

Infant Formula - *Enterobacter Sakazakii* Practice Guidance Summary

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Is powdered infant formula a source of *Enterobacter sakazakii* (bacteria) infection and illness among infants?

Enterobacter sakazakii bacteria have been found in powdered infant formula (which is a non-sterile product) and have been implicated in a number of cases of infection among infants leading to meningitis, necrotizing enterocolitis, cerebral damage, neurological impairment and death.

It is important to note that because powdered infant formula is not a sterile product, other bacteria may also be present. However, not all manufacturers of powdered infant formula indicate on the label that these products are not sterile.

Which infants are at greatest risk of *Enterobacter sakazakii* infection?

Infants under the age of 12 months are considered at risk. Infants considered at greatest risk include:

- neonates
- infants under the age of two months
- preterm infants
- immuno-compromised or ill infants
- low, very low and extremely low birth weight infants.

Also considered at risk are infants of HIV positive mothers.

However, it should be noted that infants as old as one year, toddlers and even adults have been infected with *E. sakazakii*.

The dose or numbers of *E. sakazakii* cells that are needed to cause infection are not known and the risk of infection is highly dependent on a variety of hygiene, time and temperature variables during formula preparation, handling and storage.

What steps can be taken to decrease the risk of *E. sakazakii* infection among infants from powdered infant formula?

- Formula selected should be based on the medical needs of the infant and, where possible, commercially sterile liquid formula should be used for those infants at greatest risk.
- Proper procedures for cleaning and sterilization of equipment are necessary in both the home and institutional setting. Contamination during preparation such as with contaminated equipment and utensils and inappropriate holding times and temperatures have been implicated as being at least partly responsible for some of the outbreaks and incidents of *E. sakazakii* infection.
 - *E. sakazakii* in infant formula can attach, grow and form biofilms on feeding equipment surfaces such as latex, silicon and stainless steel which makes it more difficult to disinfect and clean. This situation may be a particular concern when feeding tubes are used for sick infants.
 - *E. sakazakii* can also tolerate very dry conditions.
- WHO guidelines and microbiological studies on the thermal inactivation of *Enterobacter sakazakii* all support the use of water that is at least 70°C to reconstitute powdered infant formula because water cooler than this will not adequately destroy this bacterium.
- The WHO guidelines describe an extensive list of recommendations and accompanying rationale for the use of powdered infant formula in both in-care settings (such as hospitals) and in the home (World Health Organization. Safe preparation, storage and handling of powdered infant formula: guidelines. 2006 [cited 2008 20 February]. Available from: http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf). The guidelines recommend the following as the "safest practice" or "best practice" for the preparation of powdered infant formula. Only those

that deviate from what is typically recommended for the preparation of infant formula in general are described here as follows:

- Boil a sufficient volume of safe water. If an automatic kettle is used, the preparer should wait until it shuts off. Otherwise, ensure the water comes to a rolling boil.
 - Allow the water to cool to no less than 70°C. Check the temperature of the water with a sterile thermometer. The water should not be left for more than 30 minutes after boiling so that the temperature does not drop below 70°C.
 - Pour the required amount of water into a cleaned and sterilized feeding cup or bottle. Care should be taken to avoid scalds and feeding cups and bottles should be made from food-grade material that is suitable for pouring hot liquids.
 - After mixing, quickly cool the formula to feeding temperature by holding under cold running water or by placing in a container of cold or ice water. During cooling, ensure that any water that is used in the cooling of the formula remains below the top of the feeding cup or bottle lid so that no cross-contamination from the water occurs. Dry the outside of the bottle or feeding cup with a clean cloth.
 - Check the temperature of the mixed formula with a sterile thermometer before feeding to decrease the risk of scalding the infant. This step is essential.
 - Ideally prepare feeds fresh each time and feed immediately.
 - Discard any feed that has not been consumed within a two-hour time period.
 - Discard leftover feed.
- Health Canada and the U.S. FDA do not currently recommend the use of water that is 70°C or greater.
 - Health Canada is in the process of developing guidelines and it is expected that these guidelines will be released in 2008.
 - Additionally, WHO guidelines on safe preparation, storage and handling of powdered infant formula recommend that even if it has been reconstituted with water that is at least 70°C; once prepared it should not be stored any longer than 24 hours in a refrigerator that is maintained at maximum temperature of 5°C. This recommendation is because even one bacterium may be capable of significant growth.

What are the concerns with using water that is at least 70°C for reconstituting powdered infant formula?

The use of very hot water to reconstitute powdered infant formula introduces the possibility that:

- The preparer of the formula or the infant could be scalded during preparation or during feeding.
- More clumping of the powder could occur than would with cooler water.
- There could potentially be some loss of heat labile nutrients, such as vitamin C and thiamin. However, very little published research on the effects of hot water on the nutrient content in powdered infant formula is available. What evidence is available suggests that the loss is small. Research is needed to understand how heat treatment affects the nutrient content in a medium such as infant formula especially when the product is rapidly cooled following mixing (as is recommended in the case of powdered infant formula).
- Bacterial spores (from other bacteria) that may be present in the formula could be activated. However, *E. sakazakii*, itself, is a non-spore forming bacterium and reports suggest this risk is unlikely if the formula is cooled to feeding temperature after reconstitution or refrigerated for later use.

What is the risk of *Enterobacter sakazakii* infection among infants from powdered infant formula or powdered human milk fortifiers that have been added to human milk?

- In some cases, human breastmilk is fortified to meet the needs of preterm infants. Powdered forms are more frequently used over liquid or liquid concentrates because they provide the nutrients without significantly increasing the volume or diluting the protective components in human milk.
- Little research is available on the risk of *Enterobacter sakazakii* infection from powdered infant formulas or fortifiers when used as an addition to human milk.
- Both dry products are susceptible to contamination during manufacturing.

Note: See relevant practice questions in this knowledge pathway for references.