New EU Regulation on Foods for Special Medical Purposes for Infants

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On 22 February 2020, the new European Commission Delegated Regulation (EU) 2016/128[1] on Foods for Special Medical Purposes (FSMPs) intended for infants will come into force. It is important to remember that up until this date, manufacturers can comply with either the current or new regulations. After this date only FSMPs intended for infants which comply with the new regulation can be manufactured, however you may still see products which comply with the previous regulations being dispensed until stocks are depleted.

The new regulation updates, but largely retains, the existing rules.[2] However, the new legislation brings in marketing restrictions and some significant compositional changes based on the latest scientific research on formula milks.[3]

Compositional changes

The new regulations for FSMPs intended for infants include an increase in the minimum level of vitamin A, vitamin D, sodium, copper, folic acid and iodine. While other nutrients such as vitamin C, vitamin K, vitamin B_6 and manganese 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 thiamin, riboflavin, vitamin B_6, manganese and fluoride have changed from mg to µg.

The macronutrient compositional changes align to the new infant formula and follow-on formula regulations (Delegated Regulation (EU) 2016/127[4] as of 22 February 2020) (**Table 1**). This includes the introduction of a maximum level for alpha-linolenic acid (ALA), and an increase in the minimum level of linoleic acid and choline. Research into the health benefits of docosahexaenoic acid (DHA) for infants has brought about the mandatory addition of DHA, of which a range of 20-50 mg/100 kcal has been set. The changes can be seen in **Table 1**.

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 healthcare professionals are familiar with these changes so they can help and support parents. Manufacturers will endeavour to provide timely information to healthcare professionals, explaining the compositional changes.

Deviations from the regulations

As in previous legislation, variations in the amount of each nutrient in FSMPs intended for infants may be necessary depending on the patient's medical condition. For example, deviations in micronutrient content from the listed values within the regulation may 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 B_{12}, is required. Evidence will be needed to justify such deviations.

Communication

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

Regulation for Infant Formula and Follow-on Formula

The new EU Delegated Regulation 2016/127 for infant formula and follow-on formula will also come into force on 22 February 2020. More information can be read in the Feb/Mar 2019 issue of CN.

Table 1: Values for macro and micronutrients for FSMPs intended for infants

The current regulations and the new regulations which come into force on 22 February 2020

		Current regulations		New regulations	
		COMMISSION DIRECTIVE 2006/141/EC		COMMISSION DELEGATED REGULATION (EU) 2016/127	
Nutrient	Unit	Minimum value/100 ml	Maximum value/100 ml	Minimum value/100 ml	Maximum value/100 ml
MACRONUTRIENTS					
Energy	kJ	250	295	250	293
Energy	kcal	60	70	60	70
		Minimum value/100 kcal	Maximum value/100 kcal	Minimum value/100 kcal	Maximum value/100 kcal
Protein					
Cows/goats milk	g	1.8	3	1.8	2.5
Soya protein	g	2.25	3	2.25	2.8
Protein hydrolysates	g	1.8	3	1.86	2.8
Lipids	g	4.4	6	4.4	6
Linoleic acid	mg	300	1200	500	1200
alpha-linolenic acid	mg	50	-	50	100
Docosahexaenoic acid	mg	-	-	20	50
Carbohydrates	g	9	14	9	14
OTHER					
Taurine	mg	-	12	-	12
Choline	mg	7	50	25	50
Inositol	mg	4	40	4	40
		COMMISSION DIRECTIVE 1999/21/EC		COMMISSION DELEGATED REGULATION (EU) 2016/128	
		Minimum value/100 kcal	Maximum value/100 kcal	Minimum value/100 kcal	Maximum value/100 kcal
VITAMINS					
Vitamin A RE	µg	60	180	70	180
Vitamin D	µg	1	3	2	3
Vitamin K	µg	4	20	1	25
Vitamin C	mg	8	25	4	30
Thiamin	µg*	40	300	40	300
Riboflavin	µg*	60	450	60	450
Vitamin B_6	µg*	35	300	20	300
Niacin	mg	0.8	3	0.4	3
Folic Acid	µg	4	25		
Folate DFE**	µg	15	47.6		
Vitamin B_{12}	µg	0.1	0.5	0.1	0.5
Pantothenic Acid	mg	0.3	2	0.4	2
Biotin	µg	1.5	20	1	20
Vitamin E	mg α te	0.5	3	0.6	5
MINERALS					
Sodium	mg	20	60	25	60
Chloride	mg	50	125	60	160
Potassium	mg	60	145	80	160
Calcium	mg	50	250	50	250
Phosphorus	mg	25	90	25	100
Magnesium	mg	5	15	5	15
Iron	mg	0.5	2	0.3	2.5
Zinc	mg	0.5	2.4	0.5	2.4
Copper	µg	20	120	60	120
Iodine	µg	5	35	15	35
Selenium	µg	1	3	3	8.6
Manganese	µg*	50	200	1	100
Chromium	µg	-	10	-	10
Molybdenum	µg	-	10	-	14
Fluoride	µg*	-	200	-	200

*unit changed from mg to µg **Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0.6 µg folic acid.

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

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.** 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 **4.** EU Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant