



Version 4  
13 February 2004

## **Questions and Answers on *Enterobacter sakazakii* in powdered infant formula**

### **1. What is *Enterobacter sakazakii*? What diseases can the bacteria cause?**

*Enterobacter sakazakii* is a bacterium belonging to the family Enterobacteriaceae, which contains a number of bacterial species found in the human and animal gut and the environment. The microorganism has been implicated in outbreaks causing meningitis or enteritis, especially in infants. In the few outbreaks reported 20% to >50% of the infants who contracted the disease died. For survivors, severe lasting complications can result including neurological disorders. The outcome related to adult disease seems to be significantly milder.

### **2. Where does the bacterium come from? Does it also exist in the human gut?**

The natural habitat of *Enterobacter sakazakii* is not well understood. The bacterium can be detected in the gut of healthy humans, most probably as an intermittent guest. It can also be found in the gut of animals as well as in the environment.

### **3. How does infant formula get contaminated with *Enterobacter sakazakii*? Can other foods also be contaminated?**

Basically there are three routes by which *Enterobacter sakazakii* can enter infant formula:

- a) through the raw material used for producing the formula;
- b) through contamination of the formula or other dry ingredients after pasteurization; and
- c) through contamination of the formula as it is being reconstituted by the caregiver just prior to feeding.

*Enterobacter sakazakii* has been detected in other types of food, but only powdered infant formula has been linked to outbreaks of disease.

### **4. Which are the main groups at risk?**

*Enterobacter 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 (first 28 days), 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. 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 (see also Q10).<sup>1</sup>

## **5. How can this risk be minimized/reduced?**

The recent expert meeting recommended that caregivers to infants, particularly those at high risk (see Q 4.), should be regularly alerted to the fact that powdered infant formula is not a sterile product.

In situations where the mother cannot breastfeed, or chooses not to breastfeed for any reason, caregivers should use, whenever possible and feasible, commercially sterile liquid formula or include a decontamination step in the preparation of powdered infant formula (such as reconstituting with boiling water or heating reconstituted formula)<sup>2</sup>.

A preliminary risk assessment further indicated that reduced holding (time between rehydration of the formula and consumption) and feeding times for the reconstituted formula decrease the risk of infecting infants. A combination of control measures would have the greatest impact on reducing the risk.

With current technology it seems not to be possible to produce sterile powdered infant formula. However, recommendations are being made to the industry on how they can improve the safety of powdered infant formula.

## **6. Are there international standards for maximum levels of the bacterium? What level of safety do these standards ensure?**

The FAO/WHO Codex Alimentarius Commission sets international standards for food. Current Codex microbiological specifications for powdered infant formula limit the amount of bacteria called coliforms, which includes *Enterobacter sakazakii*. While this limit probably helps to prevent a number of outbreaks, it does not confer a sufficient level of safety as evidenced by outbreaks caused by powdered formula meeting the current specifications. Given new information on this emerging problem, the recent expert meeting recommended that Codex revise the international standard to better address the microbiological risks of powdered infant formula, including establishing a microbial specification for *Enterobacter sakazakii*.

## **7. Are there differences in the levels of *Enterobacter sakazakii* in infant formula depending on the producer?**

At the moment we do not have any data that would demonstrate any difference between the infant formulas of different producers.

## **8. Is the risk similar in all regions and countries?**

There have been reported cases of *Enterobacter sakazakii* infections due to contaminated infant formula in only a few developed countries. It is likely that there is a significant underreporting of infections in all countries. The absence of reports is probably due to a lack of awareness of the problem rather than an absence of illness. In general, the limitations of current surveillance systems in most countries would add to the explanation for the lack of reported cases. Since infant formula is

---

<sup>1</sup> The UN guidance for these infant 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 infant maybe HIV-positive and thus immunocompromised.

<sup>2</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. The formula should thereafter be cooled and handled appropriate.

widely used, the presence of *Enterobacter sakazakii* in infant formula and its potential effects in infants could well be a significant public health problem in most countries.

**9. Could there be other bacteria in infant formula that could cause problems, or is it only the *Enterobacter sakazakii*?**

The current Codex standards do not allow pathogens such as *Salmonella*, in powdered infant formula. The current Codex microbiological specification for *Salmonella* is the absence of *Salmonella* in 60 samples of 25 grams each. However, there have been reported outbreaks associated with *Salmonella* in powdered infant formula.

**10. Would these risks be avoided if an infant were breastfed instead of fed on infant formula?**

In the current state of knowledge, no exclusively breastfed infants have been reported to have *Enterobacter sakazakii* infections. Based on the available information, in 50-80 % of cases, powdered infant formula is both the vehicle and the source (direct or indirect) of *E. sakazakii*-induced illness. Breastfeeding is beneficial to infants in all instances. The WHO recommendation is that, on a population basis, infants should be exclusively breastfed for the first six months of life and that breastfeeding continue together with complementary feeding until the age of two years or beyond. There is ample evidence that infants who are partially or not breastfed are at significantly higher risk of morbidity and mortality due to diarrhoeal diseases.

Please also refer to Question 4 above, there are situations where the mother cannot breastfeed or chooses not to breastfeed.

**11. What is being done to remedy this problem?**

Since FAO and WHO first became aware of the issue, the two organizations have, together with Member countries, been working to gather data and expertise relevant to addressing this issue. This work started in 2003 and there is now good evidence on which to move forward. The FAO/WHO expert meeting, February 2004, in Geneva, examined what is known about production methods, risk factors, disease incidence, etc. and have now issued a set of recommendations to advise FAO/WHO, Codex and Member countries on relevant options to manage and avoid this risk (see Q5). A summary report of this meeting is available.

**12. What is the magnitude of the problem?**

The true magnitude of the problem is unknown due to lack of surveillance and reporting systems for *Enterobacter sakazakii* in most countries.

The magnitude of the problem is generally described in terms of frequency and severity. The frequency of the disease in infants appears to be very low, yet the disease is devastating.

A review of cases in infants reported in the English literature from 1961 to 2003 found 48 cases of *Enterobacter sakazakii* induced illness among infants. The US FoodNet 2002 survey found that the rate of invasive *Enterobacter sakazakii* infection among infants under one years old was 1 per 100 000.

Mortality rates from *Enterobacter sakazakii* infection have been reported to be from 20% to >50%. Significant long-term effects in the form of neurological deficiencies can result from the infection, especially among those with severe meningitis and cerebritis.