	Core document
Due to the ability of *Salmonella* and *E. sakazakii* to survive in dry environments for prolonged periods of time, care should be taken when construction activities are planned, e.g., modifications of layout requiring displacing pieces of equipment. Such activities may dislodge *Salmonella* or high numbers of *E. sakazakii* from harbourage sites that were thus far hidden, and contribute to their spread throughout the plant. It is therefore important to isolate this area and to reinforce cleaning procedures as well as environmental monitoring as described in Annex 2.	Core document
4.2.3 Temporary/mobile premises and vending machines Not applicable for the products considered in this Code.	Core document
4.3 EQUIPMENT **4.3.1 General** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Due to the ability of *Salmonella* and *E. sakazakii* to persist in harbourage sites for prolonged periods of time, processing equipment should be designed, constructed and maintained to avoid, for example, cracks, crevices, rough welds, hollow tubes and structures, close fittings, metal-to-metal or metal-toplastic surfaces, interfaces between floors and equipment, inadequately installed and maintained insulations, worn seals or other sites that cannot be reached during cleaning.	Core document
While these elements need to be addressed correctly in the whole establishment, particular attention is required in high hygiene areas where recontamination should be prevented.	Core document
In the case of equipment located in the high hygiene area (dry), particular attention is required to ensure that equipment can be cleaned using dry-cleaning techniques. It is also important to avoid any conditions which may lead to the occurrence of condensation, including on the internal surfaces of equipment.	Core document
4.3.2 Food control and monitoring equipment Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document

4.3.3 Containers for waste and inedible substances Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.4 FACILITIES **4.4.1 Water supply** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
In order to maintain high-hygiene areas as dry as possible, the availability and presence of water and corresponding distribution systems should be limited to the extent possible.	Core document
4.4.2 Drainage and waste disposal Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
In order to maintain high hygiene areas as dry as possible, the use of dry drains is recommended as it allows one to avoid the presence of water residues which could lead to growth and spread of the relevant pathogens and process hygiene indicators. Sealed drains which are only opened when required are an alternative.	Core document
4.4.3 Cleaning Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
In order to maintain high hygiene areas completely dry or as dry as possible, the application of appropriate dry-cleaning procedures is the recommended option, such techniques being applicable to premises as well as to equipment.	Core document
Where wet cleaning procedures are still applied, appropriate management options should be implemented such as operating procedures that would ensure a well-controlled cleaning and the rapid elimination of any water residues immediately thereafter.	Core document
4.4.4 Personnel hygiene facilities and toilets Refer to the *General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)*.	Core document
4.4.5 Temperature control Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.4.6 Air quality and ventilation Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
It is important to install air handling and ventilation units in such a way as to ensure the integrity of the zoning principles. It is important to install and maintain air handling units in order that they do not become a source of contamination. For example, appropriate design and installation of the filters should avoid any bypass	Core document

of unfiltered air and accumulation of condensates should be avoided through an appropriate design of the drainage.	
Air filters should be tightly fitted and properly sealed with gaskets to prevent the entrance of unfiltered air. Outside air intakes should be located away from the exhausts of the drier, boiler and other environmental contaminants. Filters should be replaced or cleaned and disinfected regularly in a manner that does not contaminate the processing environment.	Core document
4.4.7 Lighting Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
4.4.8 Storage Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
SECTION V – CONTROL OF OPERATION **5.1 CONTROL OF FOOD HAZARDS** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition, the procedure described in Section 5.1 of the *Code of Hygienic Practice for Milk and Milk Products*(CAC/RCP 57-2004) also applies to PF.	Core document
Although chemical, microbiological and physical hazards may be associated with PF, this Code of Practice focuses on the microbiological hazards, and specifically on *Salmonella* and *E. sakazakii*. The combination of control measures should effectively control the identified microbial hazards in PF.	Core document
When milk and milk products are used in the manufacturing process, these should meet the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).	Core document
5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS ***5.2.1 Time and temperature control*** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Temperature recording devices for any temperature control point (heating or chilling) should be checked at regular intervals and tested for accuracy against a calibrated probe. In manufacturing operations where heat treatments are CCP for the reduction or elimination of a pathogen, then appropriate records of the treatment time and temperature should be maintained.	Core document
5.2.2 Specific process steps PF is typically manufactured using a wet-mix, dry-mix or combined process. The process used should ensure that the appropriate levels of nutritional components are met, as specified in the applicable Codex Standards[16].	Core document
For all types of processes used, 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*.	Core document

Steps that contribute to food hygiene include:	Core document
5.2.2.1 Chilling **For wet-mix process**: Intermediate liquid products that support microbial growth should be refrigerated if the time between the pasteurization or other equivalent microbiocidal treatments[17] and drying would lead to the growth of pathogenic organisms.	Core document
5.2.2.2 Thermal processing Heat treatments intended as microbiocidal processes should, at a minimum, be sufficient to achieve pasteurization, which is based on the reduction of vegetative pathogens to a level where they do not constitute a significant hazard to health. The time/temperature combinations used to achieve pasteurization should take into consideration the properties of the product, e.g., fat content, dry matter, total solids, etc., which may have an impact on the heat resistance of the target organisms. These heat treatments are considered as CCPs and therefore procedures have to be in place to detect deviations, such as temperature drops, and to take appropriate corrective measures such as the redirection of the product to waste or reprocessing.[18].	Core document
For wet-mix process: Microorganisms present in raw milk should be controlled in accordance with section 5 of the *Codex Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004).	Core document
For dry-mix and combined processes: Since a dry-mix process and combined processes incorporate ingredients that do not include a microbiocidal heat treatment by the formula manufacturer, the microbiological safety of these products is dependent on the treatments performed by the ingredient suppliers and the integrity of the packaging during shipment and storage. Dry-mix processors should take into consideration the procedures and safeguards employed by their ingredient suppliers and should have in place an audit program that can verify their suppliers' performance.	Core document
5.2.2.3 Drying **For wet-mix process:** A drying process is used to convert the liquid mixture into a dry powder. For example, a spray dryer could be used, in which the liquid is heated and pumped under high pressure to spray nozzles or an atomizer mounted in a large drying chamber. This is usually not considered as a microbiocidal step. The drying step needs to be done under strict hygienic conditions to avoid microbial contamination of the final product.	Core document
5.2.2.4 Cooling **For wet-mix process:** During the drying process, the powder is cooled after the drying chamber. For example, it could pass from the drying chamber to a fluidized cooling bed. The air in contact with the product should be appropriately filtered to prevent microbial recontamination of the powder.	Core document

5.2.2.5 Blending **For dry-mix and combined processes:** Blending should be done under strict hygienic conditions to avoid contamination of the final product. Refer to Section 5.3 of the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003*)*, Incoming Material Requirements.	Core document
5.2.2.6 Storage It should be done under strict hygienic conditions to avoid contamination of the product. Refer to Section 4.4.8 of the *General Principles of Food* Hygiene (CAC/RCP 1-1969, Rev. 4-2003), Storage.	Core document
5.2.2.7 Packaging Refer to Section 5.4 of the General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003), Packaging.	Core document
5.2.3 Microbiological and other specifications Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
The main microbiological hazards associated with PF are related to the presence of *Salmonella* **(powdered formulae)** and *E. sakazakii* **(infant formulae, formulae for special medical purposes intended for infants, and human milk fortifiers)**. Microbiological specifications relevant to PF for infants are listed in Annex I **for infant formula, formula for special medical purposes intended for infants and human milk fortifiers and in Annex II for follow-up-formula**. In addition, testing of ingredients, products and the manufacturing environment for certain indicator microorganisms can be useful tools for industry in verifying the efficacy and consistent applications of GHP and HACCP programs (see Annex II**I**).	Core document Add language in bold. Rationale: *E. sakazakii* testing should be limited only to products intended for infants at greatest risk, as defined earlier. Follow-up formulae are intended for infants 6 months and older (who are not considered to be at greatest risk) as part of a weaning diet. Precise which annex will include the microbiological criteria relevant for the different products. The previous reference to Annex II on environmental monitoring needs to be modified. It may become the new Annex III.
Manufacturers are responsible to ensure compliance of finished products. In view of the limitations of end-product testing, compliance should be ensured through the design of an appropriate food safety control system, verification of the effectiveness of control measures through appropriate auditing methods, including review of monitoring records and of deviations and confirmation that CCPs are kept under control. These activities can be supplemented, as necessary, by microbiological testing based on appropriately documented sampling and analysis plans. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, production line, and finished products.	Core document
Verification and monitoring procedures using environmental testing for PF are described in Annex II**I**. Environmental samples should be taken from those areas	Core document The previous reference to Annex

most likely to lead to recontamination of the product.	II on environmental monitoring needs to be modified. It may become the new Annex III.
When monitoring of control measures or verification results demonstrates deviations, appropriate corrective action should be taken and the product should not be released until adequate investigation has shown that it complies with appropriate specifications.	Core document
5.2.4 Microbiological cross-contamination Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Recontamination of the product may occur after drying and during the subsequent processing steps such as conveying, tipping, mixing, blending with additional ingredients, up to the point of filling/packaging. Recontamination is related to the following three factors, the first two of which are linked:	Core document
(1) the presence of these microorganisms in the processing environment, i.e., external parts of equipment and surroundings of the processing lines, presenting the possibility that they may get into the processing lines;	Core document
(2) the presence of these microorganisms, originating from the processing environment (item 1 above), on internal surfaces of equipment that is in direct contact with the product; and,	Core document
(3) the presence of these microorganisms in ingredients added and mixed into the dry base powder after the heat-processing step.[19]	Core document
Raw or unprocessed foods should be physically separated from ready-to-eat foods. Where possible, packaged dry-mix ingredients should be packaged with strippable bags (bags from which the outer layer can be stripped) to prevent contamination at ingredient dumping stations. Packaging material entering restricted area should be clean.	
Pathogens such as *Salmonella* and *E. sakazakii* can, to varying degrees, contaminate and become established in PF manufacturing plants. Harborage sites can serve as a source of product contamination unless these areas are identified, cleaned and disinfected to eliminate pathogens. Manufacturers should implement an ongoing microbiological monitoring program for the drying, blending and packaging areas of the plant and for food contact equipment. When pathogens or indicators are detected in the plant environment, appropriate measures should be taken to investigate the source of contamination and to eliminate or control the microorganism(s) in the environment.	Core document
Increases in the levels of *E. sakazakii* or more generally Enterobacteriaceae in processing environments can be either due to a massive and sudden entry of microorganisms such as occurs in poorly planned construction or maintenance activities, or more commonly due to the occurrence of conditions which allow the proliferation of the low number of microorganisms already present in the environment[20].	Core document
Growth is only possible in the presence of water, therefore the environment has to be kept as dry as possible. Dry conditions should be maintained in the processing	Core document

environment, including drying, blending and packaging areas. The presence of water in the processing environment can be as a result of wet cleaning of environments or equipment without appropriate immediate drying, the formation of condensation spots, leaking water valves, backed up floor drains, etc., or occasionally as a result of water infiltration following heavy rains or the use of water showers in the case of fire emergencies[1].	
5.2.5 Physical and chemical contamination Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Manufacturers should be aware of the need to prevent contamination from food allergens. For example, manufacturers should prevent soy-based formula from contaminating milk-based formula and vice versa.	Core document
5.3 INCOMING MATERIAL REQUIREMENTS Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Manufacturers should be aware of the potential for allergens to be introduced from the raw materials or ingredients, and therefore should ensure that their suppliers have effective allergen-control systems in place.	Core document
Dry-mix and combined processes: Manufacturers should take steps to ensure that the microbiological quality of the dry-mix ingredients meets the requirements for the finished products. This can be achieved through such measures as carefully selecting suppliers, performing audits to assess the suppliers' processes, controlling and monitoring procedures, and periodic evaluations of incoming ingredients.	Core document
5.4 PACKAGING Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases, where used, should be approved for food contact and be non-toxic, such as inert gases, and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Typically, containers are flushed with inert gas, sealed, coded, labelled and packed into shipping carton.	Core document
5.5 WATER Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
5.6 MANAGEMENT AND SUPERVISION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
5.7 DOCUMENTATION AND RECORDS Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.	Core document

Manufacturers should establish documentation and records concerning all procedures and application related to the HACCP plan in addition to documentation and records pertaining to good hygienic practices. In particular, the manufacturer should keep records detailing: all incoming material (e.g., dry ingredients, liquid milk); the monitoring of CCPs (e.g., records outlining effective thermal processing with actual processing temperatures); the verification of the HACCP plan; the cleaning practices and sanitation processes; and the application of procedures to verify that microbiological specifications for finished products and environmental sampling and testing are met. Documentation should be sufficient to facilitate product traceability in the event that a recall may prove necessary in the case of a process deviation.	Core document
5.8 RECALL PROCEDURES Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
As PF is regularly traded internationally, *the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CAC/GL 19-1995, rev. 2004) and *the Principles and Guidelines for the Exchange of Information between Countries on Rejection of Imported Food* (CAC/GL 25-1997) should be used in the event of a product recall.	Core document
SECTION VI. – ESTABLISHMENT: MAINTENANCE AND SANITATION **6.1 MAINTENANCE AND CLEANING** Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
6.1.2 CLEANING PROCEDURES AND METHODS Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
Wet cleaning should be minimized and limited to parts of equipment that can be taken out to a dedicated room or where adequate drying parameters can be applied immediately after wet cleaning. Implementation of dry cleaning procedures for the processing lines, equipment and the processing environment is considered to be the most effective method of avoiding multiplication of microorganisms[21].	Core document
6.2 CLEANING PROGRAMMES Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
6.3 PEST CONTROL SYSTEMS Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
6.4 WASTE MANAGEMENT Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
6.5 MONITORING EFFECTIVENESS Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-	Core document

2003). In addition:	
A critical activity to minimize the risk associated with PF is the implementation of environmental management programs (environmental samples, product contact surfaces, finished products) based on Enterobacteriaceae, as indicators for process hygiene, ***Salmonella*** and *E. sakazakii* in relevant samples to demonstrate control or to detect deviations and assess the effect of corrective actions[22]. Guidance on the establishment of an environmental monitoring program for *Salmonella*, *E. sakazakii* and otherEnterobacteriaceae is given in Annex II.	Core document Add '*Salmonella"* Rationale: 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 of *E. sakazakii* requires more stringent measures due to the fact that it is ubiquitous while *Salmonella* is not.
SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
SECTION VIII – TRANSPORTATION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS **OBJECTIVES:** Products should bear appropriate information to ensure that:	Core document
- adequate and accessible information is available to all concerned in the food chain, in particular, retail establishments, pharmacists, caregivers of infants in the home, day care and health-care facilities and health-care professionals to enable them to handle, store, process, prepare and display PF safely and correctly; and	Core document
- the lot or batch can be easily identified, and recalled if necessary.	Core document
Caregivers of infants in the home, day care and health-care facilities and health-care professionals should be informed that the product ~~is not sterile~~ ~~[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]~~, **requires correct preparation and handling to reduce the risk of illness. Caregivers** ~~and~~ should be provided with sufficient information on food hygiene to enable them to:	Core document Delete the text under square brackets and replace it by the text in bold. Rationale: According to recent consumer research conducted by the UK FSA, the most effective means to communicate new preparation guidelines to consumers are stronger parental responsibility messaging. Scare tactics that include mention of serious illness or death are unhelpful as they may cause

	consumers to panic and reduce their ability to follow instructions. The UK FSA report also stated that including the phrase not sterile on the label "failed to communicate the nature and level of risk as most did not think it meant potentially harmful but actually harmful". Lack of sterility should be communicated subtly and in context.[2] The suggested revised text provides practical information that will be more helpful for the users.
- make informed choices appropriate to the health status of the infant; and	Core document
- prevent contamination and/or growth of foodborne pathogens by preparing, storing and using PF according to the manufacturer's instructions.	Core document
Specific information should be provided regarding the preparation and handling of PF~~, for example, that rehydration at 70°C followed by rapid cooling provides an effective way to mitigate risks~~**; suitable scenarios are available in section IX, sub-section 9.5**. For infants at 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. **This information should be provided by health professionals as well as through product labelling.**	Core document Delete the second part of the first sentence and replace it with reference to the section IX sub-section 9.5 on 'product information and consumer awareness'. Add sentence in bold. Rationale: ISDI supports the inclusion of advices to caregivers and parents on the preparation of the formula, but would prefer to have a distinct sub-section dealing with this item, based on the IDF Annex III.. The UK FSA consumer research report notes states health professionals play a critical role in educating consumers since they can potentially reach all parents and provide individual advice to improve compliance.[2]
Microbiological hazards can be controlled through the application of control measures during the reconstitution, storage, handling and use of reconstituted PF. The control measures that are necessary to maintain the safety of the formula during and after reconstitution should be communicated to the end user. The nature and combination of these depends on whether there is a need to aim for a reduction of the microbial levels during reconstitution or whether it is sufficient to focus on controlling increases in levels during reconstitution, storage and use of formulae (**section IX, sub-section 9.5**).	Core document This paragraph needs for some adaptation since the IDF Annex III on reconstitution will not be part by itself of the code anymore.

Control measures can be communicated to different users in the form of instructions for use, e.g., through product labels, **consumer** education **by health care professionals** and training. These instructions, if adhered to, would help reduce the risks associated with the product.	Core document Add words in bold. Rationale: The UK FSA consumer research report states health professionals play a critical role in educating consumers since they can potentially reach all parents and provide individual advice to improve compliance.[2]
RATIONALE: The means of implementation of the control measures recommended for application beyond manufacturing and distribution are the instructions provided to the user, either through product labelling (and/or separate written information), written procedures (e.g., in professional institutions) or through oral instructions and/or training. For parents, means of implementation other than labels/instructions are not practical or controllable.	Core document
Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to PF being mishandled at later stages in the food chain. Such mishandling could result in illness, even when adequate hygiene control measures have been taken earlier in the food chain.	Core document
9.1 LOT IDENTIFICATION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
9.2 PRODUCT INFORMATION Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003).	Core document
9.3 LABELLING Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition:	Core document
The label should contain appropriate instructions regarding the need for proper preparation, handling and storage of reconstituted PF to prevent or minimize bacterial growth. Where literacy may be low, pictograms may be useful. **The label should therefore contain instructions on (manufacturers may adapt the wording as long as the information given allows the same level of understanding and safety of the users):** - **the need to follow the manufacturer's instructions,** - **the cleanness of the working surface** - **the cleanness of the hands,** - **the cleanness of the utensils,** - **the use of appropriate water,** - **the use of correct amount of powder to the water in the bottle,**	Core document Add the proposal in bold. Rationale: ISDI believes 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.

- **the use of the scoop provided with the powder,** - **the proper closure of the packaging,** - **an advice on the storage,** - **the need to discard any unfinished feeds.**	
9.4 EDUCATION Health education programs should cover general food hygiene. The development and distribution of educational documents related to PF to caregivers of infants in the home, day care and health-care facilities and health-care professionals for infants should be encouraged. These programs should enable i) the understanding of the importance of product information, ii) following instructions accompanying products, and iii) making informed choices.	Core document
Guidelines for the safe preparation, storage and handling of powdered infant formula are being developed by the WHO/FAO and may be used as appropriate[23]. Individual countries are encouraged to provide caregivers and parents with appropriate educational material.	Core document
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 PF requires proper handling to reduce the risk of illness** ~~and may be contaminated, on occasion, with extremely low levels of pathogens that can cause serious illness (e.g., *Salmonella, E. sakasakii*).~~ It should also be noted that other ingredients which are added to infant formula (whether in powder or liquid form) may not be sterile and thus, may also present the potential for contamination. Stringent hygienic preparation and storage conditions should be emphasized. Likewise, the water used to rehydrate PF will greatly impact the safety of the product. Appropriate preparation and handling, according to manufacturer's instructions reduces the risk of illness and should be emphasized by national governments. Additionally, experience has indicated that consumers and health care providers need to be periodically reminded that bottled water is not a sterile product unless specifically indicated as such on the product.	Core document Delete part of the text and add the text in bold. Rationale: As noted above, this section is aimed at home caregivers. Therefore we suggest it would be more informative and more understandable to inform them of the need for proper handling to minimize risk. The UK FSA consumer research report notes that consumers are more apt to follow directions that are linked to increasing their responsibility as compared to inflammatory statements that cause panic and confusion.[2] Those health education programs should give a clear and understandable definition of sterility and non-sterility. so that consumers can make appropriate decisions.
Information/education about necessary hygiene practices in relation to preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized, particularly regarding the relationship between time/temperature control and foodborne illness.	Core document
It should be emphasized that the improper handling and storage of reconstituted PF can promote the growth of pathogens (e.g., *Salmonella*, *E. sakazakii*, and other microorganisms such as spore formers) which may be present initially at low levels.	Core document

The potential for cross contamination of the product from various sources, e.g., equipment, utensils, the preparation, environment, other ingredients/foods, etc., requires the implementation of good hygienic practices and this should be emphasized to caregivers.	Core document
Guidance on microbiological surveillance in ~~infant~~ **powdered** formula preparation units in health care settings is provided in Annex IV and should be followed as appropriate.	Core document Change 'infant formula' into 'powdered formula' since the Annex covers all products and not only infant formula.
In situations where the mother cannot breastfeed, chooses not to breastfeed or when banked human milk is not available, the information provided by WHO/FAO as well as information provided in ~~Annex III~~ **Section IX – sub-section 9.5** may be communicated to caregivers of infants in the home, day care and health-care facilities and health-care professionals to increase awareness on the proper preparation, storage, handling and use of reconstituted formula.	Core document This paragraph needs for some adaptation since the IDF Annex III on reconstitution will not be part by itself of the code anymore.
SECTION X – TRAINING Refer to the *General Principles of Food Hygiene* (CAC/RCP 1-1969, Rev. 4-2003). In addition, professional caregivers should receive or achieve adequate training in hygienic preparation, storage, handling and use of reconstituted PF.	Core document
ANNEX I **MICROBIOLOGICAL CRITERIA FOR POWDERED INFANT FORMULAE, FORMULAE FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AND HUMAN MILKS FORTIFIERS** Microbiological criteria should be established in the context of risk management options. ~~A number of factors will have an impact on the level of microorganisms found in reconstituted powdered infant formula. Steps should be taken during manufacturing to minimize the likelihood that microorganisms of concern (e.g., *Salmonella* and *E. sakazakii*) will be present.~~	Annex I Modify the title in accordance with the CCFH decision. Delete part of the text. 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 the new Annex III. 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.
These criteria are to be applied to the finished product (powder form):	Annex I (new) With regards to the levels, ISDI will wait until the proposal from Canada to provide its comments.

Microorganisms	N	C	M	M	Class Plan
Mesophilic Aerobic Bacteria *	5	2	[~~1000~~ 500]g	[~~10000~~ 5000]/g	3
[Enterobacteriaceae]	10	0	0/10 g	NA	2
*Enterobacter sakazakii***	[30]	0	0/10 g	N/A	2
*Salmonella****	60	0	0/25 g	N/A	2

* The proposed criteria for mesophilic aerobic bacteria are reflective of Good Manufacturing Practices and do not include non-pathogenic microorganisms that may be intentionally added such as probiotics. These criteria were revised from m=1000 and M=10,000 in order to reflect the need for improved general hygiene requirements of the product.	Annex I (new)
** The number of samples allocated for *E. sakazakii* was selected based on the preliminary risk assessment and would achieve a reasonable level of risk reduction while not unduly burdening the industry.	Annex I (new)
*** The current requirements for *Salmonella* are considered appropriate (International Commission on Microbiological Specifications for Foods, 2002, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, Kluwer Academic/Plenum Publishers).	Annex I (new)
Internationally recognized and validated methods, for example ISO methods, are to be used for all determination listed above.	Annex I (new)
ANNEX II **MICROBIOLOGICAL CRITERIA FOR FOLLOW-UP-FORMULAE (NEW)**	Annex II (new) Copy the title of Annex I and modify accordingly to the CCFH decision. ISDI believes that the Annexes I and II should only cover the microbiological criteria. With regards to the levels, ISDI will wait until the proposal from Canada to provide its comments. However, ISDI believes that *E. sakazakii* testing should be limited to infant formula, FSMPs, and human milk fortifiers and therefore Annex II should not contain any criterion for *E. sakasakii*.

ANNEX III **GUIDANCE FOR THE ESTABLISHMENT OF AN ENVIRONMENTAL MONITORING** **PROGRAM FOR *SALMONELLA*, *E. SAKAZAKII* AND ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS** Even under adequate hygienic conditions, low levels of Enterobacteriaceae, including *E. sakazakii*, may be present in the plant environment. This could lead to the sporadic presence of low levels of Enterobacteriaceae in the finished product due to post-pasteurization recontamination from the environment. Tracking the level of Enterobacteriaceae in the plant environment is a useful means of verifying effectiveness of the hygienic procedures applied and also allows undertaking corrective actions in a timely manner. Environmental monitoring of Enterobacteriaceae provides baseline levels and therefore allows the tracking of changes over time. Although it was recognized that there is no demonstrated correlation to date between counts of Enterobacteriaceae and *E. sakazakii*/*Salmonella*, it may be reasonably anticipated that a reduction in the levels of the Enterobacteriaceae in the environment would correspondingly lead to lower levels of Enterobacteriaceae (including *E. sakazakii* and *Salmonella*) in the finished product.	Annex III (new)
Manufacturers of PF should consider the potential risks to consumers in the event their products contain either *Salmonella* or *E. sakazakii* when they are released for distribution. In view of the limitations of end product testing alone, the necessity for an environmental monitoring program for these products becomes evident, particularly since recontamination has led to several recognized outbreaks.	Annex III (new)
Such a monitoring program could be used to assess control of the processing environment in the high hygiene areas (dry areas) where recontamination might take place, and, thus, would be an essential food safety management tool.	Annex III (new)
The monitoring program should be part of a food safety control system incorporating prerequisite programs such as good hygienic practices and a HACCP program.	Annex III (new)
In order to design an appropriate monitoring program, it is important to understand the ecology of *Salmonella* and *E. sakazakii* as well as the ecology of Enterobacteriaceae (used as indicators of process hygiene).	Annex III (new)
- *Salmonella* is rarely found in dry processing areas and monitoring should be designed to assess whether the control measures to prevent entry have been effective. It should also allow one to assess whether, in case of entry, establishment in harbourage sites and spread throughout the area could be prevented or has taken place.	Annex III (new)
- *E. sakazakii* is widespread and therefore, also part of the normal flora in dry processing areas. It is found regularly when using appropriate sampling and testing methods. The monitoring program should, thus, be mainly designed to assess whether the control measures to prevent additional entry are effective and whether increases to higher levels are avoided.	Annex III (new)

- Enterobacteriaceae are widespread and therefore part of the normal flora in dry processing areas. They are found regularly when using appropriate sampling and testing (quantitative) methods. Enterobacteriaceae have been used for decades as indicators of process hygiene to detect deviations in good hygienic practices or the presence of water residues, e.g., after cleaning or due to the presence of condensation.	Annex III (new)
A number of factors (a – i) should be considered when developing the sampling program to ensure its effectiveness:	Annex III (new)
(a) Type of product and process/operation The need for and extent of the sampling program should be defined according to the characteristics of the products and in particular of the consumer. While *Salmonella* is considered a pathogen for all categories of products included in this Code, *E. sakazakii* may only be relevant for specific products.	Annex III (new)
Monitoring activities should be focused in areas where recontamination is likely to occur, i.e., in the dry processing areas located in the high hygiene zones. Particular attention should be given to interfaces between these areas and external areas of a lower hygiene level as well as areas close to processing line and to equipment where contamination is more likely to occur, e.g., due to the design of equipment, presence of openings such as hatches which may be opened occasionally for inspections.	Annex III (new)
Sampling of areas far from the processing line or even external areas is of limited use.	Annex III (new)
(b) Types of samples ~~Environmental samples consist of both food contact and non-food contact surface samples.~~ **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**. Food contact surfaces, in particular those located after the dryer and prior to packaging, present a higher risk of directly contaminating the product. Examples are sifter tailings where product lumps will accumulate and which may be indicative of moisture uptake. In the case of non-food contact surfaces, the risk of contamination will depend on the location and the design of the processing line and equipment.	Annex III (new) Delete the first sentence and replace it by the sentence in bold. 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 While *Salmonella* and *E. sakazakii* are the main target organisms, industry has found it advantageous to include Enterobacteriaceae as indicators of process hygiene. Their levels are good indicators of conditions supporting the potential presence of *Salmonella* and the potential for growth of *Salmonella* and *E. sakazakii*. It is generally understood that the correlation between the presence of	Annex III (new)

Enterobacteriaceae and the presence of *E. sakazakii* is much closer than with *Salmonella*. Even very low levels of Enterobacteriaceae do not necessarily imply an absence of *Salmonella*.	
(d) Sampling locations and number of samples The number of samples will vary with the complexity of the process and processing lines.	Annex III (new)
Information on appropriate locations can be found in the published literature, can be based on process experience and expertise, or on historical data gathered through plant surveys. Sampling locations should be reviewed on a regular basis and additional ones may need to be included in the program depending on special situations such as major maintenance or construction activities or where there is any observed indication of poor hygiene.	Annex III (new)
(e) Frequency of sampling The frequency of environmental sampling for the different parameters should be based primarily on factors outlined under (a). It should be defined based on existing data on the presence of relevant microorganisms in the areas submitted to such a monitoring program. In the absence of such information, sufficient suitable data should be generated to correctly define the appropriate frequency. Such data should be collected over sufficiently long periods of time as to provide representative and reliable information on the prevalence and occurrence of *Salmonella* and/or *E. sakazakii* over time.	Annex III (new)
The frequency of the environmental monitoring program needs to be adjusted, usually increased, according to the findings and their significance in terms of risk of recontamination. The frequency needs also to be increased in situations where an increased risk of contamination can be expected, e.g. in case of maintenance or construction activities or following wet cleaning activities.	Annex III (new)
(f) Sampling tools and techniques It is important to choose and adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example, scrapings of residues or residues from vacuum cleaners provide useful samples, and ~~humidified sponges~~ **dry swabs** may be more appropriate for larger surfaces.	Annex III (new) 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**~~[24]	ISDI suggests to include the relevant sections of the IDF Annex III in the core text under a new section IX sub-section 9.5 For the other sections of the IDF Annex III - although some may be too complex for the public -, ISDI understands that this is useful information for the common understanding but does not know where it would fit the best in the code.

1. INTRODUCTION Microbiological hazards are controlled through the appropriate selection and combination of control measures applied during the manufacture of powdered infant formula[25] (PIF) in combination with control measures applied during and after reconstitution.	?
~~PIF manufactured according to the guidelines in this code will enable compliance with the specifications in Annex I and the products will have a very low level of contamination. Other means of expressing similar or lower end product specifications include Performance Objectives (POs) applicable at the end of manufacture. For instance, products complying with the microbiological criterion (MC) for *E. sakazakii* will contain mean log concentrations <10-3-10-4 CFU/g (≈ < 0.1 to <1 CFU/kg) of powder. However, even when products have been manufactured according to this Code and comply with the specifications in Annex I, a small number of servings will be initially contaminated with 1 CFU at the point immediately after reconstitution and prior to any handling and storage~~.	Do not use this section – not appropriate to the target
~~The stringency of MC (and/or POs) and the ability of the PF manufacturer to comply or be significantly below the mean log concentration influence the maximum tolerable frequency of servings initially contaminated with 1 CFU/serving and hence influence the control strategy to be applied during and after reconstitution. The ability of the caregiver to effectively apply individual control measures also impacts the strategy to be chosen.~~	Do not use this section - not appropriate to the target
For the purpose of this Annex, the means of implementation of the control measures selected to fulfill the control strategies are the instructions provided to the user (section 9.2), either through product labelling (and/or separate written information), written procedures (e.g., in professional institutions) or through oral instructions and/or training (section 9.4). For parents, means of implementation other than labels/instructions are not practical or controllable.	? In case this section would be used, than it needs to be reworded as the sections will not correspond anymore.
1.1 Purpose and scope of this Annex To control the risk associated with the small number of contaminated servings and the additional risk associated with any recontamination of the formulae that may occur during the preparation steps, the way in which the PIF is reconstituted, handled, stored and used is very important. This annex addresses key control measures which can be implemented as control steps or as Good Hygienic Practices (such as personal hygiene, facility maintenance, etc.).	Core text - Section IX-9.5 (new)
~~The information in this Annex is intended for:~~ - ~~PIF manufacturers to use when establishing the usage instructions provided with the product to parents and professional caregivers (labelling, leaflets, etc) and/or to when their written instructions should be validated,~~	Do not use this section – repetition of the core text
- ~~Professional caregivers to use when establishing internal procedures for reconstitution, handling, storage and feeding and/or when these procedures are to be audited or validated, and~~	Do not use this section – repetition of the core text
- ~~Competent authorities to use when guidance is given to professional caregivers and parents and when established procedures and/or written~~	Do not use this section –

~~instructions provided by PIF manufacturers are to be audited or validated~~.	repetition of the core text
~~The information is, however, not appropriate for direct distribution to parents.~~	Do not use this section – repetition of the core text
1.2 Process description A schematic flow of the process of reconstitution and subsequent steps up to consumption is presented in **Fig. 1.** It should be noted that the figure does not represent all scenarios and is provided for illustration purposes, only. […] **Fig. 1: Process flow chart for reconstituted powdered**	? In case this section would be used, than it needs to be reviewed to be in line with the real process.
1.3 Settings description There are a wide variety of settings in which P~~I~~F is reconstituted, stored and used, in homes, hospitals and other institutions.	? Change 'PIF' into 'PF' Rationale: Those measures can be applied to all PF.
1.3.1 Homes Practices vary according to local customs, availability of facilities (e.g., kitchens) and general level of education. Users are relying on general household skills and instructions provided by their medical advisers or health-care professionals (such as midwives) and/or by the P~~I~~F manufacturer (product labeling and inserts).	? Change 'PIF' into 'PF' Rationale: Those measures can be applied to all PF.
It may be the case that caregivers in the home do not follow recommendations for safe preparation and feeding of infant formulae, such as the recommendation to prepare fresh bottles for each feeding and use them immediately. Poor practices that can increase the risk of illness include advance preparation of the feeds and storage in the refrigerator storage of reconstituted formula at ambient temperature while travelling or out of the home and multiple feedings from the same bottle with in-between storage.	?
1.3.2 Care-giving institutions, day-care centres & hospitals Practices will vary according to local organizations and availability of trained personnel and suitable facilities. Some settings have a centralized preparation unit from which ready-to-feed preparations are transported to the wards, whereas others have on-ward preparation of servings.	?
Infants at greatest risk are most often hospitalized. Feeding times can be prolonged in sick and hypotonic infants. In the case of immature or sick infants without coordinated sucking/swallowing, feeding by naso- or orogastreal tube or gastrotomy tube is practiced. Formula can be applied continuously using a pump or by giving boluses which are adapted in volume to the tolerance of the infant (gastric volume and gastrointestinal motility). Continuous infusion into the gastrointestinal tract by pump requires control of the time of administration of one selected syringe volume as well as observation of the homogeneity of the formula in the syringe, but pre-administrative warming can be omitted. It should be recognized that use of such feeding equipment that cannot be kept clean increases the relative risk to these infants.	?

2. AVAILABLE CONTROL MEASURES The control measures options that can be applied at the various process steps are given below. These need not all be implemented, as their necessity depends on the control strategy applied (see 3.1 below), and hence the necessary combination of measures. These control measures are addressed in further detail in Appendix A.	? If this section is needed then it needs to be reworded as the sections will not be presented as such anymore.
Additional control measures that are recommended as Good Hygienic Practices are addressed in section 3.5 below.	? If this section is needed then it needs to be reworded as the sections will not be presented as such anymore.
Steps 1 & 2: Storage & portioning of PIF The control objectives during initial storage of the powder and during portioning (i.e., measuring the amount of powder subject to reconstitution) are primarily to retain the low water activity of the powder and to minimize contact with and exposure to the environment, including air, and transfer of microorganisms from utensils, the environment and additions.	? Change 'PIF' into 'PF' Rationale: Those measures can be applied to all PF.
Control measure options that achieve or contribute to achieving these objectives include: - Keeping the container tightly closed until use and between uses; - Using the product within the designated shelf life; - Finishing a package before opening the next; - Minimizing the time of exposure to ambient air; - Environmental control (including effective cleaning & drying out of surfaces in the area where portioning is made); - Use of ingredients (e.g., thickeners, sugar) that comply with the same MC for *E. sakazakii* and *Salmonella* specified for PIF (Annex I); - Sterilization of utensils, bottles and nipples immediately prior to portioning; and • Use of ready-to-use liquid ingredients (e.g., thickeners, sugar) that have been subjected to microbiocidal treatments (e.g., commercially sterile).	? Change 'PIF' into 'PF' Rationale: Those measures can be applied to all PF. If this section is needed then it needs to be reworded as the Code including the Annexes will not be presented as such anymore.
Step 3: Reconstitution The control objectives during reconstitution (i.e., mixing the powder and the water) are primarily to minimize contamination from the water added to the powder and to reduce the concentration of pathogens that may be initially present and/or which may have contaminated the formulae during steps 1 and 2.	?
Control measure options that achieve or contribute to achieving these objectives include: - Use of potable tap water; - Use of cold reconstitution water; - Use of (cooled) water that has been subjected to heat treatment, UV-treatment etc.;	? If this section is used, then it is important to state that this is only relevant to Infant formula, FSMPs for infants and Human milk fortifiers.

- Use of reconstitution water at 70 °C; - Use of reconstitution water at 65-70 °C; and - Simple heat treatment (holding at a temperature between 58 and 70 °C for a specified time) of the reconstituted formula, e.g., in a water bath.	
Reduction *of E. sakazakii* (and *Salmonella*) occurs at temperatures from 58 °C and above, and the extent of reduction (expressed in log units) is time dependent. Use of reconstitution temperatures below 58 °C does not provide any reduction – on the contrary, when using water temperatures above 20 °C, the time needed to cool off (from the reconstitution temperature to the feeding or storage temperature) the formulae "uses up" the lag phase period26 that, depending on the subsequent time control, may lead to enhanced growth prior to feeding.	?
Any combination of temperature and time that yields more than 6 log reductions will be sufficient to reduce the probability of survival of *E. sakazakii* and *Salmonella* to a level where no significant public health concern will exist.	?
Step 4: Cooling The control objective during cooling is growth control and control measure options that achieve or contribute to achieving this include: - Chilling (refrigerator); - Small batch size (to enable more rapid cooling); and - Cooling under cold water or using an alternative approach.	?
Step 5: Storage The control objective during storage (typically 2-30 hours) is growth control in the reconstituted formulae. In some hospital, wards-reconstituted PIF is prepared on the morning of day 1 and kept refrigerated until the afternoon of day 2.	?
Control measure options that achieve or contribute to achieving this objective include storage temperature & time.	?
Step 6: Feeding The control objective is growth control in the reconstituted formulae and the control measure options that achieve or contribute to achieving this include: - Rapid rewarming to feeding temperature; - Immediate feeding; - Short feeding time (during which the formula may be kept at body or room temperature); and - Discarding of leftovers after feeding.	?
Step 7: Cleaning and sterilization of bottles etc The control objective is to avoid transfer of microorganisms (from old formula residues and adherent microorganisms) to freshly reconstituted formula, which can be achieved by a proper cleaning &sterilization procedure.	?

~~**3. SELECTION AND COMBINATION OF CONTROL MEASURES**~~ ~~The control measures applied at this stage should be selected and combined to ensure that they deliver an appropriate outcome (i.e., a sufficient level of control) that corresponds to the level of protection desired, taking into account the strategies used and outcomes achieved earlier in the product chain (PIF manufacturing steps).~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~Where the tolerable level of risk is explicitly expressed, either in terms of ALOPs or in terms of FSOs as maximum frequency(ies) and maximum concentration(s) of hazards at the time of feeding, it is possible for the professionals providing guidance and instructions to caregivers to adapt the appropriate control strategy to specific purposes, target groups and/or usages, including the selection and combination of control measures that ensure that such targets can be met. The selected control measures should be appropriately described as instructions to the user, either provided through product labeling (and/or separate written information), written procedures (e.g. in professional institution) or through oral instruction and/or training (professional caregivers), and in a language suitable to the target group.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~In other cases, it is necessary to adhere to default guidance and recommended practices by experts, e.g., as provided in section 3.3 of this Annex.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~**3.1 Control strategy considerations**~~ ~~The selection and combination needed to achieve the desired outcome strongly depends on a strategic decision whether there is a need/desire to aim for a reduction of *E. sakazakii* (and *Salmonella*) or whether it is sufficient to focus on controlling increases in levels during reconstitution, storage and use of formulae.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~Which of these strategies are most feasible depends on a number of factors, in particular:~~ ~~1. The expected level of E. sakazakii (and Salmonella) in PIF (expressed as (i) Mean Log Concentration (expected level), (ii) Performance Objectives (target), or (iii) a Microbiological Criteria (verification measure). The lower the level, the lower the need for a reduction strategy;~~ ~~2. The dedication of the institution to take responsibility for the hygienic reconstitution, storage and use of PIF. The higher the dedication, the more resources (human, economic) that can be allocated;~~ ~~3. The hygienic conditions of the facilities used to prepare and handle the formulae. The poorer the conditions are, the more that may be needed to compensate through a reduction strategy;~~ ~~4. The skills of the caregiver (in terms of general education, instructions and training). The lower the skills, the less sophisticated the measures that can be applied. Different strategies for domestic practices compared to professional care-giving institutions should be implemented; and~~ 5. ~~The ability to control the fate of the PIF (lot/consignment), e.g., dedicated use for a specified group of consumers, such as infants at greatest risk.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.

~~Where such ability exists, different strategies for different usages can be applied.~~	
~~Stakeholders may, depending on their ability to design, assess and validate a proper design of control measure combinations, choose between:~~ ~~— ***a design approach***, where the control measure combination is designed in detail, taking into account the strategies used and outcomes achieved earlier in the product chain (PIF manufacturing steps) and the end usage of the product (specified target groups); and~~ ~~- ***a default approach***, where a combination of default measures is followed, e.g., as developed by experts, the competent authority, WHO, etc.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~Section 3.2 below provides examples on strategies for implementing a design approach whereas section 3.3 provides recommended combinations that would constitute a default approach as an alternative to a design approach.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~**3.2 Examples of appropriate combinations of control measures according to the "design approach"**~~ ~~The performance of the control measure combinations selected, including those that constitute the instructions to the end user, should be validated using procedures outlined in the Guidelines for the Validation of Food Hygiene Control Measures (in preparation). Results of validation studies will:~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~— either indicate that the combination is capable of providing the desired control within its predetermined context and, thus, the measures can be implemented (or maintained),~~ ~~- or indicate that the combination is not capable of providing the desired control within its predetermined context and, therefore, cannot be relied upon and should not be implemented (or be maintained unchanged). This should lead to re-evaluation of the control measure combination (e.g., implementing increased intensities, additional or different measures)~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~The main means to implement the control measures are through instructions to the user (via product labeling, separate information, oral instruction and/or training). It is important that all control measures, from the manufacturer through to the feeding, be established in a consistent manner, considering the whole food chain.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~Where labeling (and product inserts) constitutes the sole means to communicate the applicable control measures to the caregiver, it is the responsibility of the manufacturer (and/or employer) to ensure:~~ ~~— that these measures (when adhered to) are able to deliver the controls needed, and~~ ~~- that proper application is ensured through clear and unambiguous~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.

~~instructions.~~	
~~*3.2.1 Design approach strategy: Minimizing increase in the levels of E.* sakazakii *(and* Salmonella*)*~~ ~~This strategy is recommended for application where probability of recontamination at the facilities for preparation of the formulae is generally low and where:~~ ~~– the level(s) of *E. sakazakii* (and *Salmonella*) in the powder is regulated (e.g. MC as in Annex I), or~~ ~~- POs for *E. sakazakii* have been established at the corresponding level <10-3 CFU/g or lower, and~~	Do not use this section – inappropriate; the levels are regulated by Codex
~~The strategy objective is to control contamination and growth so that the increase in the levels of microorganisms is limited.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~The combination of control measures includes an appropriate GHP program (see section 3.5) and a selection among the sets of control measures specified in Tables 1 and 2, depending on the initial levels in the powder. (Note that the values provided in Tables 1 and 2 relate only to E. sakazakii and that the values relating to Salmonella need be identified as well.).~~ ~~**Table 1: Initial level of E. sakazakii in PIF ≈ MC (as specified in Annex I)**~~ ~~**Table 2: Initial level of *E. sakazakii* in PIF ≈ PO of max 10-5 cfu/g**~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~*3.2.2 Design approach strategy: Reducing the levels of E. sakazakii (and Salmonella)*~~ ~~This strategy is recommended for application to PIF intended for (or fed to) infants at greatest risk:~~ ~~– where the level(s) of E. sakazakii (and Salmonella) in the powder is not regulated (i.e., no MC or PO established), or~~ ~~- where the level is relatively high (e.g. PO for E. sakazakii >10-3 CFU/g),~~	Do not use this section – inappropriate; the levels are regulated by Codex
~~**and/or**~~ ~~– where probability of recontamination at the facilities for preparation of the formulae is generally high, or~~ ~~- where the care-giving conditions do not allow for control of growth during storage and feeding~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~The strategy objective is to reduce expected initial levels of E. sakazakii (> 10-3/g) and/or to compensate for poor hygienic conditions during reconstitution, storage and use.~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.

~~The combination of control measures includes a basic GHP program (see section 3.5) and a selection among the sets of control measures specified in Tables 3 and 4, which all include a heat treatment of the microorganisms to ensure a significant overall decimal reduction of any E. sakazakii present in the powder (and other ingredients) and contaminating the formula during its preparation (note that these tables do not take into account the lethal effect resulting from heating and cooling down from the treatment temperatures27 and that the values provided relate only to E. sakazakii, as the values relating to Salmonella need be identified as well).~~ **~~Table 3: Use of warm reconstitution water~~** **~~Table 4: Simple heat treatment (e.g. water bath)~~**	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~3.3 Examples of appropriate combinations of control measures according to the "default approach"~~ ~~The recommended combination of control measures depends on the expected levels of pathogens in PIF, skills of the caregiver and the hygienic performance of the preparation procedure, as follows:~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~Fig. 2: Decision tree on strategy selection when implementin a default approach~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~*3.3.1 Default approach strategy: Minimizing increase in the levels of* E. sakazakii~~ ~~Table~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
~~*3.3.2 Default approach strategy: Reducing the levels of* E. sakazakii~~ ~~Table~~	Do not use this section – ISDI believes that the introduction to this section on control measures is not necessary since there are much more details in sub-sections 3.4.
3.4 Handling of alternate risks Reconstitution with hot water or heat treatment above 58°C results in alternate risks some of which are only controllable when performed by specifically trained staff (i.e., professional caregivers):	Core document – Section IX – sub-section 9.6 (new)
- **Risk of scalding**[28] of the caregiver during preparation and of the infants/children during feeding, which require effective cooling prior to feeding. The risk **of scalding the infant** can be controlled through effective temperature adjustment (<43°C) prior to feeding. Pouring a few drops in the inside of the **caregiver's** wrist can test this. **The caregiver must be aware that cooling for too long can reintroduce the risk of bacterial growth.**	Core document – Section IX – sub-section 9.6 (new) Add language in bold. Rationale: Language provides greater clarity and raises awareness of additional alternate risk.

- **Likely activation and outgrowth of spores** present in the formulae, in particular spores of *B. cereus*: The practical means to counteract this is, in the context of infant formulae preparation only through a combination of: • control of the initial levels of spores in the powder by the manufacturer (spore content to be kept as low as possible); • effective growth control after reconstitution (storage temperatures of formulae below 4°C and a short storage period); • cleaning the bottles and utensils immediately after feeding; and • sterilizing the bottles and utensils prior to use.	Core document – Section IX – sub-section 9.6 (new)
- **Reduction of the content of water-soluble vitamins**, in particular vitamin C, and other heat sensitive nutrients (amino acids, formation of blocked lysine, killing of probiotics, etc)[29]. ~~Compensation by a relevant increased content in the powder (preferably to be added by the PIF manufacturer, not the care-giver).~~	Core document – Section IX – sub-section 9.6 (new) Delete part of the text. Rationale: Compensating with higher levels is either not possible due to the fact that maximum limits have been set in the Codex Standard or irrelevant (e.g. adding more probiotics will not prevent them to be killed by high temperatures)
- **Recontamination with water** from the water bath, wherefore freshly cleaned and filled water baths are necessary.	Core document – Section IX – sub-section 9.6 (new)
- **Cracks of plastic bottles and shattering of glass bottles** due to (frequent) thermal shocks. The material of the bottle should be able to withstand such thermal conditions and the bottles should be checked before each use.	Core document – Section IX – sub-section 9.6 (new)
3.5 Good Hygienic Practices *3.5.1 Facilities* Domestic caregivers: - Use a suitable area (e.g., not located next to the infants changing area) that has been properly cleaned; and, - The work surface (usually the sink) and accessories located nearby should be regularly cleaned and disinfected.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
Professional caregivers: A specific sector/area should be provided for the preparation, handling and storage of feeding bottles and syringes for enteral nutrition that has: - an adequate ventilation system that ensure a higher ambient pressure than the adjoining rooms; - adequate lighting; - floor and wall surfaces that are easy to clean and disinfect, with angles at the joins between floor and wall surfaces (to enable constant cleanliness); - windows and other openings to the outside environment preventing the	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.

accumulation of dirt and fitted with insect proof screens, which can be removed for cleaning; the windows should remain closed during formula reconstitution; and - ceilings, false ceilings and other overhead structures that enable constant cleanliness to be maintained, minimize condensation.	
Facilities should be kept dry and cool (approximately 20°C) at all times.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
The work surface for reconstitution (usually the sink) and accessories located nearby should be regularly cleaned and disinfected.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
Refrigerators used to store reconstituted formulae should be dedicated to that purpose and should be frequently washed and disinfected. The frequency should be determined according to the number of bottles being operated, e.g., daily up to once a week.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
Appropriate surfaces in the facilities (e.g., floors or drains, walls, ventilation systems) should be monitored for the presence of *E. sakazakii* and *Salmonella* (see Annex II for guidance).	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
3.5.2 Water for reconstitution, if not hot - Tap water should be used as follows: • the water should run for at last 30 seconds before it is collected; and • the tap used should be regularly maintained (cleaning and descaling in particular), - **If boiled, t**he water should be subsequently cooled.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes. Modify the second bullet point.

	Rationale: Depending on the countries, the water may not be boiled as recommended by the national food safety bodies.
3.5.3 Storage of reconstituted PIF - Refrigerators should be designed to provide rapid cooling and normal household refrigerators may not be suitable in hospital settings - Refrigerators should be kept clean. Cleaning as needed should be done with soapy water and rinsed. If needed, disinfection can be carried out.; and - The temperature should be regularly checked, e.g., by frequently checking a thermometer placed in the refrigerator.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
3.5.4 Personal hygiene - Hands should always be washed thoroughly prior to cleaning (of utensils and bottles) and to mixing powder and water; - Hand washing procedure should include the use of soap, warm hot water and clean dry cloth (in institutions, hot dry air or disposable tissue); and - Short nails should be ensured.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
Additionally, for professional caregivers: - Light-colored clothing with short sleeves should be used; - Clothing should be changed daily; - Hair should be maintained clean, short or tied back; - Protective hair net should be worn; - Watches or ~~jewelry~~ **jewellery** should be avoided (hands and wrists); and - Use of nail varnish and artificial fingernails should be avoided.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
3.5.5 Cleaning of bottles, etc. - The feeding bottle, rings, lids and silicone nipples should be rinsed in cold water then washed in a dishwasher using a complete cycle (at least 65°C and drying is important); - Rubber nipples should be rinsed and washed carefully using a clean bottle-brush, turning them inside out; - In the absence of a dishwasher, the bottles etc. should be rinsed with cold water and washed by immersion in water to which detergent product has been added (washing-up liquid) using a clean bottle brush; to remove detergents, the bottles etc. should then be rinsed; the feeding bottle and its accessories should be inverted and left to dry. Drying by the use of dishtowels should be avoided; - After cleaning, the feeding bottles should be sterilized by boiling them, by pouring boiling water over them or by using microwave; Use of chemical disinfectants may or may not be effective (depending on concentration of active substance and time) and is therefore not recommended as best practice; Chemical disinfection should only be	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.

used by professional caregivers and only if the staff in question has received appropriate training; - Bottles and utensils should be left to dry in a clean site (not toweled) or be covered by a clean towel to avoid dust collecting on them; and - Sterilization that destroys bacterial spores (e.g., in pressure cooker or autoclave) may be needed for exceptionally fragile infants. For these infants, the use of commercially available sterilized liquid products or other infant feeding options which have undergone an effective point of use decontamination procedure, should be encouraged.	
At hospitals, flushing of the naso- or orogastreal tube or gastrotomy tubes after each feeding with sterile solutions reduces slightly the microbial contamination and the accumulation of adherent microorganisms within the feeding delivery systems. Cleanliness should be verified by testing for appropriate indicators for pathogens.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
3.5.6 Staff skills & training of professional caregivers - The staff involved in reconstitution and feeding should have access to professional food safety training, tailored to the operations to be carried out; and - Training should include control of alternate risks related to the use of hot water.	Core document – Section IX – sub-section 9.5 (new) Please note that this information is relevant both to infant formula, FSMPs for infants, human milk fortifiers and follow-up-formulae but only suitable for caregivers at hospitals and not for homes.
APPENDIX A: DETAILS ON STEP CONTROL MEASURE OPTIONS This appendix provides further details with regard to the nature and effects of various control measures that effectively impact the risk associated with *E. sakazakii* (and *Salmonella*) in infant formulae. Under each step, the control measures are listed in increasing order with respect to their effect (measures with lowest effect listed first). The information provided is primarily intended for assistance in following the design approach, as described in section 3.2 of the Annex III. **STEPS 1 & 2: CONTROL MEASURES THAT CAN BE APPLIED DURING STORAGE AND PORTIONING** **STEP 3: CONTROL MEASURES THAT CAN BE APPLIED DURING RECONSTITUTION** **STEP 4: CONTROL MEASURES THAT CAN BE APPLIED DURING COOLING OF RECONSTITUTED FORMULA** **STEP 5: CONTROL MEASURES THAT CAN BE APPLIED DURING STORAGE OF RECONSTITUTED FORMULA** **STEP 6: CONTROL MEASURES THAT CAN BE APPLIED DURING FEEDING** **STEP 7: CONTROL MEASURES THAT CAN BE APPLIED DURING CLEANING & STERILIZATION OF BOTTLES ETC.**	?

ANNEX IV **MICROBIOLOGICAL SURVEILLANCE IN ~~INFANT~~ POWDERED FORMULA PREPARATION UNITS** The extrinsic microbiological contamination of infant formulae during preparation is a factor which needs to be taken into consideration in the design of preventive measures in health care facilities. Such measures are based, as in the case of the manufacture of the powdered formulae, on the application of Good Hygienic Practices as relevant for any establishment handling foods (Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003) and on the application of HACCP or similar systems to address specific hazards.	Annex IV Modify the title Rationale: This Annex covers all products and not only infant formula
Such extrinsic microbiological contamination can occur either from the preparation environment, from preparation surfaces, and/or from utensils used during preparation. It is therefore important to assess and verify that the implemented measures are effective.	Annex IV
Microbiological surveillance of infant formula storage, preparation areas, and surfaces in direct contact with the product (e.g., utensils) represents an essential element of the quality assurance program.	Annex IV
Results from a properly designed monitoring program will assist in identifying potential sources of contamination and in demonstrating the efficacy of cleaning and disinfections procedures	Annex IV
Such a surveillance program is best achieved through sampling and testing of environmental samples for relevant microorganisms such as *Salmonella* and *Enterobacter sakazakii*, **where appropriate** or hygiene indicators such as Enterobacteriaceae. It should include swabs from surfaces of preparation areas, sinks, equipment and utensils used as well as residues, for example from vacuum cleaners, collected in the area.	Annex IV Add 'where appropriate' Rationale: Although testing for *Salmonella* is relevant to all PF, testing for *E. sakasakii* is only appropriate for infant formulae, FSMPs for infants and human milk fortifiers.
It is important that the sampling be done using appropriate sampling tools and from relevant sites which may, if contaminated, lead to (extrinsic) contamination of PF. It is important as well to document sampling activities and to use the data to initiate corrective actions where necessary. For this purpose, it is important to define targets to be achieved, e.g., in terms of acceptable levels of hygiene indicators or absence of pathogens. Such targets should be based on historical data or, if not available, on an initial survey that would permit one to define the normal microbiological status of the different sampling points. It is important to review the surveillance program on a regular basis to take into account changes in the set-up, trends, etc.	Annex IV
ANNEX V: ~~DIAGRAM~~ TABLE SHOWING THE RELATION BETWEEN THE AGES AND THE PRODUCTS CATEGORIES (*ISDI)* **FORMULA TYPES & FEEDING STAGES**	Replace the diagram by the table below. Rationale: ISDI believes that it clarifies better the relation between the ages and the products categories.

Age categories	0 - 4/6 months	4/6 - 12 months	12 - 36 months
Population	Infants[2]	Infants[2]	Young Children[2]
Products	Powdered formulae[1]	Powdered formulae[1]	Powdered formulae[1]
	Infant Formulae[2]	Follow-up-Formulae[2]	Follow-up-Formulae[2]
	FSMPs for Infants[2]	Processed Cereal-based Foods[2]	Processed Cereal-based Foods[2]
	Human milk fortifiers[3]	Canned Baby Foods[2]	Canned Baby Foods[2]
Other products that may be given	Ingredients added in hospitals (e.g. starches…)	Ingredients added in hospitals (e.g. starches…)	Ingredients added in hospitals (e.g. starches…)

[1] as defined by Code of Hygienic Practice for PF
[2] as defined by Codex Std
[3] as defined by WHO