



Food Safety
AUTHORITY OF IRELAND

22

GUIDANCE NOTE

**Information Relevant to the
Development of Guidance Material
for the Safe Feeding of Reconstituted
Powdered Infant Formula**

**Guidance Note No. 22: Information Relevant to the Development of Guidance
Material for the Safe Feeding of Reconstituted Powdered Infant Formula**

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I. INTRODUCTION

Powdered infant formula (PIF) contaminated with harmful bacteria has been implicated as a source of illness in infants. In recent years, the emergence of disease associated with a bacterium, *Enterobacter sakazakii*, in PIF has necessitated a new risk assessment. The Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) have hosted two joint risk assessments on the subject (FAO/WHO, 2004 and 2006). One outcome of these risk assessments has been a risk assessment model that has allowed for the examination of the relative risk to infants of different practices regarding the reconstitution of powdered infant formula and ensuing infant feeding practices. As a result of this work, the WHO has issued new guidance on infant feeding (WHO, 2007).

The Food Safety Authority of Ireland (FSAI) has received requests for guidance on safe infant feeding of powdered infant formula both from the Department of Health and Children as well as public health nurses and dietitians working with infants in care settings and with parents of infants in the home. The FSAI facilitated the development of these guidelines by hosting a seminar on 2nd October 2006 on the topic of *E. sakazakii* and infant feeding. A consultation document was circulated for comment to participants from the health and food safety community, interested academics and the infant formula industry. Submissions were received from 26 individuals or groups of individuals containing over 220 comments. These comments have formed the basis for this current document.

2. PURPOSE OF THIS DOCUMENT

This document is written to provide the basis for the development of suitable guidance material on the safe preparation and feeding of powdered infant formula. Appropriate communication bodies should prepare clear and targeted guidance material based on the recommendations in this document.

It is not intended that this document will be used as direct guidance to stakeholder groups on the safe preparation and feeding of powdered infant formula.

3. POWDERED INFANT FORMULA

The Department of Health and Children recommends that infants be exclusively breastfed for the first six months and thereafter continue to be breastfed in combination with suitably nutritious complementary foods for up to two years of age or beyond. This practice is the safest and best way of ensuring that babies achieve optimal growth, health and development.

However, there are circumstances when breastfeeding is either partially or wholly replaced with breast milk substitutes. Various products are available in powdered form referred to throughout this document as PIF. These include:

- infant formula (as defined in Codex Standard 72-1981)
- follow-up formula (as defined in Codex Standard 156-1987)
- formula for special medical purposes intended for infants (as defined in Codex Alinorm 04/27/26 Appendix V)
- formula for special medical purposes for the partial feeding of infants (Codex Standard 180-1991)
- human milk fortifiers.

Some of these products may also be available in sterilised ready-to-feed form.

4. BACTERIA ASSOCIATED WITH POWDERED INFANT FORMULA

Powdered infant formula is not a sterile food product. Certain harmful bacteria have been associated with PIF and some have caused disease in infants. The risk assessment on *E. sakazakii* and *Salmonella* in PIF (FAO/WHO, 2006) developed a categorisation system for all bacteria of concern. This is reproduced in Table I.

Table I: Categorisation of the microorganisms or microbial toxins of concern in PIF based on the strength of evidence of a causal association between their presence in powdered infant formula and illness in infants

Category	Organisms included:
Category A organisms – clear evidence of causality	<i>Enterobacter sakazakii</i> , <i>Salmonella enterica</i>
Category B organisms – causality plausible, but not yet demonstrated	<i>Pantoea agglomerans</i> and <i>Escherichia vulneris</i> (both formerly known as <i>Enterobacter agglomerans</i>), <i>Hafnia alvei</i> , <i>Klebsiella pneumoniae</i> , <i>Citrobacter koseri</i> , <i>Citrobacter freundii</i> , <i>Klebsiella oxytoca</i> , <i>Enterobacter cloacae</i> , <i>Escherichia coli</i> , <i>Serratia</i> spp. and <i>Acinetobacter</i> spp.
Category C organisms – causality less plausible or not yet demonstrated	<i>Bacillus cereus</i> , <i>Clostridium difficile</i> , <i>Clostridium perfringens</i> , <i>Clostridium botulinum</i> , <i>Listeria monocytogenes</i> , <i>Staphylococcus aureus</i> and coagulase-negative staphylococci

Reproduced from (FAO/WHO, 2006)

Salmonella enterica and *Enterobacter sakazakii* are the two organisms present in PIF with a demonstrated causality of illness in infants. *Salmonella enterica* is a well documented pathogenic bacteria and will not be further discussed. However, *Enterobacter sakazakii* is less well characterised and the features of the disease it causes in infants are worthy of elaboration. However, the recommendations in this document for safe feeding practices for PIF address the threat posed by both of these bacteria.

5. BRIEF OVERVIEW OF *Enterobacter sakazakii* IN POWDERED INFANT FORMULA

Invasive *E. sakazakii* disease is not a common occurrence in infants. There have been approximately 60 reported cases of *E. sakazakii* infection worldwide since 1958 (Mullane *et al*, 2006). However, there is concern that it has been under reported. In 2003, a United States FoodNet survey estimated the annual rate of invasive *E. sakazakii* infection to be one per 100,000 infants (children less than 12 months of age) (U.S. Centres for Disease Control and Prevention (CDC) unpublished data). In infants of very low birth weight (less than 1,500g) the incidence was estimated to be 9.4 per 100,000 in a study of 19 neonatal intensive care units (Stoll *et al*, 2004). Children greater than 12 months of age and adults are thought to be a much lower risk group than infants. *E. sakazakii* has been associated with neonatal meningitis, necrotising enterocolitis (NEC), bacteraemia and necrotising meningoencephalitis (Muytjens *et al*, 1983; Iversen and Forsythe, 2003). Reported mortality rates are high; NEC 10-55% and meningitis 40-80% (Iversen and Forsythe, 2003).

A U.S. Centres for Disease Control and Prevention (CDC) report investigated the risk factors relating to ingestion of *E. sakazakii* in infants (Bowen and Braden, 2006). Forty-six cases were analysed (12 with bacteraemia, 33 with meningitis and one with a urinary infection). The infants with meningitis tended to be near-term infants (median 37 weeks) of normal birth weight (median 2,454g) where infection tended to occur soon after birth (median six days after birth). The infants with bacteraemia tended to have very low birth weight (median 850g), were pre-term (median 27.8 weeks) and developed infection after the first few weeks of life (median 35 days). Bowen and Braden concluded that their findings suggested that all neonates (infants \leq 28 days) as well as premature infants should be included in the 'high-risk' infant category. FAO/WHO concluded that the high-risk group are all infants in the first two months of life (FAO/WHO, 2006) based on the knowledge that infants up to about two months are known to be at elevated risk for meningitis (Dr. A. Bowen CDC, pers. comm.).

E. sakazakii has been isolated from many foods and environmental sources and can be considered ubiquitous (Iversen and Forsythe, 2004). The role of these sources in neonatal infection has not been determined. However, of the 27 infection studies cited by Iversen and Forsythe (2003), eight cite infant formula milk as the suspected source of the *E. sakazakii* infection (the source was unknown or not specified in the remaining 19 studies). Bowen and Braden (2006) found that of 26 infants where feeding patterns were specified, 24 (92%) were fed on PIF. Formula samples associated with 15 (68%) of 22 of these cases yielded *E. sakazakii*. In 13 (87%) of these cases, the clinical and formula strains were indistinguishable. *E. sakazakii* has been isolated from infant formula milk powder on many occasions (FAO/WHO, 2004; Iversen and Forsythe, 2004) although contamination can be considered as low and sporadic.

6. DEFINITION OF RISK GROUPS FOR INVASIVE *E. sakazakii* DISEASE AND SALMONELLOSIS

These foodborne diseases can affect all age groups in the population, however, in the context of this document, the following groups have been identified based on international risk assessment (FAO/WHO 2006):

Vulnerable Group: All infants (defined as persons less than 12 months of age).

Most Vulnerable Group: All infants less than two months of age and all immunocompromised infants irrespective of age.

7. RECOMMENDATIONS FOR GUIDANCE AND SUPPORTING RATIONAL

The following recommendations should be used as the basis for the development of suitable guidance material on the safe preparation and handling of powdered infant formula.

General Recommendations for Guidance Materials

- It is recommended that appropriate health promotion bodies develop guidance material for safe infant feeding targeted specifically at the following groups:
 - medical care settings where trained medical staff are responsible for the safe feeding of infants
 - child care settings where trained and/or untrained child care workers are responsible for the safe feeding of infants
 - domestic settings where parents and/or other untrained people are responsible for the safe feeding of infants.
- All guidance material should clearly state the Department of Health and Children recommendations for breastfeeding, namely: *‘infants should be exclusively breastfed for the first six months and thereafter continue to be breastfed in combination with suitably nutritious complementary foods for up to two years of age or beyond. This practice is the safest and best way of ensuring that babies achieve optimal growth, health and development.’*
- Guidance materials should be written in plain language and be suitable for the racial and cultural diversity of Irish society. Materials should be distributed widely and be freely available to all end users.

Although the rationale behind the recommendations in this document should be understood, it should only be built into guidelines where thought necessary to reinforce compliance.

(a) RECOMMENDED PROCEDURES FOR THE SAFE PREPARATION OF INFANT FEEDING EQUIPMENT

- Wash hands thoroughly before cleaning feeding equipment.
- Wash feeding and preparation equipment in hot soapy water before sterilisation. Scrub the insides and outsides of teats and bottles with a bottle and teat brush to remove all remaining traces of feed.
- Dishwashers can be used to clean feeding and preparation equipment but only if the equipment is dishwasher proof and stacked correctly following machine instructions. The suitability of feeding and preparation equipment for dishwasher use should be checked with the manufacturer of the equipment prior washing. **Dishwashers will not sterilise feeding and preparation equipment.**
- Clean feeding and preparation equipment should be sterilised prior to use:
 - steam is the best method of sterilising feeding equipment. Commercially available home electrical units or units that work in the microwave oven are available. Always follow manufacturer's instructions
 - sterilisation is also possible by immersion in boiling water. Fill a large pan with tap water and completely submerge all feeding and preparation equipment ensuring there are no trapped air bubbles. Cover the pan, bring to the boil and boil for at least three minutes making sure the pan does not boil dry
 - sterilisation is also possible using chemical sterilant added to water. Make up a batch of sterilant following manufacturer's instructions. Ensure all equipment is completely immersed in the liquid and that there are no trapped air bubbles. Leave the equipment submerged for the length of time specified by the manufacturer and follow all other manufacturer's instructions.
- Wash hands and surfaces before handling and assembling sterile feeding equipment.
- Bottles or other feeding equipment should be assembled immediately after sterilisation. Care should be taken to avoid touching the teats and the insides of the bottles, sealing discs, bottle caps and collars. Sterile tongs may be used to fix teats into collars. Once assembled correctly, bottles will remain sterile for 24 hours providing that they remain unopened.

QUESTIONS AND ANSWERS

Why is it necessary to wash hands before washing and sterilising feeding equipment?

Hands are a source of dirt and bacteria that can transfer to feeding equipment. Effective handwashing will remove dirt and reduce the number of bacteria.

Why is it necessary to wash feeding equipment and preparation equipment so thoroughly?

Feed residues are a source of food for bacteria that then grow and form a film on the feeding equipment that is difficult to remove. Infant formula is a high protein food that clings to the surfaces of equipment. Detergent, hot water and a physical scrubbing action are all necessary to remove the feed, especially from hard to reach areas of the equipment. If feed is not removed by thorough washing then sterilisation may not be effective, leaving bacteria that can grow in the new feed when it is made up.

Why is it necessary to sterilise feeding and preparation equipment?

Sterilisation of equipment is necessary to kill all of the bacteria that may be present on the equipment surfaces. If left, these bacteria could grow in new feeds made up in the bottles and could cause illness in the infant.

Why is steam a good method of sterilisation?

Steam contains more energy than boiling water and therefore kills bacteria quicker. Steam is also like a gas and can easily contact all of the equipment surfaces. Commercial steam sterilisation equipment is often easier to use.

Why must all trapped air bubbles be removed from equipment when using the boiling water or chemical sterilant methods of sterilisation?

Both the boiling water and the chemical sterilant methods require the liquid being used to come into contact with all surfaces of the equipment for the desired time period. Trapped air bubbles prevent the liquid from making contact with the equipment surface where the air is and hence these areas are not sterilised.

Why should sterile feeding equipment be assembled as soon as it is sterile?

It is possible that if feeding equipment is left in steam sterilisers or in pans after sterilisation it will come into contact with the air which could recontaminate it. By assembling the bottles correctly and immediately, the inside surfaces that will be in contact with the feed will remain sterile for 24 hours. With tight fitting lids, the outside surface of the teat should also remain sterile.

Why should I avoid touching the teats and the insides of bottles, sealing discs, caps and collars?

Even washed hands will harbour bacteria and it is important that these bacteria do not transfer to the important parts of the sterile feeding equipment. Otherwise, the bacteria could grow in the feed when it is made up in the bottles. The important parts of the equipment that must remain sterile are those that are in contact with the feed (insides of teats, bottles, sealing discs and collars) and those that will be in the infant's mouth (outside of the teat). Although the use of sterile tongs for teat assembly can be cumbersome, the maintenance of teat sterility is a worthwhile reason for perfecting the technique.

(b) RECOMMENDATIONS FOR THE SAFE FEEDING OF POWDERED INFANT FORMULA IN MEDICAL CARE SETTINGS

- There should be a clean dedicated suitable area for the preparation and handling of PIF.
- Written procedures should be in place for the preparation and handling of PIF.
- Staff with responsibility for the preparation and handling of PIF should receive appropriate training based on the written procedures in place.
- The implementation of the written procedures should be routinely monitored.
- A system should be established to ensure full traceability of PIF from infant to the actual batch of PIF used to feed that infant.
- All feeding and preparation equipment should be clean and sterilised. This includes feeding lines and other specialist equipment.
- Refrigerators used for the storage of PIF should be equipped with a fridge thermometer and subjected to regular checking and adjustment where necessary to ensure that they are operating at a temperature of 5°C or below.
- Infants in the medical care setting should, when available, be fed on ready-to-feed commercially sterilised liquid formula.
- The following steps should be followed when using PIF:

Step 1 Boil fresh tap water in a kettle or other suitable covered vessel.

Step 2 When boiled, leave the water to cool in the kettle (or other suitable covered vessel). Use a clean thermometer to ensure the water is between 70°C and 75°C before use.

Step 3 Clean the feed preparation area thoroughly and wash hands with soap and hot water and dry.

Step 4 To make up the feed:

- a) **The preferred method:** Pour the amount of hot water required into a sterile bottle **taking care to avoid scalding**. Make each feed up in a sterile bottle by adding the exact amount of powdered infant formula as instructed on the label using the clean scoop provided. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer and shake well to mix the contents, **taking care to avoid scalding**.

b) **The batch method:** Use a large clean and sterile jug with a pouring spout of no greater capacity than 1 litre. Pour the amount of hot water required into the jug **taking care to avoid scalding**. Add the exact amount of PIF for the volume of water being used as instructed on the label using the clean scoop provided. Mix thoroughly using a clean sterile spoon. Decant the feed into sterile bottles **taking care to avoid scalding**. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer.

Step 5 Cool feed quickly to feeding temperature by holding the bottle(s) under cold running tap water or immersing in a large volume of cold tap water. Ensure that the cold water does not reach above the neck of the bottle during cooling. In instances where large volumes of infant formula are being prepared, the use of a blast chiller for cooling feeds quickly is advisable.

Step 6 To feed:

a) **immediately:** ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm**.

b) **later:** wipe the bottles dry with a clean cloth and place them in the back of a refrigerator (operating at max 5°C), not in the door, and use within 24 hours. To feed, remove one bottle just before it is needed and warm to feeding temperature using a bottle warmer or by standing the feed in a container of warm water. Never leave a feed warming for more than 15 min. Ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm**.

Step 7 Discard any feed that has not been consumed within two hours of preparation. For slow feeding babies use a fresh feed after two hours.

- If infant formula milk for special medical purposes is only available in powdered form and cannot be reconstituted with water above 70°C for compositional reasons, then feeds should be made fresh and fed immediately using the following procedure:

Wherever possible, avoid making up batches of feeds for storage prior to feeding by this method. Feeds made in this way should be fed immediately.

- Step 1** Clean the feed preparation area thoroughly and wash hands with soap and hot water and dry.
- Step 2** To make up the feed, pour the amount of cooled boiled tap water required into a sterile bottle. Add the exact amount of powdered infant formula as instructed on the label using the clean scoop provided. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer and shake well to mix the contents.
- Step 3** If necessary, cool the feed quickly to feeding temperature by holding the bottle under cold running tap water or immersing in a large volume of cold tap water. Ensure that the cold water does not reach above the neck of the bottle during cooling.
- Step 4** Feed immediately. Ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm.**
- Step 5** Discard any feed that has not been consumed within two hours of preparation. For slow feeding babies use a fresh feed after two hours.

- If using human milk fortifiers, feeds should be made fresh as directed by the manufacturer's on-pack instructions and fed immediately using the following procedure:

Wherever possible, avoid making up batches of feeds for storage prior to feeding by this method. Feeds made in this way should be fed immediately.

- Step 1** Breast milk should be collected into sterile feeding bottles using sterile equipment then fully labelled with the mother's name and infant's name/identification as appropriate. Breast milk in a medical setting can be stored in the back of a refrigerator below 5°C for up to 48 hours.

Step 2 To make up the feed, warm the breast milk in the bottle to the feeding temperature. Add the exact amount of powdered human milk fortifier as instructed on the manufacturer's label using the clean scoop provided. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer and shake well to mix the contents.

Step 3 Feed immediately. Ensure the feeding temperature is correct by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm.**

Step 4 Discard any feed that has not been eaten within two hours of preparation. For slow feeding babies use a fresh feed after two hours.

- If it is necessary to transport feeds to wards from a central preparation facility then ensure feeds are made using the 70°C preparation method. Ensure the feeds are cold (less than 5°C). Move the cold feeds to the ward within 30 min of removing them from the fridge. Either warm feeds on the ward and feed immediately or replace cold feeds into the back of a refrigerator below 5°C on the ward and feed within 24 hours of the preparation time.

Feeds for special medical purposes and feeds using human breast milk that cannot be made using the 70°C preparation method should be made up under clean conditions, ideally on the ward and fed immediately.

- For infants who are being tube fed, procedures must be developed by the infection control team to ensure that equipment in contact with the feed is clean and sterile before use. If the infant is not fed on breast milk, ready-to-feed commercially sterilised liquid formula should be used where possible. In all cases, hang times must not be longer than two hours after which, fresh feed and sterile equipment should be used.
- Powdered starch should not be added to infant formula unless the formula is at a temperature greater than 70°C and the addition of starch at this temperature will not cause the starch to form lumps. If lump formation cannot be avoided, alternatives should be used where possible (there are clinical situations where the appropriate starch cannot be used at high temperatures). In these cases, wherever possible, avoid making up batches of feeds for storage prior to feeding by this method. Feeds made in this way should be fed immediately.
- Babies born at lower than average birth weights (less than 2.5kg) may require vitamin C supplementation if fed solely on infant formula prepared with water at temperatures greater than 70°C. Clinical advice must be sought to identify infants at risk and develop adequate intervention strategies.

QUESTIONS AND ANSWERS

Why is it recommended that infants in the medical care setting should, when available, be fed on ready-to-feed commercially sterilised liquid formula?

Ready-to-feed, commercially sterilised liquid formulae are subjected to a heat process by the manufacturer that is sufficient to kill *E. sakazakii* and any other bacteria like *Salmonella* that can be harmful to the health of the infants. The heat processes used by the manufacturers are carefully controlled to produce a consistently safe product. Usually, infants in medical care settings are most vulnerable to infection. Hence, the use of the safest form of infant formula is advisable.

Why is it necessary to use hot water above 70°C to make up powdered infant formula?

The FAO/WHO risk assessment model demonstrated that this practice provided the greatest degree of protection against invasive *E. sakazakii* disease in infants. Water above 70°C will kill *E. sakazakii* and any other bacteria like *Salmonella* that may be in the PIF.

Why must a thermometer be used to ensure the water is between 75°C and 70°C before use?

The higher the temperature of the water used to make PIF, the greater the degradation of essential nutrients. However, the water should be at a sufficiently high temperature to kill harmful bacteria. The use of a thermometer is the most accurate method to ensure that the most effective balance is achieved between these two risks. Water should never be used below 70°C.

What are the other concerns with using water at 70°C to make up feeds?

Scalding is the main concern and care must be taken to avoid this risk by careful handling of hot water and bottles filled with hot water or feed. Steam from the hot water could also wet the powder in the scoop preventing accurate dosage by causing powder to stick to the scoop. However, careful practice will usually avoid this potential problem.

Why is the preferred method to make up feeds in individual sterile bottles rather than a large batch container?

Feed preparation in large open containers is more prone to contamination by bacteria from the environment than feed preparation in individual bottles. It is also more difficult to sterilise large equipment properly without specialised sterilisers. However, practicality in a busy medical care setting or where multiple-ingredient feeds are required, may necessitate the use of the batch method.

Why is it important to cool feed quickly?

E. sakazakii will grow at temperatures between 6°C and 45°C and will grow quickly between temperatures of 37°C and 43°C (FAO/WHO, 2006). *Salmonella* will grow at temperatures between 5°C and 46°C and will grow quickly between temperatures of 37°C and 43°C (ICMSF, 1996). *Bacillus cereus* and some other bacterial spores that will, if present, survive the use of hot water to make up the PIF will grow between 4°C and 55°C and will grow quickly between 30°C and 40°C (ICMSF, 1996). Consequently, to avoid the growth of harmful bacteria, it is important that the feed is cooled as quickly as possible to feeding temperature and fed immediately so that there is no opportunity for the growth of these bacteria. If feed is to be fed later then it is important that the cooled feed is placed in a refrigerator and cooled further down to 5°C so that none of these bacteria can grow over the extended storage time. In instances where large volumes of infant formula are being prepared, the use of a blast chiller for cooling feeds quickly prior to refrigeration is necessary to ensure all feeds in the batch are cooled quickly.

Why is it important that cooling water is kept below the neck of the bottle during cooling?

When bottles of feed cool they will pull a vacuum that can draw non-sterile cooling water inside the bottle if it is above the neck. This increases the chance of contamination of feed with bacteria that may be in the cooling water.

Why is it necessary to check the temperature of the feed before feeding?

This is important especially when using the method of preparation using 70°C water. It is essential that the whole volume of feed is luke-warm or cooler (depending on the infant's feeding habits). Hot feed will cause serious burns to the infant's mouth.

Why is it necessary to discard unconsumed feed after two hours?

Most infants take their feed luke-warm and at this temperature bacteria in the feed may grow (see earlier question on cooling). Therefore, it is necessary to restrict the time that the feed is in this temperature range. Two hours is a compromise between practicality and the time within which bacteria could grow. After two hours harmful bacteria could grow to sufficient numbers in the feed to cause illness.

Why is it acceptable to make up some infant formula without using boiled water cooled to 70°C?

The FAO/WHO risk assessment model demonstrated that the use of 70°C water provided the **greatest degree of protection** against invasive *E. sakazakii* disease in infants. Water above 70°C will kill *E. sakazakii* and any other bacteria like *Salmonella* that may be in the PIF. However, some specialised infant formulas cannot be reconstituted with hot water for either compositional or reconstitution reasons. The proposed method of reconstitution for these formulas is an unavoidable compromise. Whilst the method will not kill harmful bacteria if they are present in the specialised PIF, it will ensure that there should be no further growth in the feed prior to feeding. Hence, this method does not provide as high a degree of protection for the infant as the method using 70°C water. However, rigorous controls at the manufacturing stage should ensure that contamination is infrequent and confined to very low levels of harmful bacteria. Unfortunately, those infants on specialised formula are often the same infants in the most vulnerable group and this must be considered when deciding on the most appropriate reconstitution method.

Why must specialised powdered infant formula made up without using 70°C water be fed immediately?

The WHO/FAO risk assessment demonstrated a marked increase in risk if feeds made with water below 70°C were not fed immediately. This is because the harmful bacteria are not killed and can grow during storage.

Why must feed be transported cold to a ward within 30 minutes?

Harmful bacteria will grow in feed above refrigeration temperatures (see question on cooling). Transport from central preparation facility to a ward allows the feed to warm up. Ensuring the feed is cold (less than 5°C) before transport and restricting transport time to 30 minutes should minimise and temperature increase and prevent growth of any harmful bacteria if they are present. Re-heating should occur on the ward because if the feed was warmed centrally and transported there would be a significantly increased risk of harmful bacteria, if present, growing in the feed during transport.

Why is it necessary to restrict the hang times to two hours and use clean sterilised equipment for each feed?

Most infants take their feed luke-warm and at this temperature bacteria in the feed may grow (see earlier question on cooling). The temperature of the ward will also affect the temperature of the feed. Therefore, it is necessary to restrict the time that the feed is in this temperature range. Two hours is a compromise between practicality and the time within which bacteria could grow. After two hours, harmful bacteria could grow to sufficient numbers in the feed to cause illness. Whilst the use of clean and sterilised feeding equipment (bag and tubes) may be obvious on first feeding, over the two hour hang time protein and fat deposits will build up on the equipment. Bacteria that may be present in the feed could adhere to these deposits and grow forming a sticky layer (biofilm) that can develop in time into growing communities of millions of bacteria. If fresh feed after two hours is fed through previously used equipment then bacteria have the time to grow and develop these biofilms. It is possible for harmful bacteria to break out of these biofilms and contaminate the fresh feed. It is also worth noting that build up of biofilms can be extremely difficult to remove during cleaning if equipment is reused. Consequently, it is safer to use clean and sterile feeding equipment for each fresh feed.

Why should powdered starch not be added to cool feed?

Powdered starch contains bacteria, some of which could be harmful. Adding the starch to cool feed will introduce these bacteria into the feed and compromises the risk reduction benefit of making up the feed with water above 70°C. Therefore, the starch should be treated just like the PIF and added when the feed is above 70°C just as it is being made up. However, starches form gels at high temperature which is why they thicken liquids. The temperature that causes thickening depends upon the starch that is being used. If the starch thickens and forms lumps when added to the feed at 70°C it could block the teat or worse – shield the bacteria in the lumps from the heat so that they are not killed. Different starches will gel at different temperatures so a change of starch might solve the problem. Otherwise, other solutions should be discussed with medical staff.

Why may vitamin C supplementation be needed for low birth weight babies?

The use of very hot water (>70°C) for the reconstitution of PIF will minimize the threat of *E. sakazakii* but there are concerns regarding the loss of heat sensitive nutrients. Data presented at the FAO/WHO expert meeting (2006) on the reduction in vitamin levels on reconstitution with boiling water, indicated that vitamin C is most vulnerable to significant losses.

In the case of vitamin C degradation, smaller babies will be at higher risk of inadequacy due to their lower intakes of formula. An analysis of the risk of inadequacy at the highest levels of vitamin C degradation reported (65.6%) found that babies of average compared with low-average birth weight (3.5 vs. 2.5kg) were provided with 54-120% vs. 40-88% of the Recommended Daily Allowance for vitamin C respectively. Furthermore, at this level of vitamin C degradation, all average birth weight babies achieved a vitamin C intake greater than the Estimated Average Requirement while none of the low-average birth weight babies met this criterion. However, it is important to consider that this risk of vitamin C inadequacy will be offset to some extent by the fact that low-average birth weight babies will be taking more vitamin C everyday as they gain body weight and consume more formula – babies born at 2.5kg are expected to weigh 3.4kg at one month old.

Among these low-average birth weight babies, therefore, the highest risk of vitamin C inadequacy due to preparation of PIF at higher temperatures will be among those infants who fail to thrive and where the expected increase in amount of formula intake with growth is compromised. Babies born at lower than average birth weights (<2.5kg) are likely to require vitamin C supplementation if fed solely on formulae prepared on water at temperatures of 70-100°C.

Recommendations later in this report urge the infant formula industry to address this issue and re-formulate to accommodate nutrient losses due to heat. Therefore, this situation might change in the future and consultation with the formula manufacturer may be prudent.

(c) RECOMMENDATIONS FOR THE SAFE FEEDING OF POWDERED INFANT FORMULA IN DOMESTIC SETTINGS

- All feeding and preparation equipment should be clean and sterilised.
- Infants can be fed exclusively or periodically on ready-to-feed commercially sterilised liquid formula available in cartons.
- The following steps should be followed when using powdered infant formula:

Step 1 Boil fresh tap water in a kettle or other suitable covered vessel.

Step 2 When boiled, leave the water to cool in the kettle (or other suitable covered vessel). To ensure the water temperature is no less than 70°C but not too hot, it should be left to cool in the kettle for 30 minutes, but no longer, before use.

Step 3 Clean the feed preparation area thoroughly and wash hands with soap and hot water and dry.

Step 4 To make up the feed, pour the amount of hot water required into a sterile bottle **taking care to avoid scalding**. Make each feed up in a sterile bottle by adding the exact amount of powdered infant formula as instructed on the label using the clean scoop provided. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer and shake well to mix the contents, **taking care to avoid scalding**.

Step 5 Cool feed quickly to feeding temperature by holding the bottle(s) under cold running tap water or immersing in a large volume of cold tap water. Ensure that the cold water does not reach above the neck of the bottle during cooling.

Step 6 To feed:

a) **immediately**: ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm not hot**.

b) **later**: wipe the bottles dry with a clean cloth and place them in the back of a refrigerator (operating at max 5°C), not in the door, and use within 24 hours. To feed remove one bottle just before it is needed and warm to feeding temperature using a bottle warmer or by standing the feed in a container of warm water. Never leave a feed warming for more than 15 minutes. Ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm**.

Step 7 Discard any feed that has not been consumed within two hours of preparation. For slow feeding babies use a fresh feed after two hours.

- When infant formula is required during travelling, if possible, use ready-to-feed commercially sterilised liquid formula available in cartons. Otherwise, the following steps should be followed when using powdered infant formula:

At home before travelling:

- Step 1** Wash hands with soap and hot water and dry.
- Step 2** Boil fresh tap water in kettle or other suitable covered vessel.
- Step 3** Pour the correct volume of boiled water specified by the PIF manufacturer, without cooling it, into sterile feeding bottles. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer.
- Step 4** Allow the bottles of water to cool to room temperature and store for use in a clean place for up to 24 hours. For convenience, a number of bottles can be prepared at the same time.
- Step 5** Any bottles of sterile water not used after 24 hours should be discarded and the feeding equipment washed and re-sterilised.

During travel:

- Step 6** Take the sterile bottles of water and the can of powdered infant formula with you.
- Step 7** When formula is needed, warm the bottle of water to feeding temperature using a bottle warmer or by standing the feed in a container of warm water.
- Step 8** Add the exact amount of powdered infant formula as instructed on the manufacturer's label using the clean scoop provided. Re-assemble the bottle tightly and carefully as instructed by the bottle manufacturer and shake well to mix the contents.
- Step 9** Ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm.**
- Step 10** Use the feed immediately and discard any feed that has not been consumed within two hours of preparation. For slow feeding babies use a fresh feed after two hours.

QUESTIONS AND ANSWERS

Why can infants be fed on ready-to-feed liquid formula?

Ready-to-feed liquid formula is subjected to a heat process by the manufacturer that is sufficient to kill *E. sakazakii* and any other bacteria like *Salmonella* that can be harmful to the health of the infants. The heat processes used by the manufacturers are carefully controlled to produce a consistently safe product. Use of these ready-to-feed liquid formulas is a safe alternative to feeding PIF.

Why is it necessary to use hot water above 70°C to make up powdered infant formula?

The FAO/WHO risk assessment model demonstrated that this practice provided the greatest degree of protection against invasive *E. sakazakii* disease in infants. Water above 70°C will kill *E. sakazakii* and any other bacteria like *Salmonella* that may be in the PIF.

Why should the boiling water not be used immediately but left to cool for 30 min?

At high temperatures, some of the heat labile vitamins and other nutrients in the PIF will be destroyed. The higher the water temperature, the greater the amount of nutrient degradation. The choice of the best water temperature is a practical balance between a high enough temperature to kill the harmful bacteria but a low enough temperature to retain sufficient amounts of nutrients. Ideally a clean thermometer should be used to ensure the boiled water is at 70°C. However, it is unlikely that such equipment is available in a domestic setting. Consequently, a practical approach must be selected. The closer the temperature of the water is to 70°C the better. Hence, using the boiled water immediately will increase nutrient degradation and is not recommended. The 30 minute rule is recommended as a practical means of achieving water temperature between 80°C and 70°C without the need for a thermometer.

Why is it important to cool feed quickly?

E. sakazakii will grow at temperatures between 6°C and 45°C and will grow quickly between temperatures of 37°C and 43°C (FAO/WHO, 2006). *Salmonella* will grow at temperatures between 5°C and 46°C and will grow quickly between temperatures of 37°C and 43°C (ICMSF, 1996). *Bacillus cereus* and some other bacterial spores that will, if present, survive the use of hot water to make up the PIF will grow between 4°C and 55°C and will grow quickly between 30°C and 40°C (ICMSF, 1996). Consequently, to avoid the growth of harmful bacteria, it is important that the feed is cooled as quickly as possible to feeding temperature and fed immediately so that there is no opportunity for the growth of these bacteria. If feed is to be fed later then it is important that the feed is placed in a refrigerator and cooled to 5°C so that none of these bacteria can grow over the extended storage time.

Why is it important that cooling water is kept below the neck of the bottle during cooling?

When bottles of feed cool they will pull a vacuum that can draw non-sterile cooling water inside the bottle if it is above the neck. This increases the chance of contamination of feed with bacteria that may be in the cooling water.

Why is it necessary to check the temperature of the feed before feeding?

This is important especially when using the method of preparation using 70°C water. It is essential that the whole volume of feed is luke-warm or cooler (depending on the infants feeding habits). Hot feed will cause serious burns to the infant's mouth.

Why is it necessary to discard unconsumed feed after two hours?

Most infants take their feed luke-warm and at this temperature bacteria in the feed may grow (see earlier question on cooling). Therefore, it is necessary to restrict the time that the feed is in this temperature range. Two hours is a compromise between practicality and the time within which bacteria could grow. After two hours harmful bacteria could grow to sufficient numbers in the feed to cause illness.

Why should bottles of sterile water be discarded after 24 hours?

This is a precautionary approach based on the ability of sealed feeding bottles to maintain the sterility of the water over long periods of storage. After 24 hours, it is possible the water could no longer be sterile.

Why is the use of 70°C water not recommended for travelling even when the infant is less than two months old?

Infants below the age of two months (based on full term birth) are in the most vulnerable group regarding infection. Therefore, the reconstitution method using boiled water cooled to 70°C is recommended. However, when travelling, this method is not practical and therefore in the first instance ready-to-feed commercially sterile feed is recommended. However, for reasons of cost or availability, this option may not be possible for some parents. Hence the alternative fresh preparation method is suggested. Although the same level of protection may not be afforded by the fresh preparation method, there are a relatively small number of feeds that are prepared whilst travelling compared to those prepared at home. Feeding of fresh feeds rather than introducing the increased risks associated with storage of feeds is felt to offset the reduction in protection to some extent. However, parents who are concerned may opt to carry boiling water in a vacuum flask and use their normal method of preparation. The risk of scalding, which might be higher when travelling compared with the handling of hot water in the home must be considered if this choice is made and extra care must be taken to avoid scalds. It is for this latter reason that the use of hot water in a vacuum flask is not recommended.

Why is it not recommended to travel with pre-prepared cold feeds?

Feeds could be prepared at home using the 70°C water method, cooled to below 5°C and stored in a refrigerator as recommended. However, the safety of these feeds relies on the maintenance of temperatures below 5°C so that harmful bacteria, if present, cannot grow during storage. The maintenance of feeds at a temperature below 5°C during short travel times is possible. However, over long travel times it is very difficult to maintain the feeds below 5°C potentially leaving feeds at higher temperatures for prolonged periods. As a consequence, this method has not been recommended other than for transport of feeds to child day-care facilities (see section on safe feeding of PIF in child day-care settings).

Is there an alternative to taking the can of powdered infant formula when travelling?

Some powdered infant formula is also sold in single dose sachets which can be used when travelling. Plastic containers are also available in some pharmacies that are designed to carry several pre-measured amounts of powdered infant formula (each amount would be enough to make up one feed). These can be filled at home and taken when travelling. Alternatively any small sealable plastic container could be used to carry pre-measured doses of powdered infant formula. However, the use of a large container to carry a large amount of powder is not recommended. In the case of any container used to transport powdered infant formula, it should be cleanable and be made of plastic that can be sterilised. The container should always be cleaned, sterilised and dried thoroughly before use so that harmful bacteria in the environment cannot contaminate the powdered infant formula placed in the container. Ready-to-feed liquid formula can always be used as an alternative when travelling.

(d) RECOMMENDATIONS FOR THE SAFE FEEDING OF POWDERED INFANT FORMULA IN CHILD DAY-CARE SETTINGS

- Infants can be fed ready-to-feed commercially sterilised liquid formula available in cartons when they are attending day-care facilities.
- The following steps should be followed when using powdered infant formula:
 - Step 1** Feeds should be prepared at home using the 70°C preparation method recommended for the safe feeding of PIF in domestic setting (Steps 1 to 5).
 - Step 2** Cooled feeds should be marked with the child's name and stored in the body of a refrigerator below 5°C until they are completely cold but no longer than 24 hours.
 - Step 3** Immediately prior to leaving for the child day-care facility, the correct number of feeds should be taken from the refrigerator and placed in a clean cool-box or bag with a suitable number of ice blocks to maintain the feed at 5°C.
 - Step 4** On arrival at the child day-care facility the feeds should be transferred from the cool-bag or cool-box to a dedicated refrigerator in the child-care facility maintained at 5°C or below. The fridge should be equipped with a fridge thermometer to enable the temperature to be checked and adjusted if necessary.
 - Step 5** To feed, child-care workers should remove one bottle just before it is needed. The bottle should be checked to ensure the name on the bottle corresponds to the infant. The feed should then be warmed to feeding temperature using a bottle warmer or by standing the feed in a container of warm water. Never leave a feed warming for more than 15 min. Ensure the feed is not too hot by shaking the bottle and placing a drop of liquid on the inside of the wrist – **it should feel luke-warm.**
 - Step 6** Discard any feed that has not been consumed within two hours of preparation. For slow feeding babies use a fresh feed after two hours.
 - Step 7** Unused feed should be discarded and the used bottles rinsed in warm tap water.
 - Step 8** All feeding bottles should be returned at the end of the day when the infant is collected.
 - Step 9** Used feeding bottles should be cleaned thoroughly at home and sterilised as recommended in the section on cleaning and sterilising feeding equipment.

QUESTIONS AND ANSWERS

Why can infants be fed on ready-to-feed liquid formula?

Ready-to-feed liquid formula is subjected to a heat process by the manufacturer that is sufficient to kill *E. sakazakii* and any other bacteria like *Salmonella* that can be harmful to the health of the infants. The heat processes used by the manufacturers are carefully controlled to produce a consistently safe product. Use of these ready-to-feed liquid formulas is a safe alternative to feeding PIF.

Why is it not recommended that child day-care facilities prepare feeds for the infants in their care?

Most child day-care facilities are domestic environments and are not appropriate places for the preparation of large numbers of feeds on a daily basis. Similarly, even purpose built premises do not always have suitable areas. Given the number of infants that can be present in child day-care facilities, there is potential for mistakes being made if feeds had to be made up from scratch, e.g. wrong powdered infant formula given to an infant. The practicality of making up multiple fresh feeds in a busy hands-on child-care environment must also be considered. These considerations have to be offset against the risks of temperature abuse of pre-prepared feeds during transport from the home. The procedure that is recommended is designed to minimise these risks to an extent where on balance, the careful transport of pre-prepared feeds by parents is the more practical and safer option.

Why is it important to mark the feeds with the child's name?

The infants in a child day-care facility are likely to be consuming different forms of powdered infant formula manufactured by different companies. Sometimes infants can have reactions to changes in feed. In a busy child day-care facility there could be a risk of feeding the wrong feed to an infant if the different feeds supplied by the parents were not labelled with the infant's name.

Why is it necessary to transport prepared feeds in a cool bag/cool box with an ice block?

E. sakazakii will grow at temperatures between 6°C and 45°C and will grow quickly between temperatures of 37°C and 43°C (FAO/WHO, 2006). *Salmonella* will grow at temperatures between 5°C and 46°C and will grow quickly between temperatures of 37°C and 43°C (ICMSF, 1996). *Bacillus cereus* and some other bacterial spores that will, if present, survive the use of hot water to make up the PIF will grow between 4°C and 55°C and will grow quickly between 30°C and 40°C (ICMSF, 1996). Consequently, to avoid the growth of harmful bacteria it is important that the feed is kept below 5°C. Short trips of 30 min or less are unlikely to raise the temperature of feed significantly, however, traffic congestion or unexpected delays can extend the time of trips that are expected to be of short duration. Therefore, the cool bag or cool box with an ice block is the safest means of ensuring that the temperature of feeds does not rise during transport to the child day-care facility. However, this method should not be used for very long travel times as cool bags or cool boxes are unlikely to be capable of maintaining feed temperatures below 5°C over long time periods. This usually isn't an issue in respect to travel to child day-care facilities.

Why is it necessary to discard unconsumed feed after two hours?

Most infants take their feed luke-warm and at this temperature bacteria in the feed may grow (see earlier question on cooling). Therefore, it is necessary to restrict the time that the feed is in this temperature range. Two hours is a compromise between practicality and the time within which bacteria could grow. After two hours, harmful bacteria could grow to sufficient numbers in the feed to cause illness.

Why is it necessary to rinse feed bottles after use in the child day-care facility and return them at the end of the day?

Washing the bottles would be preferable but may not be practical in all facilities. However, if unused feed is left in bottles at room temperature after feeding then bacteria will start to grow. If these bacteria form films on the bottles (biofilms) these can be extremely difficult to remove even by subsequent washing. Since used bottles are likely to be left at room temperature for several hours before being collected, returned to the home and washed, there is ample opportunity for this growth to happen. This is particularly an issue if the bottles are not all returned at the end of the day therefore extending the time for growth to occur. Rinsing or preferably washing the bottles immediately after use will prevent this and ensure that the bottles are cleanable and safe for subsequent use.

(e) ADDITIONAL RECOMMENDATIONS

- Parents and guardians and medical and childcare workers that are handling PIF should receive appropriate training in safe preparation practices.
- The Health Protection Surveillance Centre should inform appropriate medical staff about invasive *E. sakazakii* disease to ensure that it is accounted for during clinical diagnosis. Clinical microbiology laboratories should ensure that they have the microbiological methods in place to ensure accurate isolation and identification of *E. sakazakii*.
- Manufacturers of PIF should amend their on-pack instructions to align them with national safe preparation guidelines. Once this is done, a clear and prominent warning message on-pack should inform parents of the risk to infants of not following manufacturers' preparation instructions.
- Manufacturers of PIF should conduct studies to ensure that all infant formula powders contain sufficient quantities of all heat labile nutrients (vitamin C in particular) at the point of manufacture to ensure the infant formula milk reconstituted using water at temperatures greater than 70°C maintains adequate nutrient levels on feeding. Testing must account for nutrient losses that occur following storage and reconstitution of infant formula powders at temperatures exceeding 70°C as well as any legal limits on the levels of vitamin C that may be added to these products.
- Manufacturers of PIF should take all necessary steps to ensure that the PIF they produce will disperse effectively in water between 80°C and 70°C.

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