



**IBFAN** *The International Baby Food Action Network*

## **Another Serious Public Health Risk of Powdered Infant Formula: Contamination with Pathogenic Microorganisms**

### **Did you know that?**

The presence of heat-resistant pathogens such as *Enterobacter sakazakii* in powdered infant formula has been identified by the Joint FAO/WHO Codex Alimentarius Commission as a "**Known public health risk**". Codex defines this risk as having "**high impact in terms of severity for a wide range of consumers and for specific sensitive populations**" (ref. 1).

A number of high profile case studies of severe illness and death in vulnerable newborns as well as in healthy newborn infants has heightened awareness of the critical need to address the serious health risks associated with the intrinsic contamination of powdered infant formulas. In view of the seriousness of this concern, the **Codex Committee on Nutrition and Foods for Special Dietary Uses**, which is currently revising the **Standard for Infant Formula**, requested the **Codex Committee on Food Hygiene** to revise the **Recommended International Code of Hygienic Practices for Foods for Infants and Young Children**.

As background to the revision, Member States, the USA and Canada prepared Risk Profiles to state the gravity of the problem and question the adequacy of current Codex standards, especially for specific categories of newborns: "***E. sakazakii* is known to be present in a proportion of powdered infant formula, such formula has been epidemiologically linked with illness in neonates, and such illness may be life threatening. That alone is enough to seriously consider appropriate strategies to reduce this documented risk**".

Furthermore the **Risk Profiles of *Enterobacter sakazakii* and other Microorganisms in Powdered Infant Formula** notes, "***a variety of severe and life-threatening conditions including meningitis, septicemia and necrotizing enterocolitis due to Enterobacter sakazakii. Reported case-fatality rates have varied considerably, with rates as high as 50% in some instances***", and that: "***While the overall frequency of E. sakazakii infections appears to be low, the consequences can be dire***", because "***the organism appears to have a propensity to infect the central nervous system to cause meningitis, cysts or brain abscess. Subsequent developmental delay or hydrocephalus is a well-recognized sequela***".

Health departments in a number of countries, including Canada, the USA and Belgium have already started to take action and have issued warnings to their health care systems. Studies have shown that in 141 powdered milk-based formulas tested in 35 countries, members of the *Enterobacter* family could be recovered from 20 (14%) of 141 samples. The advisories warn that *E. sakazakii* is a rare but life-threatening cause of diseases with high case fatality rates of 40-80%. "***Healthy infants may not always be immune to E. sakazakii infections***", and emphasize that "***powdered infant formulas are not commercially sterile products ... they are not processed at high enough temperatures for sufficient time to achieve commercial sterility....***".

## ***Key Issues raised***

- *E. sakazakii* appears to be one of the most heat tolerant organisms of the *Enterobacteriaceae* family isolated from dairy products. A study by Nazarowec-White
- concludes that "*E. sakazakii* appears to be one of the most thermo-tolerant organisms", and suggests that "*The high thermal resistance of E. sakazakii in comparison with other members of the Enterobacteraceae can possibly explain their high prevalence in powdered and prepared formula milk*".
- Increased heat treatment of powdered infant formulas will affect the levels of heat-labile nutrients, such as key vitamins, and may cause adverse chemical reactions in the product. Since formula fed infants need to be able to depend exclusively on powdered formulas as a complete source of nutrition, this poses serious questions about the efficacy of powdered formulas to adequately support growth and development.
- Even low levels of *E sakazakii* may pose a safety concern. A study by J. van Acker states: "*The presence of even low-grade pathogens in powdered formula cannot be allowed. Even levels of contamination of less than 1 coliform per gram of milk powder can cause outbreaks of fatal disease among newborns.*"
- The risk of potentially fatal infections appears to be highest for neonates in hospital settings, especially if low birth weight or immunocompromised. While the risk may diminish for older infants, reports in the literature indicate that there is still some degree of risk to this older population.
- In developing countries a significant under-reporting of infections is likely where **the problem may be even greater.**

## **IBFAN seeks urgent action**

- IBFAN calls on WHO to uphold its mandate for the protection of consumer health and safety in the Codex Alimentarius standard setting process.
- IBFAN notes that parents and care givers have the right to full and unbiased information and calls on manufacturers to place clear warnings of possible intrinsic contamination on containers of powdered infant formulas.
- IBFAN calls for the revision of hygienic standards for the production of foods for infants and young children towards reducing the risk of contamination.
- IBFAN calls for independent collection of evidence to improve safety of infant formulas.
- IBFAN calls upon Member States to prohibit the use of nutrition and health claims on the labeling and advertising of baby foods.

*IBFAN, the International Baby Food Action Network, works with Consumers International to protect the health of the smallest and most vulnerable consumers, infants and young children (see note iii). IBFAN defends to right of all children to the highest attainable standard of health, irrespective of whether they are breastfed or fed on breastmilk substitutes.*