



IBFAN *The International Baby Food Action Network*

Pathogenic Microorganisms in Powdered Infant Formula: The Serious Public Health Risk

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 (i) 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, in 2003 the USA and Canada prepared a **Risk Profile** on *Enterobacter sakazakii* in powdered infant formula and then in 2004 a **Revised Risk Profile** (refs. 2, 3). Both documents 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 Profile 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. In April, 2002, the US Food and Drug Administration issued a letter to all health care professionals warning of the high mortality rate due to invasive disease caused by *Enterobacter sakazakii* in the tins of powdered baby milk. This letter quoted studies showing 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. *Enterobacter sakazakii* was among the species most frequently isolated (see note ii).

In July, 2002, Health Canada issued a similar alert, the Health Professional Advisory, that repeated the warning that *E. sakazakii* is a rare but life-threatening cause of diseases with high case fatality rates of 40-80%. The Advisory noted that "*Healthy infants may not always be immune to E. sakazakii infections*". It emphasized the fact 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 QUESTIONS RAISED BY THE RISK PROFILE

The Risk and Revised Risk Profile raise critical questions about the hazards inherent in *E. sakazakii* contamination of powdered formulas as well as the technological dilemmas associated with its presence. The subsequent Joint FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula, was held in Geneva from 2-5 February 2004 (see note iv). The Report, **Key Findings and Recommendations** prepared by this Joint FAO/WHO Workshop for the Codex Committee on Food Hygiene reiterate these concerns:

- ***What level of heat treatment must be applied to destroy E. sakazakii in powdered formulas?***

E. sakazakii appears to be one of the most heat tolerant organisms of the *Enterobacteriaceae* family isolated from dairy products. The **Risk Profile** cites the study by Nazarowec-White concluding that "*E. sakazakii appears to be one of the most thermo-tolerant organisms*", and suggesting 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*" (ref. 5).

- ***How will increased heat treatment during manufacturing and during preparation for consumption affect nutritional composition?***

Increased heat treatment 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.

- ***What is an acceptable level of E. sakazakii contamination of powdered infant formula?***

The Report notes that "even low levels of *E sakazakii* may pose a safety concern." As the study by J. van Acker (ref. 6) 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. Indeed, the law in Belgium (of 18 February 1991) requires less than this amount in all formula samples*". In the Netherlands, the letter of 30 October, 2003, from the Director-General of the Dutch Food Safety Authority to the Minister of Health gives the recommendation that there should be NO *Enterobacter sakazakii* detectable in 50 grams of powdered formula (ref. 7).

- ***Does this risk vary depending on the age or immune status of the consumer?***

In its conclusions the Report makes the following key observation: *“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”*.

- ***How extensive is the problem in developing countries?***

The Report notes “a significant under-reporting of infections is likely”, and “the lack of reports from developing countries”, and that **“the problem may be even greater in developing countries”**, and states further that “the number of susceptible infants is likely to be greater”. In view of the prevalence of HIV/AIDS in some settings, *“Information is needed from all geographic regions in order to determine the extent of the problem. For example, some areas with higher rates of HIV/AIDS may be at increased risk, where concerns about HIV transmission through breastfeeding lead to increased use of infant formula”*.

IBFAN SEEKS URGENT ACTION

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.

- IBFAN is of the opinion that urgent action is needed to find answers to these questions. Firstly, IBFAN notes that the parents view powdered infant formula products to be germ free. Marketing of these products has created an image of safety, trust and purity. To offset this deceptive imagery IBFAN believes it is critical that meaningful warnings should be put out to the public, expectant parents and new mothers. These warnings should state that when babies are fed powdered infant formula there is a risk that the product is contaminated by pathogenic bacteria such as *Enterobacter sakazakii*. The Risk Profile emphasises that: *“A number of outbreaks that have resulted in serious adverse health consequences underscore the need to better manage the risk of E. sakazakii in powdered infant formula”* (ref. 2).
- IBFAN is also of the opinion that the work being done by Codex will be valuable in resolving some of the contamination risks associated with the use of powdered infant formula. However, the Codex process is limited in its ability to develop standards and recommendations for the manufacturers of these products and the labelling of potentially contaminated products in a way that addresses the ***immediate urgency of the problem***. A number of reasons for this exist, including the sometimes conflicting mandates of Codex to facilitate simultaneously fair trade and protect consumer health and safety.
- IBFAN is also of the opinion that the infant formula industry's reaction to the gravity of this problem has been to deny the reality and seriousness of the harm. Industry's response has been to focus on method of preparation – placing the responsibility squarely on the user, rather than acknowledging the source of the contamination as the manufacturing process. In a recent request for information from a leading infant formula manufacturer, the following response was received:

“Contamination may occur during the preparation of baby bottles (at health facilities or at home) because the presence of the E. sakazakii is in the environment or on utensils or bottles. All formulas should be prepared under strict hygienic conditions as it is explained on the package of the product and fed immediately, discarding any unused formula. Under such conditions, infant formulas are safe”.

- IBFAN has serious concerns about the practicality of the advice as currently given on the labels of powdered formula tins.
We recognize that guidelines for preparation and handling do need to be developed and this may reduce the multiplication of *E. sakazakii* organisms during preparation and feeding of the formula, but will not eliminate the presence nor the risk of illness related to *E. sakazakii* infection.
- Where there are economic constraints, the cost and/or lack of fuel, the lack of electricity, the lack of refrigeration, the lack of time to prepare fresh feeds, the ability to discard left over formula, are major barriers to the ability of parents to adhere to practices recommended to improve hygienic preparation.
- Infant feeding needs and behaviours may also present barriers to adherence to procedures recommended to reduce risk for those fed powdered formulas. High needs infants, low-birth weight infants, infants who are born prematurely, newborn infants need to be fed every two to three hours, including night feeds. Infants frequently fall asleep during a feed, to awake a short time later, wanting to be fed again. It will be very difficult for a tired mother/father/caregiver to boil and cool water and freshly prepare formula for every feed especially when they have a hungry, crying baby, leading to the practice of feeding left over formulas.

* IBFAN therefore supports the work of the Codex Alimentarius Commission, particularly the Codex Committee on Food Hygiene.

* IBFAN calls on the WHO to fully and adequately uphold its mandate for the protection of consumer health and safety in the Codex Alimentarius standard setting process.

* IBFAN calls for the revision of the Codex International Code of Hygiene practice for Foods for Infants and Young Children, dating from 1979, to address the problem of intrinsic contamination of powdered infant formula by pathogenic organisms.

* IBFAN calls for independent and objective research, free from commercial influence, on the microbiological contamination of powdered infant formula by pathogens during the manufacturing process and guidelines for the preparation, use and handling of infant formula to reduce risk.

* IBFAN calls upon manufacturers to recognize their responsibilities towards the youngest and most vulnerable consumers and to place clear warnings on containers of powdered infant formulas.

* IBFAN calls on governments to ensure that that health care providers, parents and caregivers are provided full and un-biased information that powdered infant formulas may be contaminated with pathogenic microorganisms.

Notes:

- (i) The Committees of the Codex Alimentarius Commission are the highest standard-setting authority in the field of food safety and hygiene.
- (ii) *E. sakazakii* was formerly named "Yellow-pigmented *Enterobacter cloacae*" and it has high thermal resistance - a heat-resistant strain, which is not destroyed by pasteurizing the powdered formulas.
- (iii) IBFAN has worked since its founding in 1979 by six international NGOs, including Consumers International, towards improving infant and young child health by protecting, promoting and supporting breastfeeding and countering the irresponsible promotion of artificial feeding.
- (iv) The Joint FAO/WHO Workshop met in Geneva from 2-5 February 2004, and reported to the Codex Committee on Food Hygiene's 36th session in Washington from 29 March-3 April 2004. The other toxigenic microorganisms reviewed by the Workshop include *Salmonella*, *Clostridium botulinum* and *Staphylococcus aureus*, which can all cause severe food-borne illness.

References:

1. Joint FAO/WHO Food Standards Programme: *Development of Process, Procedures and Criteria to Establish Priorities for the Work of the Codex Committee on Food Hygiene*, December 2003, Document CX/FH/ 04/5-Add. 2.
2. Joint FAO/WHO Food Standards Programme : [Risk Profile of *Enterobacter sakazakii* in Powdered Infant Formula](#), January 2003, Document CX/FH 03/13.
3. Joint FAO/WHO Food Standards Programme : [Risk Profile of *Enterobacter sakazakii* in Powdered Infant Formula](#), January 2004, Document CX/FH 04/12: http://ftp.fao.org/codex/ccfh36/fh04_12e.pdf
4. Joint FAO/WHO Activities on Risk Assessment of Microbiological Hazards in Foods: [Call for Data on *Enterobacter sakazakii* and other micro-organisms in powdered infant formula](#), December 2003: http://ftp.fao.org/es/esn/food/request_for_data_7.pdf and Executive Summary and [Report of the Joint FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula](#), Geneva, 2-5 February, 2004: <http://ftp.fao.org/codex/ccfh36/fh0412ae.pdf>
5. Nazarowec-White, M and Farber JM. Thermal resistance of *Enterobacter sakazakii* in reconstituted dried infant formula. *Lett Appl Microbiol* 1997; 24:9-13.
6. Van Acker J et al. Outbreak of Necrotizing Enterocolitis Associated with *Enterobacter sakazakii* in Powdered Milk Formula. *J. Clin Microbiology*, Jan. 2001; 39 (1): 293-297
7. The following website provides more information from the Dutch Food Safety authority: http://www.vwa.nl/php/page_sub.php?structure_id=109&page_sub_id=109

IBFAN Briefing Paper prepared 57th World Health Assembly for Agenda item 12.15, Implementation of Resolutions (Progress reports): Infant and young child nutrition, biennial progress report.