Changes to the compositional, labelling and marketing regulations for breastmilk substitutes that come into force in February 2020[1]

Background:

The current macro and micronutrient requirements for infant formula and follow-on formula and labelling and marketing restrictions are set out in EC/UK legislation (EU Commission Directive, 2006, Food Standards Agency, 2007 (Statutory Instrument (SI) 2007/3521, The Infant Formula and Follow-on Formula (England) Regulations 2007 and equivalent regional regulations as well as any amendments made to these) and Foods for Special Medical Purposes (EU Commission Directive, 1999/21, in England SI 2000/85 The Medical Food (England) Regulations 2000 and equivalent regional regulations).

On the 20th July 2016 a new EU directive informing UK SI *Regulations on Foods for Specific Groups* (FSG) (609/2013) came into force. This directive contains delegated acts (EU delegated regulation 2016/127) relating to infant and follow-on formula and (EU delegated regulation 2016/128) relating to infant milks that are marketed as foods for special medical purposes. Whilst the FSG directive has been in force since July 2016, companies were given up to four years to make changes in line with the delegated acts, and new regulations must be met from February 2020.[2] It is currently suggested that the UK will adopt these regulations regardless of if or how it exits from the European Community.

Key changes in the new regulations:

For infant formula and infant milks marketed as food for special medical purposes (FSMP):

- No nutrition and health claims permitted.

For infant formula, follow-on formula and for infant milks marketed as foods for special medical purposes:

- A reduction in the upper limit of protein
- An increase in the lower limit for linoleic acid and a maximum limit for alpha-linolenic acid content
- The mandatory addition of Docosahexaenoic acid (DHA)
- Some minor changes to the upper and lower limits of micronutrients
- The term folic acid will be replaced by the term folate.

[1] It is currently assumed that these regulations will come into force, but consideration is still needed that there may be unknown changes relating to whether and how the UK leaves the EU.

[2] The exception to this is infant formula and follow on formula manufactured from protein hydrolysates, to which the regulation applies from 22nd February 2021.

For infant milks marketed as FSMP[3]

- Nutrition and health claims shall not be made on food for special medical purposes and consumption of these products must not be promoted.
- All mandatory particulars for food for special medical purposes developed to satisfy the nutritional requirements of infants shall appear in a language easily understood by the consumers.
- No idealising images or text to be used in labelling and advertising.
- The design should make a clear distinction between food for special medical purposes and infant formula and follow-on formula to avoid confusion.
- Advertising is restricted to publications specialising in baby care and scientific publications
- All advertising must only provide information that is scientific and factual in nature.
- No point-of-sale advertising or the giving of samples or other promotional devices (such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales) to induce sales at the retail level.
- Manufacturers and distributors of food for special medical purposes shall not directly provide free or subsidised products, samples or any other promotional gifts to members of the general public (including mothers, pregnant women and their families).

For infant formula and follow-on formula:

- Labelling, presentation and marketing must make a clear distinction between infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them.

The full interpretation of the new legislation will be set out in updated Guidance Notes by the regulatory authorities in the UK when the new delegated acts come into force. Currently the Guidance Notes make explicit that *claims are subject to regulation wherever they appear on the labelling, on a website or in advertising or presentation, and that it is not the case that statements constitute claims only when they appear in headings or banners.*

New regulations should have impacts on product labelling and marketing such as:

- Promotions of FSMP products at point of sale would not be allowed, for example no special displays or sales techniques perceived to be promotional at a retail level.
- SMA HA (a partially hydrolysed infant formula) would not be able to make a claim that it reduced the risk of cows' milk protein allergy on the label, on websites or in advertising and marketing materials.
- Nutrition claims related to the addition of taurine, fructo-oligosaccharides and galacto-oligosaccharides (GOS/FOS) and nucleotides to infant formula would not be allowed on labels, on websites or in advertising and marketing materials.
- Products that add DHA for the first time will not be able to highlight this; products that previously added DHA can use the statement 'contains DHA (as required by the legislation for all infant formula)'
- Services such as the Nestlé sample service or Abbott direct to patient sample service, delivering infant milks marketed as FSMP direct to customers would not be allowed.
- There should be greater visual distinction between the packaging of infant and follow-on formula milks belonging to the same brand and so the current practice of almost identical colours, texts and images on packaging should end.

[3] The European Commission issued an additional guidance note on the classification of foods for special medical purposes (FSMP) in 2017 (2017/C 401/01) which clearly stated that these foods should be used under medical supervision. This aims to ensure that milks marketed as FSMP are not misclassified which can negatively affect the protection of consumers interests. More information about this and why many health professional groups agree that some FSMP products should be removed from open sale in the UK can be found here www.bflg-uk.org/news-and-events

1. Infant Formula

Table 1. Macro and micronutrient requirements for infant formula[4] in the current regulations and the new regulations in force from February 2020.

Changes to the regulations are highlighted in **bold**.

	Current regulations[a] Infant formula		New regulations[b] for Infant formula	
	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy kJ	250	295	250	**293**
kcal	60	70	60	70
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Protein g	1.8	3.0	1.8	**2.5**
Carbohydrate g	9.0	14.0	9.0	14.0
of which lactose g	4.5	N/S	4.5	N/S
Fat g	4.4	6.0	4.4	6.0
Linoleic acid mg	300	1200	**500**	1200
Alpha-Linolenic acid mg	50	N/S	50	**100**
Docosahexaenoic acid (DHA) mg	-	-	**20**	**50**
VITAMINS				
Vitamin A µg-RE	60	180	**70**	114
Vitamin C mg	10	30	**4**	30
Vitamin E mg	0.5 [1]	5.0	**0.6**	5.0
Vitamin D µg	1.0	2.5	2.0	3.0
Vitamin K µg	4.0	25	1.0	25
Thiamin (B_1) µg	60	300	40	300
Riboflavin (B_2) µg	80	400	60	400
Niacin µg	300	1500	**400**	1500
Vitamin B_6 µg	35	175	**20**	175
Vitamin B_{12} µg	0.1	0.5	0.1	0.5
Folic acid µg	10	50		
Folate µg-DFE[2]			**15**	**47.6**
Biotin µg	1.5	7.5	**1**	7.5
Pantothenic acid µg	400	2000	400	2000
MINERALS				
Calcium mg	50	140	50	140
Chloride mg	50	160	**60**	160
Copper µg	35	100	**60**	100
Iodine µg	10	50	**15**	**29**
Iron mg	0.3	1.3	0.3	1.3
Magnesium mg	5.0	15	5.0	15
Manganese µg	1.0	100	1.0	100
Phosphorus mg	25	90	25	90
Potassium mg	60	160	**80**	160
Selenium µg	1.0	9.0	**3.0**	**8.6**
Sodium mg	20	60	**25**	60
Zinc mg	0.5	1.5	0.5	**1.0**
Other				
Choline mg	7.0	50	**25**	50

[4] Not including recommendations for formula made from soy protein isolates alone or in mixtures with cows' milk or goats' milk protein or formula made from protein hydrolysates.

	Current regulations for infant formula		New regulations for infant formula	
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
L-carnitine[3] mg			**1.2**	N/S
May be added but not essential				
Fluoride µg	N/S	100	N/S	100
Molybdenum µg			N/S	**14**
Total Nucleotides mg	N/S	5.0	N/S	5.0
Cytidine-5'-monophosphate	N/S	2.5	N/S	2.5
Uridine – 5'-monophosphate	N/S	1.75	N/S	1.75
Adenosine-5'-monophosphate	N/S	1.5	N/S	1.5
Guanosine-5'-monophosphate	N/S	0.5	N/S	0.5
Inosine-5'-monophosphate	N/S	1.0	N/S	1.0
Taurine	N/S	12	N/S	12
Prebiotic fibre g	N/S	0.8[4]	N/S	0.8[4]

N/S = not stated

1 Vitamin E: 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg per 100kcal, maximum 5.0mg/100kcal.

2 Dietary folate equivalent 1 µgDFE -= 1 µg food folate = 0.6 µg folic acid

3 In the 2007 regulations L-carnitine concentration is only specified for formula containing protein hydrolysates or soya protein isolates on their own or in a mixture with cows' and goats' milk proteins. For both types of formula the minimum concentration specified is 1.2mg/100kcal. No upper level is set.

4 Fructo-oligosaccharides and galacto-oligosaccharides (prebiotic fibre) may be added to infant formula. In that case their content shall not exceed 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and glactose-oligosaccharides may be used provided their suitability for infants is demonstrated in accordance with Article 5 (old regs) Article 3(3) (new regs)

Source:

a. Current regulations: Infant Formula and Follow-on Formula (England) Regulations 2007 (based on Commission Directive 2006/141/EC) and equivalent regulations in Scotland, Wales and Northern Ireland.

b. New regulations: Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/21013 of the European Parliament and of the Council as regards the specific composition and information requirements for infant formula and follow on formula and as regards requirements on information relating to infant and young child feeding.

Additional regulatory information about infant formula composition:

Amino Acids

In both the current and new regulations, it is stated that infant formula must contain an available quantity of each indispensable amino acid and conditionally indispensable amino acid at least equal to that contained in the reference protein (breastmilk) as shown below. The concentration of methionine and cysteine may be added together if the methionine ratio is not less than 2[5], and the phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

[5] In the current regulations: the ratio of methionine to cysteine may be greater than 2 but not 3 if the suitability of the product for use of infants is demonstrated through appropriate studies.

Amino-Acid	Per/100kcal	Amino-Acid	Per/100kcal
Cysteine	38	Phenylalanine	83
Histidine	40	Threonine	77
Isoleucine	90	Tryptophan	32
Leucine	166	Tyrosine	76
Lysine	113	Valine	88
Methionine	23		

Lipids

Current regulations	New regulations
• Sesame seed oil and cotton seed oil are not permitted • Erucic acid content shall not exceed 1% total fat content • Trans fatty acid content should not exceed 3% total fat • Eicosapentaenoic acid (20:5, n-3) content shall not exceed that of docosahexaenoic acids (22:6, n-3) content • The amount of phospholipids in infant formula shall not be greater than 2g/l	Consistent with current regulations
Lauric and myristic acid should not be >20% of total fat content.	No statement on amount of lauric and myristic acid
The docosahexaenoic acid (22:6 n-3) content shall not exceed that of n-6 LCP	Specific criteria for DHA content established in new regulations (minimum of 20mg and maximum of 50mg/100kcal).
Long chain (20 and 22 carbon) polyunsaturated fatty acids (LCP) may be added but their content must not exceed 1% of the total fat content of n-3 LCP or 2% of the total fat content for n-6 LCP (1% of total fat content for arachidonic acid (20:4 n-6))	Long chain (20 and 22 carbon) polyunsaturated fatty acids shall not exceed 2% of the total fat content for n-6 long chain polyunsaturated fatty acids (1% of the total fat content for arachidonic acid (20:4 n-6))

Carbohydrates

Current regulations	New regulations
Only the following carbohydrates can be used in infant formula made from cows' or goats' milk protein: • Lactose • Maltose • Maltodextrins • Precooked starch (naturally free of gluten) • Gelatinised starch (naturally free of gluten). • Sucrose (only in infant formula made from protein hydrolysates) • Glucose (only in infant formula made from protein hydrolysates) • Glucose syrup or dried glucose syrup	Consistent with current regulations
If pre-cooked starch or gelatinised starch is added this should not exceed 2g/100ml and 30% of the total carbohydrate content.	Consistent with current regulations

	Glucose syrup or dried glucose syrup can be added to infant formula made from cows' milk or goats' milk protein, or from soya protein isolates (alone or in a mixture with cows' or goats' milk protein) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products the glucose resulting from glucose syrup or dried glucose syrup *shall not exceed 0.84g/100kcal.* For infant formula made from protein hydrolysates, maximum amounts for glucose in infant formula made from protein hydrolysates (2g/100kcal) shall apply where glucose syrup or dried glucose syrup is added.
Sucrose may only be added to infant formula made from protein hydrolysates and shall not exceed 20% of the total carbohydrate content.	Consistent with current regulations
Glucose can only be added to infant formula made from protein hydrolysates and shall not exceed 2g/100kcal.	Consistent with current regulations
Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula but their content should not exceed 0.8g/100ml in a combination of 90% oligogalactosyll-lactose and 10% higher molecular weight oligofructosyl-saccharose.	Consistent with current regulations

Minerals

In both current and future regulations:

- In both the current and new regulations, the calcium to available phosphorous molar ratio shall not be <1 nor greater than 2.
- The new regulations also state that the amount of available phosphorus should be calculated as 80% of total phosphorus

Labelling and marketing regulations

Current regulations	**New regulations**

The labelling of infant formula may bear nutrition claims only in the cases listed and in accordance with the conditions set out. These claims include:
• Lactose only and Lactose free
• Added LCP or equivalent nutrition claim related to the addition of docosahexaenoic acid
• Nutrition claims on the addition of the following optional ingredients:
  ○ Taurine
  ○ Fructo-oligosaccharides and galacto-oligosaccharides
  ○ Nucleotides
	• Nutrition and health claims shall not be made on infant formula.
	• However, the statement 'lactose only' may be used for when lactose is the only carbohydrate present in the product.
	• The statement 'lactose free' may be used when the lactose content is not greater than 10mg/100kcal.
	• The statement 'contains docosahexaenoic acid (as required by the legislation for all infant formula)' or 'contains DHA (as required by the legislation for all infant formula)' may only be used for infant formula previously placed on the market.

• A health claim is allowed related to the reduction of risk to allergy to milk proteins, reduced allergen or reduced allergen properties provided certain conditions are met	
Current regulations	**New regulations**
• Any labelling of infant formula shall not include pictures of infants, or other pictures or text which may idealise the use of the product, although graphic representation which easily identifies the product and for illustrating methods of preparation may be used. It should be labelled in a way that enables consumers to make a clear distinction between such products to avoid confusion between infant formula and follow-on formula.	• Any labelling, presentation and marketing of infant formula should be designed in a way that enables consumers to make a clear distinction between infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them.
• Advertising is restricted to publications specialising in baby care and scientific publications. All advertising must only provide information that is scientific and factual in nature and must not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding.	Consistent with current regulations
• There shall be no point-of-sale advertising or the giving of samples or other promotional devices to induce sales at the retail level.	Consistent with current regulations
• Manufacturers and distributors of infant formula shall not directly provide free or subsidised products, samples or any other promotional gifts to members of the general public (including mothers, pregnant women and their families).	Consistent with current regulations
• The labelling shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breastfeeding • The use of the terms ‘humanised’, ‘maternalised’, ‘adapted’ or similar terms shall not be used.	Consistent with current regulations
• There must be a clearly stated ‘important notice’ concerning the superiority of breastfeeding and a statement recommending that the product be used only on the advice of an independent and qualified person.	Consistent with current regulations

2. Follow-on Formula

Table 2. Macro and micronutrient requirements for follow-on formula[6] in the current regulations and the new regulations which may come into force in February 2020.

Changes to the regulations are highlighted in **bold**.

	Current regulations for follow-on formula[a]		New regulations for follow-on formula[b]	
MACRONUTRIENTS				
	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy kJ	250	295	250	**293**
Kcal	60	70	60	70
	Min/ 100kcal	Max/ 100kcal	Min/ 100kcal	Max/ 100kcal
Protein g[7]	1.8	3.5	1.8	**2.5**
Carbohydrate g	9.0	14.0	9.0	14.0
– of which lactose g	4.5	N/S	4.5	N/S
Fat g	4.0	6.0	**4.4**	6.0
Linoleic acid mg	300	1200	**500**	1200
Alpha-linolenic acid mg	50	N/S	50	**100**
Docosahexaenoic acid (DHA) mg/100kcal	-	-	**20**	**50**
VITAMINS				
Vitamin A µg	60	180	**70**	**114**
Vitamin D µg	1.0	3.0	**2.0**	3.0
Vitamin K µg	4.0	25	**1.0**	25
Vitamin B_{12} µg	0.1	0.5	0.1	0.5
Vitamin C mg	10	30	**4.0**	30
Vitamin E mg	0.5[1]	5.0	**0.6**	5.0
Thiamin µg	60	300	**40**	300
Riboflavin µg	80	400	**60**	400
Niacin µg	300	1500	**400**	1500
Vitamin B_6 µg	35	175	**20**	175
Folic acid µg	10	50	-	-
Folate µg-DF[2]	-	-	**15**	**47.6**
Biotin µg	1.5	7.5	**1.0**	7.5
Pantothenic acid µg	400	2000	400	2000
MINERALS				
Calcium mg	50	140	50	140
Chloride mg	50	160	**60**	160
Copper µg	35	100	**60**	100
Iodine µg	10	50	**15**	**29**
Iron mg	0.6	2.0	0.6	2.0
Magnesium mg	5.0	15	5.0	15

[6]Not including recommendations for formula made from soy protein isolates alone or in mixtures with cows' milk or goats' milk protein or formula made from protein hydrolysates.

[7] In the current regulations, follow-on formula manufactured from protein hydrolysates had a minimum protein requirement of 2.25g to 3.5g/100kcal. In the new regulations, this range has changed to 1.86g to 2.8g/100kcal.

		Current regulations for infant formula		New regulations for infant formula
Manganese µg	1.0	100	1.0	100
Phosphorus mg	25	90	25	90
Potassium mg	60	160	**80**	160
Selenium µg	1.0	9.0	**3.0**	**8.6**
Sodium mg	20	60	**25**	60
Zinc mg	0.5	1.5	0.5	**1.0**
May be added but not essential				
Fluoride µg	N/S	100	N/S	100
Molybdenum µg			N/S	14
Total Nucleotides mg	N/S	5.0	N/S	5.0
Cytidine-5'-monophosphate	N/S	2.5	N/S	2.5
Uridine – 5'-monophosphate	N/S	1.75	N/S	1.75
Adenosine-5'-monophosphate	N/S	1.5	N/S	1.5
Guanosine-5'-monophosphate	N/S	0.5	N/S	0.5
Inosine-5'-monophosphate	N/S	1.0	N/S	1.0
Taurine	N/S	12	N/S	12
Prebiotic fibre[3] g	N/S	0.8	N/S	0.8

N/S = not stated

[1] Vitamin E: 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg per 100kcal, maximum 5.0mg/100kcal.

[2] Dietary folate equivalent 1 µgDFE -= 1 µg food folate = 0.6 µg folic acid

[3] Fructo-oligosaccharides and galacto-oligosaccharides (prebiotic fibre) may be added to follow-on formula. In that case their content shall not exceed 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and glactose-oligosaccharides may be used provided their suitability for infants is demonstrated in accordance with Article 5 (old regs) Article 3(3) (new regs).

Source:

a. Current regulations: Infant Formula and Follow-on Formula (England) Regulations 2007 (based on Commission Directive 2006/141/EC) and equivalent regulations in Scotland, Wales and Northern Ireland.

b. New regulations: Commission Delegated Regulations (EU) 2016/127 supplementing Regulations (EU) No 609/2013 and of the European Parliament and of the Council as regards the specific composition and information requirements for infant formula and follow on formula and as regards requirements on information relating to infant and young child feeding.

Additional regulatory information about follow-on formula composition:

Amino-acids

In both the current and new regulations, it is stated that for an equal energy value follow-on formula must contain an available quantity of each indispensable amino acid and conditionally indispensable amino acid at least equal to that contained in the reference protein (breastmilk) as shown below. The concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

Amino-Acid	Per/100kcal	Amino-Acid	Per/100kcal
Cysteine	38	Phenylalanine	83
Histidine	40	Threonine	77
Isoleucine	90	Tryptophan	32
Leucine	166	Tyrosine	76
Lysine	113	Valine	88
Methionine	23		

Carbohydrates

Current regulations	New regulations
• The use of ingredients containing gluten shall be prohibited • Sucrose, fructose and honey can be added separately or as a whole to a maximum of 20% of the total carbohydrate content • Glucose can only be added to follow-on formula made from protein hydrolysates. If added the glucose should not exceed 2g/100kcal.	Consistent with current regulations
	Glucose syrup or dried glucose syrup can be added to follow-on formula made from cows' milk or goats' milk protein, or from soya protein isolates (alone or in a mixture with cows' or goats' milk protein) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products the glucose resulting from glucose syrup or dried glucose syrup shall not exceed 0.84g/100kcal. For follow-on formula made from protein hydrolysates, maximum amounts for glucose in follow-on formula made from protein hydrolysates (2g/100kcal) shall apply where glucose syrup or dried glucose syrup is added
Fructo-oligosaccharides or galacto-oligosaccharides may be added but their content may not exceed 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose.	Consistent with current regulations

Minerals

- In both the current and new regulations the calcium to available phosphorous molar ratio shall not be <1 nor greater than 2.
- The new regulations also state that the amount of available phosphorus should be calculated as 80% of total phosphorus.

Lipids

Current regulations	New regulations
• Sesame seed oil and cotton seed oil are not permitted • Erucic acid content shall not exceed 1% total fat content • Trans fatty acid content should not exceed 3% total fat • Eicosapentaenoic acid (20:5, n-3) content shall not exceed that of docosahexaenoic acid (22:6, n-3) content • The amount of phospholipids in follow-on formula shall not be greater than 2g/l	Consistent with current regulations
Lauric and myristic acid should not be >20% of total fat content.	No statement on amount of lauric and myristic acid
The docosahexaenoic acid (22:6 n-3) content shall not exceed that of n-6 LCP	Specific criteria for DHA content established in new regulations (minimum of 20mg and maximum of 50mg/100kcal).
Long chain (20 and 22 carbon) polyunsaturated fatty acids (LCP) may be added but their content must not exceed 1% of the total fat content of n-3 LCP or 2% of the total fat content for n-6 LCP (1% of total fat content for arachidonic acid (20:4 n-6))	Long chain (20 and 22 carbon atoms) polyunsaturated fatty acids shall not exceed 2% of the total fat content for n-6 long chain polyunsaturated fatty acids (1% of the total fat content for arachidonic acid (20:4 n-6))

Different compositional requirements for follow-on formula manufactured for soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Changes to the regulations are highlighted in **bold**.

	Current regulations for follow-on formula containing soya protein isolates		New regulations for follow-on formula containing soya protein isolates	
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Protein g	2.25	3.5	2.25	**2.8**
Iron mg	0.9	2.5	0.9	**2.25**
Phosphorous[8] mg	30	100	30	100
Zinc mg	0.5	1.5	0.75	1.25

Minimum levels for lactose does not apply when soya protein isolates represent more than 50% of the total protein content.

[8] The amount of available phosphorus shall be calculated as 70% of total phosphorus for follow-on formula manufactured from soya protein isolates.

Labelling and marketing regulations for follow-on formula

Current regulations	New regulations
• Any labelling of follow-on formula labelled in a way that enables consumers to make a clear distinction between such products to avoid confusion between infant formula and follow-on formula.	• Any labelling, presentation and marketing of follow-on formula should be designed in a way that enables consumers to make a clear distinction between infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them.
• The labelling shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breastfeeding • The use of the terms 'humanised', 'maternalised', 'adapted' or similar terms shall not be used.	Consistent with current regulations

3. Infant milks marketed as foods for special medical purposes (FSMP)

Apart from the changes to vitamins and minerals which are specific to FSMP, all other changes will comply with the changes for infant formula (where FSMP products are designed for use from birth) or follow on formula (where FSMP products are designed for use from 6 months of age). The table below considers the composition of FSMP marketed as suitable for use from birth in the current and future regulations.

Table 3. Macro and micronutrient requirements for infant milks marketed as foods for special medical purposes in the current regulations and the new regulations which may come into force in February 2020.

Changes to the regulations are highlighted in **bold**.

	Current regulations[a] Foods for special medical purposes		New regulations[b] for Foods for special medical purposes	
	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy kJ	250	295	250	**293**
Kcal	60	70	60	70
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Protein g	1.8	3.0	1.8	**2.5**
Carbohydrate g	9.0	14.0	9.0	14.0
of which lactose g	4.5	N/S	4.5	N/S
Fat g	4.4	6.0	4.4	6.0
Linoleic acid mg	300	1200	**500**	1200
Alpha-Linolenic acid mg	50	N/S	50	**100**
Docosahexaenoic acid (DHA) mg	-	-	**20**	**50**
VITAMINS				
Vitamin A µg-RE	60	180	**70**	180
Vitamin C mg	8.0	25	**4.0**	**30**
Vitamin E mg	0.5[1]	3.0	**0.6**	**5.0**
Vitamin D µg	1.0	3.0	2.0	3.0
Vitamin K µg	4.0	20	**1.0**	**25**
Thiamin (B_1) µg	40	300	40	300
Riboflavin (B_2) µg	60	450	60	450
Niacin µg	800	3000	**400**	3000
Vitamin B_6 µg	35	300	**20**	300
Vitamin B_{12} µg	0.1	0.5	0.1	0.5
Folic acid µg	4	25		
Folate µg-DFE[2]			**15**	**47.6**
Biotin µg	1.5	20	**1**	20
Pantothenic acid µg	300	2000	**400**	2000
MINERALS				
Calcium mg	50	250	50	250
Chloride mg	50	125	**60**	**160**
Copper µg	20	120	**60**	120
Iodine µg	5.0	35	**15**	35
Iron mg	0.5	2.0	**0.3**	**2.5**
Magnesium mg	5.0	15	5.0	15
Manganese µg	5.0	200	1.0	**100**
Phosphorus mg	25	90	25	**100**
Potassium mg	60	145	**80**	**160**

Selenium µg	1.0	3.0	**3.0**	**8.6**
Sodium mg	20	60	**25**	60
Zinc mg	0.5	2.4	0.5	2.4
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Choline mg	7	50	7	50
Inositol mg	4.0	40	4	40
L-carnitine[3] mg			**1.2**	N/S
May be added but not essential				
Chromium µg	N/S	10	N/S	10
Fluoride µg	N/S	100	N/S	100
Molybdenum µg	N/S	10	N/S	**14**
Total Nucleotides mg	N/S	5.0	N/S	5.0
Cytidine-5'-monophosphate	N/S	2.5	N/S	2.5
Uridine – 5'-monophosphate	N/S	1.75	N/S	1.75
Adenosine-5'-monophosphate	N/S	1.5	N/S	1.5
Guanosine-5'-monophosphate	N/S	0.5	N/S	0.5
Inosine-5'-monophosphate	N/S	1.0	N/S	1.0
Taurine	N/S	12	N/S	12
Prebiotic fibre g	N/S	0.8[1]	N/S	0.8[1]

[1] Fructo-oligosaccharides and galacto-oligosaccharides (prebiotic fibre) may be added to infant formula. In that case their content shall not exceed 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and glactose-oligosaccharides may be used provided their suitability for infants is demonstrated in accordance with Article 5 (old regs) Article 3(3) (new regs).

[2] Vitamin E: 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg per 100kcal, maximum 5.0mg/100kcal.

[3] In the 2007 regulations L-carnitine concentration is only specified for formula containing protein hydrolysates or soya protein isolates on their own or in a mixture with cows' and goats' milk proteins. For both types of formula the minimum concentration specified is 1.2mg/100kcal. No upper level is set.

Source:

a. Current regulations: Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes

b. New regulations: 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.

Additional regulatory information on composition:

Other changes will be as specified in the sections on infant formula (for products marketed as suitable from birth) or follow-on formula for products marketed as suitable from 6 months of age. The most significant changes are those relating to marketing and labelling.

Changes to labelling and marketing of milks marketed as foods for special medical purposes.

The changes to the regulations relating to labelling and marketing are significant and these are summarised in the next table.

Current regulations	New regulations
No regulation related to claims	Nutrition and health claims shall not be made on food for special medical purposes and consumption of these products must not be promoted
No regulation related to language	All mandatory particulars for food for special medical purposes developed to satisfy the nutritional requirements of infants shall appear in a language easily understood by the consumers.
• No regulation on idealising pictures or text • No regulation on making a clear distinction between food for special medical purposes and infant formula and follow-on formula.	• Any labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not include pictures of infants, or other pictures or text which may idealise the use of the product, although graphic representation which easily identifies the product and for illustrating methods of preparation may be used. • The design should make a clear distinction between food for special medical purposes and infant formula and follow-on formula to avoid confusion.
No statement on where advertising can take place and the nature of advertising	• Advertising is restricted to publications specialising in baby care and scientific publications. • All advertising must provide only information that is scientific and factual in nature.
No statement on point-of-sale advertising, promotional devices, gifts or samples.	• No point-of-sale advertising or the giving of samples or other promotional devices (such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales) to induce sales at the retail level. • Manufacturers and distributors of food for special medical purposes shall not directly provide free or subsidised products, samples or any other promotional gifts to members of the general public (including mothers, pregnant women and their families).
The labelling must have a statement with 'important notice' or equivalent stating: • The product must be used under medical supervision • Whether it is suitable for use as the sole source of nourishment • That the product is intended for a specific age group (as appropriate) • That the product poses a health hazard when consumed by persons who do not	Consistent with current regulations

have the diseases, disorders or medical conditions for which the product is intended	
The label shall include: • a statement about which disease, disorder or medical condition the product is intended • a statement concerning adequate precautions and contra-indications • a description of the properties and/or characteristics that make the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product • where appropriate a warning that the product is not for parenteral use • instructions for the appropriate preparation, use and storage after opening the container.	Consistent with current regulations