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Filtration KNOCKS OUT Deadly Bacteria in Nursery

The presence of *E. sakazakii* in powdered infant formula calls for a new technology to wipe out the pathogen without compromising nutrition

BY ANITA GAREM

The presence of *Enterobacter sakazakii* in powdered infant formula has been of serious concern because of recent outbreaks of infectious diseases. The FDA has determined that powdered infant formula has been the source of one-half to two-thirds of the infections caused by this bacterium. One study that sampled 141 cans of various brands of powdered formula concluded that *E. sakazakii* was present in 14 percent of the samples. In 2002, the FDA recalled 1.5 million cans of powdered infant formula because of possible contamination.

Enterobacter sakazakii is a gram-negative, rod-shaped member of the Enterobacteriaceae family. It has been implicated in rare, but potentially life threatening outbreaks of necrotizing enterocolitis, sepsis, and meningitis, mostly among premature infants and newborns. As many as a third of those affected die, and survivors may experience serious, chronic health problems such as severe digestive disorders, organ damage, hydrocephaleae, quadriplegia, and retarded neural development. The outbreaks in neonatal intensive care units worldwide have been of such concern that the FDA has instituted strict regulations for the use of powdered formula in neonatal intensive care units in the United States.

Need for Improved Method of Bacteria Removal

Powdered formula undergoes intensive heat treatment during processing to remove bacteria. The processed formula must meet the criteria set by the FAO/WHO Codex Alimentarius Commission for the presence of coliforms, including *Enterobacter sakazakii*. This criteria, which applies internationally, is less than 10 colony-forming units per gram (<10 cfu/g) of powdered formula. A problem is that one of the *E. sakazakii* phenotypes has demonstrated exceptionally high thermal resistance (more than three times that of other enterobacteriaceae). This may explain why some *E. sakazakii* remain in the powdered infant formula, even after heat treatment.

The *E. Sakazakii* bacteria remaining in this nonsterile formula, though at low levels, can cause infection. And these bacteria can survive in the formula powder for up to 24 months. Besides, scientific literature has shown that drastic heat treatment of powdered infant formula has numerous undesirable effects. It can cause poor nutrition and chronic inflammatory reactions, which themselves can bring about other health conditions. The higher the temperature at which the formula is processed, the greater the nutrient loss. Particularly affected are the solubility and nutritional value of proteins. When Maillard reaction occurs, irreversible changes in protein structure, irreversible interactions with sugar, and salt imbalance result. In the early Maillard reaction, there is a reduction in essential amino acids such as lysine and tryptophan. Powdered infant formula contains 20-25 % less lysine than breast milk. Since lysine is an essential nutrient, formula is enriched with proteins, and enriched formula has been linked to obesity. In the late Maillard reaction, carboxymethyllysine (CML) is produced. This molecule is known to cause chronic inflammatory reactions that can lead to sensitivities and allergies. Powdered infant formula has twice as much CML as fresh cow's milk.

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Out With the Old...

Manufacturers of powdered infant formula are committed to providing a safe, high quality product and have responded to the challenge of eliminating *E. sakazakii* by implementing more stringent process controls. These include the use of extremely rigorous hygiene practices, labels with explicit instructions for product preparation, and specific measures to satisfy HACCP. Additionally, most manufacturers have developed more stringent microbiological standards than those of the FDA and the FAO/WHO Codex Alimentarius, namely no coliform cells in 25 grams (0 cfu/25g) of powdered formula. While implementing this standard has probably helped reduce outbreaks, evidence shows that it has not completely eliminated them1. This is the reason why, to fully address the problem, the production process itself must be looked at.

Hurdle technology, typically used in the manufacture of food and beverage products to protect against pathogens, involves a series of hurdles that are placed between the pathogen and the product. Typical hurdles are temperature and chemicals, but when too much is applied, nutritional deficiencies in the formula can result. When the hurdles are not set high enough, bacteria can develop adaptive responses. If hurdle intensities are reduced to meet nutritional quality requirements, the technology may fail to ensure pathogen control and product safety.

The recently developed total fluid management (TFM) solution uses filtration for bacteria

Up to 6 log reduction of microbial contaminants by crossflow microfiltration at room temperature.

Validated double-layer-membrane sterile filters for ultimate retention of pathogens.

control and is based on hurdle technology. The filters are placed at the source of each fluid, ingredient, or air that will become part of the process or final product. The focus is on the strategic and systematic placement of these discriminating physical barriers to target pathogens only. Since this system does not require high temperatures to destroy the pathogens, the quality of the product is not impacted, and there are no harmful thermally-induced effects.

The following flow diagram of a sample process illustrates how TFM can be applied in the manufacture of powdered infant formula. A preliminary risk assessment and a process survey determine the process-critical points for contamination. In this scenario, there are two general paths during which contamination can occur: input of raw materials to produce the formula and recontamination of the formula after heat treatment.

Protection Against Pathogens

For a successful TFM model that uses filtration for powdered infant formula processing, each critical point for contamination and specific filter sequence must be addressed individually. Each filtration sequence includes exceptionally durable and reliable membrane filters for maximum biological protection against bacteria, endotoxins, and viruses.

An effective filter will have the following characteristics, capabilities, and conformance.

- Long service life
- Ultralow binding properties
- Broad chemical and temperature resistance
- Ability to accommodate high flow rates
- Ability to withstand steam sterilization
- Absolute retention of pathogens, including *E. Sakazakii*, validated by a nondestructive integrity test.
- Conformance with Good Manufacturing Practices/Good Hygienic Practices (GMP/GHP) requirements
- Conformance with USFDA and HACCP requirements for tank venting and water, air, and gas sterile filtration
- Conformance with HACCP requirements for sterile filtration of heat-sensitive nutrients and additives.

The TFM model that uses filtration in the processing of powdered infant formula allows safety levels of 0 cfu/100 g. to be reached. Using high-quality filters and a unique, highly effective hurdle technology, in combination with efficient process environment management and HACCP process control, eliminates the need for higher temperatures during production. The nutritional value of the formula is preserved, and its superior protection against the *E. Sakazakii* bacterium ensured. ■

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Reference:

1 van Acker et al. 2001, Outbreak of necrotizing enterocolitis associated with Enterobacter sakazakii in powdered milk. In J.Clin. Microbiology 2003 N°39].

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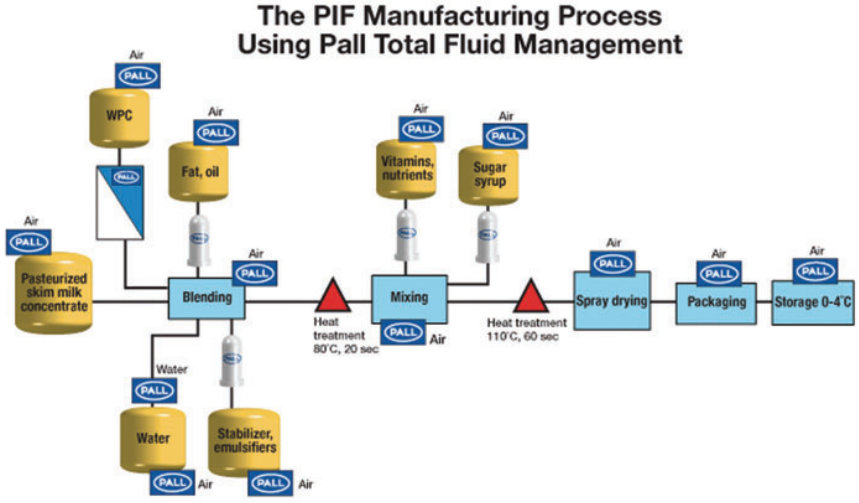

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