codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-sixth Session
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JOINT FAO/WHO MEETING ON *ENTEROBACTER SAKAZAKII* AND OTHER MICROORGANISMS IN POWDERED INFANT FORMULA

Prepared by FAO and WHO

INTRODUCTION

1. The 35th session of the Codex Committee on Food Hygiene requested FAO and WHO 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 (Alinorm 03/13A). In response to this request FAO and WHO convened a meeting on *E. sakazakii* and other microorganisms in powdered infant formula in Geneva on 2 – 5 February 2004.

2. The meeting took into consideration the updated risk profile (CX/FH 04/12) and the discussion paper on the proposed draft revision of the recommended international code of hygienic practice for foods for infants and children (CX/FH 04/11) in its deliberations. The meeting aimed to provide input for the revision of the Recommended International Code of Hygienic Practice for Foods for Infants and Children. It also aimed to provide pertinent information to the Member countries of both organizations.

KEY FINDINGS

3. After reviewing the available scientific information the expert meeting concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* and *Salmonella* has been a cause of infection and illness in infants, including severe disease, and can lead to serious developmental sequelae and death. No link has been established between illness and other microorganisms in powdered infant formula.

4. E. sakazakii has caused disease in all age groups. From the age distribution of reported cases it is deduced that infants (children less than 1 year old) are at particular risk. Among infants those at greatest risk for *Enterobacter sakazakii* infection are neonates (up to 4 weeks of age), particularly pre-term infants, low-birth-weight infants or immunocompromised infants. Infants of HIV-positive mothers are also at risk both because they may specifically require infant formula and may be more susceptible to

infection[1]. This, and low birth weight, may be of particular concern for some developing countries, where the proportion of such infants is higher than in developed countries

5. It is important to note that powdered infant formula meeting current standards is not a sterile product and may occasionally contain pathogens. Even product meeting existing Codex standards, can be contaminated with pathogens that can cause serious illness. It seems not to be possible, using current technology, to produce commercially sterile powders or completely eliminate the potential of contamination.

6. E. sakazakii is an opportunistic pathogen emerging as a public health concern. Little is known about its ecology, taxonomy, virulence and other characteristics. Recent data, however, point to differences in the microbial ecology of *Salmonella* and *E. sakazakii*.

7. Data from industry and national control authorities indicate that the detection of *Salmonella* in finished powdered infant formula is rare. The current Codex specification for *Salmonella* is the absence of organisms in 60 samples of 25 grams each. *E. sakazakii* is more commonly found in the manufacturing environment, which is a potential source of post-pasteurization contamination. Specific criteria for *E. sakazakii* are not included in the current Codex Code.

8. Even low levels of contamination of *E. sakazakii* in powdered infant formula were considered to be a significant risk factor given the potential for multiplication during the preparation and holding time under certain conditions prior to consumption of reconstituted formula.

9. Based on a preliminary risk assessment, the inclusion of a lethal step at the point of preparation and a decrease in the holding and feeding times effectively reduced risk. A combination of intervention measures had the greatest impact.

RECOMMENDATIONS

10. The expert meeting made the following recommendations to FAO, WHO, Codex, and member countries. Some of these recommendations are based on the outputs of a risk assessment that was undertaken to evaluate control measures aimed at reducing the risk associated with the presence of pathogens (*E. sakazakii* and *Salmonella enterica*) in powdered infant formula.

11. Caregivers, particularly for infants at high risk, should be regularly alerted that powdered infant formula is not a sterile product.

12. Caregivers, particularly of high-risk infants, should be encouraged to use, whenever possible and feasible, commercially sterile liquid formula or formula which has undergone an effective point of use decontamination procedure (e.g. use of boiling water to reconstitute or by heating reconstituted formula)[2].

13. Guidelines should be developed for the preparation, use and handling of infant formula to minimize risk.

14. The infant food industry should be encouraged to develop a greater range of commercially sterile alternative formula products for high-risk groups.

[1] The UN guidance for these infants is that where replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding is recommended, and powdered infant formula may be an option. Some of these infants may be HIV-positive and thus immunocompromised

[2] Nutritional and other factors need to be considered, e.g. alteration of nutritional content, risk from burns due to handling boiling or hot water/formula, and potential for germination of bacterial spores. The formula should thereafter be cooled and handled appropriately**.**

15. The infant food industry should be encouraged to reduce the concentration and prevalence of *E. sakazakii* in both the manufacturing environment and powdered infant formula. To this end, industry should consider implementing an effective environmental monitoring programme and the use of *Enterobacteriaceae* rather than coliform testing as an indicator of hygienic control in factory production lines.

16. In revising its Code of Practice, Codex should better address the microbiological risks of powdered infant formula, including the establishment of appropriate microbiological specifications for *E. sakazakii* in powdered infant formula. No specific criteria was recommended as this was beyond the scope and capabilities of the meeting. The current microbiological specifications for *Salmonella* were considered by the meeting to be adequate, they are near the limit of practical microbiological testing. Promoting the use of use of *Enterobacteriaceae* rather than coliform testing as an indicator of hygienic control was also recommended.

17. FAO/WHO should address the particular needs of some developing countries, in establishing effective measures to minimize risk in situations where breast-milk substitutes may be used in exceptionally difficult circumstances, e.g. feeding infants of HIV-positive mothers.

18. The use of internationally validated detection and molecular typing methods for *E. sakazakii* and other relevant microorganisms should be promoted.

19. Investigation and reporting of sources and vehicles, including powdered infant formula, of infection by *E. sakazakii* and other *Enterobacteriaceae* should be encouraged. This could include the establishment of a laboratory-based network.

20. Research should be promoted to gain a better understanding of the ecology, taxonomy, virulence and other characteristics of *E. sakazakii* and on ways to reduce its levels in reconstituted powdered infant formula.

FOLLOW-UP

21. The report of the meeting is now being finalised and will be made available on the FAO and WHO webpages in mid March.

22. The committee is invited to consider the report in its entirety in revising the recommended international code of hygienic practice for foods for infants and children (CX/FH 04/11).

23. A more complex risk assessment model framework has also being developed. This has the potential to evaluate more complex scenarios and can be further developed if more detailed information and evaluations of risk management options are requested by the committee.