

## EXECUTIVE SUMMARY

Consistent with the need to provide safe feeding for all infants,<sup>1</sup> the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) jointly convened an expert meeting on *Enterobacter sakazakii* and other microorganisms in powdered infant formula (WHO, Geneva, 2-5 February 2004). The meeting was organized in response to a specific request to FAO/WHO for scientific advice from the Codex Committee on Food Hygiene 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.

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 which can lead to serious developmental sequelae and death. No link has been established between illness and other microorganisms in powdered infant formula, although such a link was considered plausible for other Enterobacteriaceae.

*E. sakazakii* has caused disease in all age groups. From the age distribution of reported cases, it is deduced that infants (children <1 year) are at particular risk. Among infants, those at greatest risk for *E. sakazakii* infection are neonates ( $\leq 28$  days), particularly pre-term infants, low-birth-weight infants or immunocompromised infants. Infants of HIV-positive mothers are also at risk, because they may specifically require infant formula and they may be more susceptible to infection.<sup>2</sup> 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.

It is important to note that powdered infant formula meeting current standards is not a sterile product and may occasionally contain pathogens. The meeting did not identify a feasible method, using current technology, to produce commercially sterile powders or completely eliminate the potential of contamination.

*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*.

<sup>1</sup> As a global public health recommendation, infants should be exclusively breastfed for the first 6 months of life to achieve optimal growth, development and health. Thereafter, to meet their evolving nutritional requirements, infants should receive nutritionally adequate and safe complementary foods while breastfeeding continues until up to 2 years of age or beyond. Infants who are not breastfed require a suitable breastmilk substitute, for example an infant formula prepared in accordance with applicable Codex Alimentarius standards. Information provided in this connection to mothers and other family members who need to use it should include adequate instructions for appropriate preparation and the health hazards of inappropriate preparation and use (WHO, 2002).

<sup>2</sup> 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.

Data from the infant food 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 g each. *E. sakazakii* is more commonly found than *Salmonella* in the manufacturing environment, which is a potential source of post-heat-treatment contamination. Specific criteria for *E. sakazakii* are not included in the current Codex Code.

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

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.

### **Summary of recommendations**

The expert meeting made recommendations to FAO, WHO, Codex, their member countries, NGOs and the scientific community. These are summarized below.

- In situations where infants are not breastfed, caregivers, particularly of infants at high risk, should be regularly alerted that powdered infant formula is not a sterile product and can be contaminated with pathogens that can cause serious illness; they should be provided with information that can reduce the risk.
- In situations where infants are not breastfed, caregivers 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).<sup>3</sup>
- Guidelines should be developed for the preparation, use and handling of infant formula to minimize risk.
- The infant food industry should be encouraged to develop a greater range of commercially sterile alternative formula products for high-risk groups.
- 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, the infant food 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.

<sup>3</sup> 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.

- In revising its code of practice, Codex should better address the microbiological risks of powdered infant formula and, if deemed necessary, include the establishment of appropriate microbiological specifications for *E. sakazakii* in powdered infant formula.
- FAO/WHO should address the particular needs of some developing countries and establish effective measures to minimize risk in situations where breastmilk substitutes may be used in exceptionally difficult circumstances, e.g. feeding infants of HIV-positive mothers or low-birth-weight infants.
- The use of internationally validated detection and molecular typing methods for *E. sakazakii* and other relevant microorganisms should be promoted.
- 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.
- Research should be promoted to gain a better understanding of the ecology, taxonomy, virulence and other characteristics of *E. sakazakii* and of ways to reduce its levels in reconstituted powdered infant formula.