

Position on the safe preparation and handling of powdered infant formula - concerns around WHO recommendation to prepare at 70°C

1. Introduction

The Infant Nutrition Council fully supports advice that helps to protect infants from harm by *E. sakazakii*, but also caution that they must be protected from harm from other issues such as scalding and nutrient insufficiency.

The Infant Nutrition Council is concerned about the WHO recommendation to prepare formula by using water at 70°C to prevent *E. sakazakii* and other bacterium. This option has a number of drawbacks that have not been fully appreciated and which, while potentially minimising one problem, may increase other infant health risks.

E. sakazakii infection has a very low incidence rate of 0.001% in infants. The possibility of scalding is a much higher risk.

For guidelines to effectively protect infants against infection with *E. sakazakii* they must focus on the practices that could lead to the problem. Infants may be at risk of *E. sakazakii* infection when infant formula is stored incorrectly or from extended feeding periods. Infants are not at risk under current preparation guidelines.

Therefore, it is careful storage of any prepared infant formula, and clear feeding advice, that is key to protecting infants from harm by *E. sakazakii*.

2. Specific concerns on the preparation of formula at 70°C

2.1 Potential for harm to baby through scalding

Water and formula at 70°C is hot enough to cause serious burns. This may occur in a matter of seconds and poses a genuine risk to baby. The below chart demonstrates the time required for hot water to cause serious harm:

Temperature of Water	Time to Cause a Bad Burn
66°C	2 seconds
60°C	6 seconds
52°C	2 minutes
49°C	10 minutes

(Ref: http://www.med.umich.edu/llibr/pa/pa_hotwatr_hhg.htm)

Current advice is that previously boiled water is cooled to 'lukewarm' and then used to prepare formula. It should then be tested on the back of the wrist to ensure it is an appropriate temperature for baby, it should feel just warm, but cool is better than too hot. This means the temperature of prepared formula when offered to baby is approximately body temperature, i.e. 37°C. Feeding formula at this temperature poses no risk of scalding to the infant.

For a bottle of formula, prepared at 70°C to cool to a safe temperature of approximately 37°C, it will need to sit for at least 30 minutes, possibly longer. This may allow bacteria time to multiply and is contradictory to usual safety advice for any other foods.

Whilst parents may be advised to speed this process by running the prepared formula under cold water, the resulting temperature of the formula will vary widely depending on a number of variables:

- the time the bottle is held under the water
- the temperature of the running water
- the volume of formula in the bottle
- the degree of shaking/swirling of the formula while held under the running water

Given these variables, it will be impossible to give an accurate amount of time required for this cooling process, to guide parents. If they do undertake to quickly cool the formula prepared at 70°C, they may only reduce the temperature by an insufficient amount, 50°C for example. As illustrate above, formula at 50°C will cause a bad burn to baby (many babies will feed for more than 10 minutes from one bottle).

Most homes are not equipped with kitchen thermometers, so parents will be left to determine these temperature changes as best they can. In the absence of a kitchen thermometer how will parents ascertain that they are preparing the formula at 70°C? Then how will they ascertain that they have allowed the formula to cool to a safe temperature?

Under recommendations to prepare formula at a dangerously high temperature, the risk of scaling infants is high. Despite well intended advice on how to cool the very hot formula, the reality will be that some infants will be offered formula at a temperature that will cause a bad burn. This will be due to:

- Not enough time allowed for the formula to cool

- Inadequate cooling technique, insufficient mixing to avoid hot spots
- Poor assessment of the temperature
- Accidental spilling of the hot formula
- Feeding of the formula too soon, due to demands of an unsettled and hungry baby

These risks are avoided if formula is mixed with previously boiled at lukewarm temperature. This means baby can only be offered formula that is at temperature that will not cause harm.

2.2 Nutrient destruction and quality of formula

There is genuine risk of nutrient destruction under advice to mix formula with water at 70°C.

Several organisations including the FDA (2002), ESPGHAN (2004) and AFSSA (2005) have warned that reconstituting formula at over 70°C risks losing certain nutrients.

The most likely source of the hot water for parents to prepare formula is from the electric kettle. Water boils at 100°C. If parents fail to allow the boiled water to cool sufficiently to reach 70°C, then the hot water can destroy some of the nutrients in the formula. Nutrients most destructible by heat are the vitamins; thiamin, folate, pantothenic acid and vitamin C. For example, thiamin is destroyed at 100°C.

Mixing formula with just-boiled water may produce a formula that does not supply the sufficient level of all nutrients that is required for total nutrition of the infant. This is a serious risk if the practice is carried out over a period of time. Infant formula can be the sole source of nutrition for formula-fed infants from birth until they start on solids between four and six months. If their formula is deficient in one or more nutrients, over a period of time, this can cause illness and even death.

The WHO view that vitamin loss can be compensated for by increasing the vitamin content in the manufacturing process does not take into account stringent national and international regulations and recommendations governing the nutritional composition of infant formula. It also fails to address how overdosing should be dealt with given the different temperatures of reconstitution. Furthermore, the WHO guidelines neglect to consider nutrients other than vitamins. Reconstitution at over 70°C may also affect essential micronutrients such as amino acids, polyunsaturated fatty acids and other active ingredients. It may also lead to reactions causing blockage of lysine, precipitation of mineral salts or proteins, fat separation or the formation of unwanted components. This may be particularly problematic for speciality formulas including those for premature infants or specific metabolic conditions.

For the safety of the infant, the quality of infant formula must not be compromised by inappropriate preparation advice.

2.3 Encouraging the practice of storing prepared formula

It is likely that advice to prepare formula at 70°C will lead to an increase in the practice of storing prepared formula for later use.

Parents wanting to avoid the complicated preparation and cooling process, particularly for night time feeds, may well prepare multiple bottles during the day and store for later use. This practise may well increase also in the child-care environment where staff have limited time throughout the day to spend on a more complicated and stressful process.

Ironically it is incorrect *storage* of prepared infant formula that poses genuine risks from bacteria such as *E. sakazakii*, not incorrect *preparation* of infant formula. If refrigeration of the prepared formula is inadequate conditions may actually support the growth of *E. sakazakii*. *E. sakazakii* will multiply between six and 46°C in the presence of moisture.

2.4 Potential for other hazards mixing at 70°C

2.4.1 Time

To reach 70°C water will need to be allowed to cool after boiling. Most parents and carers will not have time to wait for water to cool, up to seven times a day. Again, this is likely to encourage the preparation of multiple bottles at one time and storing for later use during the day.

2.4.2 Thermometers

The most accurate way to determine water temperature will be to use a thermometer. Firstly most kitchens are not equipped with one. For those that do have one, it will need to be sterilised, presenting even more risks. To sterilise, they will either need to use boiling water or a chlorine based sterilant. This presents a glass hazard for glass thermometers. A parent/carer may not notice if the glass at the bottom of the thermometer is broken until such time it is being sterilised for the next feed. This raises the fear that the glass may have contaminated the previous feed. It may also be possible that the infant had consumed some of the expansion fluid.

Metal thermometers also present problems. They can be corroded if sterilised in chlorine based sterilants and thereby become inaccurate.

2.4.3 Steam

Water will produce steam at 70°C. When preparing a bottle of formula the water is added first to the bottle, then the powder. This ensures the correct concentration in the feed.

When the scoop that is used to add the powder into the bottle, comes into contact with steam it can be left wet. When this scoop is re-entered to the powder in the can, the moisture can be transferred to the powder. Too much moisture in the can of powder may encourage growth of bacteria, damaging the quality of the formula and potentially poses a risk to the infant at a later feed.

Mixing formula at high temperatures in a sealed bottle also poses a risk. Steam from very hot water produces pressure which can result in the bottle top 'exploding' if it is shaken.

2.5 *Causing undue stress and concern for parents*

The safe preparation and handling of infant formula can be stressful for parents. It is important they are given clear and practical directions to ensure they offer safe and nutritious formula to their infant.

Adding complexity to the instructions for preparing formula can increase the level of stress and anxiety. Directing parents to prepare the formula at one specific temperature, and then ensuring they feed it at another, safer temperature, is over complicating the current (safe and practical) advice.

When parents are hurried, confused and tired, they can make mistakes. It is important that parents ensure they prepare formula at the right concentration. Adding confusion around the temperature of the formula, parents may not prepare formula using the correct number of scoops required for the water level. Formula that is either too dilute or too concentrated can be a risk to infants.

It is also quite possible that when parents are hurried by a crying, hungry baby, they may rush the cooling process and feed formula at a dangerously high temperature, risking burns to baby.

2.6 *Liability for industry*

The health and safety of infants is the top priority for Industry. Ultimately, it is the industry that is responsible for providing a safe product that will ensure essential nutrition for infants from birth. Industry is also responsible for the provision of accurate and clear directions for the safe preparation and storage of infant formula on the product labels.

If Industry is forced to give advice that leads to any harm to an infant due to:

- scalding, or
- nutrient insufficiency

the Industry will be liable. Governments should not impose this liability on the Industry.

3. **Advice to ensure safety for formula-fed infants**

The Infant Nutrition Council strongly encourages Governments and public health organisations to consider the real issues around the risk from *E. sakazakii*. The Infant Nutrition Council fully supports guidelines that help to protect infants from harm by *E. sakazakii*, but also they must be protected from harm from other issues such as scalding.

Powdered infant formula is not a sterile product. Manufacturer analyses can ensure that infant formula does not contain bacteria at levels that pose harm to infants under current advice for the correct preparation and storage of infant formula.

Infants are not at risk from *E. sakazakii* when formula is prepared with lukewarm (body temperature) previously boiled water and fed within one hour. Infants may be at risk when conditions allow the bacteria to multiply to harmful levels. This problem is encountered through poor storage practices of infant formula (not preparation).

The Infant Nutrition Council suggests that infants are best protected from risks of harm due to *E. sakazakii* infection, scalding from hot formula and/or nutrient deficiency illnesses, through clear and consistent advice on the preparation, handling and storage of infant formula; noting the particular points below that effectively control growth of bacteria:

1. Formula should always be prepared in a clean area.
2. Fresh water should be boiled and allowed to cool until lukewarm (this can be done well in advance of preparing the feeds).
3. After adding the powder to the measured water in the bottle, mix well and test the temperature of the milk with a few drops on the inside of the wrist. It should feel just warm, but cool is better than too hot.
4. Ideally only one bottle of formula should be prepared at a time, and it should be offered immediately.
5. A feed should take no longer than one hour. Any formula that has been at room temperature for longer than one hour should be discarded.
6. Any formula left at the end of the feed must be discarded.
7. If formula is prepared in advance (for example for a babysitter) it must be refrigerated (at 4°C or below) and used within 24 hours. Alternatively, refrigerate prepared sterilised bottles of boiled water and use as required, first warming by standing bottle in a container of warm water and then adding formula.

A full copy of The Infant Nutrition Council's best practise for Safe Preparation, Storage and Handling of Powdered Infant Formula is at Appendix 1.

Appendix 1.

The Infant Nutrition Council recommends that the best practise for Safe Preparation, Storage and Handling of Powdered Infant Formula is as below:

1. Always wash hands before preparing formula and ensure that the formula is prepared in a clean area.
2. Wash bottles, teats and caps, and knife. Sterilise by boiling for five minutes or using an approved sterilising agent.
3. Boil fresh water and allow it to cool until lukewarm.
4. Ideally prepare only one bottle of formula at a time, just prior to feeding.
5. Always read the instructions to check the correct amount of water and powder as shown on the feeding table on the back of the pack. This may vary between different formulas.
6. Add water to the bottle first, then powder
7. Pour the correct amount of previously boiled water into a sterilised bottle.
8. Fill the measuring scoop with formula powder and level off, using the levelling device provided or the back of a sterilised knife. Take care to add the correct number of scoops to the water in the bottle. Always measure the amount of powder using the scoop provided in the can - scoop sizes vary between different formulas.
9. Place the teat and cap on the bottle and shake it until the powder dissolves.
10. Test the temperature of the milk with a few drops on the inside of your wrist. It should feel just warm, but cool is better than too hot.
11. Feed baby. Any formula left at the end of the feed must be discarded.
12. A feed should take no longer than one hour. Any formula that has been at room temperature for longer than one hour should be discarded.

Preparing feeds in advance:

1. Ideally prepare only one bottle at a time. If you do need to prepare formula in advance (for example for a babysitter) it must be refrigerated (at 4°C or below) and used within 24 hours. Alternatively, refrigerate prepared sterilised bottles of boiled water and use as required, first warming by standing bottle in a container of warm water and then adding formula.
2. If using refrigerated prepared formula, before feeding baby, warm by standing bottle in a container of warm water. Using the microwave to heat infant formula is not recommended as heating can occur unevenly and burn the baby's mouth.

Preparing formula correctly will ensure that baby gets the right amount of nutrients.