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ISDI Position on the reconstitution of Powdered Infant Formulae

Summary

In the light of FAO/WHO meeting on *E. sakazakii* and WHO recommendations on the reconstitution of infant formulae, ISDI considers that the **appropriate management of the microbiological safety** of formula feeding depends on the compliance with a) **strict microbiological criteria** for powdered infant formulae and b) **safe formula feeding practices**.

In order to assure safe formula feeding practices, **strict application of manufacturers' reconstitution recommendations**, and in particular the use of safe water and the **immediate feeding of fresh prepared formula is very important**.

It is important to realise that **reconstitution** of infant formula powder at **70°C**, as currently proposed by WHO, **cannot be considered as the ultimate solution** to manage *E. sakazakii* in view of the FAO risk assessment. Moreover, this recommendation may introduce **other risks related to the use of hot water**, such as scalding or degradation of functional formula properties.

1. Introduction

Over the last decade emerging scientific developments and enhanced public health monitoring programs enabled improvements in food safety as well as new and more measured regulatory provisions.

Safety of food for infants, and in particular microbiological safety, is at the forefront of preoccupations of health authorities and formula manufacturers due to the sensitivity of the target population. As a consequence, infant formula manufacturers have welcomed the recent initiatives of FAO/WHO concerning the risk management of *E. sakazakii*, an opportunistic pathogen, during infancy.

Infant formula manufacturers through their professional association ISDI (International Special Dietary Food Industry) actively follow and participate in these initiatives.

ISDI would like to share its position on the management of formula safety, in particular on the compliance with strict microbiological criteria for infant formulae and safe formula feeding practices.

2. Compliance with strict microbiological criteria for infant formulae

Management of microbiological safety of infant formula feeding requires application of stringent criteria for microorganisms, and in particular *E. sakazakii*. Risk evaluations have been independently conducted by FAO/WHO scientific expert bodies and the European Food Safety Authority (EFSA).

Codex Alimentarius is currently redrafting the Code of Hygienic Practice for Powdered Formulae and specifically focuses on the management of *E. sakazakii* and *Salmonella* in powdered infant formulae.

EFSA has issued an opinion on the microbiological safety of infant formula in September 2004¹, reviewed in 2007². Consequently, the European Commission has published the Regulation n°2073/2005 on microbiological criteria for foodstuffs.

In conclusion, expert bodies and regulatory authorities agree that a strict criterion for *E. sakazakii* in powdered infant formula is indispensable to appropriately manage risk related to formula feeding during early life.

Powdered infant formulae are produced according to international standards of hygiene and fulfil stringent microbiological criteria, set by Public Health Authorities and deemed to ensure their safety.

3. Compliance with recommendations for safe formula feeding

In addition to stringent microbiological criteria, expert bodies recognise that safe feeding practices of infant formulae are very important in managing the risk related to *E. sakazakii* in young infants.

3.1. Recognised safety measure: fresh preparation

In the report from FAO/WHO (2006)³, it is recognised that when an infant is immediately fed with freshly prepared infant formula, then whatever the temperature used for the reconstitution, there is no increase in the relative risk.

3.2. Compliance with manufacturers' instructions

Consumers should carefully follow the manufacturers' preparation instructions to ensure proper reconstitution. Since powdered infant formula products may perform differently when reconstituted, manufacturers are the most reliable source of preparation instructions for their particular products.

Manufacturers ensure that the instructions are clearly placed on the formula label and are easily implementable by consumers. Meaningful directions include the following:

¹ Opinion of the scientific Panel on Biological Hazards on the request from the Commission related to the microbiological risks in infants formulae and follow-on-formulae (N°EFSA-Q-2003-111)

² Scientific opinion of BIOHAZ Panel on the request from the Commission for review of the opinion on microbiological risks in infants formulae and follow-on-formulae with regards to Enterobacteriaceae as indicators (EFSA-Q-2006-078)

³ FAO/WHO (2006) *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Meeting Report – Advanced pre-publication copy 2.5.2006. ftp://ftp.fao.org/ag/agn/jemra/e_sakazakii_salmonella.pdf

- the need to follow the manufacturer’s instructions,
- the cleanness of the working surface
- the cleanness of the hands,
- the cleanness of the utensils,
- the use of appropriate water,
- the use of correct amount of powder to the water in the bottle,
- the use of the scoop provided with the powder,
- the proper closure of the packaging,
- an advice on the storage,
- the need to discard any unfinished feeds.

Manufacturers do not recommend storage for feeds made up in the domestic/home situation. Reconstitution has to be done prior to immediate consumption. However, the practice of advance preparation continues in some countries and cultures. To avoid abuse of product that may be made up and held for excessively long times in the absence of any instructions, manufacturers may continue to include storage instructions for these countries/cultures until this practice ceases to exist. However, they will also continue to support local authorities and health care professionals in bringing this practice to an end.

In institutions such as hospitals where it is not possible to prepare feeds immediately before use, hospital policy and procedures should be implemented in full accordance with risk management principles. It is recommended that hospitals have centralised units for reconstitution and that staff is trained in good hygienic practice to avoid contamination. There should be written procedures for the safe preparation, handling and storage of powdered infant formulae.

On their labels, manufacturers stress the importance of adhering to their instructions and warn that failure to do so could make infants fed the formula ill.

4. WHO recommendation for reconstitution of powdered infant formulae at 70°C

4.1. Global risk evaluation of 70°C reconstitution

Reconstitution at temperatures > 70°C is recognised by FAO/WHO as a food safety measure to reduce the numbers of heat-sensitive *E. sakazakii* occasionally present in individual servings.

However, according to the FAO/WHO report (2004)⁴, the overall (worldwide) risk reduction would be negligible if the 70°C reconstitution would be applied by only 80% of users.

*Full compliance with the WHO recommendation is required to have a significant impact on risks related to *E. sakazakii*.*

4.2. Practical issues with high temperatures

Since it is recommended that formula be fed immediately upon reconstitution, the caregiver is likely to be trying to soothe (and perhaps even carry) at least one hungry infant while he/she is preparing the bottle.

⁴ FAO/WHO (2004) *Enterobacter sakazakii* and other microorganisms in powdered infant formula: meeting report, Microbiological Risk Assessment Series No. 6 WHO, Geneva
http://www.who.int/foodsafety/publications/micro/enterobacter_sakazakii/en/

Under these circumstances, the caregiver may not be able to give the preparation process the careful attention required for working with very hot water. Or, they may skimp on the time necessary to let the formula cool, thereby exposing the infant to additional risk. Internal and external burns and scalding of infants due to spilled hot water or ingestion of overly hot beverages can be severe and have long-term consequences. As such, they represent a major public health issue (e.g. Reig et al., 1993⁵ and Jeffrey et al., 2000⁶).

Stating that burning and scalding can be solved by providing appropriate information is an oversimplification. Such incidents have been observed irrespective of warning and information provided to caregivers. The WHO's recommendation of reconstituting at temperatures over 70°C is only likely to exacerbate the problem. It is apparent that there is limited data with information at what temperatures mothers/careers can comfortably handle a bottle and make up a feed in the region of >70°C, without causing any risk.

From a practical point of view, high temperatures such as 70°C are difficult to use both at homes and in hospitals and are not in line with the real capabilities of mothers and caregivers.

4.3. Risk related to reconstitution at 70°C - scalding

For the caregiver

Reconstitution with previously boiled water within 30 min of boiling implies the water temperature is at or above 70°C, depending on the kettle design and material from which it is made (75°C-95°C). Unlike cups, mugs etc., baby feeding bottles do not have handles to protect the preparer's hand from the heat and have to be shaken to mix the contents. In addition plastic feeding bottles are not always stable on the work surface and usually need to be secured with the hand when they are being filled with water from the kettle. Handling hot water and mixing feeding bottles, not designed for shaking at 70°C, are likely to introduce a risk factor of scalding for the mother or caregiver.

For the caregiver and the baby

When a bottle is being shaken, even if it is sealed with a plastic insert and cap, some formulae can "spurt" out of the bottle, creating a risk of scalding not only for the caregiver, but also any baby or young child who might be in the vicinity.

Risk of scalding for the baby

Infants and young children are at particular risk for burns including scalds due to their natural curiosity and their lack of experience in assessing danger and risk³. ISDI is aware of at least 20 reports worldwide from 1984 to the present⁷ that identify scalds from hot liquid (primarily water) to be the most common cause of burns amongst infants and young children under 4 years of age in the home¹⁻²⁵. Children 3 years and under are particularly at risk^{3,12}. Such burns are more frequently related to the presence of hot liquids in the kitchen as compared any other room in the house^{3,4,9,12,13,15,17}. Scalding related injuries can be serious and more likely to result in hospitalization than other types of burns^{3,10}.

Industry is concerned that authoritative guidelines calling for the use of extremely hot water in the preparation of powdered infant formula will increase the likelihood of the occurrence of these

⁵ Reig, A., Tejerina, C., Baena, R. and Mirabet, V. (1993) Epidemiological study of scalding in children. Ann. Medit. Burns Club, 6, http://www.medbc.com/annals/review/vol_6/num_3/text/vol6n3p157.htm

⁶ Jeffery, S.L.A., Cubison, T.C.S., Greenaway, P.M., Gilbert, P.M., and Parkhouse, N. (2000) Warming milk – a preventable cause of scalds in children. Brit. Med. J., 320, 235. <http://bmj.bmjournals.com/cgi/reprint/320/7229/235>

unfortunate events. Use of 70°C water contradicts public safety measures designed to reduce the incidence of scalds. Such recommendations include storing water at no greater than 60°C⁴.

Industry is also concerned about the increased occurrence of injury associated with the handling and consumption of formula prepared with extremely hot water, despite efforts to educate consumers about proper handling including cooling formula before feeding. The infant's oral cavity is vulnerable to scalding related injuries from consumption of excessively hot formula. There are several reports in the literature of oropharynx and palatal burn in infants due to scalding from "hot spots" when formula has not been adequately cooled, or when a microwave oven was used to reheat the formula^{26,27}. Skin burns have also been reported in infants as a result of accidents during the preparation and warming of formula^{2,18}.

Additional public health efforts will be required to minimize the risk of scalding associated with the handling of 70°C water for the preparation of powdered infant formula. Industry is concerned that based on the ineffectiveness of past strategies, such efforts will have minimal impact and that preparers and infants will be at increased risk of injury.

High temperatures such as 70°C can cause non-negligible damages both to caregivers and to the infants.

4.4. Modification of nutritional and functional properties of the formulae

Nutritional composition

Several organisations (i.e., the FDA⁸ (2002), ESPGHAN⁹ (2004) and AFSSA¹⁰ (2005)) have expressed concerns on the effect of reconstituting formula at or above 70°C on the nutritional/functional formula properties. Although, increasing the vitamin content in the manufacturing process could compensate this issue, the WHO's view does not take into account stringent national and international regulations and recommendations (including tolerances) legislating the nutritional composition of infant formula. It also fails to address how overdosing should be dealt with given that many caregivers would not be expected to use the 70°C reconstitution recommendation.

Starches and fats

Formula properties may change when infant formula powder is reconstituted at high temperatures.

Indeed, reconstitution at high temperatures may result in separation of the fat fraction or may lead to foaming, depending not only on the formulation of the product, i.e. the source of protein (if milk based whey or casein dominant/ soya...), the carbohydrate source and how well it protects the fat, but also on the spray drying process or drier type that produces it.

Several different types of infant formulae can contain starch, usually to assist with some problem in feeding the infant. Starch-containing infant formulae may get thicker when reconstituted with hot water that may lead to poor flow characteristics. In most instances formulae containing starch require different conditions/temperatures for reconstitution, some hotter and some much colder. Starch works by thickening under the conditions found in the infant's stomach (temperature (37°C) and low pH). For this reason, these formulae have specific instructions for reconstitution like as for example reconstitution with water that has been previously boiled, cooled, and refrigerated to 4°C then warmed gently to room temperature for feeding. This method of reconstitution ensures that the product will flow through the holes in the teat unit without blocking them.

⁸ FDA (2002) Health professionals letter on *Enterobacter sakazakii* infections associated with use of powdered (dry) infant formulas in neonatal intensive care units. <http://www.cfsan.fda.gov/~dms/inf-ltr3.html>

⁹ ESPGHAN (2004) Preparation and handling of powdered infant formula: a commentary by the ESPGHAN Committee on Nutrition. *J. Ped. Gastroenterol. Nutr.*, **39**, 320 – 322. http://www.espghan.med.up.pt/position_papers/con_19.pdf

¹⁰ AFSSA (2005) Hygiene recommendations for the preparation, handling and storage of feeding bottles. http://www.sante.gouv.fr/hm/actu/biberon/rapport_afssa.pdf

Both phenomena may introduce confusion about the formula quality to the mother or caregiver.

New developments

The requirement of reconstitution temperatures at >70°C could limit product development in the future with regards to nutrients/ingredients that could be beneficial to the infant but would not tolerate these reconstitution temperatures, such as probiotics or sensitive enzymes.

Both FAO/WHO reports (2004, 2006) highlight new developments for enhancing product safety and minimising microbiological risks. For example, the use of probiotic strains has been shown to either significantly inhibit the growth of potentially harmful micro-organisms or avoid their adherence to intestinal mucosa (e.g. Collado et al., 2005¹¹).

The current 70°C recommendations would seriously affect such developments and potentially limit innovation in this field including the addition of enzymes, active proteins... to infant formulae, as well as future innovations that might emerge from scientific and technological research.

In the cases above, even if it such ingredients were allowed by the legislation, following the strategy to control product safety by increasing reconstitution temperatures would not solve the issue.

High temperatures could damage the products and are not in line with the specific and appropriate reconstitution needs of each formula.

5. Conclusion

ISDI, representing the international food manufacturers of powdered infant formulae, highlighted in its paper that it really takes into consideration the potential microbiological risks of those products (i.e. in applying strict microbiological criteria) and therefore recommends that:

- the baby is immediately fed with fresh prepared powdered infant formula,
- the consumers strictly follow the manufacturers' instructions,
- the 70°C reconstitution is not considered as the unique alternative.

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¹¹ Collado, M.C., Gueimonde, M., Hernandez, M., Sanz, Y. and Salminen, S. (2005) Adhesion of selected *Bifidobacterium* strains to human intestinal mucus and the role of adhesion in enteropathogen exclusion. *J. Food Prot.*, **68**, 2672-2678.

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