Food Safety
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22

GUIDANCE NOTE

Information Relevant to the Development of Guidance Material for the Safe Feeding of Reconstituted Powdered Infant Formula (Revision 2)

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CONTENTS

1. INTRODUCTION

Powdered infant formula (PIF) contaminated with harmful bacteria has been implicated as a source of illness in infants. In recent years, *Cronobacter* species[1] associated with PIF has emerged as a cause of disease in infants. In 2007, the World Health Organization (WHO) issued guidelines on the safe preparation, storage and handling of powdered infant formula (WHO, 2007). These guidelines were informed by two risk assessments on the subject, jointly hosted by the Food and Agricultural Organization (FAO) of the United Nations and the WHO (FAO/WHO, 2004 and 2006).

The Food Safety Authority of Ireland (FSAI) has received requests from the Department of Health, public health nurses, dietitians and parents for guidance on the safe preparation, storage and handling of PIF. In order to develop this guidance, the FSAI hosted a seminar on *Cronobacter* species and infant feeding in October 2006, which was attended by participants from the health and food safety community, interested academics and the infant formula industry. The FSAI presented a consultation document to participants for comment. Over 220 comments were received from 26 individuals or groups and these comments have formed the basis for this *Guidance Note No. 22 Information Relevant to the Development of Guidance Material for the Safe Feeding of Reconstituted Powdered Infant Formula.*

2. PURPOSE OF THIS DOCUMENT

This guidance note is written to provide the basis for developing suitable guidance material on the safe preparation and feeding of PIF. It is not intended to be used as direct guidance to stakeholder groups. Appropriate communication bodies should prepare clear and targeted guidance material based on the recommendations in this guidance note.

[1] Note: prior to 2008 *Cronobacter* species was known as *Enterobacter sakazakii,* but for the purposes of this document, the term *Cronobacter* species will be used throughout.

3. POWDERED INFANT FORMULA

The Department of Health recommends that infants are 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 – commonly referred to as formula. Various products are available in powdered form referred to throughout this document as PIF. These include:

- Infant formula (as defined In Commission Directive 2006/141/EC)
- Follow-on formula (as defined In Commission Directive 2006/141/EC)
- Formula for special medical purposes intended for infants (as defined in Commission Directive 1999/21EC)

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

This guidance note also discusses the use of powdered starch and human milk fortifiers.

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 *Cronobacter* species and *Salmonella* in PIF (FAO/WHO, 2006) developed a categorisation system for all bacteria of concern (Table 1).

Table 1. Categorisation of the microorganisms or microbial toxins of concern based on the strength of evidence of a causal association between their presence in PIF and illness in infants

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

Reproduced from (FAO/WHO, 2006)

Salmonella enterica and *Cronobacter* spp. are the two organisms present in PIF with a demonstrated causality of illness in infants. *Salmonella enterica* is a well documented pathogen and will not be discussed further in this guidance note. However, *Cronobacter* spp. 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 risks posed by both bacteria.

5. *CRONOBACTER* INFECTION IN INFANTS

Invasive disease caused by *Cronobacter* spp. is not a common occurrence in infants. However, there is concern that it has been under reported. Between 1992 and 2007, there were 105 reported cases worldwide of neonatal *Cronobacter* infections – including meningitis, bacteraemia and necrotising enterocolitis (NEC) (Friedemann, 2009). Although *Cronobacter* infection in infants is rare, there is a high rate of fatal outcome and neurological complications. Fatality rates of up to 42% (Friedemann, 2009) and 80% (Iversen and Forsythe, 2003) have been reported for *Cronobacter* meningitis, and 19% (Friedemann, 2009) and 55% for NEC (Iversen and Forsythe, 2003).

Adults and children older than 12 months of age are thought to be a much lower risk group than infants (children less than 12 months of age). In 2003, a United States FoodNet survey estimated the annual rate of invasive *Cronobacter* infection to be one per 100,000 infants (U.S. Centres for Disease Control and Prevention (CDC) unpublished data). In infants of very low birth-weight (less than 1.5kg), the incidence was estimated to be higher at 9.4 per 100,000 (Stoll *et al*, 2004).

A CDC report investigated the risk factors relating to ingestion of *Cronobacter* spp. in infants (Bowen and Braden, 2006). Forty-six cases were analysed (12 with bacteraemia, 33 with meningitis and 1 with a urinary infection). The infants with meningitis tended to be near-term infants (median 37 weeks) of normal birth-weight (median 2kg) where infection tended to occur soon after birth (median 6 days after birth). Whereas 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 ≤ 28 days) as well as premature infants should be included in the 'high-risk' infant category. The FAO/WHO concluded that the high-risk group are all infants in the first 2 months of life (FAO/WHO, 2006) based on the knowledge that infants up to about 2 months are known to be at elevated risk for meningitis (Dr A. Bowen CDC, pers. comm.).

5.1 Risk Groups for Invasive *Cronobacter* 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 (children less than 12 months of age)

Most Vulnerable Group: All infants less than 2 months of age, and all immuno-compromised infants, irrespective of age

6. *CRONOBACTER* SPP. IN POWDERED INFANT FORMULA

Cronobacter spp. 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), 8 cite infant formula milk as the suspected source of the *Cronobacter* infection (the source was unknown or not specified in the remaining 19 studies). Bowen and Braden (2006) found that of 26 infants with *Cronobacter* infection (where feeding patterns were specified), 24 (92%) were fed on PIF. Formula samples associated with 15 (68%) of 22 of these cases yielded *Cronobacter* spp. In 13 (87%) of these cases, the clinical and formula strains were indistinguishable.

Cronobacter spp. has been isolated from infant formula milk powder on many occasions (FAO/WHO, 2004; Iversen and Forsythe, 2004) although contamination can be considered to be low and sporadic. Between January 2002 and March 2012, there were 11 notifications of *Cronobacter* spp. in PIF through the European Rapid Alert System for Food and Feed (RASFF).

7. 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's 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. The National Adult Literacy Agency's (NALA) website – www.simplyput.ie – provides advice on presenting information in plain English.
- Materials should be distributed widely and be freely available to all end users.
- Although the rationale behind the recommendations presented in the questions and answers sections of this guidance note should be understood, it only needs to be built into guidance material where thought necessary to reinforce compliance.

8. CLEANING AND STERILISING INFANT FEEDING EQUIPMENT

- Wash hands thoroughly before cleaning feeding equipment.
- Wash feeding and preparation equipment in hot soapy water before sterilising it. 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 according to the machine's instructions. The suitability of feeding and preparation equipment for dishwasher use should be checked with the manufacturer of the equipment prior to washing. Dishwashers will not sterilise feeding and preparation equipment.
- Feeding and preparation equipment that has been cleaned should be sterilised prior to use:
    - **Steam:** commercially available home electrical units or units that work in the microwave oven are available. Always follow the manufacturer's instructions
    - **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
    - **Chemical sterilant added to water:** make up a batch of sterilant following the 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.
- Feeding bottles 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.

8.1 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 hand washing 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 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.

Until what age should bottles be sterilised?

Bottles should be sterilised until the baby is at least one year old.

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 and hence these areas are not sterilised.

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

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.

9. MEDICAL CARE SETTINGS

9.1 General Requirements for Preparing PIF

- There should be a dedicated, clean and suitable area for the preparation and handling of PIF.
- 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.
- 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 the infant back to the actual batch of PIF used to feed that infant.
- In the medical care setting, if infants are fed formula, it is preferable to use sterile ready-to-feed liquid formula where available rather than PIF (not all types of infant formula are available in sterile ready-to-feed form).

9.2 To Prepare 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) **Single bottle method (preferred):** 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 PIF 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 one 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. Pour 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

a) **To feed immediately:** ensure the feed is not too hot by placing a drop of liquid on the inside of the wrist – it should feel lukewarm

b) **To feed 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 lukewarm

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.

9.3 Using PIF that can't be Prepared with Water above 70°C

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. Do not store for use later.

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 PIF 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 lukewarm.

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.

9.4 Using Human Milk Fortifiers

If adding human milk fortifiers to breast milk, the fortifier should be added to the breast milk as directed by the manufacturer's on-pack instructions and fed immediately. Do not store breast milk *to which milk fortifiers have been added* for use later.

- **Collecting breast milk** – breast milk should be collected into sterile feeding bottles using sterile equipment, then fully labelled with:

    1. Mother's name
    2. Infant's name/identification, and
    3. Date and time expressed

- **Storing breast milk** – if breast milk is not used immediately it can be stored in the back of a refrigerator at 5°C or below up to 5 days or in a chest freezer (-18°C) for up to 6 months.

- **Adding human milk fortifiers**

Step 1 If necessary, warm the breast milk in the bottle to the feeding temperature.

Step 2 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 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 lukewarm. Feed immediately, do not store for use later.

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.

9.5 Adding Powdered Starch

Powdered starch should not be added to infant formula unless the formula is at a temperature greater than 70°C. 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.

9.6 Transporting Feeds

If it is necessary to transport feeds to a ward from a central preparation facility:

- Ensure feeds are made using the 70°C preparation method
- Ensure the feeds are cold (5°C or below)
- Move the cold feeds to the ward within 30 minutes 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 5°C or below on the ward and feed within 24 hours of the preparation time
- Feeds that cannot be prepared using the 70°C preparation method (such as those for special medical purposes or breast milk with fortifiers added) should be transported to the ward immediately, ensuring that the time from preparation to end of feeding is no longer than two hours. If this is not possible, feeds should be made up on the ward, under clean conditions, by suitably trained staff and fed immediately

9.7 Tube Feeding

- 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.

9.8 Low Birth-weight Babies

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.

9.9 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 rather than powdered infant formula?

Ready-to-feed, commercially sterilised liquid formulae are subjected to a heat process by the manufacturer that is sufficient to kill *Cronobacter* spp. 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 PIF?

The FAO/WHO risk assessment model demonstrated that this practice provided the greatest degree of protection against invasive *Cronobacter* disease in infants. Water above 70°C will kill *Cronobacter* spp. 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 water should be at a sufficiently high temperature to kill harmful bacteria, but the higher the temperature of the water used to make PIF, the greater the degradation of essential nutrients. The use of a thermometer is the most accurate method to ensure that the most effective balance is achieved between these two risks.

Is it possible to use a water from a water boiler that maintains water at 70-80°C to make up feeds?

No. Freshly boiled water should always be used because holding water at high temperature for long periods (or repeatedly re-boiling it) can lead to minerals becoming concentrated in the water, which would affect the mineral concentration in the feed.

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. A damp scoop should not be re-inserted into the bulk dry powder as it could cause the powder in the tin to become moist and allow bacterial growth. If powder sticking on the scoop is a problem, formula could be measured into a clean, sterile dry container and then added to the water in one go.

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?

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.

Cronobacter spp. 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). If feed is to be fed later, it is important that the cooled feed is placed in a refrigerator and cooled further down to 5°C or below 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 70°C water to prepare PIF. It is essential that the whole volume of feed is lukewarm 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 lukewarm 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 *Cronobacter* disease in infants. Water above 70°C will kill *Cronobacter* spp. 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 PIF 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 held above refrigeration temperatures (see question on cooling). Transport from a central preparation facility to a ward allows the feed to warm up. Ensuring the feed is cold (5°C or below) before transport and restricting transport time to 30 minutes should minimise any 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 lukewarm 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 the fresh feed is fed through previously used equipment, 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 minimise the threat of *Cronobacter* spp. 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 1 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.

10. IN THE HOME

10.1 General

- 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.

10.2 To Prepare 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).

Step 3 To ensure the water temperature is no less than 70°C but is not too hot, it should be left to cool in the kettle for 30 minutes, but no longer, before use.

Step 4 Clean the feed preparation area thoroughly and wash hands with soap and hot water and dry.

Step 5 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 PIF 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 6 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 7

a) **To feed immediately:** ensure the feed is not too hot by placing a drop of liquid on the inside of the wrist – it should feel lukewarm not hot.

b) **To feed 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 lukewarm.

Step 8 Discard any feed that has not been consumed within two hours of preparation. For slow feeding babies, use a fresh feed after two hours.

10.3 Using PIF when Out and About

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

At home

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. Take care to avoid scalding.

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.

When out and about

Step 6 Take the sterile bottles of water and PIF with you.

Step 7 When formula is needed, warm the bottle of water to feeding temperature (if required) using a bottle warmer or by standing the feed in a container of warm water.

Step 8 Add the exact amount of PIF as instructed on the manufacturer's label. 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 lukewarm.

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.

10.4 Questions and Answers

What is sterile ready-to-feed liquid formula?

Sterile ready-to-feed liquid formula is pre-prepared infant formula that has been subjected to a heat process by the manufacturer that is sufficient to kill *Cronobacter* spp. and any other bacteria like *Salmonella* that can be harmful to the health of the infants. 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 PIF?

The FAO/WHO risk assessment model demonstrated that this practice provided the greatest degree of protection against invasive *Cronobacter* disease in infants. Water above 70°C will kill *Cronobacter* spp. 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 before adding PIF?

At high temperatures, heat sensitive vitamins and other nutrients in PIF can be destroyed. The higher the water temperature is, 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 75°C and 70°C without the need for a thermometer.

Why is it important to cool feed quickly?

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.

Cronobacter spp. 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). If feed is to be fed later, it is important that the feed is placed in a refrigerator and cooled to 5°C or below 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 lukewarm 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 lukewarm 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. But 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. However, this method is not recommended for two reasons.

1) The risk of scalding, which might be higher when travelling compared with the handling of hot water in the home, must be considered 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.
2) Parents must wait until the feed has cooled down to a suitable feeding temperature (lukewarm) or find a method of cooling the hot feed quickly (such as holding the bottle under cold running tap water or immersing in a large volume of cold tap water).

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 or below and stored in a refrigerator as recommended. However, the safety of these feeds relies on the maintenance of temperatures 5°C or below so that harmful bacteria, if present, cannot grow during storage. The maintenance of feeds at a temperature of 5°C or below during short travel times is possible.

However, over long travel times it is very difficult to maintain the feeds at 5°C or below, 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 11 on safe feeding of PIF in child day-care settings).

Can bottled water be used to prepare PIF?

Bottled water can be used to prepare PIF, but it must:

- Have sodium (Na) content less than 20mg per litre (this will be written on the label)
- Be boiled before using to prepare PIF
- Be still water, not sparkling

Can tap water that has a water softener system be used to prepare PIF?

No. Water softening systems add sodium to the tap water. If this water is used to prepare PIF, the feed may have too much sodium for the baby. Instead, use bottled water to prepare the PIF – see advice above on using bottled water.

When I boil the water and pour it into bottles, there is a clear 'scum' on top of the water. Is this harmful?

No it isn't harmful. The scum is limescale, formed when minerals (mainly calcium carbonate) naturally present in the water, solidify after boiling. There are higher levels of limescale in hard water. If you live in an area with hard water, you can reduce limescale by keeping your kettle de-scaled using vinegar, or a commercial de-scaling solution. You may also prefer to boil water that has first been passed through a filter jug (as this reduces limescale).

Is there an alternative to taking the can of PIF when travelling?

Some PIF is also sold in single dose sachets which can be used when travelling. Plastic containers that are designed to carry several pre-measured amounts of PIF are also available. These can be filled at home and taken when travelling. Alternatively, any sealable plastic container could be used to carry pre-measured doses of powdered infant formula. In the case of any container used to transport PIF, 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 PIF placed in the container. Ready-to-feed liquid formula can always be used as an alternative when travelling.

11. CHILD DAY-CARE SETTINGS

It is not recommended that child day-care facilities prepare PIF for the children in their care. It is safest for parents to prepare PIF at home (as outlined in Section 10). Alternatively, use ready-to-feed commercially sterile liquid.

In most child day-care environments, facilities are not appropriate for preparing large numbers of PIF feeds on a daily basis. Given the number of infants that can be present in child day-care facilities, there is potential for mistakes if feeds are made up from scratch, e.g. wrong PIF 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 (in Section 10) is designed to minimise these risks to an extent where on balance, the careful transport of pre-prepared feeds by the parent is the more practical and safer option.

11.1 Preparing PIF at Home and Transporting to the Child Day-care Setting

Step 1 Feeds should be prepared at home using the 70°C preparation method recommended for the safe feeding of PIF in a domestic setting (see section 10, steps 1-6).

Step 2 Cooled feeds should be marked with the child's name and stored at the back of a refrigerator (not in the door) at 5°C or below until they are completely cold prior to transportation, but for 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, ideally, in a clean cool-box or cool-bag with ice-blocks, to maintain the feed at 5°C or below.

11.2 Storing and Feeding PIF in the Child Day-care Facility

Step 1 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 2 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. If necessary (some children drink milk at refrigeration temperatures), 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 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 lukewarm.

Step 3 Discard any feed that has not been consumed within two hours of warming/first use. For slow feeding babies, use a fresh feed after two hours.

Step 4 All unused feed should be discarded and the used bottles rinsed in warm tap water.

Step 5 All feeding bottles should be returned at the end of the day when the infant is collected.

Step 6 Used feeding bottles should be cleaned thoroughly at home and sterilised as recommended in Section 8 (cleaning and sterilising infant feeding equipment).

11.3 Preparing PIF in the Child Day-care Facility

If a child day-care facility decides to prepare PIF on-site, the guidelines below should be followed.

11.3.1 General requirements

- All feeding equipment must be thoroughly washed in hot soapy water and sterilised as outlined in Section 8.
- There must be a dedicated, clean and suitable area (kitchen, milk kitchen or separate dedicated area) for preparing and handling PIF. Feeds should not be prepared in the care room. If the preparation is taking place in the main kitchen, the main kitchen facilities/ equipment can be dual use but PIF should not be prepared at the same time as other food is being prepared.
- The area should have a:
    - Sink
    - Wash hand basin
    - Refrigerator
    - Preparation area and storage space
- Written procedures must be in place for the safe preparation and handling of PIF. These procedures must demonstrate adequate food safety controls and should form part of the food safety management system.
- The implementation of these written procedures should be routinely monitored.
- Staff with responsibility for the preparation and handling of PIF must receive appropriate training based on the written procedures in place. Where possible, there should be staff dedicated to PIF preparation and handling and different staff dedicated to nappy changing/ toilet or cleaning duties. If this is not practical, there should be proper separation of duties and scrupulous hand washing must be observed.
- A system should be established to ensure full traceability of PIF from infant back to the actual batch of PIF used to feed that infant.
- All bottles should be labelled with the child's name and date of preparation.
- Each infant formula tin/container should be labelled to include the date of opening and name of child it belongs to. The PIF should be kept in its original container.
- Refrigerators used for the storage of PIF should be equipped with a fridge thermometer. The temperature should be checked regularly and adjusted where necessary to make sure the fridge is operating at 5°C or below.

11.3.2 Preparing and feeding 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 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 PIF 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 (care should be taken that each scoop is stored with its original container).

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. Suitable refrigeration, ideally solely dedicated to the storage of infant formula, must be provided for the prepared feed where it is made in advance.

Step 6

a) **To 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 lukewarm.

b) **To feed 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 on the day of preparation. To feed, remove one bottle just before it is needed and if necessary, 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 lukewarm.

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

Step 8 All unused feed should be discarded at the end of each day and the bottles rinsed in warm tap water.

Step 9 All feeding bottles should be returned at the end of the day when the infant is collected (unless the day-care facility washes and sterilises the bottles and retains them). The used feeding bottles should be cleaned thoroughly at home and sterilised as recommended in Section 8 (cleaning and sterilising infant feeding equipment).

11.4 Question and Answers

What are the alternatives to using PIF for infants in child day-care facilities?

Sterile ready-to-feed liquid formula can be used. This is subjected to a heat process by the manufacturer that is sufficient to kill *Cronobacter* spp. 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 formulae 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 have 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 in Section 10 (in the home) 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?

To avoid the growth of harmful bacteria it is important that the feed is kept at 5°C or below. *Cronobacter* spp. 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). Short trips of 30 minutes 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 5°C or below 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 lukewarm 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, bacteria will start to grow. If these bacteria form films on the bottles (biofilms), they 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.

12. ADDITIONAL RECOMMENDATIONS

- Parents and guardians and medical and child-care workers who are handling PIF should receive appropriate training in safe preparation practices.
- The Health Protection Surveillance Centre should inform appropriate medical staff about invasive *Cronobacter* spp. 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 *Cronobacter* spp.
- Manufacturers of PIF should conduct studies to ensure that all infant formula powders contain sufficient quantities of all heat sensitive 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.

13. ADDITIONAL RESOURCES

Information on the preparation, storage and handling of PIF, which is in line with recommendations in this guidance note, has been published by the following bodies:

- World Health Organization (2007) Guidelines for the safe preparation, storage and handling of powdered infant formula. Available at: http://www.who.int/foodsafety/publications/micro/pif2007/en/index.html
- safefood (2012) How to prepare your baby's bottle. Available at: http://www.safefood.eu/SafeFood/media/SafeFoodLibrary/Documents/Publications/Consumer/Baby-Bottle-Feed-2012.pdf
- Health Service Executive (2012) What's Up Mum? website, available at: www.whatsupmum.ie

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FAO/WHO (2004) *Enterobacter sakazakii* and other microorganisms in powdered infant formula. Microbiological risk assessment Series No 6, ISBN 92-4-156262-5 http://www.who.int/foodsafety

FAO/WHO (2006) *Enterobacter sakazakii* and *Salmonella* in powdered infant formula. Microbiological risk assessment series 10, ISBN: 92-5-105574-2 ftp://ftp.fao.org/ag/agn/jemra/e_sakakazii_salmonella.pdf

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