



IBFAN *The International Baby Food Action Network*

The Public Health Risk of Harmful Bacteria in Infant Formula

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

Health care providers in Canada and the USA have already received an alert. 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%. It noted that "*Healthy infants may not always be immune to E. sakazakii infections*". It emphasised 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....*".

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 therefore welcomes the Joint FAO/WHO Workshop on *Enterobacter sakazakii* and Other Microorganisms in Powdered Infant Formula, which will be held in Geneva from 2-5 February 2004 (see note iv). These other toxigenic microorganisms include *Salmonella*, *Clostridium botulinum* and *Staphylococcus aureus*, which can all cause severe food-borne illness. In view of the concern from Codex Member States, the USA and Canada prepared a Risk Profile on *Enterobacter sakazakii* (ref. 2) which stated the problem and questioned 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*".

The Risk Assessment Needs and Questions on page 5 of the document asks further:

"*What is an acceptable level of E. sakazakii contamination of powdered infant formula? Does this vary depending on the age or immune status of the consumer?*" These vital questions are repeated in the *Call for Data* for the Workshop (ref. 3):

"*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 is of the opinion that it is high time to find answers to these questions because of the seriousness of the problem as identified by Codex Member States in the Risk Profile (ref. 2). This states that when babies are fed powdered infant formula that is contaminated by bacteria such as *Enterobacter sakazakii*, they are at risk of *"a variety of severe and life-threatening conditions including meningitis, sepsis or bacteraemia and necrotizing enterocolitis"* (ref. 2). In scientific terms, these diseases have *" a high case fatality rate, as high as 50% in some instances"*, and even if death does not result *"the consequences can be dire"* (ref. 2), with babies left brain damaged and with *"subsequent developmental delay"* (ref. 2) caused by cerebral abscesses.

The subsequent Codex Call for Data (ref. 3) for the Joint FAO/WHO Workshop notes that there is scarce information from developing countries, although a study from Thailand (ref. 4) reports bacterial contamination in 459 out of 500 home-prepared bottle-feeds used to feed the sick infants under six months brought to the outpatient clinic in the Children’s Hospital, Bangkok. *Enterobacter* species were the second dominant pathogen (41.3 %) after *Klebsiella* species (56.6%) in the 82.8% of samples contaminated by enteric bacteria. **This study unequivocally recommends the promotion of breastfeeding.**

The reaction of the baby food industry to the Codex’s Alimentarius Commission’s identification of the problem of bacterial contamination of formula by deadly bacteria as a “Known public health risk” is to attack the scientific evidence. The industry uses Codex as a shield, claiming that their products are safe according to present Codex standards. Yet the Codex Committee on Food Hygiene is revising its standards to make them safer, and has convened the Joint FAO/WHO Workshop to provide advice for the revision of The Recommended Code of Practice For Foods for Infants and Children (ref. 1). As the study by J van Acker (ref. 5) 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. 6).

IBFAN therefore asks the following questions of the baby food industry, of national and of international authorities:

- Why is it that there has not been any information for the parents and carers of newborn babies, although every health care professional in the USA, Canada and Belgium has been informed about the risks of the use of powdered infant formula, starting in April 2002?
- The International Code of Marketing of Breast-milk Substitutes already clearly stated in 1981 in Article 4.2 of the Code that: *“Informational and educational materials” “should include clear information on the health hazards of inappropriate foods or feeding methods, and in particular the health hazards of improper use of infant formula and other breast-milk substitutes”*. The Code and national laws to implement

the Code are intended to protect the health of infants and young children. Why is it that 23 years after its adoption, baby food manufacturers and governments have still not taken action on this vital provision of the Code?

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 formula. The USA and Canada's Risk Profile (ref. 2) 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. Nazarowec-White, M and Farber JM. Thermal resistance of *Enterobacter sakazakii* in reconstituted dried infant formula. Lett Appl Microbiol 1997; 24:9-13)§.

(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 will meet in Geneva from 2-5 February, 2004, and will report to the Codex Committee on Food Hygiene's 36th session in Washington from 29 March-3 April, 2004.

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 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
4. Suthienkul O et al. Bacterial contamination of bottle milk in infants under 6 months in Children's Hospital, Bangkok, Thailand. J. Dairy Sci 1999 Dec; 82 (12): 2620-4
5. 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
6. See under "Advice", first bullet point. See the website listed below provides more information from the Dutch Food Safety authority.

LINKS:

1. ftp://ftp.fao.org/es/esn/food/request_for_data_7.pdf
6. http://www.vwa.nl/php/page_sub.php?structure_id=109