

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 11

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-sixth Session

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#### DISCUSSION PAPER ON THE PROPOSED DRAFT REVISION OF THE RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN

*Prepared by Canada with the assistance of Finland, France, Germany, the Netherlands, Switzerland, the United Kingdom, the United States, International Commission on Microbiological Specifications for Foods (ICMSF) and International Special Dietary Industries (ISDI)*

#### BACKGROUND:

At the last meeting of the Codex Committee on Food Hygiene (35<sup>th</sup> Session, January 2003), the Committee agreed to revise the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979), particularly for dried infant formula. The Committee requested Canada to initiate work towards the revision of the Code with the help of a drafting group composed of Finland, France, Germany, the Netherlands, Switzerland, the United Kingdom, the United States, ICMSF and ISDI for further consideration at its 36<sup>th</sup> Session.

The Committee also agreed that the United States would update the Risk Profile of *Enterobacter sakazakii* in Powdered Infant Formula (CX/FH 03/13). In addition, FAO and WHO were requested to convene an expert consultation on the *Enterobacter* genus, including *E. sakazakii*, and *Clostridium botulinum*, at the earliest opportunity, subject to the provision of adequate funding.

#### I. PRELIMINARY REVIEW:

The drafting group initiated a review of the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) and made the following observations:

- The Scope includes all prepackaged foods produced, represented or purported to be for the special use of infants and/or children. Infant is defined as a person not more than 12 months of age, and children, as persons from the age of more than 12 months up to the age of three years.
- The Code provides general recommendations on hygienic practice for foods for infants and children, however, there are no specific recommendations regarding infant formula.
- The recommendations of the Code are not more stringent or more specific than those laid out in the Recommended International Code of Practice, General Principles of Food Hygiene

(CAC/RCP 1-1969, Rev. 3-1997, Amd. 1999) (General Principles). In addition, the Code does not reflect changes made to the 1999 version of the General Principles, including its Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application.

- Only sections 8.3 and 8.4 of the Code regarding Microbiological Specifications and Methods of Microbiological Analysis for Foods for Infants and Children, deal specifically with foods for infants and children.

## II. PROPOSED APPROACH FOR CONSIDERATION BY CCFH:

The drafting group was tasked to initiate work towards revision of the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979) particularly for dried-infant formula. The outcome of the meeting on *Enterobacter sakazakii* and other Microorganisms in Powdered Infant Formula, scheduled to be held in Geneva, Switzerland, 2 - 5 February 2004, will be used to initiate the work. However, in light of the above preliminary review, the drafting group would like to seek further guidance from the Committee regarding the degree of revision deemed appropriate, particularly with regard to its scope, as there might be a need to include more commodities for the use of infants and children.

The drafting group suggests the following approach to be considered:

1. Identify food hygiene issues specific to any prepackaged foods produced, represented or purported to be specifically manufactured for the use of infants and/or children, in addition to those related to dried-infant formula.
2. Examine if existing Codex Codes of hygienic practice adequately address the issues identified, or if there is a need for additional guidance. A particular consideration should be given to the General Principles, the annex on HACCP and the Principles for the Establishment and Application of Microbiological Criteria for Foods, as all these address many of the general hygiene issues relevant to foods for infants and children.
3. If additional guidance is needed, assess the degree of revision necessary to be made to the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979). The revised text should include recommendations relative to products of concern identified by the Committee, in addition to dried-infant formula (as identified in step 1 above), which are not already appropriately covered by Codex codes and guidelines (as referred to in step 2 above).

## III. RECOMMENDATIONS FROM THE DRAFTING GROUP:

The drafting group considers it important to include, in addition to *E. sakazakii* in dried-infant formula, other *Enterobacter* species and *C. botulinum* as deemed appropriate, following the *Scientific Advice on Pathogens of Concern in Infant Formula* workshop.

The most relevant pathogens are *Salmonella* spp. (for all age categories) and *C. botulinum* (up to 12 months; infant botulism), followed by opportunistic *Enterobacteriaceae* such as *E. sakazakii*, as well as *Clostridium diversus* (premature infants and up to 4/6 months). In the context of HACCP, a number of other microbiological hazards may need to be considered (e.g., *Listeria monocytogenes*, *Staphylococcus aureus*, *Bacillus cereus*, *Clostridium perfringens*) and controlled by appropriate processing steps.

The drafting group identified food products that could feed into the step 1 analysis described in Section II above. The Committee should determine, however, whether existing Codex codes of hygienic practice adequately address the products identified, or if there is a need for additional guidance (as suggested in Section II, step 2). The suggested products to possibly be included are as follows:

- dry-infant cereals,
- biscuits for infants,
- chilled and/or frozen minimally processed pureed baby foods,
- certain dairy products marketed as suitable for infants,
- baby food in jars and cans, including juice,
- heat treated liquid infant formula, and
- honey if used as a sweetener in these food categories.

#### **IV. PROPOSED OUTLINE OF THE PROPOSED DRAFT REVISED RECOMMENDED INTERNATIONAL CODE OF HYGIENIC PRACTICE FOR FOODS FOR INFANTS AND CHILDREN:**

A proposed outline is suggested to consider the hygienic issues associated with dried-infant formula, and other foods for infants and children as identified by the Committee.

#### **CONTENTS**

The Table of Contents would follow the Recommended International Code of Practice, General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3-1997, Amd. 1999). Only recommendations additional to the General Principles would be included. Special considerations should be given to:

##### **SECTION I - OBJECTIVES**

Specific objectives of the Recommended International Code of Hygienic Practice for Foods for Infants and Children should be clearly stated.

##### **SECTION II - SCOPE, USE AND DEFINITION**

A clear statement whether the Code includes several types of foods for infants and children or only powdered infant formula. Under the Scope, the phrase “for the special use of infants and children” should be changed to “particularly intended for the use of infants and young children” to improve clarity and harmonize with the Codex Standard for Canned Baby Foods (STAN 73-1981, amended 1985, 1987, 1989) which defines young children as “persons from the age of more than 12 months up to the age of three years”. Consequently, in Definitions, it is recommended that the term “children” be replaced by “young children”.

It may be necessary to determine whether the two age categories currently considered (persons not more than 12 months of age and persons from the age of more than 12 months to the age of 3 years) are sufficient. There may be a need to complement age categories by including specific reference to premature or debilitated infants which have greater sensitivities.

##### **SECTION V - CONTROL OF OPERATION**

This section should list the types of processes involved based on the food items included in the Scope (e.g., infant formula, dry cereals, purees) as appropriate. The key aspects to control specific hazards involved with foods for infants and children (e.g., *E. sakazakii* in powdered infant formula) should be included in this section. Recommendations may be needed to address specific challenges, such as controlling *E. sakazakii* in food establishments, the role of air and dust sampling where appropriate, and the importance of selection/specification of raw materials, notably where normal processing may be insufficient to control the hazard.

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**SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS**

In particular, specific handling procedures for consumers and personnel in hospital environments should be addressed, as appropriate. Emphasis should include information to limit contamination of the product during preparation and to prevent abusive storage and handling conditions (e.g., specific instructions for preparing infant formula and storing and handling re-hydrated infant formula).

**SECTION X - TRAINING**

This section should include, in particular, the training of personnel preparing, storing and using foods for infants and children (e.g., hospital employees using infant formula).