

7. RISK REDUCTION STRATEGIES FOR FORMULA-FED INFANTS

Possible control measures and their relative effectiveness in reducing the risk from *E. sakazakii* as estimated by the preliminary risk assessment are given below.

7.1 REDUCING THE CONCENTRATION/PREVALENCE OF INTRINSIC CONTAMINATION OF POWDERED INFANT FORMULA BY *E. SAKAZAKII*

The risk assessment estimated that a significant reduction in the frequency of contamination of powdered infant formula could reduce the relative risk between four- and fivefold (Appendix C, Table A1). Possible approaches for achieving this are described below:

- Employing a supplier assurance scheme and monitoring for raw materials, especially for ingredients not undergoing additional heat treatment prior to mixing.
- Reducing the level of Enterobacteriaceae in the production environment – the main source of contamination appears to be the manufacturing environment, therefore, such a reduction should also reduce the concentration and prevalence of contamination in the finished product. Key aspects could include an effective separation of wet and dry processing operations and an effective management programme of plant hygiene including an environmental monitoring programme within a HACCP plan.
- Monitoring and testing the concentration and prevalence of Enterobacteriaceae in finished products by industry.
- Tightening the current microbiological specifications for powdered infant formula.

These strategies were not specifically evaluated in the risk assessment. It should be noted that the level of relative risk reduction could be varied depending on the initial level of concentration/prevalence of intrinsic contamination of powdered infant formula and the status of the risk mitigation strategies implemented in each manufacturing establishment.

7.2 REDUCING THE LEVEL OF CONTAMINATION THROUGH HEATING RECONSTITUTED POWDERED INFANT FORMULA PRIOR TO USE

The risk assessment estimated that the use of temperatures in excess of 70°C for reconstitution to achieve a 4-log reduction of *E. sakazakii* (Edelson-Mammel and Buchanan, 2004) could result in a 10 000-fold risk reduction. However, this intervention would need to be applied consistently to be effective. For example, if only 80% of servings received this treatment, the estimated risk reduction would be only fivefold (Appendix C, Table A5). Possible means for achieving this reduction are as follows:

- Where feasible, use of commercially available sterilized liquid products as a replacement for powdered formula, especially for high risk infants.
- Employment of an effective point-of-use pasteurization step following formula reconstitution (e.g. a number of hospitals use a commercial steamer in their formula preparation area).
- Use of hot water (70°-90°C) during the reconstitution of powder. A number of powders clump when water is used at very high temperatures. Other risks that need to be taken into consideration include scalding and the potential for activation of bacterial spores (FSANZ, 2003).

7.3 MINIMIZING THE CHANCE OF CONTAMINATION OF RECONSTITUTED FORMULA DURING PREPARATION

The risk assessment estimated that a significant decrease in the rate of environmental contamination would probably decrease the relative risk 1.2-fold (Appendix C, Table A3). In order to achieve this, one must ensure the use of good hygienic practice in the preparation area, through either guidelines (in the hospital) or labelling and education (in the home). This should include the prevention of cross-contamination from the environment and equipment (e.g. blenders) used during preparation.

7.4 MINIMIZING THE GROWTH OF *E. SAKAZAKII* FOLLOWING RECONSTITUTION PRIOR TO CONSUMPTION

The risk assessment estimated that extended holding times can greatly increase the relative risk of *E. sakazakii* if present. Due to the exponential nature of bacterial growth, the risk will also increase exponentially once the organism comes out of the lag period. For example, after 6 hours at 25°C, the relative risk increases thirtyfold and after 10 hours at 25°C, the relative risk increases 30 000-fold compared to the baseline (Appendix C, Table A2). Risk reduction can be achieved by:

- ensuring rapid cooling and storage below 10°C if not for immediate use; and
- minimizing the length of time between reconstitution and consumption.

Using current dry-mix technology, it does not seem possible to produce commercially sterile powders or to completely eliminate the potential of contamination. Furthermore, even low levels of *E. sakazakii* present in powdered infant formula have the potential to multiply during the preparation and holding prior to consumption. Therefore, a combination of intervention measures is recommended to effectively reduce the risk. On the basis of the preliminary risk assessment, it is clear that the inclusion of a bactericidal step at the point of preparation and a decrease in feeding time were the most effective control measures for reducing risk. A number of combined control measures and their likely effects on reducing risk are presented in Appendix C, Table A6.

The basic risk control principles demonstrated within the preliminary risk assessment for *E. sakazakii* would also hold true for *S. enterica*, although the specific risk reductions achieved would vary to some degree based on the mode and sources of *Salmonella* contamination and its growth and survival characteristics. Example risk reduction scenarios for *S. enterica* are also given in Appendix C.