

NEW Delegated Regulation for Infant and Follow-on Formula

What you need to know

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Key messages:

- The regulations for infant and follow-on formula are changing
- Changes are likely to be noticeable in the formulations
- Healthcare professionals (HCPs) should be familiar with these changes so they can help and support parents.

Background

Food regulations play a fundamental role in ensuring safety, quality and high nutritional standards, while also guaranteeing the appropriate supply of consumer information. Under EU law, manufacturers are required to ensure that their food products are safe in accordance with General Food Law. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28th January 2002, lays down the general principles and requirements of food law.

For certain foods, additional specific regulatory requirements exist. In the case of specialist products, including infant formula (IF), follow-on formula (FoF), food for special medical purposes (FSMPs) and complementary weaning foods, detailed regulations are in place to further safeguard the vulnerable consumers for which these products are intended. These regulations have been updated, with a number of compositional and labelling changes which healthcare professionals should be aware of.

Regulatory Background: Parnuts to FSG

Infant formula and follow-on formula are amongst the most strictly regulated of all food stuffs. EU legislation incorporates the principles and aims of the World Health Organization (WHO) Code of Breastmilk Substitutes and is strictly enforced. Up until July 2016, IF and FoF have been regulated by the 2009/39/EC European Framework Directive on 'Foods for Particular Nutritional Uses' (the 'PARNUTS' Framework). Under the PARNUTS Framework sits the specific specialist Directive 2006/141/EC on IF and FoF. This regulation specifies the nutritional composition of IF and FoF, including labelling and claims provisions specific for these products. The PARNUTS legislation has been replaced by Regulation (EU) No 609/2013, otherwise known as the Regulation on 'Foods for Specific Groups' (FSG). Under the FSG framework, the specific specialist Directive 2006/141/EC on infant formula and follow-on formula has been updated and will be replaced by Commission Delegated Regulation (EU) 2016/127. **This European Commission Delegated Regulation (EU) 2016/127 will apply from 22nd February 2020, except in respect to infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 21st February 2021.**

Hopefully you are still reading, because here is the important bit...

While the IF and FoF legislation entered into force in February 2016, it is not fully applicable until February 2020. Therefore, during this time, companies can sell IF and FoF which is compliant with either the previous or the new legislation.

In accordance with Regulation (EU) No 609/2013: '(48) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation'. To ensure compliance by 22nd February 2020, companies are starting to implement the new changes, with some new products due to land on shelves imminently. It is, therefore, particularly important that HCPs are sufficiently informed and aware of these changes.

What you need to know

These changes update, but largely retain, the existing rules. However, the new legislation brings about some significant

compositional changes, based on the latest scientific research to IF and FoF. This follows a request from the European Commission, when in 2014 the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies (NDA) delivered a scientific opinion on the essential composition of infant and follow-on formula.¹ This extensive report brings about changes to the legislation, which had previously allowed the addition of docosahexaenoic acid (DHA) as an optional ingredient, but now requires the mandatory addition of DHA (see below). A range of 20-50 mg/100 kcal has been set. Levels of DHA will change, or be newly added, to IF, FoF and infant FSMPs.*

Some other nutritional changes include an increase in the maximum levels for alpha-linolenic acid (ALA), and small increases in the minimum levels of copper, iodine, selenium, sodium, potassium, chloride, vitamin A, vitamin D and folic acid. While other nutrients such as vitamin B6, biotin, vitamin C and vitamin K have had lower minimum levels set.

These changes may result in updated nutritional declarations on product labels.

Small labelling changes will also occur, such as folic acid to be declared as folate, while the units for niacin and pantothenic acid have changed from µg to mg.

Due to the formulation changes, parents may notice a slight difference in the smell, appearance or taste of the products; settling issues may also be noticed but these should only be temporary and minimal. In both cases, parents should be reassured that the formulation changes are based on the latest scientific evidence and made for the benefit of their baby's nutrition. It is important that HCPs are familiar with the changes so that they are able to help and support parents of bottle fed infants.

While manufacturers will endeavour to provide timely information to HCPs, explaining the compositional changes to IF, FoF and infant FSMPs, there are limitations on what can be communicated to consumers on infant milks, especially those suitable for use from birth. Hence, it is vital HCPs are adequately informed.

DHA – The Value of Research in Improving the Quality of Infant Formula

Over the past 25 years, research has been steadily growing around the health benefits of docosahexaenoic acid (DHA). This fatty acid, along with arachidonic acid (ARA) are present in breast milk and play an essential role in early infant development, particularly the structure and function of neural tissues, most notably those of the retina and brain.² Compared with other long-chain fatty acids, both DHA and ARA are preferentially transferred to the foetus across the placenta.³ Their accumulation in the foetal brain takes place mainly during the last trimester of pregnancy. This continues at very high rates up to the end of the second year of life (the period considered the primary growth phase for the human brain when measured in terms of brain weight).^{4, 5} Intervention studies have shown the important role of DHA supplementation in nutritional status benefits in specific cognitive function, visual acuity and immune responses.⁴

NEW Infant Nutrition Industry Code of Practice

The British Specialist Nutrition Association (BSNA) has launched a new Code of Practice for the manufacturers of formula milks in the UK. Danone, Nestlé, Abbott, HiPP and Mead Johnson have committed to adhere to the Infant Nutrition Industry (INI) Code, which is designed to shed more light on how the UK infant nutrition industry operates and the high standards that can be expected. The Code will be regulated by a new, independent Code of Practice Authority (INICPA) which will investigate any complaints made and have the power to require any company found to be in breach of the INI Code to take appropriate corrective steps.

The Code demonstrates the infant nutrition industry's commitment to responsible marketing and transparency as per the World Health Organisation's International Code of Marketing of Breastmilk Substitutes 1981, and covers areas of industry practice including product quality, composition, safety, sales, marketing and clinical research.

To view the Code in full please visit the BSNA website at: www.bsna.co.uk

References: **1.** EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies) (2014). Scientific Opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*; 12(7): 3760. **2.** Lien EL, Richard C, Hoffman DR (2018). DHA and ARA addition to infant formula: Current status and future research directions. *Prostaglandins Leukot Essent Fatty Acids*; 128:26-40. **3.** Haggarty P, et al. (1997). Long-chain polyunsaturated fatty acid transport across the perfused human placenta. *Placenta*; 18(8): 635-642. **4.** Lauritzen L, et al. (2016). DHA Effects in Brain Development and Function. *Nutrients*; 8(1): 6. **5.** Kuratko CN, et al. (2013) The relationship of docosahexaenoic acid (DHA) with learning and behavior in healthy children: a review. *Nutrients*; 5(7): 2777-810.

* Under the new Delegated Regulation (EU) 2016/128, from February 2020, infant FSMPs will be similarly affected by changes to the composition, labelling and advertising.

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

