



Food and Agriculture
Organization of
the United Nations



World Health
Organization

JOINT FAO/WHO ACTIVITIES ON RISK ASSESSMENT OF MICROBIOLOGICAL
HAZARDS IN FOODS

January 2008

Call for data

***Enterobacter sakazakii* in follow-up formulae**

Deadline 14 April 2008

Background

The 39th session of the Codex Committee on Food Hygiene Committee (CCFH) made substantial progress on the development of the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. The Committee finalized and agreed to forward the proposed draft Code including Annexes I (Microbiological criteria for powdered infant formulae, formulae for special medical purposes and human milk fortifiers) and III (Guidance for the establishment of monitoring programs for *Salmonella*, *Enterobacter sakazakii* and other Enterobacteriaceae in high hygiene processing areas and in powdered formulae preparation units), for final adoption by the Commission at Step 5/8 with the recommendation to omit Steps 6 and 7.

However, in doing so the Committee also agreed to return Annex II, which specifically addresses microbiological criteria for follow-up formulae to Step 2 for further revision. This decision was preceded by a lengthy discussion on the establishment of microbiological criteria for *E. sakazakii* for follow-up formulae intended for infants up to 12 months of age. Positions on this were clearly divided with several delegations expressing the opinion that follow-up formulae should be excluded, since there was no scientific justification for criteria on *E. sakazakii* for this type of product, while others considered that this product needed to be included because the criteria developed were based on the available scientific information and that it was important to take precaution in this instance. In the course of the discussion it was clarified that, to date, in the elaboration of scientific advice on *E. sakazakii* in powdered infant formula, FAO and WHO had not given separate consideration to powdered infant formula versus follow-up formula as this had not been identified as an issue for consideration in the initial request for scientific advice. Given the differences of opinion on this issue within the Committee, it was agreed to submit a specific request to FAO and WHO for scientific advice to facilitate the Committees' decision on whether or not to establish a microbiological criterion for *E. sakazakii* for follow-up formulae intended for infants up to 12 months of age.

Thus, following an extensive discussion, the Committee requested FAO/WHO to collate and review available data and then to convene an expert meeting to address a number of specific questions as follows:

- What is the number and incidence rate of confirmed *E. sakazakii* infection in infants up to 12 months, presented by month, as compared to the incidence rate in all other age groups, including young children (12 – 36 months), older children and adults?
- Critically review all documented cases of confirmed *E. sakazakii* infections in infants between 6 and 12 months of age and consider specifically i) the clinical history and outcomes as well as ii) the strength of the descriptive, epidemiological and/or microbiological evidence concerning the origin or source of these infections?
- Estimate the relative risk of *E. sakazakii* infections in infants 6 – 12 months of age, associated with the consumption of follow-up formula, as well as any other sources as identified in the previous question?
- What is the number and incidence rate of immunocompromised infants up to 12 months, presented by month, as compared to the number and incidence rate of immunocompromised in all other age groups, including young children (12 – 36 months), older children and adults and does this vary regionally?
- Taking into consideration the information generated in the above four questions, and given the application of risk management options as advocated in the Code, what is the relative risk reduction achieved by the application of microbiological criteria, as proposed in Annex 1 of the Code, to follow-up formula?
- Identify and describe active and passive surveillance systems for *E. sakazakii* in countries.
- What is the proportion of infants less than 6 months of age that consume follow-up formula and does this vary regionally?

In order to address these questions FAO and WHO have identified a range of data needs. Member countries, interested international organizations, industry, academia, non-governmental organizations and any other interested parties are requested to carefully review the data needs listed below and submit any available data to the FAO/WHO JEMRA secretariat. Such information is critical to the provision of appropriate and relevant scientific advice to the Codex Committee on Food Hygiene.

Information should be sent (preferably in word file) to the addresses indicated below by **14 April 2008**.

Data is requested on the following issues. Specific questions are included under each of the issues, to assist you in responding to this Call for data.

1. Incidence and number of *E. sakazakii* infections in all age groups

- a. Have there been any cases or outbreaks of *E. sakazakii* illness in your country in any age group of the population in the last 10 years? If so please indicate the following:
- i. The date.
 - ii. The number of people affected including their age (in months up to 12 months; and in years for subsequent age groups).
 - iii. The health and immune status of the patients.

- iv. The clinical history and outcome of infection (type of illness, long term impact etc.).
 - v. Whether the case / outbreak was “confirmed” or “suspected” and how this was determined (e.g. through laboratory confirmation, epidemiological investigations, identification of risk factors etc.).
 - vi. The implicated commodity, including any details of production, processing, distribution, storage and use (e.g. preparation for consumption, where and how it was consumed) where available and, if determined, the source of contamination of the commodity.
 - vii. Follow-up actions taken to stop the outbreak and /or prevent new outbreaks of this type.
 - viii. Details of any reports or references describing the case/outbreak and related investigations (published or unpublished).
- b. Does your country have an operational foodborne disease surveillance system in place?
- i. Has this been successful in identifying cases of foodborne illness caused by *E. sakazakii*?
 - ii. If not, is there any system in place that would facilitate the detection of foodborne disease linked to *E. sakazakii*?(e.g. infectious diseases surveillance programme etc.)
- c. Is illness due to *E. sakazakii* a notifiable disease in your country?

2. Number and Incidence of immunocompromised people in the population

- a. What is the number and incidence rate of immunocompromised infants up to 12 months of age in your country (if possible please provide this information on a month by month basis i.e. incidence and number of immunocompromised 1 month olds, incidence and number of immunocompromised 2 month olds etc.)?
- b. What is the number and incidence rate of immunocompromised people in all other age groups, including young children (12 – 36 months), older children and adults?
- c. Is there any geographical, socio-economic or gender-related variation in the number and incidence of immunocompromised people in your country?

3. Consumption of follow-up formulae

- a. Is follow-up formula available in your country? If so, is it locally produced or imported?
- b. If follow-up formula is available, for what age-group is it marketed.
- c. What proportion of infants (< 12 months) consumes follow-up formula in your country? At what age does consumption of follow-up formula begin? What proportion of infants less than 6 months of age consumes follow-up formula? What is the volume and proportion of follow-up formula consumed annually by infants less than 6 months of age, infants 6 - 12 months and young children (1 – 3 years)?

4. Manufacture of follow-up formula

- a. Is follow-up formula produced in your country or are you a producer of follow-up formula? If so, please provide information on the number of manufacturers and / or the range of follow-up

formula products, the volume of production, the proportion that goes into international trade and whether it is exported pre-packaged or for repackaging?

b. If you answered yes to the previous question please provide information on the current industry practices (methodology of manufacturing, time & temperature combinations of heat treatments, cleaning and disinfecting practices for the equipment etc) and any specific differences that exist between the production of powdered infant formula and follow-up formula.

c. Please provide information on the frequency and levels of contamination of follow-up formula with *E. sakazakii* (last 10 years).

5 Contact person for follow-up and further details if needed

Provide name, title and full contact details. If appropriate, one contact name may be provided for each of the four areas on which information is requested.

Request for risk assessments and other relevant information

FAO and WHO are requesting governments, interested organizations, health care providers, industry, academia, laboratories and individuals to submit any available data on the specific areas indicated above. This data may be published or unpublished. Reference should be made to related published studies, where applicable.

Confidential and/or unpublished risk assessment

FAO and WHO recognize that some of the information and relevant data which is now required may be unpublished or of a confidential nature. With regard to unpublished information and data, this remains the property of the author for subsequent publication by the owner as original material. Unpublished confidential studies that are submitted will be safeguarded in so far as it is possible to do so without compromising the work of FAO and WHO. Specific issues relating to confidentiality should be discussed directly between the information and data owners and FAO/WHO. For these and other issues please contact FAO and WHO at the contacts provided below.

Deadline: Please submit any relevant information (electronic and / or hard copies) to either of the following addresses, not later than **14th April 2008**.

Contact Information:

Food Quality and Standards Service
Attention: JEMRA / Sarah Cahill
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**Dept. of Food Safety, Zoonoses and
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