



**ISDI Comments on the Proposed Draft Recommended
International Code of Hygienic Practice for Powdered Formulae
for Infants and Young Children
- Step 2 -**

Text: Text as modified by Canada
Text: Additional text proposed by ISDI
~~Text:~~ Text proposed for deletion by ISDI

ISDI PROPOSALS FOR TEXT CHANGES	ISDI JUSTIFICATIONS
<p>INTRODUCTION</p> <p>It is recognized internationally that breast milk is the best source of nutrition for infants. However, there are instances where it 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 formulae.</p>	
<p>Powdered formulae (infant formula, follow-up formula, formula for special medical purposes intended for infants 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.</p>	<p>ISDI supports the modification.</p>
<p>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.</p>	
<p>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, <i>Salmonella enterica</i> and <i>Enterobacter sakazakii</i>; B) microorganisms for which the causality is plausible but not yet</p>	

<p>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 <i>Bacillus cereus</i>, <i>Clostridium difficile</i>, <i>C. perfringens</i>, <i>C. botulinum</i>, <i>Staphylococcus aureus</i> and <i>Listeria monocytogenes</i>.</p>	
<p><i>Salmonella</i> 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). Infants are also more likely to experience severe illness or death from salmonellosis, and infants with immunocompromising conditions are particularly vulnerable. It is unclear whether the increased incidence of salmonellosis 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.</p>	<p>ISDI supports the modification.</p>
<p>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 <i>Salmonella</i> 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.</p>	
<p><i>Enterobacter sakazakii</i> has recently emerged as a pathogen of infants. There have been approximately 70 reports of <i>E. sakazakii</i>-related infection in infants, primarily who were premature or low birth weight, since the first case was reported in 1958 (Drudy et al 2006).¹ The FAO/WHO expert consultations have identified infants as the population at particular risk for <i>E. sakazakii</i> 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}. However, 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 <i>E. sakazakii</i> and <i>Salmonella</i> in powdered infant formula is very low.</p>	<p><u>Add</u> the sentence in bold at the beginning of the paragraph.</p> <p><u>Rationale:</u> Additional information is important for assessing the public health risk of <i>E sakazakii</i>.</p> <p><u>Add</u> the sentence in bold at the end of the paragraph.</p> <p><u>Rationale:</u> To put the issue in perspective.</p> <p>This sentence is extracted from <i>EFSA journal (2007) 444-1-14 “Review of the opinion on microbiological risks in infant formula and follow-on formula with regard to Enterobacteriaceae as indicators”</i></p>
<p>Infections from <i>E. sakazakii</i> have been documented as both sporadic cases and outbreaks. While the incidence of these <i>E. sakazakii</i> infections in infants appears to be low, the consequences can be severe. The primary manifestations of <i>E. sakazakii</i> infection in infants, i.e., meningitis and bacteraemia, tend to vary with age. <i>E. sakazakii</i> meningitis tends to develop</p>	

¹ Drudy D et al. *Enterobacter sakazakii*: An emerging pathogen in powdered infant formula. *Clinical Infectious Diseases* 2006;42:996-1002.

<p>in infants during the neonatal period, while <i>E. sakazakii</i> 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.</p>	
<p>Reported fatality rates of <i>E. sakazakii</i> 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 (<i>IBFAN – reversed order of sentences</i>). 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).</p>	<p>ISDI supports the modification.</p>
<p>While PIF was established as the source of <i>E. sakazakii</i> 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. <i>E. sakazakii</i> is widely found in the environment, so older infants, children and adults would be exposed to this organism from a range of sources.</p>	
<p>The outbreaks of <i>E. sakazakii</i> infections have led to the link with PIF, especially in the context of neonatal intensive care setting. <i>E. sakazakii</i> 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 disease⁵.</p>	<p><u>Delete</u> ‘5’. <u>Rationale</u>: Editorial comment; no footnote is attached to this figure.</p>
<p>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.</p>	<p><u>Delete</u> the paragraph. <u>Rationale</u>: To be consistent. This is a control measure which does not need to be included in the introduction.</p>
<p>There are three routes by which <i>E. sakazakii</i> and Salmonella 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 during and in the steps following the drying, and 3) through contamination of the formula either after the package is opened and/or as it is being reconstituted by the caregiver prior to feeding. <i>E. sakazakii</i> 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 organism from the manufacturing environment.</p>	<p>Either <u>add</u> ‘and <i>Salmonella</i>’ or <u>delete</u> the paragraph. <u>Rationale</u>: To be consistent. The routes described here are valid both for <i>E. sakazakii</i> and <i>Salmonella</i>. <u>Add</u> ‘during and’. <u>Rationale</u>: To reflect the reality in the manufacturing plants.</p>
<p>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.</p>	

<p>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. If applicable, labelling provisions should also take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981).</p>	<p><u>Delete</u> the last sentence. <u>Rationale:</u> To avoid redundancy The need to apply the Code of Marketing is already included in the Draft Codex Standard for Infant formulae and FSMPs for infants (section 1.4)</p>
<p>SECTION I. – OBJECTIVES</p> <p>The objective of this Code is to provide practical guidance and recommendations to governments, industry, health care professionals/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.</p>	<p>ISDI supports the modification.</p>
<p>The Code supplements the <i>Recommended Code of Practice: General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003) and the <i>Codex Code of Hygienic Practices for Milk and Milk Products</i> (CAC/RCP 57-2004), with an emphasis on the control of microbiological hazards, in particular <i>Salmonella</i> and <i>E. sakazakii</i>. 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.</p>	
<p>SECTION II. – SCOPE, USE AND DEFINITIONS</p> <p>2.1 SCOPE</p> <p>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 or in combination with other foods as part of the diet of older infants and young children. Products included are infant formula, follow-up formula, formula for special medical purposes intended for infants, and human milk fortifiers.</p>	<p><u>Delete</u> ‘either’ <u>Rationale:</u> For better clarity of the sentence. <u>Add</u> the text in bold. <u>Rationale:</u> For consistency with the definition of FUF. Follow-on formula is not a breast milk substitute, therefore last part needs to be added.</p>
<p>The nutritional specifications of these products are beyond the scope of this document. Products should meet the nutritional specifications of the applicable Codex standards¹⁰.</p>	
<p>2.1.2 ROLES OF GOVERNMENTS, INDUSTRY, AND CONSUMERS¹¹</p> <p>Intended users of the document include national governments, manufacturers, health care professionals and professional caregivers to infants and young children.</p>	<p><u>Add</u> ‘professional’ <u>Rationale:</u> To be consistent with Codex. This document should not be intended to non professional caregivers.</p>
<p>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 professional caregivers of infants and young children, to assure the safety and suitability of PF.</p>	<p>ISDI supports the modification.</p>
<p>The interrelationship and impact of one segment of the food chain on another</p>	<p>Seek for clarification of ‘potential gaps</p>

<p>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.</p>	<p>in the continuum’.</p>
<p>To achieve an effective continuum for the purpose of reducing risk the various parties should pay attention, in particular, to the following responsibilities.</p>	
<ul style="list-style-type: none"> - 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. 	
<ul style="list-style-type: none"> - 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. 	
<ul style="list-style-type: none"> - 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. 	
<ul style="list-style-type: none"> - 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. 	
<ul style="list-style-type: none"> - Distributors, transporters and retailers should assure that PF under their control are handled and stored properly and according to the manufacturers’ instructions. 	
<ul style="list-style-type: none"> - Hospitals and institutions should establish hygienic kitchen design and good hygiene practices (HACCP, labelling of prepared food, hygiene & cleaning instructions, temperature control, first in-first out,...) and should provide effective training to their caregivers of infants and 	<p><u>Add</u> the text in bold. <u>Rationale:</u> To ensure the safety of the feed. To minimise risk of contamination with <i>E. sakazakii</i> and/or subsequent growth.</p>

<p>- 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.</p>	<p>ISDI supports the addition of this bullet point.</p> <p><u>Rationale:</u> 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 Agency², health care professionals play a critical role in educating consumers about appropriate preparation and handling of powdered formula.</p>
<p>- Caregivers of infants should ensure that PF are prepared handled and stored properly and according to the manufacturer's instructions. In addition, hygienic training should be provided to caregivers of infants¹².</p>	<p>ISDI supports the modification.</p>
<p>To ensure effective implementation of 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 <i>Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems</i> (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 guidance and consumer education programs should be provided.</p>	<p>ISDI supports the modification.</p>
<p>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 resolved in an expeditious manner, and that the integrity of the entire food chain is maintained.</p>	
<p>2.2 USE</p> <p>This document follows the format of the Codex <i>Recommended International Code of Practice – General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). The provisions in this document are supplemental to and should be used in conjunction with the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003), including its Annex on <i>Hazard Analysis</i></p>	<p>ISDI believes that a reference/presentation of the Annex V on Guidance on microbiological surveillance in infant formula preparation units in health care settings should be added to this section as it has</p>

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

<i>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).</i>	been made for the IDF Annex III.
<p>2.3 DEFINITIONS</p> <p><i>Infant</i> – a person not more than 12 months of age¹³.</p>	
<i>Infants at greatest risks</i> – infants <2 months of age, particularly pre-term, low birthweight and immunocompromised infants ¹⁴ .	ISDI supports the modification of the definition for ‘Infants at greatest risks’.
<i>Young Children</i> – persons from the age of more than 12 months up to the age of three years (36 months) ¹⁵ .	
<i>Human milk fortifier</i> – (also referred to as <i>Human milk complement</i> in some countries) product that may be added to human milk to provide additional nutrients for feeding low-birth weight and premature infants.	
<i>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).</i>	<p><u>Add</u> the Codex definition of Infant formula.</p> <p><u>Rationale:</u> To be consistent</p>
<i>Formula for special medical purposes intended for infants</i> 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).	<p><u>Add</u> the Codex definition of Formula for Special Medical Purposes Intended for Infants.</p> <p><u>Rationale:</u> To be consistent</p>
<i>Follow-up-formula</i> - 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)).	<p><u>Add</u> the Codex definition of Follow-up-formula.</p> <p><u>Rationale:</u> To be consistent</p>
<i>Powdered formula</i> – 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, and human milk fortifiers, but excluding processed cereal-based products for infants and young children and foods for special medical purposes.	<p><u>Add</u> ‘processed’</p> <p><u>Rationale:</u> To be in line with the term used in the relevant Codex standard.</p> <p><u>Add</u> a clear exclusion of ‘foods for special medical purposes’ like it is done for processed cereal-based foods.</p> <p><u>Rationale:</u> To be in line with the decision that was taken at the CCFH plenary session held in 2006 in Houston.</p>
<i>Wet-mix process</i> – 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.	

<p>Dry-mix process – manufacturing process by which all constituents of the infant formula are processed dry and blended to obtain the desired final formula.</p>	
<p>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.</p>	
<p>SECTION III – PRIMARY PRODUCTION Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES Objectives: Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>Facilities and equipment should be designed, constructed and laid out to prevent entry of <i>Salmonella</i> and <i>E. sakazakii</i> into high hygiene areas and to minimize their establishment or growth in harbourage sites.</p>	ISDI supports the modification.
<p>Rationale:</p> <ul style="list-style-type: none"> - The entry of <i>Salmonella</i> and <i>E. sakazakii</i> 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. 	
<ul style="list-style-type: none"> - The establishment of <i>Salmonella</i> and <i>E. sakazakii</i> in harbourage sites is favoured by conditions such as the presence of water and the occurrence of sites or structures preventing their rapid elimination through appropriate cleaning procedures. 	ISDI supports the modification.
<ul style="list-style-type: none"> - The increase of <i>E. sakazakii</i>, 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 spots. 	
<ul style="list-style-type: none"> - The application of wet cleaning procedures has been linked to the occurrence and spread of <i>Salmonella</i> and particularly <i>E. sakazakii</i>. 	ISDI supports the modification.
<p>4.1 LOCATION Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.1.1 Establishments Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.1.2 Equipment Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	

<p>Whenever possible, equipment should be designed, placed and installed in a manner that facilitates effective cleaning, thus avoiding the occurrence of sites where accumulation of residues can take place. If water is available, such residues may lead to microbial growth and the formation of a harbourage site, thus increasing the risk of recontamination.</p>	<p>ISDI supports the modification.</p>
<p>4.2 PREMISES AND ROOMS Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.2.1 Design and layout Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>Dry processing areas where all necessary operations are performed, from the drying up Dry processing areas where all necessary operations are performed, from the moment the product is dried 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.</p>	<p><u>Reword</u> the first sentence. <u>Rationale</u>: To reflect the reality in manufacturing plants. The whole drying area is not always completely high care. Indeed the high care area can start only from the moment the product leaves the spray drier.</p>
<p>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.</p>	
<p>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 transportation out of the high hygiene areas and back in 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.</p>	<p>ISDI supports the modification.</p>
<p>Condensation should be prevented in high hygiene areas.</p>	<p>ISDI supports the modification.</p>
<p>4.2.2 Internal structures and fittings Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>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.</p>	

<p>Due to the ability of <i>Salmonella</i> and <i>E. sakazakii</i> 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 <i>Salmonella</i> or high numbers of <i>E. sakazakii</i> 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 III.</p>	
<p>4.2.3 Temporary/mobile premises and vending machines Not applicable for the products considered in this Code.</p>	
<p>4.3 EQUIPMENT 4.3.1 General Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>Due to the ability of <i>Salmonella</i> and <i>E. sakazakii</i> 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-to-plastic surfaces, interfaces between floors and equipment, inadequately installed and maintained insulations, worn seals or other sites that cannot be reached during cleaning.</p>	
<p>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.</p>	
<p>In the case of equipment located in the high hygiene area, 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.</p>	<p><u>Delete</u> the first sentence of the paragraph. <u>Rationale:</u> To reflect the reality in manufacturing plants. This is not always feasible and sometimes wet cleaning & disinfection is needed to remove product rests or disinfect. This is not a problem as long as proper drying of the equipment and environment is ensured.</p>
<p>4.3.2 Food control and monitoring equipment Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.3.3 Containers for waste and inedible substances Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.4 FACILITIES 4.4.1 Water supply</p>	

Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:	
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.	
4.4.2 Drainage and waste disposal Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:	
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 microorganisms including relevant pathogens and process hygiene indicators. Sealed drains which are only opened when required are a preferred alternative.	ISDI supports the modification.
4.4.3 Cleaning Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:	
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.	
Where wet cleaning procedures are 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.	ISDI supports the modification.
4.4.4 Personnel hygiene facilities and toilets Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).	
4.4.5 Temperature control Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).	
4.4.6 Air quality and ventilation Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:	
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 so that they do not become a source of contamination. For example, appropriate design and installation of the filters should avoid any bypass of unfiltered air and accumulation of condensates should be avoided through an appropriate design of the drainage.	ISDI supports the modification.
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.	
<p>4.4.7 Lighting</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>4.4.8 Storage</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>SECTION V – CONTROL OF OPERATION</p> <p>5.1 CONTROL OF FOOD HAZARDS</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition, the procedure described in Section 5.1 of the <i>Code of Hygienic Practice for Milk and Milk Products</i>(CAC/RCP 57-2004) also applies to PF.</p>	
<p>Although chemical, microbiological and physical hazards may be associated with PF, this Code of Practice focuses on the microbiological hazards, and specifically on <i>Salmonella</i> and <i>E. sakazakii</i>. The combination of control measures should effectively control the identified microbial hazards in PF.</p>	
<p>When milk and milk products are used in the manufacturing process, these should meet the <i>Code of Hygienic Practice for Milk and Milk Products</i> (CAC/RCP 57-2004).</p>	
<p>5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS</p> <p>5.2.1 Time and temperature control</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>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, appropriate records of the processing time and temperature should be maintained.</p>	
<p>5.2.2 Specific process steps</p> <p>PF is typically manufactured using a wet-mix, dry-mix or combined process¹⁶.</p>	
<p>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 <i>S. enterica</i> <i>Salmonella</i> and <i>E. sakazakii</i>.</p>	<p>Replace '<i>S. enteritica</i>' by '<i>Salmonella</i>' <u>Rationale</u>: To be consistent.</p>
<p>Steps that contribute to good manufacturing practices include:</p>	<p>ISDI supports the modification.</p>

<p>5.2.2.1 Chilling</p> <p>For wet-mix process:</p> <p>Intermediate liquid products that support microbial growth should be promptly refrigerated if the time between the pasteurization or other equivalent microbiocidal treatments¹⁷ and drying could lead to the growth of pathogenic organisms.</p>	<p>ISDI supports the modification.</p>
<p>5.2.2.2 Thermal processing</p> <p>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.</p>	
<p>For wet-mix process:</p> <p>Microorganisms present in raw milk should be controlled in accordance with section 5 of the <i>Codex Code of Hygienic Practice for Milk and Milk Products</i> (CAC/RCP 57-2004).</p>	
<p>For dry-mix and combined processes:</p> <p>Since a dry-mix process and combined processes incorporate ingredients that may not include a microbiocidal heat treatment by the formula manufacturer, the microbiological safety of these ingredients is dependent on the treatments performed by the ingredient suppliers and the assurance that the integrity of the packaging has been maintained 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.</p>	<p>ISDI supports the modification.</p>
<p>5.2.2.3 Drying</p> <p>For wet-mix process:</p> <p>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.</p>	
<p>5.2.2.4 Cooling</p> <p>For wet-mix process:</p> <p>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 contamination of the powder.</p>	

<p>5.2.2.5 Blending</p> <p>For dry-mix and combined processes:</p> <p>Blending should be done under strict hygienic conditions to avoid contamination of the final product. Refer to Section 5.3 of the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003), Incoming Material Requirements.</p>	
<p>5.2.2.6 Storage</p> <p>Finished products should be stored under strict hygienic conditions to avoid contamination of the product. Refer to Section 4.4.8 of the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003), Storage.</p>	ISDI supports the modification.
<p>5.2.2.7 Filling and primary Packaging</p> <p>Refer to Section 5.4 of the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003), Packaging. In addition, the following principles should be applied to the manufacture of PF:</p>	<p><u>Add</u> 'Filling and primary'.</p> <p><u>Rationale:</u> To be consistent.</p> <p>This whole section is only relevant to primary packaging and not to others (e.g. secondary packaging)</p>
<p>Access to the packaging room should be limited to essential personnel only (<i>General Principles of Food Hygiene</i>, section 5.2.4 (CAC/RCP 1-1969, Rev. 4-2003)). Access to the packaging area should be through ante rooms where personnel can wash their hands and change their outer garments, hair covering and footwear or footwear covers.</p>	ISDI supports the modification.
<p>The packaging area should be supplied with suitably filtered air to prevent airborne contamination of product or packaging. Ideally, the packaging area should be maintained under positive air pressure to prevent the infiltration of contaminated air from the outside or surrounding areas of the manufacturing facility (<i>General Principles of Food Hygiene</i> section 4.4.6 (CAC/RCP 1-1969, Rev. 4-2003)).</p>	ISDI supports the modification.
<p>Packaging materials (including cans and flexible packaging) should be protected from contamination during shipment, storage and use. Packaging should be inspected immediately prior to use to ensure that it is not contaminated or damaged. Container cleanliness can be ensured by the use of can inverters, air jets and anti-static electricity devices.</p>	ISDI supports the modification.
<p>Proper attention must be given to the prevention of cross-contamination with allergens in the packaging room. If both milk and soy based PIF are packaged in the same room, care must be taken to ensure that equipment is completely cleaned between product filling cycles or that these products are completely segregated on separate filling lines. Manufacturers should have systems in place to assure that allergens are identified on labelling.</p>	<p><u>Delete</u> the paragraph.</p> <p><u>Rationale:</u> To be aligned with the purpose of this Code.</p> <p>The scope of the code clearly focuses on microbiological hazards. Therefore the mentioning of measures to control allergen risks, here and further on in the document is not appropriate and should all be removed from this document.</p>
<p>5.2.3 Microbiological and other specifications</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	

<p>The main microbiological hazards associated with PF are related to the presence of <i>Salmonella</i> (powdered formulae) and <i>E. sakazakii</i> (infant formulae, formulae for special medical purposes intended for infants, and human milk fortifiers). Microbiological specifications are listed in Annex I for infant formula, formula for special medical purposes and human milk fortifiers, and in Annex II for follow-up formula. In addition, testing of incoming ingredients, finished 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 III).</p>	<p>Add language in bold.</p> <p><u>Rationale:</u> <i>E. sakazakii</i> 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.</p>
<p>Manufacturers are responsible for ensuring the 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 and 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 appropriately documented microbiological sampling and analysis plans. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, production line, and finished products. Verification and monitoring procedures using environmental testing for PF are described in Annex III. Environmental samples should be taken from those areas most likely to lead to recontamination of the product.</p>	<p>ISDI supports the modification.</p>
<p>When monitoring of control measures or verification results demonstrates deviations, appropriate corrective action should be taken and the finished product should not be released until adequate investigation has shown that it complies with appropriate specifications.</p>	
<p>5.2.4 Microbiological cross-contamination</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>Recontamination of the product with <i>Salmonella</i> and/or <i>E. sakazakii</i> 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:</p>	<p>ISDI supports the modification.</p>
<p>(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;</p>	
<p>(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,</p>	
<p>(3) the presence of these microorganisms in ingredients added and mixed into the dry base powder after the heat-processing step.¹⁹</p>	
<p>Raw or unprocessed foods should be physically separated from processed/ready-to-use foods. Where possible, packaged dry-mix ingredients</p>	<p>ISDI supports the modification.</p>

<p>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.</p>	
<p>Pathogens such as <i>Salmonella</i> and <i>E. sakazakii</i> can, to varying degrees, contaminate and become established in PF manufacturing plants. Harbourage 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 surfaces/equipment. When pathogens or indicator microorganisms 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.</p>	<p>ISDI supports the modification.</p>
<p>Increases in the levels of <i>E. sakazakii</i> or more generally Enterobacteriaceae in processing environments can be either due to a massive and sudden entry of microorganisms due to poorly planned construction or maintenance activities, or more commonly due to conditions which allow the proliferation of the low number of microorganisms already present in the environment²⁰.</p>	<p>ISDI supports the modification.</p>
<p>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 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 emergencies¹.</p>	
<p>5.2.5 Physical and chemical contamination Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>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.</p>	<p><u>Delete</u> the paragraph. <u>Rationale:</u> To be aligned with the purpose of this Code. The scope of the code clearly focuses on microbiological hazards. Therefore the mentioning of measures to control allergen risks, here and further on in the document is not appropriate and should all be removed from this document.</p>
<p>5.3 INCOMING MATERIAL REQUIREMENTS Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>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.</p>	<p><u>Delete</u> the paragraph. <u>Rationale:</u> To be aligned with the purpose of this Code. The scope of the code clearly focuses</p>

	on microbiological hazards. Therefore the mentioning of measures to control allergen risks, here and further on in the document is not appropriate and should all be removed from this document.
<p>Dry-mix and combined processes:</p> <p>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.</p>	
<p>5.4 PACKAGING</p> <p>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.</p>	
<p>5.5 WATER</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>5.6 MANAGEMENT AND SUPERVISION</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>5.7 DOCUMENTATION AND RECORDS</p> <p>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.</p>	
<p>Manufacturers should establish documentation and records concerning all procedures, and application related to the HACCP plan and records of supplier audits and analytical data of raw materials of suppliers 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.</p>	<p><u>Add</u> the text in bold.</p> <p><u>Rationale</u>: To be complete.</p>
<p>5.8 RECALL PROCEDURES</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-</p>	

2003). In addition:	
As PF is regularly traded internationally, <i>the Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations</i> (CAC/GL 19-1995, rev. 2004) and <i>the Principles and Guidelines for the Exchange of Information between Countries on Rejection of Imported Food</i> (CAC/GL 25-1997) should be used in the event of a product recall.	
<p>SECTION VI. – ESTABLISHMENT: MAINTENANCE AND SANITATION</p> <p>6.1 MAINTENANCE AND CLEANING</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>6.1.2 CLEANING PROCEDURES AND METHODS</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>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 microorganisms²¹.</p>	
<p>6.2 CLEANING PROGRAMMES</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>6.3 PEST CONTROL SYSTEMS</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>6.4 WASTE MANAGEMENT</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>6.5 MONITORING EFFECTIVENESS</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
<p>Manufacturers of PIF PF should establish effective supervisory procedures to ensure that critical procedures such as manual cleaning, CIP systems operation, and equipment maintenance are conducted according to established protocols and standards. In particular, it is important to ensure that cleaning and sanitizing solutions are of the proper identity and concentration, that temperature and flow rate requirements are met for CIP systems and that equipment is properly rinsed when required.</p>	<p><u>Change</u> ‘PIF’ into ‘PF’ <u>Rationale</u>: To be consistent.</p>
<p>A critical activity to minimize the risk associated with PF is the implementation of environmental management programs (environmental</p>	<p>ISDI supports the addition of a</p>

<p>samples, product contact surfaces, finished products) based on Enterobacteriaceae, as indicators for process hygiene, and <i>Salmonella</i> and <i>E. sakazakii</i> in relevant samples to demonstrate control or to detect deviations and assess the effect of corrective actions²². Guidance on the establishment of an environmental monitoring program for <i>Salmonella</i>, <i>E. sakazakii</i> and other Enterobacteriaceae is given in Annex III.</p>	<p>reference to '<i>Salmonella</i>'.</p>
<p>SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>SECTION VIII – TRANSPORTATION Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>SECTION IX – PRODUCT INFORMATION AND CONSUMER AWARENESS Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	<p>ISDI supports the modification.</p>
<p>OBJECTIVES: Products should provide information that is adequate, appropriate and clear in order to inform all distributors, health care professionals, and caregivers of the measures regarding:</p>	<p>ISDI supports the modification.</p>
<ul style="list-style-type: none"> - the storage and shelf-life of the powdered formula to ensure proper rotation; 	<p>Delete the end of this bullet point. Rationale: To be consistent. This text covers internal management issues but does not represent an objective.</p>
<ul style="list-style-type: none"> - the type of formula appropriate to the health status or age of the infant or young child; 	<p>ISDI supports the modification.</p>
<ul style="list-style-type: none"> - the hygienic preparation and use of formula to minimize the risk of contamination and growth of <i>Salmonella</i> and <i>E. sakazakii</i>; and 	<p>ISDI supports the modification.</p>
<ul style="list-style-type: none"> - any additional details or specific precautions that should be taken with respect to the preparation and use of the product due to age, health status, etc., of the infant and/or young child. 	<p>ISDI supports the modification.</p>
<p>RATIONALE: Control measures should be communicated to different stakeholders through product labelling (and/or separate written information), written procedures (e.g., in professional institutions) and/or through oral instructions and/or training. These instructions, if adhered to, would help reduce the risks associated with the product.</p>	<p>ISDI supports the modification.</p>
<p>All health care professionals and caregivers should be aware informed that powdered formula is not sterile and that the use of Good Hygienic Practices during reconstitution, handling, feeding time, including appropriate storage</p>	<p>Change 'informed' into 'aware'. Rationale: Better wording.</p>

is essential to minimize the risk of foodborne illness.	
Various risk reduction strategies for preparation, storage and handling can be found in Annex IV and in the FAO/WHO guidelines (include reference).	<p><u>Delete</u> the paragraph.</p> <p><u>Rationale:</u> To avoid confusion.</p> <p>ISDI is not in favour of giving many different approaches to minimize the risk, this will only confuse and not guarantee safe preparation and handling. Therefore either here or in Annex IV a clear statement on preparation is needed.</p>
Recommendations regarding the type of formula to be used, e.g., commercially sterile, powder, etc., should be made by health care professionals, as needed.	ISDI supports the modification.
Information regarding feeding practices should be provided. For example, feeding the formula as soon as it is reconstituted is one practical approach to minimize risk. The feeding time should be minimized and should not exceed two hours. Leftover formula should be discarded. Any formula prepared for later use should be refrigerated immediately following reconstitution and used within 24 hours (FAO/WHO Guidelines). Other approaches, which can also be used to reduce the risk, can be found in Annex IV and in the FAO/WHO Guidelines.	<p><u>Delete</u> the end of the paragraph.</p> <p><u>Rationale:</u> To avoid confusion.</p> <p>Guidance on the preparation on the formulae should be given at only one place (Annex IV) in the document and not disseminated at different place.</p>
<p>9.1 LOT IDENTIFICATION</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>9.2 PRODUCT INFORMATION</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003).</p>	
<p>9.3 LABELLING</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (CAC/RCP 1-1969, Rev. 4-2003). In addition:</p>	
The label should contain appropriate instructions regarding the need for hygienic preparation, handling and the need to refrigerate the reconstituted PF as soon as possible (no later than two hours after reconstitution) to prevent or minimize bacterial growth. The importance of discarding leftovers should be emphasized. Where literacy may be low, pictograms may be useful.	ISDI supports the modification.
Where applicable, labelling provisions should also take into account the recommendations of the International Code of Marketing of Breast Milk Substitutes (1981).	<p><u>Delete</u> the paragraph.</p> <p><u>Rationale:</u> To avoid redundancy.</p> <p>The need to apply the Code of Marketing is already included in the Draft Codex Standard for Infant formulae and FSMPs for infants</p>

	(section 1.4)
<p>Guidance should be provided on the following: i) on the use of hygienic practices, e.g., clean hands, preparation surfaces, and clean utensils (nipples, caps, utensils, including sterilization, as necessary.); ii) the need to boil water and utensils, as necessary; iii) the need to cool the formula before feeding if using hot water (>60°C) for reconstitution; and iv) the need to refrigerate product, if formula is not used immediately.</p>	<p><u>Delete</u> the paragraph.</p> <p><u>Rationale:</u> To avoid confusion.</p> <p>Incomplete and inconsistent examples are given here. ISDI favours clear preparation instructions on the labels (see the below proposal)</p>
<p>The label should contain guidance on*:</p> <ul style="list-style-type: none"> - 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, - 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. <p>* manufacturers may adapt the wording as long as the information given allows the same level of understanding and safety of the users</p>	<p><u>Add</u> the text in bold.</p> <p><u>Rationale:</u> 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.</p> <p>See detailed ISDI Position 07/106 rev.</p>
<p>Failure to follow the manufacturer's guidelines may increase the risk of illness. Proper hygiene, preparation, dilution and storage are important when preparing PF. PF, as well as other powdered products added to PF, are not sterile and should not be fed to premature infants or infants who might have immune problems, unless directed and supervised by their doctor or professional caregiver.</p>	<p><u>Delete</u> the second sentence.</p> <p><u>Rationale:</u> To be aligned with the purpose of this Code.</p> <p>Information about feedings for infants at risks should be communicated by health care professionals (noted in beginning of Section IX).</p>
<p>9.4 EDUCATION</p> <p>Health education programs should cover general food hygiene. The development and distribution of educational documents related to preparation, handling and use of PF to all caregivers should be encouraged. These programs should enable one to i) understand the importance of product information, ii) follow instructions accompanying products, and iii) make informed choices after discussing with professional caregivers, as needed.</p>	<p>ISDI supports the modification.</p>
<p>In situations where the mother cannot breastfeed, chooses not to breastfeed or when banked human milk is not available, and PF is chosen, the Guidelines for the safe preparation, storage and handling of powdered infant formula developed by the WHO/FAO should be used²¹. National governments are encouraged to provide all caregivers with appropriate</p>	<p>ISDI supports the modification.</p>

educational material.	
All caregivers should be aware that PF is not a sterile product and may be contaminated with low levels of pathogens which can cause serious illness (e.g., <i>Salmonella</i> , <i>E. sakazakii</i>). 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.	ISDI supports the simplification of this paragraph.
Stringent hygienic preparation and storage conditions should be emphasized due to the potential for cross contamination of the product from various sources, e.g., equipment, utensils, the preparation environment, other ingredients/foods. Likewise, the water used to rehydrate PF will greatly impact the safety of the product. Appropriate preparation and handling, according to manufacturer's instructions reduces the risk of illness and should be emphasized by national governments. Additionally, experience has indicated that all caregivers need to be periodically reminded that bottled water is not a sterile product unless specifically indicated as such on the product. Information/education about the need to follow good hygiene practices during preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized. It is important to stress the fact that reconstituted formula may allow the growth of microorganisms, thus it should be kept refrigerated if in case not used immediately following preparation. Refrigerated storage should not exceed 24 hours following reconstitution. Temperature abuse may lead to foodborne illness. Improper handling and storage of reconstituted PF can promote the growth of pathogens (e.g., <i>Salmonella</i> , <i>E. sakazakii</i> , and other microorganisms such as sporeformers) which may be present initially at low levels or which may have contaminated the product during handling and preparation.	<p><u>Delete</u> part of the paragraph.</p> <p><u>Rationale:</u> To reflect the real understanding of caregivers.</p> <p>A study carried on in the UK³ shown that that mothers do not understand the significance of 'non sterile' but do understand the necessity to follow the manufacturers' instructions.</p> <p>See detailed ISDI Position 07/106 rev.</p> <p><u>Change</u> 'if' into 'in case'.</p> <p><u>Rationale:</u> To avoid confusion.</p> <p>As written, one can read that the refrigerated storage is an option; prepared food should only be stored under strict hygiene and controlled settings prepared formula, storage needs to be time and temperature controlled.</p>
Guidance on microbiological surveillance in powdered formula preparation units in health care settings is provided in Annex IV and should be followed as appropriate.	
<p>SECTION X – TRAINING</p> <p>Refer to the <i>General Principles of Food Hygiene</i> (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 and should have access to professional food safety training, tailored to the operations to be carried out. If hot water is used in the preparation of the formula, training should include control of alternate risks related to such practice, e.g., scalding.</p>	ISDI supports the modification.
<p>ANNEX I</p> <p>MICROBIOLOGICAL CRITERIA FOR POWDERED INFANT FORMULA, FORMULA FOR SPECIAL MEDICAL PURPOSES AND HUMAN MILK FORTIFIERS</p> <p>Microbiological criteria should be established in the context of risk management options. These criteria are to be applied to the finished product (powder form):</p>	ISDI supports the modification.

³ <http://www.food.gov.uk/multimedia/pdfs/powderinfantform.pdf>

Criteria for pathogenic organisms						ISDI supports the modification.
Microorganisms	N	C	M	M	Class Plan	ISDI supports the modification.
<i>Enterobacter sakazakii</i> *	[30]	0	0/10 g	N/A***	2	
<i>Salmonella</i> **	60	0	0/25 g	N/A	2	
*The number of samples allocated for <i>E. sakazakii</i> was selected based on the preliminary risk assessment ²⁴ and would achieve a reasonable level of risk reduction.						ISDI supports the modification.
** Both FAO /WHO technical meetings on <i>E. sakazakii</i> and other microorganisms in powdered infant formula ²⁵ concluded that the current requirements for <i>Salmonella</i> are considered appropriate (International Commission on Microbiological Specifications for Foods, 2002, <i>Microorganisms in Foods 7: Microbiological Testing in Food Safety Management</i> , Kluwer Academic/Plenum Publishers).						ISDI supports the modification.
*** N/A: Not Applicable						ISDI supports the modification.
[Criteria for product and process hygiene						<u>Put</u> the section under square brackets. <u>Rationale:</u> To avoid confusion. The term process hygiene indicator needs to be clarified before ISDI can provide comments on.
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	
* 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. Internationally recognized and validated methods, for example ISO methods, are to be used for all determination listed above.]						
The current standard for <i>Salmonella</i> (n=60, c=0, m= 0/25g) was considered adequate by both FAO/WHO technical meetings. The criteria for <i>Enterobacter sakazakii</i> previously proposed by the ICMSE would be						Delete this paragraph. <u>Rationale:</u> To be aligned with the

<p>effective at detecting a mean concentration of around 1 cell in 100g of product and would provide a roughly two fold reduction in relative risk based on the preliminary risk assessment (FAO/WHO technical meeting, Rome, 2006). This was considered to be a reasonable balance between the ability of a sampling plan to effectively reduce risk and the practicalities of being able to still manufacture the product. The data submitted by ISDI/Industry was examined to see if there was a consistent ratio of Enterobacteriaceae (EB) to <i>Enterobacter sakazakii</i> (ES). The data were from different commercial operations and were collected using different methods of sampling and detection and did not show a consistent ratio for EB/ES. As there is not a consistent and reliable ratio between EB/ES, the use of a criterion for EB as an indicator for ES without testing for ES was not recommended. The criteria for EB should therefore be considered to be a measure of process hygiene.</p>	<p>purpose of this Code.</p> <p>Although very useful for the discussions during the ad-hoc WG meeting, the reasoning and the background for having set the criteria should not be part of the final text; only the levels and the methods of testing should be included.</p>												
<p>It would be more usual to recommend the use of a three class plan for an indicator organism. However, given the importance of maintaining stringent hygiene conditions in infant formula Manufacturing, a two class plan was recommended. The performance of a number of three class plans was previously considered but concluded not to be practical because of the small difference between m and M. A number of two class plans with different positive results being allowed (c values) were considered. A plan allowing two positives (c=2) in 10, 10g samples was proposed. This plan would allow a mean concentration of around 1 EB per 10g of product to be reliably detected and was regarded as being a good indicator for process hygiene.</p>	<p><u>Delete</u> this paragraph.</p> <p><u>Rationale:</u> To be aligned with the purpose of this Code.</p> <p>Although very useful for the discussions during the ad-hoc WG meeting, the reasoning and the background for having set the criteria should not be part of the final text; only the levels and the methods of testing should be included.</p>												
<p>ANNEX II</p> <p>MICROBIOLOGICAL CRITERIA FOR POWDERED FOLLOW-UP FORMULA</p>	<p>ISDI supports the modification.</p>												
<p>Microbiological criteria should be established in the context of risk management options.</p>	<p>ISDI supports the modification.</p>												
<p>These criteria are to be applied to the finished product (powder form).</p>	<p>ISDI supports the modification.</p>												
<p>Criteria for pathogenic microorganisms</p>	<p>ISDI supports the modification.</p>												
<table border="1"> <thead> <tr> <th>Microorganisms</th> <th>n</th> <th>c</th> <th>m</th> <th>M</th> <th>Class Plan</th> </tr> </thead> <tbody> <tr> <td><i>Salmonella</i>*</td> <td>60</td> <td>0</td> <td>0/25 g</td> <td>N/A</td> <td>2</td> </tr> </tbody> </table>	Microorganisms	n	c	m	M	Class Plan	<i>Salmonella</i> *	60	0	0/25 g	N/A	2	<p>ISDI supports the modification.</p>
Microorganisms	n	c	m	M	Class Plan								
<i>Salmonella</i> *	60	0	0/25 g	N/A	2								

<p>*Both FAO /WHO technical meetings on <i>E. sakazakii</i> and other microorganisms in powdered infant formula⁴ concluded that the current requirements for <i>Salmonella</i> are considered appropriate (International Commission on Microbiological Specifications for Foods, 2002, <i>Microorganisms in Foods 7: Microbiological Testing in Food Safety Management</i>, Kluwer Academic/Plenum Publishers).</p>	<p>ISDI supports the modification.</p>																		
<p>[Criteria for products and process hygiene (to be determined)]</p> <table border="1" data-bbox="84 461 997 680"> <thead> <tr> <th>Microorganisms</th> <th>n</th> <th>c</th> <th>m</th> <th>M</th> <th>Class Plan</th> </tr> </thead> <tbody> <tr> <td>Mesophilic Aerobic Bacteria*</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>[Enterobacteriaceae]</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>Internationally recognized and validated methods, for example ISO methods, are to be used for all determination listed above.]</p>	Microorganisms	n	c	m	M	Class Plan	Mesophilic Aerobic Bacteria*						[Enterobacteriaceae]						<p>Put the section under square brackets.</p> <p><u>Rationale:</u> To avoid confusion.</p> <p>The term process hygiene indicator needs to be clarified before ISDI can provide comments on.</p>
Microorganisms	n	c	m	M	Class Plan														
Mesophilic Aerobic Bacteria*																			
[Enterobacteriaceae]																			
<p>ANNEX III</p> <p>GUIDANCE FOR THE ESTABLISHMENT OF AN ENVIRONMENTAL MONITORING PROGRAM FOR SALMONELLA, E. SAKAZAKII AND OTHER ENTEROBACTERIACEAE IN HIGH HYGIENE PROCESSING AREAS</p> <p>Even under adequate hygienic conditions, low levels of Enterobacteriaceae, including <i>E. sakazakii</i>, 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 <i>E. sakazakii/Salmonella</i>, 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 <i>E. sakazakii</i> and <i>Salmonella</i>) in the finished product.</p>	<p>ISDI supports the modification.</p>																		

⁴ FAO/WHO Technical meeting on *Enterobacter sakazakii* and *Salmonella* in powdered infant formula, 16-20 January 2006, Rome, Italy; and FAO/WHO Technical meeting on *Enterobacter sakazakii* and other microorganisms in powdered infant formula, 2-4 February 2004

<p>Manufacturers of PF should consider the potential risks to consumers in the event their products contain either <i>Salmonella</i> or <i>E. sakazakii</i> 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.</p>	
<p>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.</p>	
<p>The monitoring program should be part of a food safety control system incorporating prerequisite programs such as good hygienic practices and a HACCP program.</p>	
<p>In order to design an appropriate monitoring program, it is important to understand the ecology of <i>Salmonella</i> and <i>E. sakazakii</i> as well as the ecology of Enterobacteriaceae (used as indicators of process hygiene).</p>	
<ul style="list-style-type: none"> - <i>Salmonella</i> 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. 	
<ul style="list-style-type: none"> - <i>E. sakazakii</i> 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 measures have been taken to prevent the growth of the organism. 	ISDI supports the modification.
<ul style="list-style-type: none"> - 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. 	
<p>A number of factors (a – i) should be considered when developing the sampling program to ensure its effectiveness:</p>	
<p>(a) Type of product and process/operation</p> <p>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 <i>Salmonella</i> is considered a pathogen for all categories of products included in this Code, <i>E. sakazakii</i> may only be relevant for specific products.</p>	
<p>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</p>	

<p>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.</p>	
<p>Sampling of areas far from the processing line or even external areas is of limited use.</p>	
<p>(b) Types of samples</p> <p>Two types of samples should be included in monitoring programs:</p> <p>(1) Environmental samples consisting of non food contact surface samples such as external parts of equipments, floors surrounding the line, pipeline and platforms. In this case, the risk of contamination will depend on the location and design of the processing line and equipment as well as on the levels determined.</p>	<p>ISDI supports the additional text.</p> <p><u>Rationale:</u> 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 <i>E. sakazakii</i> or <i>Salmonella</i> 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.</p>
<p>(2) Food contact surfaces (line samples), collected from inside the equipment 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. The presence of indicator microorganisms, <i>E. sakazakii</i> or even <i>Salmonella</i> represents a very high risk of directly contaminating the product.</p>	<p>ISDI supports the modification.</p>
<p>(c) Target organisms</p> <p>While <i>Salmonella</i> and <i>E. sakazakii</i> 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 <i>Salmonella</i> and the potential for growth of <i>Salmonella</i> and <i>E. sakazakii</i>.</p>	<p>ISDI supports the modification.</p>
<p>(d) Sampling locations and number of samples</p> <p>The number of samples will vary with the complexity of the process and processing lines.</p>	
<p>Information on appropriate locations can be found in the published literature and 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.</p>	<p>ISDI supports the modification.</p>
<p>(e) Frequency of sampling</p> <p>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,</p>	<p>ISDI supports the modification.</p>

<p>sufficient suitable data should be generated to correctly define the appropriate frequency. Such data should be collected over sufficiently long periods of time so as to provide representative and reliable information on the prevalence and occurrence of <i>Salmonella</i> and/or <i>E. sakazakii</i> over time.</p>	
<p>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 also needs 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.</p>	<p>ISDI supports the modification.</p>
<p>(f) Sampling tools and techniques</p> <p>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 (or dry swabs) may be more appropriate for larger surfaces.</p>	<p>ISDI supports the change from ‘humidified sponges’ to ‘dry swabs’.</p> <p><u>Rationale</u>: this utensil seems more adapted to this type of sampling.</p>
<p>ANNEX IV</p> <p>[...]</p>	<p>ISDI believes that parts of both proposals for this Annex IV should be used to create only one document and therefore suggests <u>holding a sub-ad-hoc WG within the Ottawa meeting to come up with a proposal</u>.</p>
<p>ANNEX V</p> <p>MICROBIOLOGICAL SURVEILLANCE IN INFANT FORMULA PREPARATION UNITS</p>	<p>ISDI supports the modification.</p>
<p>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.</p>	
<p>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.</p>	
<p>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.</p>	
<p>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.</p>	

Such a surveillance program is best achieved through sampling and testing of environmental samples for relevant microorganisms such as <i>Salmonella</i> and <i>Enterobacter sakazakii</i> 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.	
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.	

TABLE SHOWING THE RELATION BETWEEN THE AGES AND THE PRODUCTS CATEGORIES FORMULA TYPES & FEEDING STAGES	
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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