

REPORT OF THE STAKEHOLDER MEETING TO DISCUSS ISSUES AROUND THE MICROBIOLOGICAL SAFETY OF POWDERED INFANT FORMULA

**Conference Rooms 3 & 4
Food Standards Agency Headquarters
Aviation House
125 Kingsway
London WC2B 6NH**

Thursday 18th January 2007

Attendees.

Annex A attached.

Abbreviations

Annex B attached.

1. Chair's Introduction and Welcome

1.1 The Chair, Judith Hilton welcomed everyone to the stakeholder meeting to discuss key issues concerning the microbiological safety of powdered infant formula. She also thanked the external speakers; Jenny Bishop (WHO), Elaine Underwood (IDFA) and Justine Currell (DH) who had agreed to give presentations at the meeting.

1.2 The Chair provided a short summary of the background to the meeting. Infants and young children are known to be particularly vulnerable to foodborne infections. Whilst breast milk is the recommended feeding option, parent/carers also feed infants with UHT-treated liquid formula or reconstituted powdered infant formulae (PIF) as an alternative to breast milk. PIF and other types of powdered formula (e.g. formula for special medical purposes intended for infants, breast milk fortifiers) are not sterile products and there has been international concern about the risk to infants from *Salmonella* and *Enterobacter sakazakii* if these organisms are present in these products. Although these infections are rare they can be severe and the risk is considered to be greatest for pre-term, immunocompromised and low birth weight infants.

1.3 The issue has been considered in recent years by the World Health Organisation (WHO), Food and Agriculture Organization (FAO), Codex Committee on Food Hygiene, World Health Assembly (WHA) and European Food Safety Authority (EFSA). This work has resulted in recommendations for

the production of guidance for caregivers (and hospitals) for the safe preparation, storage and use of PIF. The WHA consideration of the issue also resulted in a recommendation that caregivers should be informed through an explicit warning on the packaging that PIF may contain pathogenic micro-organisms.

1.4 In response to these recommendations the Department of Health (DH) revised its bottle feeding advice for parents around preparation and storage of PIF milk, and the DH and Food Standards Agency (FSA) have issued advice jointly to health professionals on the preparation and storage of powdered infant milk.

1.5 In the UK the best practice recommendation is to reconstitute the formulae using freshly boiled water at 70°C. In real terms this is boiled water that has been left to cool for no more than 30 minutes. This is because the temperature will help to minimise survival of any *E. sakazakii* and/or other harmful bacteria that may be present in the PIF or through cross contamination during preparation. Ideally feeds should be made up fresh each time and used immediately. This advice is in line with the recommendations provided by EFSA and WHO.

1.6 The chair explained that the Agency arranged this meeting with interested parties to discuss these issues and in particular the recommendation that parents and carers should be informed that PIF is non-sterile. A series of presentations were made to provide a stimulus for later discussion.

2. WHO initiatives for the control of *Enterobacter sakazakii*. **- Jenny Bishop, World Health Organisation (WHO), Geneva, Switzerland**

2.1 The Chair thanked Jenny Bishop for standing in for Dr Peter Karim Ben Embarek who was unable to attend. Jenny Bishop provided a summary of the various strands of work that the WHO has in place with respect to PIF.

2.2 In 2004, the WHO and FAO convened an expert meeting on *E. sakazakii* and related microorganisms in PIF. A key finding was that *E. sakazakii* infections can affect all infant age groups but that infection is more likely in those that are low birth weight and neonates. A further WHO/FAO expert consultation which considered *E. sakazakii* and *Salmonella* in PIF was held in 2006. This examined new scientific data and a quantitative risk assessment model on *E. sakazakii* in PIF which had been developed for WHO/FAO following the first consultation.

2.3 A particular focus of the risk assessment was to compare the effect of different preparation and storage methods on the relative reduction in risk of *E. sakazakii* infection. Different scenarios were evaluated and those that involved periods of holding prepared PIF at room temperature were

associated with the greatest risk. Reconstitution with liquids at 70°C was an effective risk mitigation strategy for all scenarios investigated.

2.4 The Codex Committee on Food Hygiene (CCFH) is currently revising the code of hygiene practice for foods intended for infants and young children. The risk assessment developed for WHO/FAO will assist the drafting group revising the code by providing information to inform risk mitigation strategies and the relative risk reduction achieved through different sampling plans for *E.sakazakii* in PIF.

2.5 As a result of the risk assessment the WHO has concluded that some of the instructions available on PIF product labels and given by health authorities may lead to an increased risk of *E.sakazakii* infection and should be reviewed. The risk assessment model will be used to help develop guidance for homes and health care settings. WHO guidelines have been developed with the assistance of FAO and the Food Safety Authority of Ireland. These are currently in draft format and are expected to be made available on the WHO website, www.who.int/foodsafety in the near future.

3. Department of Health Bottle Feeding Policy. - Justine Currell, Department of Health (DH), London

3.1 At the Chair's invitation Justine Currell provided a summary of the Department of Health's bottle feeding policy. DH recognises that breastfeeding is the best form of nutrition for infants and recommends exclusive breastfeeding for the first six months of an infant's life, as it provides all the nutrients a baby needs. DH also acknowledges that if a mother chooses not to, or cannot, breastfeed for what ever reason and makes the decision to bottle feed, then to ensure that this is conducted safely guidance must be provided to inform both parents and health professionals of the correct practices.

3.2 There is concern about labelling of PIF inappropriately as this could have the potential to scare parents into thinking that the alternatives to breastfeeding are not safe.

3.3 DH developed the bottle feeding policy together with the FSA, health care professionals such as the Royal College of Midwives, Royal College of Nurses, Community Practitioners and Health Visitors Association and the British Dietetic Association.

3.4 Consideration is given to health concerns, costs and other issues such as risk management, safety within different population groups, the practical implementation within various settings such as home, nurseries, hospitals and concerns of interested parties including the industry.

3.5 Information is disseminated through a number of different avenues including publications and the DH website.

4. Agency funded research to determine understanding of the term 'non sterile' in relation to powdered infant formula
- Marion Castle, Food Standards Agency (FSA), London

4.1 Marion Castle presented the findings from a FSA funded study to determine consumers' understanding of the term 'non-sterile' when used in relation to powdered infant formulae. This was in response to the 2005 World Health Assembly resolution that Member countries should inform health care workers, parents and other caregivers about best practices for preparation, use and handling of PIF and that caregivers should be informed through an explicit warning on the packaging that PIF may contain pathogenic micro-organisms.

4.2 The FSA funded a qualitative research project that involved holding a series of focus groups across the UK with a representative group of parents, all who had a baby under the age of six months and used PIF as the primary source of nutrition. Discussions were also held with health professionals and parents of at risk infants as they were expected to be more knowledgeable about the risks and best practice.

4.3 The study concluded that, whilst parents understood the term 'non sterile', they were surprised that PIF and other baby foods were not sterile and may contain micro-organisms. Everyone who participated in the study agreed that any information relating to the risk of harmful consequences to babies must be clearly communicated to parents so that they can make an informed choice about the use, storage and preparation of the product.

4.4 Those taking part in the study agreed that the information should be included on packs and should be presented through a simple and clear message, i.e. that PIF is a non-sterile product. Further guidance should be issued by Government departments and other interested groups in leaflets and via websites to help inform caregivers of best practice.

5. Industry perspective with regard to labelling of powdered infant formula.
- Dr Elaine Underwood (SMA), on behalf of the Infant & Dietetic Food Association (IDFA), London

5.1 At the Chair's invitation Elaine Underwood presented the industry perspective with regard to labelling of powdered infant formula. In the UK the IDFA represents manufacturers of specialist nutrition products.

5.2 The manufacturers of PIF support education on the benefits of breastfeeding which should always be recommended as the ideal way of feeding infants.

5.3 Manufacturers of PIF are committed to providing products that are both safe and meet the nutritional requirements of infants. They take seriously any reports identifying PIF as a potential source and vehicle for infections.

5.4 The UK industry has reviewed manufacturing practices and has made process changes to minimise the risk of infection due to PIF. Products intended for use in the hospital environment by health care professionals have been labelled as non-sterile and there are many ready-to-feed versions available for infants including the high-risk groups. For parents and caregivers there is simple and clear labelling on pack as required by law and the instructions for advance preparation have been removed. Following discussions with DH and FSA, the warning “Failure to follow instructions may make your baby ill” has been repositioned to make it more visible to consumers. There are concerns that the inclusion of further information on pack, such as that PIF is non-sterile, may detract from the fact that the equipment and environment are also non-sterile.

5.5 There is a need for harmonised recommendations to be agreed internationally to ensure the safety of all infants. International discussions are on-going and until these are completed there is a danger that national health agencies will develop local guidelines that will differ and introduce mixed messages. For the UK, this is relevant between Northern Ireland and the Republic of Ireland and within the European Union this is especially relevant given the frequent travel between Member States by consumers.

5.6 In conclusion, close co-operation between global and national health agencies, the infant food industry, and health care providers must continue in several areas (manufacture, preparation, handling, information and research), in order to achieve the greatest degree of risk reduction.

6. Open Discussions.

6.1 The Chair explained that the main microbiological risk associated with PIF is *E. sakazakii*. Whilst acknowledging that this is a very rare infection, when it has caused outbreaks these have had devastating results. Both the WHO and EFSA have issued advice that countries should make the risks clearer so that carers do not assume that PIF is sterile and take less care over preparation and handling. The Chair invited the stakeholders to present questions or observations relating to the presentations, specifically around the microbiological safety of powdered infant formula.

6.2 Ellie Lee (University of Kent) asked Jenny Bishop to elaborate further on the numerical incidence of infection from formula milk by the bacteria in question, since the figures mentioned in her presentation seemed very low indeed.

6.3 Jenny Bishop (WHO) explained that cases of *E. sakazakii* infection in infants have been reported from a number of countries including; New Zealand, the United States of America and France. However we will never know the true number of cases due to under reporting.

6.4 Stephen Forsythe (Nottingham Trent University) noted that there have been approximately 117 documented/reported cases [incidents] worldwide in the last 50 years. The last UK case was in 1958 (published in 1961) for which there was no attributable route of infection. More recent cases have shown a link, though not in every case, with contaminated reconstituted infant formula powder. The majority of the reported cases of *E. sakazakii* infection are hospital acquired. *E. sakazakii* infection is not unique to infants and documented adult cases are known.

6.5 Tyrone Pitt (HPA) mentioned that there had been a small study that tested samples of vacuum cleaner dust from houses selected at random. Of the households tested, *E. sakazakii* was found in 6 of 18 houses. Results were confirmed by PCR. The identification of *E. sakazakii* in routine diagnostic clinical laboratories is problematic as many isolates of *E. cloacae* (by some way the most common species of Enterobacter) may give reactions in conventional tests suggestive of *E. sakazakii*. On subsequent testing in the reference laboratory as few as 2% of such isolates prove to be *E. sakazakii* which suggests that this species is often mis-diagnosed.

6.6 It was suggested that the differences between health regions in the UK may lead to differences in the reporting of infections such as *E. sakazakii* and given the severity of disease, that there should be an undertaking to make this a notifiable disease. The Agency is not in a position to be able to influence the list of notifiable micro-organisms in terms of public health, but the voluntary reporting system tends to identify those micro-organisms that are invasive by nature. Following a case of *E. sakazakii* in New Zealand it has been made a notifiable disease. Conducting a prospective survey to identify the true prevalence of *E. sakazakii* would not be cost effective given that this is a very rare infection, with only 117 cases during the last 50 years worldwide. In general there is limited information about the number of cases of foodborne disease due to under reporting even in countries such as the UK where there is a good reporting system.

6.7 Ellie Lee noted that some sociological research indicates the demoralising and disorienting effects on the public of messages that continually elevate the risks faced by people in everyday life. From these accounts, when everyday life is more and more presented as simply 'risky' then people find it difficult to work out what to do, and lose faith and trust in authorities which emphasise the need to be risk averse. There is evidence to show, unfortunately, that public disorientation is now an accomplished fact.

6.8 Marion Castle (FSA) explained that the FSA study asked consumers for their views on a number of different forms of words that conveyed the non-sterile message, e.g. may contain *Salmonella* and *E. sakazakii*, may contain pathogenic micro-organisms or may contain harmful bacteria, etc. 'Non-sterile' was the term focus groups participants preferred.

6.9 Janet Fyle (RCM) said that it is important not to underestimate the consumer, they would understand messages that explained where there is a

low risk and that this can be reduced through taking further action, i.e. following the preparation instructions through messages such as “This product is non-sterile so you should follow these instructions to minimise any risk.” If the message was included, midwives would be able to explain the importance of following best practice. Informed consumers would be unlikely to use similar foods that would be unsuitable for an infant, e.g. powdered skimmed milk.

6.10 Janet Fyle also raised concerns about some hospital practices. Some hospitals were unable to afford to provide sterile ready-to-feed formulae for non-breast feeding mothers and in others the kettle had been removed for fear of litigation arising from scalding and parents were unable to prepare feeds in the correct manner.

6.11 There was some general agreement that the fact that PIF may be non-sterile together with poor practices when preparing and storing bottled feeds contributes to illness. Therefore it is important to explain the risks to carers so that they follow best practice guidelines.

6.12 In terms of training, whilst acknowledging that there are shortages of midwives within the NHS, there is scope for further training for health care professionals to enable them to educate parents as they leave hospital or at home. It is also important that industry educates the consumer through clear labelling and instructions on packs and that information is available in a variety of forms.

6.13 Revised guidance issued by DH in response to the advice from EFSA recommends that freshly boiled water should be used to prepare bottles. The advice suggests that water should be left to cool for no more than 30 minutes because few homes have access to a thermometer. Judy Brander (National Council of Women GB) queried where there been cases of mains water contamination whether using boiled water as recommended would be sufficient to remove any other micro-organisms present.

6.14 Elaine Underwood (IDFA) explained that the infant formulae industry conduct extensive testing of powdered infant formulae for *Enterobacteriaceae*, *Salmonella* and *Enterobacter sakazakii* using ISO methodology. Typically a composite of 333g (FDA) or 300g (EU) sample is taken from a number of cans as the distribution of bacteria is unlikely to be homogenous throughout the PIF. Absence of harmful bacteria cannot be guaranteed by testing so the industry has concentrated on the monitoring of critical control points throughout the manufacturing process using food safety management procedures based on HACCP to provide a greater level of assurance. Michael Collyer (IDFA) further added that efforts are taken throughout manufacturing sites to reduce contamination and controls extend to people, water etc and the external environment where even birds can present a risk. Andy Davies (IDFA) also explained that microbiological criteria have been established across the European Union and for *Enterobacteriaceae* this is absence in 10 samples of 10g each. He also noted that *E. sakazakii* is a

ubiquitous micro-organism and the majority of reported cases of illness have occurred in hospitals. The cross-contamination of PIF during the preparation of a feed is a potential risk and one that can be reduced if a heat step is introduced during preparation.

6.15 Tyrone Pitt confirmed that there was no evidence that *E. sakazakii* was developing antibiotic resistance.

6.16 Stephen Forsythe explained that *E. sakazakii* has not been reported at levels greater than 1 cfu/g from PIF. The highest recorded contamination was 66 cfu/100g in a 1980's survey. *E. sakazakii* present in PIF is in a stressed state due to the manufacturing processes. The addition of warm water during reconstitution in effect resuscitates the micro-organism and it can then multiply. If hot water is used to prepare PIF feeds then this may provide a kill step. To further reduce the risk, carers should avoid storing prepared bottles of feed as this could lead to multiplication of the bacterium. The response was given that the FSA should make greater efforts to inform carers about the change in guidelines and should explain the reasoning.

6.17 Janet Fyle explained that first-time mothers receive the DH Birth to Five book when they leave hospital and so would be aware of the change to preparation and storage of PIF guidelines. However mothers in subsequent pregnancies do not receive this book and therefore would be unlikely to be reached. In addition, consideration should be given to those mothers who would not be able to afford to use ready-to-feed liquid formulae or who may not have access to a kettle or kitchen facilities to follow the advice. Sally Griffiths (IDFA) said that in most parts of Europe, bottles of PIF are never prepared in advance because of the common practice of storing boiled water in sterilised bottles and adding formula when required.

6.18 The WHO/FAO risk assessment model indicated that water above 50°C reduced the risk of *E.sakazakii* multiplying during subsequent storage. Andy Davies (IDFA) therefore asked whether this should be the suggested reconstitution temperature rather than 70°C which could present a risk of scalding whilst preparing bottles of feed. The current advice to leave boiled water to cool for no more than 30 minutes is ambiguous as this could be used after only 5 minutes and hence present a risk of scalding.

6.19 Another issue identified with the use of water at 70°C was the balance between the nutrient profile and microbiological safety, specifically whether there is any negative effect on the level of vitamins, particularly Vitamin C. Further whether industry can make products that meet the nutrient profiles set out in legislation when using water at this temperature. Issues were also identified for other types of PIF where there may be fat separation, organoleptic issues or where probiotics are included. There was also the fear that the use of a standard reconstitution temperature may prevent innovation of new products and nutrients that breast fed infants would have an advantage of receiving.

6.20 Janet Fyle explained that, although other bacteria should not be disregarded, the issue of this meeting was to discuss whether parents need to know whether PIF is non sterile. Whilst Elaine Underwood (IDFA) was in agreement that this was the purpose of the meeting, she added that it was important that health care professionals have the appropriate training so that this information and best practice can be passed on to parents.

6.21 Paul Cook (FSA) clarified that the FSA was working with DH and industry to develop policy on the microbiological safety of powdered infant formulae. An example of the collaborative working has been the IDFA agreeing to label hospital products as non-sterile, to which Sally Griffiths confirmed that there had not been any adverse comment. Paul explained that the issues surrounding the use of hot water should be considered as a balance of risks; the need to maintain the nutrient profile whilst reducing microbiological risks. The FSA is also aware that the industry is making moves to label product as non-sterile in other countries including the USA.

6.22 Tyrone Pitt suggested that there is still a lack of information with respect to all the proven risks associated with PIF, including the microbiological consequences associated with making up PIF incorrectly. This data should be produced and the protective effects of breast feeding should be teased out when considering risks and risk management.

6.23 The Chair concluded that the meeting had been a useful exchange of views. Whilst a form of wording to be used on packs of powdered infant formulae had not been resolved there was a majority view that consumers should be informed that PIF is non-sterile. She noted that progress had been made by the industry to control *E. sakazakii* and other micro-organisms during the manufacture of PIF. She also noted that some companies are labelling PIF as non-sterile whether intended for hospital use or consumers. However there remains scope for further progress towards meeting the recommendations from WHO/FAO and EFSA. In addition, it is important to alert carers to the benefits of using water at 70°C when making up infant feeds. Other issues highlighted were the effects of a shortage of midwives and the possible misinterpretation of the UNICEF/NICE guidelines.

6.24 The FSA would consider the outcomes of the meeting when developing proposals for the possible labelling of PIF as non-sterile. These would be circulated to interested parties for further consideration. As there was no further business, the Chair thanked everyone for attending and closed the meeting.

Stakeholder meeting to discuss issues around the microbiological safety of powdered infant formula.

Delegates:-

Stakeholders

Judy Brander	National Council of Women GB
Judy More	Department of Health
Justine Currell	Department of Health
Janet Fyle	Royal College of Midwives
Tyrone Pitt	Health Protection Agency
Anthony Williams	University of London
Susanne Surman-Lee	Health Protection Agency
Roger Clarke	Infant & Dietetic Foods Association
Katharine Hudspeth	South Midlands PCT
Jenny Bishop	World Health Organisation
Steve Forsythe	Nottingham Trent University
Chris Griffiths	University of Wales Institute Cardiff
Christine Carson	National Institute for Clinical Excellence
Ellie Lee	University of Kent
Wayne Anderson	Food Safety Authority of Ireland
Elaine Farrell	British Dietetic Association
Elaine Underwood	SMA
Rosemary Dodds	National Childbirth Trust
Carol Williams	Baby Feeding Specialist
Anne Murcott	Independent Advisor
Michael Collyer	Infant & Dietetic Foods Association
Andy Davies	Heinz
Sally Griffiths	Nutricia

Food Standards Agency

Judith Hilton - Chair	Microbiological Safety Division
Paul Cook	Microbiological Safety Division
Marion Castle	Microbiological Safety Division
Adam Hardgrave	Microbiological Safety Division
Harriette Lascelles	Microbiological Safety Division
Louise Farmer	Microbiological Safety Division
Mark Toal	Nutrition Division
Chris Pratt	Primary Production Division
Shaun Whelan	Communications Division
Sandy McDougall	FSA Scotland

ANNEX B

Abbreviations

PIF	Powdered Infant Formula
cfu	Colony forming unit
DH	Department of Health
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FSA	Food Standards Agency
IDFA	Infant & Dietetic Food Association
WHO	World Health Organization

Attached

- Copies of powerpoint slide presentations.
- WHO/FAO reports