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Recommendations for the hygienic preparation of powdered infant formula

Updated BfR Opinion no. 009/2022 of 29 March 2022

Infant formula is subject to very stringent hygiene regulations. Infections caused by pathogenic microbes are accordingly rare. However, some microbial species can survive the manufacturing process for powdered formula and are then able to multiply in the prepared formula. Microbes can also be transferred into the formula from spoons, teats or drinking bottles during preparation.

In light of these facts, the German Federal Institute for Risk Assessment (BfR) recommends preparing powdered infant formula only shortly before consumption. Boiled water should be used wherever possible when preparing formula for infants who are only a few months old. For the preparation of the formula, water temperatures ranging from roughly 20 °C to 50 °C are appropriate for full-term, healthy infants. Leaving prepared formula to stand for more than two hours until consumption – or leaving it to cool down and then reheating it later – at temperatures above 5 °C should always be avoided and any leftovers discarded. To reduce the risk of transferring microbes into the formula during preparation, the utensils used should be thoroughly cleaned using detergent and hot water. When infants are only a few months old, it is particularly important that these utensils are also sterilised by boiling them before preparing the formula.

These recommendations apply to the preparation of powdered infant starter formula for full-term, healthy infants in private households, childcare facilities and hospitals. In a hospital environment, the BfR considers it appropriate to set up dedicated milk prep rooms for the preparation of infant formula, where comprehensive hygienic requirements can be ensured. This applies in particular when preparing formula for premature babies and immunocompromised infants. In addition, a child's state of health may also mean that these infants will require an individually tailored nutritional recommendation from a medical practitioner.

The following, updated assessment relates to the contamination of infant starter formula and special formula for premature babies with *Cronobacter* spp. While infections with *Cronobacter* spp. are very rare, they can have serious consequences for health by causing conditions such as meningitis. Infants with a birth weight under 2,500 g (grams) and immunocompromised infants are at particular risk, as their body's own defences do not provide a sufficient level of protection against infection. The recommendations that result from this risk assessment apply not only to the avoidance of infections with *Cronobacter*, but can also protect against infections by other microbes.

1 Subject of the assessment

While powdered infant formula is in principal manufactured according to high standards of hygiene, it is not sterile. Microorganisms can be present at low concentrations in the powder. Bacteria cannot proliferate in the powdered formula, but some may remain viable there for a long time. Potentially pathogenic bacteria may also be subsequently transferred into the formula by, for example, contaminated utensils used during preparation. Bacteria can then multiply rapidly in the ready-prepared formula if it is not properly cooled.

An expert group from the WHO/FAO (World Health Organisation/Food and Agriculture Organisation of the United Nations) has identified *Salmonella* and *Cronobacter* spp. as the most important causative agents of neonatal infections which can be transmitted through the consumption of infant formula (FAO und WHO, 2004). Infections with *Cronobacter* spp. transmitted by infant formula are very rare and primarily affect infants with a birth weight under 2,500 g as well as immunocompromised infants. While rare, such infections can still have severe consequences for health.

The BfR has updated its Opinion on the hygienic preparation of powdered infant formula, published in 2012, to reflect the latest scientific data available. In addition, the BfR Committee for Biological Hazards and Hygiene has been consulted on this revision. In this Opinion, the term 'infant formula' is understood to cover both infant starter formula, which is intended for infants in the first months of life, as well as special formula for premature babies.

In updating the Opinion, particular attention was paid to immediate consumption, as experience has shown that storage of prepared formula is the most critical aspect for hygiene. This is also why most manufacturers recommend the immediate consumption of infant formula on the product packaging. Chilled storage below 5 °C is only considered in the context of professional baby care – such as in a hospital environment – and for a maximum of 24 hours.

2 Results

In order to minimise the health risks arising from infection with *Cronobacter* (as well as *Salmonella* and other pathogens) due to the consumption of infant formula, the hygienic preparation and handling of the formula is critical. Especially important steps in this process include the cleaning and treatment of all utensils with hot water, the fresh preparation of formula, its immediate consumption and the discarding of leftovers. If the formula is prepared under especially strict hygienic conditions – such as in a professional care facility – it can be stored for a maximum of 24 hours before consumption if it is chilled to below 5 °C immediately after preparation.

The BfR recommends using boiled drinking water as the starting point for the preparation of dry formula. When dissolving the powder in water, the temperature requirements specified by the manufacturer must be observed. The BfR considers water temperatures ranging from roughly 20 °C to 50 °C as appropriate for full-term, healthy infants when making up the powdered infant formula. Leaving prepared formula to stand for a long time (more than two hours) at temperatures above 5 °C until feeding should be avoided.

For infants with a birth weight of less than 2,500 g as well as immunocompromised infants, the administration of an individually tailored infant formula by the attending medical doctor is often necessary to ensure an optimum level of nutrition. When using powdered formula, the decision must be made on a case-by-case basis as to whether higher water temperatures are needed to reduce microbial load when dissolving the powder and whether some nutrient loss due to heat is acceptable. If recommended by the attending medical doctor, sterile liquid infant formula can be used to minimise hygiene risks.

3 Rationale

3.1 Risk assessment

3.1.1 Hazard identification

Powdered infant formula is non-sterile. European Regulation (EC) No 2073/2005 specifies microbiological criteria for infant starter formula. Specifically, the absence of *Salmonella* and *Cronobacter* spp. (formerly: *Enterobacter sakazakii*) must be confirmed using mandatory sampling plans. Investigations for other microorganisms, such as bacteria from the *Enterobacteriaceae* family or *Bacillus cereus*, are also used to prove that a hygienic manufacturing process has been applied.

Follow-on formula, which is intended for older infants as they begin complementary feeding, is not subject to these stringent microbiological regulations in relation to *Cronobacter*. In the following, *Cronobacter* spp. are to be considered as representatives of other potentially pathogenic vegetative bacteria, since they possess an increased resistance to heat and desiccation, can occur in powdered foodstuffs, may remain viable here for long periods and pose a health risk to especially susceptible infants. Furthermore, *Cronobacter* spp. are widespread (ubiquitous) in the environment and can therefore also be transferred into foods by contaminated kitchen utensils during food preparation. Thus, the preparation instructions are also valid in relation to minimising the risk of infection by other potentially pathogenic bacteria.

Originally, the genus *Cronobacter* (C.) was considered to be an *Enterobacter* species (*E.*) *sakazakii*. In 2007, *E. sakazakii* was reclassified as the genus *Cronobacter* (Iversen et al., 2007). Following this reclassification, the genus currently comprises the species *C. sakazakii*, *C. turicensis*, *C. muytjensii*, *C. malonaticus*, *C. helveticus*, *C. pulveris*, *C. zurichensis*, *C. dublinensis*, *C. condimenti* and *C. universalis*. The *C. dublinensis* species also comprises the subspecies *C. dublinensis* subsp. *lausannensis*, subsp. *dublinensis* and subsp. *Lactardi* (Iversen et al., 2008; Joseph et al., 2012, Brady et al. 2013).

With the exception of *C. condimenti*, all *Cronobacter* species have since been isolated from clinical samples (Yemis et al., 2020). To date, only *C. sakazakii*, *C. malonaticus* and *C. turicensis* have been associated with severe illness in humans, with the contamination of infant formula being primarily attributable to *C. sakazakii* and *C. malonaticus*. *C. sakazakii* sequence type (ST 4) has been identified as the dominant type for neonatal infections, although ST 8 and ST 12 are also considered pathogenic (Hennekinne et al., 2018).

The genotyping scheme is publicly accessible at the following URL: <http://www.pub-MLST.org/cronobacter>.

Cronobacter spp. are ubiquitous in the environment, and occur in water, soil, parts of plants, spices and a wide range of foodstuffs (Jaradat et al., 2009; Kandhai et al., 2004; Schmid et al., 2009, Forsythe, 2018). The bacteria can also accumulate and remain viable as a biofilm on abiotic surfaces (Iversen et al., 2004; Henry and Fouladkhah, 2019).

As mesophilic bacteria, *Cronobacter* spp. grow at temperatures from 25–45 °C but not at temperatures below 5 °C or above 45 °C (Nazarowec-White und Farber, 1997). At temperatures of 5–10 °C, proliferation is greatly diminished (latency phase 37 hours followed by a generation time of approx. 5 hours). At temperatures of 37–43 °C, their generation time is approximately 20 minutes, which slows to roughly 2 hours at room temperature (Iversen et al., 2004). As with other bacterial species, *Cronobacter* spp. survive the spray drying process used in the manufacture of powdered milk and can remain viable for up to 2 years in the dry state (Arku et al., 2008; Edelson-Mammel et al., 2005).

Powdered infant formula can be dissolved (shaken) with water at various temperatures, which can also be referred to as 'reconstituting' the formula. At water temperatures of 40–50 °C, the powder generally dissolves better than at room temperature and drinking temperature is achieved after brief cooling. The WHO recommends the use of hot water of at least 70 °C for reconstitution, which, according to a mathematical model, leads to a reduction of the microbial load by four orders of magnitude (WHO, 2006). However, this kind of inactivation is achieved only if an appropriate temperature/time combination is maintained (e.g. 70 °C for at least two minutes). As a result of cooling effects due to the small amounts in typical glass or plastic bottles, a significantly lower level of inactivation can be assumed in practice during preparation, at least in private households (Chen et al., 2009). In practice, the originally 70 °C water cools down too rapidly to effectively kill off *Cronobacter* bacteria (Losio et al., 2018). Preparation with water of at least 70 °C also involves other health risks, such as the loss of nutrients due to heat or the risk of an infant being scalded during consumption. The BfR is aware of only a handful of studies on the heat stability of ingredients found in infant formula during reconstitution at different temperatures. Most of these studies focus on vitamins (FAO und WHO, 2006). As the composition of infant formula is governed by strict legal limits, adding higher levels of nutrients in order to compensate for potential losses due to heat is possible only to a limited extent (Regulation (EU) 2016/128).

Powdered infant formula can also be reconstituted with water at room temperature, although the powder may then require more effort to completely dissolve. However, the cooling temperatures necessary for the interim storage of prepared formula are achieved more quickly in this way.

3.1.2 Hazard potential/hazard characterisation

Reports of neonatal infections involving *Cronobacter* spp. are very rare. Since the first cases were described in 1958 (Urményi und Franklin, 1961), around 180 cases of infection with *Cronobacter* spp. have been published internationally (Stryško et al., 2020). A *Cronobacter* outbreak was also documented in Germany in 2021 (Ärzte Zeitung online, 23 June 2021). The incidence¹ is about 1 infection with *Cronobacter* spp. per 100,000 infants per year, rising to 9.4 per 100,000 in very low birth weight infants (<1,500 g)(FAO und WHO, 2006). In 95 percent of cases, the infants are no more than two months old (Stryško et al., 2020). Since infections with *Cronobacter* bacteria have not been notifiable in Germany to date, the real figure is likely to be higher.

While the minimal infectious dose is currently unknown, it is likely to be somewhere in the region of 1,000 to 10,000 bacterial cells per meal (Blackshaw et al., 2020). The typical clinical manifestation involves meningitis (inflammation of membranes covering the brain), sepsis (life-threatening multiple organ failure resulting from an excessive immune response to an infection) and necrotising enterocolitis (bowel inflammation accompanied by tissue death)(AFSSA, 2006; Friedemann, 2008; van Acker *et al.*, 2001), with meningitis being a more common clinical syndrome in full-term neonatal infants. In contrast, sepsis is more frequently observed in premature babies (Stryško et al., 2020). According to the literature, the case fatality rate² for infections with *Cronobacter* bacteria ranges from 20 to 80 percent and is especially high in cases with meningitis (AFSSA, 2006; Friedemann, 2008; Lehner und Stephan, 2004; Muijtjens *et al.*, 1983; van Acker *et al.*, 2001). Sequela (late symptoms) often occur in survivors, and may manifest as a brain abscess, infarction or hydrocephalus (Stryško et al., 2020).

¹ Number of new cases of a specified illness within a population group during a specified period of time

² The case fatality rate (CFR) is the proportion of people who die from the disease

The literature describes powdered infant formula as the most common source of infection by *Cronobacter* spp. (Stryzko et al., 2020). If *Cronobacter* bacteria are present in the powdered formula, the infectious dose can be reached under conditions that promote *Cronobacter* growth. The bacteria may have originated in the powder's production environment or the formula may have been exposed to secondary contamination during preparation as a result of poor hygiene (Blackshaw et al., 2020). However, infections with *Cronobacter* have also been observed in infants not fed with synthetic infant formula, which means that other vectors must be considered. In some cases, it was possible to identify the water and utensils used for formula preparation or feeding as the source of infection (Stryzko et al., 2020). Furthermore, biofilms involving members of the *Enterobacteriaceae*, including *Cronobacter* spp., present in stomach probe tubes used to feed premature babies and in milk pumps used for collecting breast milk were identified as the source of infection. The detection of these biofilms was independent of the food given (whether starter formula, breast milk or sterile, ready-to-feed formula products) (Hurrell et al., 2009; Henry and Fouladkhah, 2019; Stryzko et al., 2020). Too long storage time of prepared formula and hygiene deficiencies constitute significant risk factors for a *Cronobacter* infection (Blackshaw et al., 2020).

3.1.3 Exposure assessment

Most cases of infection have occurred in hospitals caring for premature babies and immunocompromised infants. However, a smaller number of cases are regularly observed outside the hospital environment, where the children involved can be older than four weeks (Henry and Fouladkhah, 2019). In addition, an outbreak was reported at a secondary school in Nanjing (China), in the course of which 156 adolescents showed mild symptoms of gastroenteritis. In this case, methods from molecular biology and a case-control study were able to identify the cause as *Cronobacter sakazakii*, which was present in the meals provided by the school (Wei Yong et al., 2018). This outbreak shows that there is no clear age limit above which *Cronobacter* spp. can be said to no longer cause disease (i.e. to be apathogenic).

Cronobacter spp. have been successfully isolated from a range of foodstuffs, especially from dry and dried products, as well as from surfaces in hospital environments, in food production and in private households (Yemis et al. 2020). *Cronobacter* spp. have also been detected in human samples of teeth, saliva, skin and breast milk (Forsythe, 2018).

Powdered infant starter formula consistently plays a key role in serious infections with *Cronobacter* spp. affecting neonates, although other sources such as contaminated preparation utensils, surfaces and asymptomatic human carriers have also been identified (Forsythe, 2018). In light of these facts, several international studies aimed at detecting *Cronobacter* spp. in powdered infant starter formula have been conducted. *Cronobacter* bacteria were identified in 1.4 percent (Jaradat et al., 2009) and up to 30 percent (Parra-Flores et al., 2020) of the samples of powdered infant formula investigated, while *Salmonella* was detected only on rare occasions.

The results of the German Nationwide Control Plan (BÜp) in 2006 revealed a contamination rate of 5.9 percent (n = 118), while four years later in 2010, *Cronobacter* spp. were detected in samples of powdered infant starter formula (n = 496) in only 0.2 percent of samples (BVL, 2011). *Salmonella* was not detected.

Quantitative estimates of the presence of *Cronobacter* using the most probable number (MPN) method resulted in an average concentration of 0.54 MPN/100 g, with values ranging from 0.22 MPN/100 g to 1.61 MPN/100 g (Siqueira-Santos et al., 2013). Since the distribution of *Cronobacter* bacteria in powdered formula is extremely inhomogeneous, values may

even range from 2.3 MPN/100 g to 230 MPN/100 g (Parra-Flores et al., 2020). While a naturally contaminated batch of powdered formula was rejected by the manufacturer's Quality Control unit as *Cronobacter*-positive, more detailed investigations were able to detect *Cronobacter* cells in only 8 of 2,290 samples and colony-forming units (CFU) were calculated ranging from a minimum of 0.0032 CFU/g to a maximum of 560 CFU/g. A bioburden of <0.000038 CFU/g was calculated for the uncontaminated reference batch (Jongenburger, 2011). According to exemplary manufacturer instructions for the preparation of infant formula, a child aged up to 2 months will consume roughly 8 portions weighing 13 g (3 scoops x 4.4 g) every day. This is equivalent to roughly 100 g of powder per day. Based on this quantity of powder, the presumed infectious dose of at least 1,000 bacterial cells would only very rarely be exceeded.

The majority of the rare but serious cases of *Cronobacter* infection in infants are triggered by a significant prior proliferation of the microbes in the reconstituted formula or on the surfaces of utensils such as feeding tubes (Kucerova et al., 2011). In their preparation instructions, most manufacturers recommend reconstitution of the formula at a temperature between 40 °C and 50 °C (BVL, 2011). The WHO recommends preparing powdered formula with hot water at 70 °C. While this can potentially reduce contamination it cannot eliminate it entirely (Lo-sio et al., 2018). There is therefore always a background risk of pathogenic microbes being able to proliferate in prepared formula.

3.1.4 Risk characterisation

Since infections with *Cronobacter* bacteria have not been notifiable in Germany to date, the BfR currently has no valid data on the frequency of cases of infection involving infants in Germany. The risk assessment is therefore based solely on details as provided by the literature.

In general, the risk of an infection with pathogenic microbes in infant formula is dependent on the following parameters:

- The initial bacterial count present in the dried formula
- Any potential introduction of microbes from external sources during preparation and feeding (e.g. contaminated kitchen utensils, baby bottles, teats, contaminated drinking water, hands)
- Temperature- and time-dependent proliferation of the microbes in the prepared formula

The following factors are relevant in this context:

Products

The product is assumed to involve powdered infant formula of varying compositions. Products such as infant formula based on milk powder, hydrolysed infant foods, soya-based foods, manufacturer claimed 'therapeutic' foods for infants and powdered supplements such as anti-reflux thickeners and 'fortifiers' (i.e. nutrient supplements) are all affected in equal measure. Since *Cronobacter* is regularly detected at very low concentrations in infant starter formula (approx. 1 CFU/g), the powdered infant formula may already be contaminated with *Cronobacter*.

The occurrence of other pathogens, including Salmonella, has been detected only on rare occasions in powdered infant formula in Germany to date.

Preparation

When the water is at a temperature of 50 °C or less, it can be assumed that the *Cronobacter* bacteria present in the powdered infant formula will also be present in the prepared food and can proliferate there, as this temperature range is not sufficient to deactivate the bacteria by heat. Preparation with water at a temperature of above 70 °C can reduce the microbial load, but cannot reliably eliminate all *Cronobacter* present. Instead, this would require an adequate level of heat treatment, such as reconstituting the powdered formula with water at a temperature of at least 70 °C for at least two minutes under controlled conditions. However, additional health risks then arise, such as impairments of the nutritional quality of the formula, as well as a risk of scalding for the infant.

The risk of infection can be minimised by ensuring that the formula is fed immediately after preparation. Leaving prepared formula to stand for extended periods (over two hours) until feeding or leaving the prepared formula to cool and then reheating it to drinking temperature can increase the risk of infection, however, as these temperature ranges will favour the proliferation of pathogens.

Furthermore, contamination with pathogens can occur during preparation through hands, water or utensils used for preparation, among other things. Particular attention must therefore be paid to good hygiene when preparing formula for premature babies with a low birth weight or immunocompromised infants.

Age groups affected

Past experiences have shown that infections with *Cronobacter* bacteria are reported only on very rare occasions. When a *Cronobacter* infection does occur, however, a serious clinical progression with a fatal outcome is possible.

Infants aged two months or less are primarily affected: the risk of infection is significantly lower in older individuals.

For full-term, healthy infants with a normal birth weight, the risk of contracting an infection with *Cronobacter* is considered to be extremely low if minimally contaminated formula is prepared and fed directly.

Premature babies with a low birth weight (under 2,500 g) and immunocompromised infants have a significantly higher risk of falling ill than healthy infants with a normal birth weight. If the formula can be assumed to be minimally contaminated, prepared hygienically and fed directly, the risk of contracting a *Cronobacter* infection is still to be classified as low.

4. Risk management options, recommended measures

In general, the recommendation is to feed infant starter formula directly after preparation (i.e. within two hours)(FAO und WHO, 2004). This recommendation should be followed in private households without exception. In some cases, it may be useful to prepare larger quantities of formula in advance if preparation just before consumption is not possible (e.g. in day nurseries or hospitals – see below). This approach requires an effective hygiene regimen and precise temperature monitoring, however. Sterile (aseptic) conditions are required in the facility used for preparation, and both the storage and transportation of the prepared formula must

be temperature-controlled (no more than 24 hours below 5 °C)(FAO und WHO, 2004). For these reasons, the preparation of formula in advance should only be practised in a professional environment, and even here, the alternative option of using commercial sterile liquid formula should be considered, since the storage of prepared infant formula always involves greater risk(FAO und WHO, 2004).

4.1 Water quality

Due to food safety reasons, the BfR recommends using boiled water for the preparation of powdered infant formula for children during their first months of life. While the quality of drinking water in Germany is very good and microbiological limit values are exceeded only rarely (BMG und UBA, 2011), most consumers are typically uninformed about the quality of the water that actually comes out of the household tap. Local sources of contamination as well as long holding times for water in pipes or the formation of biofilms on taps can result in higher levels of microbes and pathogens in drinking water. This has been confirmed by the detection of a range of microbes in drinking water sampled directly from the tap in households in Germany (Daschner *et al.*, 1996; Hussein *et al.*, 2009; Trautmann *et al.*, 2006; Kohnen *et al.*, 2005; von Baum *et al.*, 2010). Sterile filters, as an alternative to boiling water, are not recommended, since recontamination may simply take place at the tapping point. They are also expensive and must be replaced regularly in order to guarantee a uniformly high standard of the water quality.

As when preparing any hot drink or meal, the process of boiling water beforehand must be conducted carefully in order to ensure that the infant is not exposed to any risk of scalding or burn injuries. Potential hazards in this context include scalding from hot liquids, touching hot surfaces such as the kettle or pan used to boil water, and feeding the infant with formula before it has cooled down sufficiently. The standard recommendation here is to put a few drops of the prepared formula from the baby bottle on the inside of the wrist to test the temperature. These drops of formula should not feel warm and certainly not hot.

Trying the formula oneself from the bottle has to be avoided at all costs, since this could transfer microbes from one's mouth to the infant that could later cause problems such as dental caries.

4.2 Recommendations for the preparation of powdered infant starter formula for full-term, healthy infants in private households, childcare facilities and day care centres

The temperatures specified by the manufacturer should be strictly observed when mixing powdered infant formula with water. The BfR considers water temperatures ranging from roughly 20 °C to 50 °C as appropriate for full-term, healthy infants when preparing the infant formula. The formula must have cooled down to drinking temperature before feeding.

The BfR considers it particularly important to observe the following hygiene rules when preparing infant formula (fig. 1):

- Before preparation, the hands should be washed thoroughly with soap and hot water (under a running tap).
- Bottles, spoons and teats should always be thoroughly cleaned with detergent and hot water, and then dried properly. An additional level of safety can be achieved by boiling these utensils or immersing them in boiling water for at least two minutes, or by using a commercial steriliser for baby bottles. In childcare facilities and day care

centres for infants aged under six months (crèches), these heat deactivation techniques are especially recommended after each use to avoid the transmission of pathogens between children.

- The preparation of powdered infant formula should always be separated both in terms of time and location from the preparation of other raw foodstuffs, and from equipment cleaning activities.
- The manufacturer's recommendations for powder storage should be followed at all times. In particular, powdered milk formula must be stored tightly sealed in a dry place well away from heat sources.
- Particular attention must be paid to avoiding the proliferation of potential microbes in prepared formula. Bacteria are unable to proliferate in formula while it is in its powdered form. Accordingly, the BfR therefore recommends preparing bottles only shortly before feeding, cooling them to drinking temperature as quickly as possible (max. 15 min) and feeding within two hours.
- Any prepared formula leftovers should always be disposed of.
- Bottles and teats should be rinsed out with drinking water immediately after use to avoid formula drying in the equipment.
- Measuring scoops should not be stored in the powder itself but, for example, in a sealed jar. The scoop should only be touched by the handle or removed with a clean set of tweezers.
- When travelling with infants, feeding infants at night or preparing daily portions of formula for later feeding in childcare facilities, the best approach is to portion the powdered infant starter formula into clean and dry bottles, store the boiled drinking water in a clean and sealed Thermos flask, and to prepare (mix) the powdered infant starter formula with the water only shortly before feeding.
- If it is absolutely necessary that prepared formula needs to be stored, the preparation must take place under particularly strict conditions of hygiene, which can typically only be achieved in a professional childcare facility.
The freshly prepared formula should be portioned immediately into separate bottles. If the water for the preparation of the formula is not already at room temperature, the formula should be cooled down to room temperature outside the refrigerator as quickly as possible under running water and then stored in the refrigerator at temperatures below 5 °C for a maximum of 24 hours. In such cases, the refrigerator temperature must be checked at regular intervals, since slow but constant bacterial growth is possible in the formula at temperatures above 5 °C.
Immediately before feeding, the formula should be brought to drinking temperature (max. 37 °C) using a bottle warmer as fast as possible (max. 15 min) and fed to the infant within two hours, since these temperatures offer ideal conditions for bacterial growth.
- In childcare facilities and day care centres, the procedures and rules used for the hygienic preparation of formula should be specified in writing and properly documented.
- Childcare facility personnel should be regularly instructed in the hygienic handling of infant formula.

4.3 Recommendations for the preparation of powdered infant formula in hospitals

In the case of hospitals, the BfR recommends establishing a dedicated milk prep room.

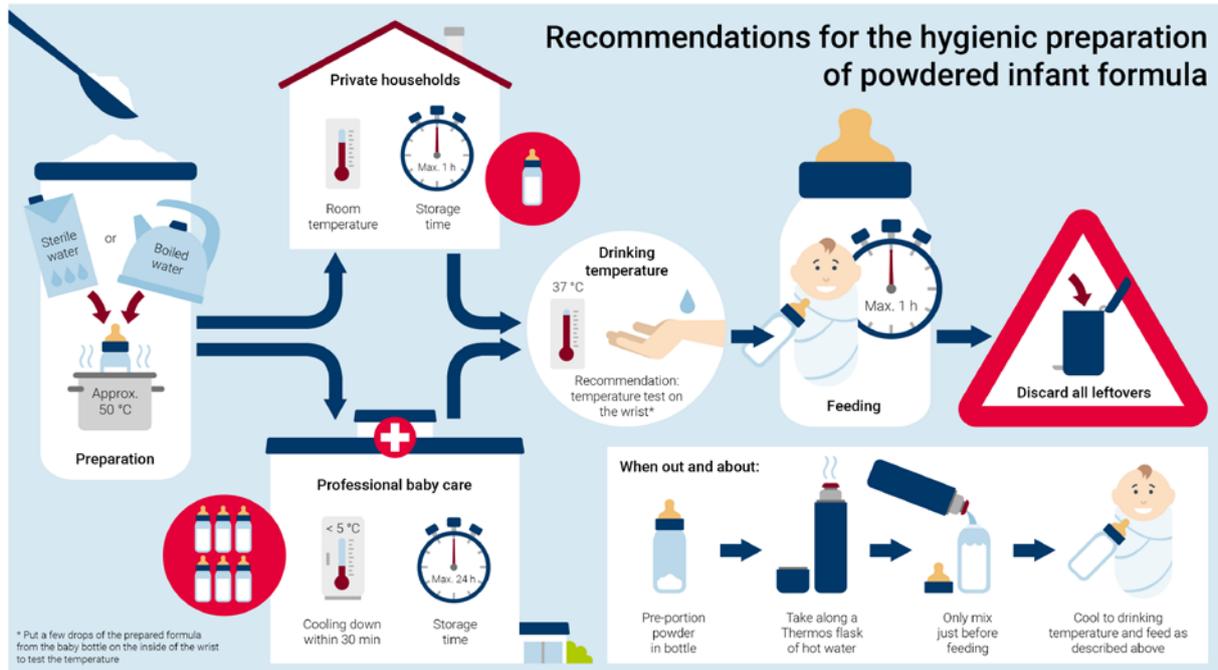
Hygienic requirements for milk preparation rooms in hospitals have been set out in a guideline that is currently being revised by the German Society for Paediatric Hospitals and Children's Wards. The updated version will be published at <https://www.gkind.de/>.

The hygiene requirements for the milk prep room should be described in detail in a hygiene plan that covers the following aspects as a minimum:

- Structural requirements
- Equipment
- Procedures
- Cleaning and disinfection
- Hygiene monitoring in the milk prep room
- Requirements for personnel (personal hygiene, conduct in/near the milk prep room, work clothing)
- Quality controls (microbiological monitoring)

Personnel working in the milk prep room have a key role to play. In order to ensure compliance with these special hygienic requirements, the personnel employed must have the appropriate qualifications. Personnel must be familiar with the in-house monitoring systems and hygiene management measures, and receive regular instruction. Hygiene rules affect personal hygiene on the one hand (e.g. regular, hygienic hand washing, wearing of hygienic clothing, including a head covering and possibly disposable gloves), as well as a hygienic approach to the preparation of infant formula and the observation of all guidelines, together with the full documentation and reporting of deviations from these rules.

In the case of premature babies and immunocompromised infants, an individual nutritional recommendation should be obtained from a medical practitioner. In many cases, sterile ready-to-feed formula products do not meet the individual nutritional needs of this especially susceptible group of infants to the fullest extent. Accordingly, these products or the breast milk must often be enriched with food supplements. Commonly known as 'fortifiers', these supplements must be handled as hygienically as possible before being added to the sterile liquid formula or breast milk. The preparation of formula for premature babies and immunocompromised infants must at least meet or exceed the general requirements set out for the preparation of powdered infant formula in hospitals. The selection of a temperature for the water used to reconstitute formula supplements should be made on a case-by-case basis by weighing up the potentially damaging effects of heat on the individually formulated nutrient concentrate against the benefits from a further reduction in microbiological risks.



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Figure 1: Overview of the maximum period of time from preparation to discarding the prepared formula

Further information on food safety is available from the BfR website

Index page for food safety topics: https://www.bfr.bund.de/en/a-z_index/food_safety-129949.html



BfR 'Opinions app'

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