

Putting nutrition at the heart of patient care

An Update on Specialist Nutrition

Specialist nutrition supports positive health outcomes and reduces costs to the NHS.

New EU Regulation on Foods for Special Medical Purposes

In February 2019, the new European Commission Delegated Regulation (EU) 2016/128¹ on Foods for Special Medical Purposes (FSMP) will come into force. This regulation updates, but largely retains, the existing rules for FSMPs,² including the definitions of the category and the nutritional composition. However, it updates specific requirements for FSMPs, including labelling and formulation. The deadline for compliance is February 2019 for all FSMPs for use in patients from one year old, with the rules for FSMPs developed for infants applying from February 2020.

Labelling

The labelling for FSMPs must clearly highlight properties and characteristics relevant for the appropriate clinical and safe use of the product; this is still supported in the new regulation, however some labelling requirements for FSMPs have been amended. For example, some units for micronutrients will be updated within the nutritional declaration and information included in the mandatory nutrition declaration should not be repeated elsewhere on the labelling. Authorised nutrition and health claims should not be used on FSMPs as they have been developed with healthy people in mind. Where information is deemed a property and characteristic of the FSMP useful for the appropriate use, this would remain compliant with the regulation.

Communication

The new Delegated Regulation has more closely aligned communication practices for FSMPs designed for infants with the regulation of infant and follow-on formula. However, it is still important for infant FSMPs to be distinguished from infant and follow-on formula, and that healthcare professionals (HCPs) should still be able to assess the suitability of different products for their intended use through appropriate communications.

Composition

The minimum and maximum amounts of each macro and micro-nutrient for infant FSMPs are specified within legislation. The guidance amounts have been updated in the new regulation, again to more closely align the formulation of infant FSMPs with the scientific updates regarding the nutritional requirements of infants³ (as updated by EFSA Opinions of 2013 and 2014). For example, the new minimum level of selenium is 3 µg/100 kcal (the maximum level in the previous Directive) and there is now a mandatory addition of 20 mg/100 kcal docosahexaenoic acid (DHA) to infant products.

Variation in the amount of each micronutrient in FSMPs may be necessary depending on the patient's medical condition. Deviations in micronutrient content from the listed values within the FSMP regulation may also occur if the product is specifically formulated for a specific disease, disorder or clinical condition where a reduced or increased amount of a vitamin, mineral or trace element, such as sodium or vitamin B12, is required. For example, a person with cystic fibrosis may need extra vitamins A, D, E and K, as well as calcium. There will be no change in the ability to deviate from these minima and maxima though evidence will be needed to justify such deviations.

Infant FSMPs

As these updates include some significant changes, additional time has been allowed for formulation assessment and reformulation, where appropriate, for updating infant FSMPs, with all the new regulation changes applying from February 2020 for these products.

References: 1. EU Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes. 2. Directive 1999/21/EC on dietary foods for special medical purposes. 3. European Food Safety Authority (EFSA), Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. EFSA Journal 2015;13(11):4300 [24 pp.]

About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diagnosed disorders and medical conditions, including parenteral nutrition, and gluten-free foods on prescription. www.bsna.co.uk