

6. RISK CHARACTERIZATION

6.1 APPROACHES AND OUTPUTS

As a means of providing a conceptual framework for the evaluation of the factors affecting the impact of *E. sakazakii* and other pathogens associated with powdered infant formula on public health, an initial risk assessment was undertaken. Due to the limited time available in the meeting, the risk assessment was, of necessity, preliminary in nature and primarily targeted to identifying key parameters that may need to be considered in evaluating and addressing risk reduction strategies. The objectives of the risk assessment were to address four questions:

- What are the factors that contribute to the microbial food safety risks associated with powdered infant formula and what is their relative importance?
- What are potential interventions that could mitigate these risks, and what is the relative efficacy of those interventions?
- What key scientific knowledge and/or data are needed to reduce the uncertainty associated with the estimates of risks and the estimates of the relative effectiveness of identified risk control options?
- What are potential consequences associated with the identified risk control options if implemented?

The risk assessment focused on two of the identified microbiological hazards, *E. sakazakii* and *S. enterica*. As noted in chapter 3, other members of the Enterobacteriaceae are occasionally associated with episodes of septicaemia or meningitis in infants. These appear to have pathogenesis similar to *E. sakazakii* and hence similar risk factors were assumed. To that end, an attempt was made to provide an estimate of the risk associated with these microorganisms by development of a simple “multiplier” to be used in conjunction with the risk estimate for *E. sakazakii*. Other microorganisms were not considered in the risk assessment, partly because of the divergent ecologies, aetiologies and technologies that would be needed to achieve enhanced risk control. This decision was also in keeping with the scope of the products considered within the risk assessment.

The range of products that could potentially be included within the designation, powdered infant formula – or that might be added to powdered infant formula – is extensive. For the purposes of risk assessment, the products considered were those that meet the definition of products sold in powdered form for subsequent rehydration and feeding in a liquid form as a complete or partial substitute for human milk. The range of products considered included materials specifically manufactured as supplements to human milk or infant formulas for the purposes of producing specific, desirable nutritional or physical characteristics. Examples of included products are: powdered infant formula, follow-up formula, FSMP intended for infants and human milk fortifiers. Products not included in the risk assessment were those that were not manufactured for the specific purpose of being added to human milk or infant formula. For example, this did not include the practice by certain consumers of adding honey to infant formula for the purposes of increasing consumption

rates. Thus, diseases, such as infections associated with the presence of low levels of *C. botulinum* spores in honey added to infant formula leading to intestinal colonization (i.e. infant botulism), were not considered in the risk assessment.

The risk assessment was intended to be global in its consideration of both developed and developing countries, however available surveillance data were largely limited to a small number of countries. In developing the risk assessment, both the risks associated with the inherent contamination of powdered infant formulas and that acquired during preparation and feeding were evaluated for the three consumption settings considered: neonatal hospital wards, neonatal intensive care units and the home. Factors associated with the microbiological quality of the water used for rehydrating the products were not considered, though it was fully appreciated that the presence of pathogenic microorganisms in water can greatly influence the microbiological safety of infant formula, particularly in developing countries. However, the risk control strategies for controlling this hazard can be significantly different from those considered in the current risk assessment.

Cases of salmonellosis and *E. sakazakii* infections associated with powdered infant formula have been documented in children older than 1 year; however, given that the rate of infection is substantially higher in infants, it was decided to concentrate the risk assessment on children of 1 year or younger. This population was in turn subdivided into groups and the effect of susceptibility was estimated in comparison with infants of 28 days or less (baseline). This decision was undertaken to take into account the apparent increased susceptibility associated with the youngest age group. Differences in apparent incidence rates were used as a means of estimating the relative susceptibility of the two age groups.

The flow chart in Figure 2 provides the simplified scheme for production, distribution and use that was used to assess the risks associated with both pathogens. Potential points where environmental contamination of the powdered infant formula or reconstituted formula prior to consumption could occur are indicated. In this flow chart, it is assumed that the pasteurization step(s) employed during the wet blending are of sufficient magnitude to eliminate both pathogens and that any contamination of that product is due to subsequent recontamination. As discussed in chapter 5 with dry-blending processes, most ingredients will have undergone a pasteurization treatment at some point in their manufacture. Modification to the general model describing the general flow chart were made in developing various “what-if” scenarios to consider the impact of different potential risk-reduction interventions.

6.2 EVALUATION OF POTENTIAL RISK REDUCTION OPTIONS FOR FORMULA-FED INFANTS

A simplified risk assessment for the purposes of articulating key concepts and providing simple “what-if” scenarios was developed. This risk assessment focused on the scientific information available in relation to disease in medical neonatal facilities. The basic approach of the risk assessment was to estimate the risk for a baseline scenario. Modifications to current practices or potential mitigation strategies were then compared relative to this baseline. A second, more complex risk assessment was conducted to more fully explore a wider range of factors that affect the microbiological risks associated with *S. enterica* and *E. sakazakii* in powdered infant formula.

While estimates derived from the more complex risk assessment generally agreed with the simpler version, there was insufficient time within the context of this meeting to verify the model's quality and present its findings. As a result, the more complex model was not applied to generate risk assessment conclusions.

In addition to demonstrating the interactions between the various factors that affect the risks, the risk assessment provided important insights into additional data that are needed to make informed decisions related to risk control. Details of how the more simple risk assessment was undertaken are provided in Appendix C.

The key findings of the risk assessments are listed below:

1. Key factors affecting the microbiological risks associated with powdered infant formula factors include:
 - the level of contamination in the powdered infant formula;
 - the level of hygiene in the preparation and delivery of the reconstituted formula;
 - inclusion of a bactericidal treatment at the time of preparation; and
 - the duration of the feeding period and the temperature.
2. Two factors that were predicted to produce the greatest reductions in the risks associated with *S. enterica* and *E. sakazakii* were:
 - the duration of the time to consumption; and
 - the inclusion of a bactericidal treatment at the point of rehydration.
3. The degree of risk reduction that can be achieved by reducing the levels of *E. sakazakii* and *S. enterica* in powdered infant formula is dependent in part on the extent of contamination that is attributable to the presence of the pathogens in the preparation environment.
4. Control measures can be combined to achieve a greater degree of risk reduction than that achieved through the use of any single control measure.
5. There is considerable uncertainty in all risk estimates due to a general lack of scientific data specifically related to powdered infant formula. This is particularly important in relation to information on the sources and contributing factors (e.g. duration of feeding periods) associated with both outbreaks and sporadic cases of disease.

