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Infants who are not breastfed and who suffer from frequent or prolonged diarrhoea do not generally require special formula

There is no scientific evidence to support the need for special dietary management

In brief

- The German Federal Institute for Risk Assessment (BfR) has carried out a technical assessment to determine whether dietary management is necessary for non-breastfed infants with prolonged or frequent diarrhoea and, if so, how a product for dietary management should be formulated in terms of its macronutrient content.
- The background to this is the fact that infant formula is available which has been manufactured for dietary management in cases of (frequent or prolonged) diarrhoea in infants.
- Some of the products currently on the market differ from conventional infant formulae in terms of their macronutrient content (such as protein, starch or lactose).
- In the BfR's view, there is no scientific evidence to suggest that special dietary management is required for infants who are not breastfed or are partially breastfed and suffer from prolonged or frequent diarrhoea. In particular, there is a lack of scientific evidence to suggest that specially formulated infant formula is necessary in these cases.
- Affected infants should be offered their usual age-appropriate food, and care should be taken to ensure adequate fluid intake. In particular, restrictive diets should be avoided.

1 Subject of the assessment

The German Federal Institute for Risk Assessment (BfR) was asked to provide an opinion on whether dietary management in the form of a specially formulated infant formula is necessary for non-breastfed or partially breastfed infants with frequent or prolonged diarrhoea and, if so, how such a product would need to be formulated in terms of its macronutrient content in order to comply with the requirements of Article 2(2) of Delegated Regulation (EU) 2016/128.

Infant formulas designed for dietary management in cases of frequent or prolonged diarrhoea in infants are marketed as foods for special medical purposes, with a composition that deviates from the provisions of Delegated Regulation (EU) 2016/127 applicable to standard infant formulas. For example, there are products with an increased protein or starch content or a reduced lactose content.

With regard to increased protein content, three publications were submitted to the BfR for assessment (Jackson 1993; Mann et al., 1982; Roediger 1986). In addition, a literature search was carried out in scientific databases for the purpose of this opinion, and particular reference was made to medical guidelines on the management of gastrointestinal complaints in infants, as well as to opinions and consensus papers from medical societies on the use of specialised infant formula.

2 Results

In the BfR's view, there is no scientific evidence to suggest that special dietary management is indicated for infants who are not breastfed or are partially breastfed and who suffer from frequent or prolonged diarrhoea. In particular, there is a lack of scientific evidence to suggest that infants with the symptoms mentioned require a special infant formula with a composition that differs from that of standard infant formula.

Instead, paediatric advice should be sought for infants with severe acute diarrhoea or frequent or persistent diarrhoea, particularly due to the risk of dehydration. Regardless of any rehydration treatment, infants should continue to receive their usual diet (breast milk, standard infant formula and/or complementary feeding) even in cases of diarrhoea.

Particularly if diarrhoea lasts for more than 14 days, further investigation is required to diagnose or rule out persistent infections or re-infections, or other underlying conditions such as cow's milk protein allergy, carbohydrate malabsorption, primary lactose intolerance, coeliac disease or chronic gastrointestinal disorders (chronic inflammatory bowel diseases), in which diarrhoea may be a primary symptom. The dietary measures required in these cases must therefore be determined on an individual basis – depending on the underlying cause and on the clinical and biochemical assessment.

3 Rationale

3.1 Definition: Food for special medical purposes

Foods for special medical purposes (FSMP) are defined as specially processed or formulated foods intended for the exclusive or partial diet of patients, including infants, for whose dietary management a modification of the normal diet and/or other foods are insufficient for special nutritional purposes (Regulation (EU) 2016/128).

Regulation (EU) 2016/128 stipulates that such foods shall be safe, beneficial and effective, and must meet the specific nutritional requirements of the persons for whom it is intended, which must be demonstrated by generally accepted scientific data. However, the Regulation does not specify the scientific requirements that must be met regarding the quality of the data.

A guidance document (Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013) issued by the European Food Safety Authority (EFSA) states that, in addition to available guidelines and consensus papers from scientific (medical) professional societies, manufacturers should also submit, amongst other things, human data to scientifically demonstrate the suitability of the specific food for the dietary management of the patients for whom it is intended (EFSA, 2015).

Foods for special medical purposes developed for the diet of infants must, provided this does not conflict with the requirements arising from their intended use, comply with the provisions relating to other nutrients applicable to infant formulae and follow-on formulae laid down in Regulation (EU) 2016/127. Furthermore, these foods must be used under medical supervision (Regulation (EU) 2016/128).

3.2 Characterisation of the target group

Acute infectious gastroenteritis, also known as gastroenteritis, is one of the most common paediatric conditions according to an S2k guideline published by medical societies. Infants and young children are most commonly affected, experiencing 1 to 2 episodes of acute infectious gastroenteritis per year (Posovszky et al., 2024; Guarino et al., 2014).

In Europe, acute gastroenteritis (AGE) in children is primarily caused by viruses and, less commonly, by bacteria. In Germany, noroviruses and rotaviruses, followed by adenoviruses, are the most common causes of AGE in children under five years of age (Posovsky et al., 2020; RKI, 2020; Posovsky et al., 2024). Bacterial pathogens are detected less frequently in stool samples; the main causative agents include *Campylobacter* and *Salmonella*, but also pathogenic *Escherichia coli*, *Clostridium difficile*, *Shigella* and *Yersinia* (Posovsky et al., 2024).

In a German retrospective study, AGE caused by rotavirus infections in hospitalised children was more frequently associated with more severe and prolonged diarrhoea than AGE caused by noroviruses or adenoviruses (Wiegering et al., 2011). Even after the introduction of the rotavirus vaccine, rotaviruses remained the most commonly detected pathogens in children under five years of age with severe AGE (Operario et al., 2017; Walker et al., 2013). AGE caused by *Salmonella* can also be very protracted (Wiegering et al., 2011). In addition to persistent infections, causes of chronic diarrhoea can include, for example, congenital metabolic disorders, severe underlying conditions involving malabsorption and

inflammation, or food hypersensitivities (Thiagarajah et al., 2018; Posovszky et al., 2024; Claßen, 2022; Thapar and Srivastava, 2024).

The key symptoms of acute gastroenteritis (AGE) are a sudden change in stool consistency and an increase in stool frequency (more than three bowel movements in 24 hours), with or without vomiting or fever; however, normal stool frequency in newborns and infants can vary greatly, depending on their diet (Posovsky et al., 2024). In breastfed infants, stool frequency is highly variable – ranging from once every one to two weeks to up to 10 stools a day, usually after each breastfeeding feed, whilst in non-breastfed infants it is less frequent (one to three times a day). Consequently, a clear definition of diarrhoea is difficult, particularly in infants and young children (Thiagarajah et al., 2018). An evaluation of over 100 clinical studies revealed 64 different definitions of diarrhoea in children and adolescents up to and including the age of 18, generally based on a combination of stool frequency and consistency (Johnston et al., 2010).

According to the German medical guideline “S2k-Leitlinie akute infektiöse Gastroenteritis im Säuglings-, Kindes- und Jugendalter – Update 2024”, diarrhoea is defined as the passage of excessively loose stools (Posovszky et al., 2024). Diarrhoea associated with AGE usually lasts 5 to 7 days, and in some cases up to 2 weeks. Diarrhoea lasting more than 14 days is classified as chronic in children and adolescents, regardless of aetiology (congenital, acquired, functional), or as ‘persistent’ diarrhoea if caused by an infectious agent (Posovszky et al., 2024; Lo Vecchio et al., 2016; Guarino et al., 2014).

The main complications of (chronic) diarrhoea, particularly in infants, are dehydration with hypovolaemia (a reduction in the volume of circulating blood or plasma) and disturbances in acid-base and electrolyte balance. These are due to the fact that fluid loss from diarrhoea (and vomiting) can amount to three times the circulating blood volume, and the body draws fluid from the intracellular space to maintain a constant blood volume (Posovszky et al., 2020). If additional symptoms develop and/or the diarrhoea persists for longer than 14 days, other underlying conditions should be considered in accordance with the S2k guideline (Posovszky et al., 2024).

3.3 Dietary management in infants with diarrhoea

There is no explicit guideline on the management of frequent or persistent diarrhoea in infancy. The S2k guideline on acute infectious gastroenteritis in infants, children and adolescents does not recommend any special diet for gastroenteritis without dehydration. Instead, the usual age-appropriate food should be offered and care taken to ensure adequate fluid intake (Posovszky et al., 2024). In particular, restrictive diets are not recommended.

In cases of dehydration, such as during the occurrence of frequent or persistent diarrhoea, the primary treatment should be oral rehydration combined with a prompt reintroduction to a normal, age-appropriate diet. Fluid losses should be treated by administering sufficient oral fluids and electrolytes (oral rehydration solution (ORS), e.g. glucose-electrolyte solution). In parallel, breastfeeding should be continued for breastfed infants. Infants who are not breastfed or are partially breastfed should be offered age-appropriate diet as early as possible following oral rehydration in order to prevent or correct a catabolic metabolic state and to promote the regeneration of enterocytes (Posovszky et al., 2024).

For most specialised diets or dietary regimens in reintroduction to a normal diet, such as vegan or gluten-free diets, there is no evidence of positive effects (Posovszky et al., 2020 and 2024). Nor do the publications submitted to the BfR (Jackson, 1993; Mann et al., 1982; Roediger, 1986), which discuss protein metabolism in chronic malnutrition as well as protein and fat intake in cases of persistent diarrhoea, provide no evidence that infants in industrialised countries such as Germany who suffer from frequent or prolonged diarrhoea could benefit from infant formula with an increased protein content.

It is known that acute diarrhoea can lead to a – temporary – lactase deficiency and thus to lactose intolerance. Consequently, there is some controversy as to whether a reduction in lactose intake should be considered in cases of prolonged or chronic diarrhoea (Lo Vecchio et al., 2016; Giannatassio et al., 2016; MacGillivray et al., 2013; Florez et al., 2018; Florez et al., 2020). However, the quality of the evidence supporting the benefits of a lactose-free diet is considered to be low (Posovszky et al., 2024). The European Society for Paediatric Gastroenterology, Hepatology and Diet (ESPGHAN) also points out in a guideline on the management of AGE that the majority of studies are based on data from hospitalised children and that, in two studies conducted in an outpatient setting, no positive effect of a lactose-free formula was observed (MacGillivray et al., 2013; Guarino et al., 2014). German and European guidelines on the treatment of acute gastroenteritis therefore do not recommend the routine administration of lactose-free infant formula, particularly in the outpatient setting (Florez et al., 2020; Guarino et al., 2014; Posovszky et al., 2024). A review of publications that appeared following the update of the S2k guideline on AGE in childhood revealed no new findings in this regard.

Apart from the fact that lactose-free infant formula is not routinely recommended for AGE in infancy, lactose-reduced infant formulas may have higher glucose levels compared to standard infant formula, which generally contains only lactose, as these products contain, in addition to/in place of lactose, other carbohydrates, such as maltodextrins or glucose syrup, are added as alternative carbohydrate sources (Mokhatri et al., 2024; Larson-Nath et al., 2025). This would be considered a cause for concern, particularly in the case of prolonged use during infancy. There is evidence that the use of a lactose-reduced, glucose syrup-based infant formula is associated with an increased risk of obesity in early childhood (Anderson et al., 2022).

In summary, in cases of frequent or persistent diarrhoea in infancy, there is no general benefit to be gained from a specialised infant formula with a modified composition compared with conventional infant or follow-on formula. Instead, care should be taken to ensure adequate fluid intake, and the usual age-appropriate food should generally be offered.

In particular, in cases of persistent diarrhoea or diarrhoea lasting more than 14 days, as well as where other symptoms are present, other conditions such as persistent infections or re-infections, cow's milk protein allergy, carbohydrate malabsorption, primary lactose intolerance, coeliac disease or chronic gastrointestinal disorders (chronic inflammatory bowel disease), in which diarrhoea may be a primary symptom, should be included in the investigation of the cause (Posovszky et al., 2024; Claßen 2022). Dietary measures for persistent diarrhoea must therefore be tailored to the individual – depending on the underlying cause and on the clinical and biochemical assessment. Finally, for a few, precisely defined clinical conditions that may be the cause of diarrhoea symptoms, there are indeed

indications for the use of specially formulated infant formulas. However, such formulas should only be used following a medically confirmed diagnosis and under medical supervision. For example, therapeutic special-purpose formulas may be indicated in cases of food allergies, whilst lactose-free infant formulas based on soya protein isolate may be indicated in cases of galactosaemia and hereditary lactose intolerance (congenital lactase deficiency).

3.4 General recommendations from medical societies regarding specialised infant formulas

Two recent opinions from the nutrition committees of German-speaking and European medical and paediatric professional societies address the use of dietary foods for special medical purposes in infants (DGKJ, 2022; Haiden et al., 2024). Although the two opinions do not explicitly address specialised infant formulae marketed for diarrhoea, the use of specialised infant formulae marketed for various gastrointestinal complaints in infants is not recommended. It is also pointed out that, regardless of whether an infant is breastfed or fed infant formula, it is important to reassure parents that functional gastrointestinal disorders are normal and do not usually require treatment or change to a specialised infant formula (Haiden et al., 2024). Finally, it is emphasised that specialised infant formulas should only be used on the advice of doctors or healthcare professionals and under medical supervision; when sold in supermarkets or chemists, there is no guarantee that these requirements will be met (DGKJ, 2022).

German Society for Paediatrics and Adolescent Medicine (Deutsche Gesellschaft für Kinder- und Jugendmedizin e.V. (DGKJ)) Information for Parents: Diarrhoea (in German only)

- <https://www.dgkj.de/eltern/dgkj-elterninformationen/elterninfo-durchfall>

Further information on the BfR website regarding infant formula

Recommendations for the hygienic preparation of powdered infant formula
<https://www.bfr.bund.de/en/opinions/recommendations-for-the-hygienic-preparation-of-powdered-infant-formula/>

BfR opinion: Health benefits of infant formula with added 'probiotics' still not scientifically proven (in German only)
<https://www.bfr.bund.de/stellungnahme/gesundheitslicher-nutzen-von-saeuglingsnahrung-mit-zusatz-von-probiotika-wissenschaftlich-weiterhin-nicht-belegt/>

BfR opinion: Health benefits of infant formula and follow-on formula containing human milk oligosaccharides and/or galactooligosaccharides not yet proven (in German only)
<https://www.bfr.bund.de/stellungnahme/gesundheitsliche-vorteile-von-saeuglingsanfangs-und-folgenahrung-mit-humanen-milch-oligo-und-oder-galactooligosacchariden-noch-nicht-belegt/>

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