codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 4 **CX/FH 05/37/4**
December 2004

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-Seventh Session
Buenos Aires, Argentina, March 14 – 19, 2005

PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

Prepared by Canada with the assistance of Belgium, EC, France, Germany, Italy, Japan, the Netherlands, Spain, Switzerland, the United Kingdom, the United States of America, Uruguay, FAO/WHO, IBFAN, ICMSF and IDF

Governments and interested international organizations are invited to submit comments on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy **to**: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by I February 2005.**

BACKGROUND

At the last meeting of the CCFH (March 2004), the Committee agreed that a working group, lead by Canada, with the assistance of Belgium, EC, France, Germany, Italy, Japan, the Netherlands, Spain, Switzerland, the United Kingdom, the United States of America, Uruguay, FAO/WHO, IBFAN, ICMSF and IDF should proceed with the revision of the *International Code of Hygienic Practice for Foods for Infants and Children* and the development of microbiological criteria on *Enterobacter sakazakii* and other relevant microorganisms. The Committee agreed to revise the Code particularly for dried infant formula. During the Committee's discussion the following issues were emphasized:

- the need to take into consideration the range of microorganisms of concern including the availability of appropriate microbiological methods;
- the need to control the safety of infant formula by applying control measures during production, and during and after reconstitution;
- the need to identify and define high risk infant populations;
- the necessity to provide more specific guidance for hospitals, day-care centres, food handlers, and caregivers for infants;
- the development of specific information and/or recommendations on the labeling regarding the

preparation, use, and handling of powdered infant formula for users;

- the need for realistic expectations about implementation of controls that depends on consumer behavior;
- the necessity to take into account the situation in developing countries (e.g. availability of boiling water and refrigerators for keeping bottles with reconstituted milk);
- to carefully consider the use of commercially sterile liquid infant formula with regard to microbiological aspects and secondary recontamination;
- to consider other foods for infants that contain powdered infant formula (e.g. foods containing both cereals and powdered infant formula).

A working group meeting was convened in November 2004 in Ottawa, Canada to consider these issues in light of the Discussion Paper, the Risk Profile of *Enterobacter sakazakii* in Powdered Infant Formula and the FAO/WHO report *Enterobacter sakazakii* and other microorganisms in powdered infant formula: meeting report, MRA Series 6. ISBN: 92 4 156262 5 (WHO). Country comments were also received electronically from members of the working group. The Proposed Draft Code is attached for the Committee's review.

The working group suggested changing the title to the *Proposed Draft Recommended International Code of Practice for Powdered Infant Formula* as the revised Code covers exclusively powdered products used for infants. It is also suggested that the Code replaces the *Recommended International Code of Hygienic Practice for Foods for Infants and Children - CAC/RCP 21-1979*. Hygiene recommendations for foods for infants and children other than powdered infant formula, covered by the previous document, are considered to be appropriately covered by the *General Principles of Food Hygiene* and other existing Codes of Hygienic Practices.

The working group proposed Microbiological Specifications for Powdered Infant Formula as per the Annex I of the Code which includes 2-class plans for Enterobacteriaceae and *E. sakazakii.* Some members of the working group expressed the desire to consider further the proposal with their government or organization, and, particularly, to compare the proposed 2-class plan for Enterobacteriaciae with a 3-class plan. The representative from ICMSF agreed to provide further information regarding this aspect. The information is included in the Annex I for further consideration by the Committee.

Appendix

PROPOSED DRAFT RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR POWDERED INFANT FORMULA

(Intended to replace the Recommended International Code of Hygienic Practice for Foods for Infants and Children - CAC/RCP 21-1979)

INTRODUCTION

Powdered infant formula has been safely consumed by infants for more than 50 years and constitutes over 80% of the infant formula used worldwide. The powder form offers some advantages compared to the liquid form particularly for its lower cost. However, it is important to note that powdered infant formula meeting current standards is not a sterile product and may contain low levels of (opportunistic) pathogens. It is not feasible, using current processing technology, to eliminate completely the potential for microbial contamination. A review of the available scientific information reveals that, in rare cases, contamination of powdered infant formula with *Enterobacter sakazakii* and *Salmonella* has been a cause of colonization, illness and death in infants.

While the incidence of *E. sakazakii* infections in infants appears to be low, the consequences can be severe. Most reported cases have involved infants, however, reports have also described infections in children and immunocompromised adults. Reported fatality rates of *E. sakazakii* infections in infants vary considerably with rates as high as 50 percent reported in at least one instance. Infections from *E. sakazakii* have been documented as both sporadic cases and outbreaks. It is the latter that has led to the link with powdered infant formula, especially in the context of neonatal intensive care settings. *Enterobacter sakazakii* is known to be present in a proportion of powdered infant formula. Clearly, developing and adhering to appropriate risk-reduction strategies are warranted.

The group at particular risk is infants (i.e., children <1 year). Among infants, those who are immunocompromised and neonates (<28 days) are considered to be at greatest risk, particularly neonates of low birth weight (<2 500 g). Infants of HIV-positive mothers are also of concern because they may specifically require infant formula and may be more susceptible to infection[1].

SECTION I. - OBJECTIVES

The objective of this Code is to identify principles of food hygiene in the food chain, from manufacturer to consumer, that are essential to ensure the safety of powdered products used for infants. These products are specifically manufactured and presented to be used either as breast-milk substitutes, to modify prepared breast-milk substitutes or to fortify human milk.

The Code provides guidance on hygiene requirements specific to the manufacturing of these products using a wet-mix or a dry-mix process, or a combination thereof, with special attention being paid to environmental monitoring. The major issues are covered under Section V, Control of Operation, outlining the manufacturing aspects of powdered products and Section IX, Product Information and Consumer Awareness, highlighting the fact that powdered products used for infants are not sterile and providing specific guidance for the handling and storing of such products after reconstitution.

SECTION II. - SCOPE, USE AND DEFINITIONS

II.1 SCOPE

[1] *Enterobacter sakazakii* and other microorganisms in powder infant formula: meeting report, MRA Series 6. ISBN: 92 4 156262 5 (WHO)

This Code covers products in powdered form specifically manufactured to be used for infants 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 and human milk fortifiers. This Code also covers the above-mentioned products when used as ingredients in other infant foods (e.g. powdered infant formula as an ingredient of cereal-based foods for infants).

II.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 (hereby referred to as the *General Principles of Food Hygiene*) and should be used in conjunction with it, including its Annex on *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application*. Sections for which the *General Principles of Food Hygiene* provides adequate guidance and recommendations are not repeated in this text. Sections for which additional guidance and recommendations are required are complemented with additional text or replaced by new text.

II.3 DEFINITIONS

Infant - a person not more than 12 months of age (Codex Standard for Infant Formula, Codex STAN 72-1981 (amended 1983, 1985, 1987), currently under revision at step 6 of the Procedure (Appendix IV of Alinorm 05/28/26,).

Infants at greatest risks - infants who are immunocompromised and neonates (<28 days), particularly neonates of low birth weight (<2 500 g)[2].

Infant formula - as defined in the Codex Standard for Infant Formula, Codex STAN 72-1981 (amended 1983, 1985, 1987), currently under revision at step 6 by the CCNFSDU).

Follow-up formula - as defined in the Codex Standard for Follow-up Formula, Codex STAN 156-1987 (amended 1989).

Formula for special medical purposes intended for infants – as defined in the Draft Revised Codex Standard for Infant Formula and formulas for Special Medical Purposes Intended for Infants, Section B, at step 3 of the Procedure (Appendix IV (B) of Alinorm 05/28/26).

Human milk fortifier - product added to human milk for feeding low-birth weight and premature infants. It provides enriched nutrition needed by these special babies while still allowing them to receive their mother's milk. It increases the levels of protein, energy, calcium, phosphorus, or other nutrients, producing a diet more suited to the nutritional needs of these infants.

Wet-mix process - process by which all constituents of the infant formula are handled in a liquid phase, heat-treated, concentrated by evaporation, homogenized and then dried.

Dry-mix process - process by which all constituents of the infant formula are processed dry and blended to obtain the desired final formula.

Combined process - 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.

[2] *Enterobacter sakazakii* and other microorganisms in powder infant formula: meeting report, MRA Series 6. ISBN: 92 4 156262 5 (WHO)

SECTION V. - CONTROL OF OPERATION

V.1 CONTROL OF FOOD HAZARDS

Manufacturers should control food safety hazards through the use of a HACCP system (refer to the Annex *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application* of the *General Principles of Food Hygiene*. A system based on expert advice and involving documentation would be appropriate. In particular, manufacturers should:

- **identify** any steps in their operations which are critical to the safety of powdered products used for infants;
- **implement** effective control procedures at those steps;
- **monitor** control procedures to ensure their continuing effectiveness; and
- **review** control procedures periodically, and whenever the operations change.

Control processes and procedures should include the necessary steps to address all aspects of the production, particularly, the liquid part up to the drying process, the dry part from the drying to the filling stage and the dry blending, when used. Typically, Critical Control Points (CCPs) would include a microbiocidal step.

V.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

V.2.1 Time and temperature control

Refer to the *General Principles of Food Hygiene*. In addition:

Temperature recording devices should be checked at regular intervals, tested for accuracy by routinely calibrating against a reference instrument. If a continuous chart recording is maintained, the chart should include the date and batch number, location of recorder, reading of the indicating thermometer, amount and type of product, signature or initials of operator, record of unusual occurrences.

For raw milk and other foods requiring refrigeration, appropriate temperature control and monitoring is required.

V.2.2 Specific process steps

Powdered infant formula is typically manufactured using a wet-mix, dry-mix or combined process. The process used should ensure that the appropriate level of nutritional components is met. Steps that contribute to food hygiene include:

- Chilling

  For wet-mix process:

  Certain intermediate liquid products may be stored at low temperature before drying. Appropriate chilling to the required combination of time/temperature is necessary.

- Thermal processing

  For wet-mix process:

  If some raw ingredients are used, such as raw milk, and likely to be contaminated with microorganisms, effective control measure such as a heat treatment is necessary.

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).

The heat process applied should achieve an appropriate reduction of vegetative microorganisms.

- Drying

  For wet-mix process:

  A drying process is used to convert the liquid mixture into a dry powder. This is typically done using a spray dryer 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 kill step. Spray driers, conveyors and sifters should be constructed with no projecting flanges, rods, braces or dead spaces where material may accumulate. Drier exhausts should be equipped to prevent fine powder residues in the surrounding areas. The drying step needs to be done under strict hygienic conditions to avoid microbial contamination of the final product.

- Air chilling

  For wet-mix process:

  During the drying process, the powder should pass from a drying chamber to a fluidized cooling bed where it is quickly cooled in an appropriate manner, for example, using cool air filtered through High Efficiency Particulate Air (HEPA) filters (EU ≥ 10). Air filters should be tightly fitted and properly sealed against 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 changed or cleaned and sanitized regularly.

- Blending

  For dry-mix and combined processes:

  Blending should be done under strict hygienic conditions to avoid contamination of the final product. Dry ingredients used at this stage should have been subjected to a thermal process (see above) at an appropriate point in their manufacture.

- Packaging

  Upon completion of the drying and/or blending steps, the final product is filled into cans or flexible containers. This step needs to be done under strict hygienic conditions to avoid contamination of the final product.

V.2.3 Microbiological and other specifications

Refer to the *General Principles of Food Hygiene*. In addition:

The main microbiological issues associated with powdered infant formula are related to the presence of *Salmonella* and other *Enterobacteriaceae*, including *E. sakazakii*. In addition, manufacturers may consider testing for other appropriate microorganisms. Microbiological specifications relevant to powdered infant formula are listed in Annex I.

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 should be supplemented, as necessary, by microbiological testing based

on random sampling and analysis. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, production line, environment and finished products. Verification procedures using environmental testing for powdered infant formula are described in Annex II.

When monitoring of control measures demonstrates deviations, the product should not be released until adequate verification has shown that it complies with appropriate microbiological specifications.

V.2.4 Microbiological cross-contamination

Refer to the *General Principles of Food Hygiene*. In addition:

Raw or unprocessed foods should be physically separated from ready-to-eat foods. Where possible, packaged raw materials 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. Equipment should be cleaned and disinfected appropriately.

Pathogens such as *Salmonella* and *E. sakazakii* can become established in niche environments in powdered infant formula manufacturing plants. These niche environments 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 their 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.

As much as possible, dry conditions should be maintained in drying, blending and packaging areas. This can be achieved by eliminating any water sources and applying dry cleaning procedures for the processing lines, equipment and the processing environment. Wet cleaning should be minimized and limited to parts of equipment that can be taken out to a dedicated room and where adequate drying parameters are applied.

V.2.5 Physical and chemical contamination

Refer to the *General Principles of Food Hygiene*. In addition:

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.

V.3 INCOMING MATERIAL REQUIREMENTS

Refer to the *General Principles of Food Hygiene*. In addition:

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.

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 by carefully selecting suppliers, completing audits to assess the suppliers' processes, controlling and monitoring procedures, and periodic evaluations of incoming ingredients.

V.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 must be approved for food contact and 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.

V.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.

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 cleaning practices and sanitation processes; and the application of microbiological monitoring plans including all sampling and testing.

V.8 RECALL PROCEDURES

Refer to the *General Principles of Food Hygiene*. In addition:

As powdered infant formula 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.

SECTION VI. – ESTABLISHMENT: MAINTENANCE AND SANITATION

VI.5 MONITORING EFFECTIVENESS

Sanitation systems should be monitored for effectiveness and periodically verified by pre-operational inspections / audits and microbiological sampling of environment and food contact surfaces. Sanitation systems should be verified and regularly reviewed and adapted to reflect changed circumstances such that sources of contamination are identified and corrected in a timely manner. Verification Procedures Using Environmental Testing for Powdered Infant Formula are given in Annex II.

SECTION IX. - PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:

Products should bear appropriate information to ensure that:

- adequate and accessible information is available to all concerned in the food chain, in particular, retail establishments, caregivers of infants in the home, day care and health-care facilities and health-care professionals to enable them to handle, store, process, prepare and display, powdered infant formula safely and correctly; and

- the lot or batch can be easily identified, and recalled if necessary.

Caregivers of infants in the home, day care and health-care facilities and health-care professionals should be informed that the product does not undergo a sterilization process and should be provided with sufficient information on food hygiene to enable them to:

- make informed choices appropriate to the infant; and

- prevent contamination and/or growth of foodborne pathogens by storing, preparing and using powdered infant formula correctly.

Specific information should be provided regarding the use of powdered infant formula for infants at greatest risk.

RATIONALE:

Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead-to powdered infant formula being mishandled at later stages in the food chain. Such mishandling can result in illness, even when adequate hygiene control measures have been taken earlier in the food chain.

IX.3 LABELLING

Refer to the *General Principles of Food Hygiene*. In addition:

Labels should be considered on products, reminding those who prepare formula and who feed infants that powdered infant formulas do not undergo a sterilization process. Therefore, the label should contain appropriate information regarding the need for proper preparation, handling and storage of reconstituted powdered infant formula to prevent or minimize bacterial growth.

IX.4 EDUCATION

Health education programs should cover general food hygiene. The development and distribution of educational documents related to powdered infant formula 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 any product information, ii) following any instructions accompanying products, and iii) making informed choices.

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 powdered infant formula is not a sterile product and may be contaminated, on occasion, with extremely low levels of pathogens that can cause serious illness in case of mishandling or improper storage of reconstituted infant formula.

Information/education about necessary hygiene practices in relation to preparation, handling and storage at home, in hospitals, day care or other settings should be emphasized, particularly regarding the relationship between time/temperature control and foodborne illness. It should be emphasized that the improper handling and storage of reconstituted powdered infant formula can promote the growth of pathogens (e.g. *Salmonella*, *E. sakazakii*, and possibly other microorganisms such as sporeformers) which may be present initially at low levels.

It should be noted that the addition of other ingredients to infant formula (whether in powder or liquid form) may also present a potential for contamination which may require more stringent preparation and storage conditions than that for commercially-manufactured powdered infant formula.

In situations where the mother cannot breastfeed, chooses not to breastfeed or when banked human milk is not available, the following points should be communicated to caregivers of infants in the home, day care and health-care facilities and health-care professionals to increase awareness. These elements should be considered in making informed choices appropriate to the infant.

- They should be informed that powdered infant formula may be contaminated with extremely low levels of pathogens that can cause rare but serious illnesses, particularly for infants at greatest risk.

- When feasible, the use of commercially available sterilized liquid products should be used as a replacement for powdered infant formula when feeding infants at greatest risk, particularly neonates of low-birth weight (<2 500 g).
- When using and handling powdered infant formula, the following should be emphasized to minimize risk:
  - ◊ Strictly adhere to manufacturer's instructions.
  - ◊ Reconstitute and feed immediately, particularly when adequate refrigeration is not available;
  - ◊ Minimize the length of time between reconstitution and consumption of powdered infant formula. Attention should be paid to the length of time that formula is: i) kept at room temperature ii) stored in the refrigerator [a maximum of 6 °C for 24 h], and iii) retained after feeding has begun[3];
  - ◊ Leftovers of reconstituted infant formula should be discarded.

For health-care providers/professionals and hospitals:

- When feasible, the use of commercially available sterilized liquid products should be used as a replacement for powdered infant formula when feeding infants at greatest risk, particularly neonates of low-birth weight (<2 500 g). Reconstituted formula which has undergone an effective final decontamination procedure could also be used in a hospital setting (e.g., use of a commercial steamer in formula preparation).
- Guidelines should be developed by hospitals for the preparation, use and handling of powdered infant formula to minimize risk. These should consist of:
  - ◊ Using aseptic preparation techniques.
  - ◊ Cleaning and disinfection of equipment used in the preparation of powdered infant formula.
  - ◊ Cleaning and disinfection of bottles, nipples and enteral feeding lines.
  - ◊ Using sterile or boiled water as appropriate.
  - ◊ Portioning into appropriate containers immediately after preparation.
  - ◊ Labelling containers with the date, time, and name of the product.
  - ◊ Ensuring a rapid cooling of reconstituted product and storage [a maximum of 6°C] if not for immediate use.
  - ◊ Keeping a daily record of the product and lot number.

[3] Risk assessment modelling of time and temperatures may provide guidance.

Annex I

MICROBIOLOGICAL SPECIFICATIONS FOR POWDERED INFANT FORMULA

Microbiological specifications 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.

These criteria are to be applied to the finished product (powder form):

Microorganism	n	c	m	M	Class Plan
Mesophilic Aerobic Bacteria*	5	2	10^3/g	10^4/g	3
[Enterobacteriaceae]**	10	0	0/10 g	0/ g	2
[*Enterobacter sakazakii*]	30	0	0/10 g	0/ g	2
*SALMONELLA******	60	0	0/25 g	0/ g	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.
** Reductions in the levels of Enterobacteriaceae in powdered infant formula will lead to lower levels of *E. sakazakii*.
*** The current requirements for *Salmonella* is considered adequate.
ISO methods are to be used for all determination listed above.

Comparison of Proposed 2-Class plan for Enterobacteriaceae to 3-Class Plan

The representative from ICMSF took the initiative to compare the performance of a possible 3-class plan for Enterobacteriaceae to see if this would represent an alternative option to the proposed 2-class plan. This information is provided below for the Committee's consideration.

The following tables show the relative stringency of various 3-class plans in terms of the probability of rejecting a lot on the correct basis if the mean concentration was 1 in 25g (or –1.39 log) for various 3-class plans (Table 1) as well as the mean concentration that would be rejected with 95% probability for different 3-class plans (Table 2). Both tables assume a log normal distribution with a standard deviation of 0.8.

In order to achieve an equivalent stringency to the proposed 2-class plan, a 3-class plan would have to be, for example, n=15, m= 0.1/g, M=1/g and c=1. The practicalities of using such a plan with m=0.1/g may be difficult and from an analytical standpoint the proposed 2-class plan would be easier to handle.

Table 1. Probability of rejecting a lot if the mean concentration is 0.04 CFU/g (–1.39 log) for Different 3-Class Sampling Plans

		m =10/g M =100/g					m = 1/g M=10/g					m = 0.1/g M=1/g				
	n	5	10	20	30	60	5	10	20	30	60	5	10	20	30	60
C=0	P_r	.01	.01	.03	.04	.08	.19	.34	.57	.78	.92	.85	.98	1.0	1.0	1.0
C=1	P_r	.00	.00	.00	.00	.00	.02	.07	.21	.36	.72	.54	.88	1.0	1.0	1.0

Table 2. Mean concentration that would be rejected with a 95% probability for different 3-Class sampling plans

3-Class Plan	Mean Concentration Rejected with 95% Probability
n=10, m=0.1/g, M=1/g, c=1	-1.24 log (1 in 17g)
n=10, m=0.1/g, M=1/g, c=2	-1.05 log (1 in 11g)
n=15, m=0.1/g, M=1/g, c=1	-1.48 log (1 in 30g)
n=15, m=0.1/g, M=1/g, c=2	-1.32 log (1 in 20g)
n=10, m=1.0/g, M=10/g, c=1	-0.24 log (1 in 1.7g)
n=10, m=1.0/g, M=10/g, c=2	-0.05 log (1 in 1.1g)
n=15, m=1.0/g, M=10/g, c=1	-0.48 log (1 in 3g)
n=15, m=1.0/g, M=10/g, c=2	-0.32 log (1 in 2g)

Annex II

VERIFICATION PROCEDURES USING ENVIRONMENTAL TESTING FOR POWDERED INFANT FORMULA

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 environmental contamination. Environmental monitoring of Enterobacteriaceae provides baseline levels and therefore allows the tracking of changes over time. It can be reasonably anticipated that a reduction in the levels of the Enterobacteriaceae in the environment will correspondingly lead to lower levels of Enterobacteriaceae (including *E. sakazakii*) in the finished product. Tracking the levels of the 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.

A food safety control system incorporating prerequisite programs such as good hygienic practices and a HACCP program should be in place. Verification and monitoring methods, procedures and tests, including random sampling and analysis, should be used to determine if the food safety control system is performing correctly.

Verification may be performed through testing of different types of samples:

- Finished product;

- food-contact surfaces;

- non-food contact surfaces.

Verification of finished product and product-contact surfaces should be based on the use of Enterobacteriaceae as an indicator. In the case of a positive sample, testing for *E. sakazakii* should done.

Verification of environmental samples should be based on the enumeration of the Enterobacteriaceae and the establishment of internal microbial limits. A pre-established action plans should be set by the company.

Sampling tools and techniques

It is important to adapt the type of sampling tools and techniques to the type of surfaces and sampling locations. For example, humidified sponges may be used for large flat surfaces, swabs may be more appropriate for cracks and crevices, scrapers for hard residues and vacuum cleaners for dusty residues.

Analytical methods

The analytical methods used for the analysis of samples taken from food-contact and non-food contact surfaces should be suitable for the detection and/or enumeration of Enterobacteriaceae, and for *E. sakazakii,* if necessary. Considering the importance of environmental samples, it is important to validate that the methods are able to detect and identify the target organisms. This should be documented appropriately.

Data management

The verification procedures should include a system to record and evaluate the data, e.g., performing trend analyses. A long-term review of the data is important to revise and adjust verification programs.

Actions in case of positive results

The purpose of the verification procedures is to track Enterobacteriaceae in the environment. Two situations, which trigger different pre-established action plans, should be considered:

(1) Positives samples from food contact surfaces should be considered as equivalent to positive samples in finished products and should be managed according to a pre-established action plan. The plan should define the specific actions and the rationale. This should include, as appropriate, rejecting product for use as infant formula or reprocessing.

(2) Levels above baseline levels in samples of non-food contact surfaces should be managed according to a pre-established action plan. This plan should define the specific actions and the rationale. This could range from no action (no risk of contamination), to intensified cleaning, point source tracing (increased environmental testing), or review of hygienic practices up to holding and testing of the finished product.

Note: The approach described in this annex can be applied to *Salmonella*.