

IBFAN CRD submission to the CCFH55 Agenda item 10 Other Business and Future Work

IBFAN is requesting the CCFH55 to address the serious contamination of powdered infant formulas (PIF) with *Clostridium botulinum* spores, a potential risk for serious illness in infants. IBFAN is requesting the CCFH55 to start work to review and update the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* CAC/RCP 66/2008.

IBFAN is greatly concerned about the current outbreak of infant botulism resulting from *Clostridium botulinum* spores contaminating powdered infant formula manufactured by ByHeart. To date there are 39 confirmed cases and over 70 are under investigation in the US. The company distributes its PIF via on-line platforms and is thus available in countries where the product is not registered for use.

Infant botulism is a serious condition that can lead to paralysis and even death, and must be treated as quickly as possible. *Botulism Immune Globulin* (referred to as *BabyBig*) administered intravenously is the single treatment for infants under one year of age and is only available in the US. Access to the *BabyBig* treatment outside of the US is available only on 'a case-by-case evaluation basis.' International requests must go through an onerous process requiring the affected infant's attending physician to contact an on-call *BabyBig* physician for approval; after which a letter of authorization from the importing country's Medicine Regulatory Authority must be issued; payment made; customs cleared; all with a required international courier account and more.

Needless to say, access to treatment for infants diagnosed with botulism outside of the US, is likely to be a costly and time consuming process that will be unavailable for the many and too late for an effective treatment.

The global marketing, both digital and direct as well as the use of on-line platforms has resulted in contaminated products which are often unregulated, available for purchase by parents in third countries. Thus, exacerbating the risk of infant illness. Moreover the *Codex Code of Ethics in International trade and Food Aid* forbids the international trade of any food (including re-exported food) which is unsafe, unsuitable, poisonous, harmful or otherwise injurious to health or "is labelled or presented in a manner that is false, misleading or deceptive."

US Food and Drug inspection documents of the production facilities of the *C. botulinum* contaminated PIF (although with some redaction) released in late November, reveal systemic violations of hygienic controls. These include:

- receiving and releasing X ingredient used in infant formula powder that was not held under conditions that prevent adulteration
- not taking action to eliminate rodent issues
- not monitoring floor conditions adequately
- approval and release of an ingredient that was not manufactured, packaged, labelled or held under conditions that prevent adulteration,
- did not remove pest from plant to protect against contamination,

- did not maintain the manufacturing building in clean and sanitary condition

The heat resistant *Clostridium botulinum* spores, which are ubiquitous, and which require high temperatures, time and pressure to eliminate cannot be applied to powdered infant formula without negative impact on the nutritional requirement of the products that “should meet the nutritional specifications of applicable Codex standards”. Nor is it feasible for parents and care givers to apply measure for the elimination *C. botulinum* spores.

IBFAN is concerned that manufacturing facilities for PIF are not meeting hygienic requirements to minimize microbial contamination - *Cronobacter* and *Salmonella* species have a history of frequent recalls due to contamination of PIF. Since measures required to eliminate *C. botulinum* spores, are not feasible for PIF, manufacturing facilities and procedures need to be reviewed and updated to eliminate this serious and all too frequent risk infant illness. Additionally, governments must ensure with adequate inspections and surveillance of production facilities, that they meet all hygienic practices and standards during all phases of the manufacturing process.

IBFAN notes that the *Code of Hygienic Practice on Powdered Formulae for Infants and Young Children* CAC/RCP 66/2008 was developed in response to outbreaks of *Enterobacter sakazakii* (now reclassified as *Cronobacter sakazakii*) and *Salmonella* species. Since its development, outbreaks of other contaminants have necessitated product recalls and warnings to parent. This includes *Bacillus cereus*, also a spore forming and toxin producing bacterium, and now the more serious *C. botulinum*. Hence the need for a review and revision of the Code of Hygienic Practice for powdered infant formula for infants and young children.

IBFAN is requesting the CCFH55 to address this urgent need to reduce the risk of *C. botulinum* spores in powdered infant formula, a potential cause of serious illness in infants, and review and update the *Code of Hygienic Practice of Powdered Formulae for Infants and Young Children* CAC/RCP 66/2008.