

SCHEDULE 1

Regulations 8, 11 and 13(1)(f)

**ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN
RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER**
(All values refer to the product ready for use)

Energy**1.**

<i>Minimum</i>	<i>Maximum</i>
250 kJ (60 kcal/100 ml)	315 kJ (75 kcal/100 ml)

Proteins

2. (Protein content=nitrogen content \times 6.38) for cows' milk proteins.

(Protein content=nitrogen content \times 6.25) for soya protein isolates.

(2.1) Formulae manufactured from unmodified cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.56 g/100 kJ (2.25 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

- The chemical index of the proteins present shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule 6); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together.
- The “chemical index” shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

(2.2) Formulae manufactured from modified cows' milk proteins (alteration of the casein/ whey protein ratio)

<i>Minimum</i>	<i>Maximum</i>
0.45 g/100 kJ (1.8 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).

(2.3) Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.56 g/100 kJ	0.7 g/100 kJ

- Only soya protein isolates may be used in manufacturing these formulae.
- The chemical index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule 6).
- For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).
- The L-carnitine content shall be at least equal to 1.8 μ moles/100 kJ (7.5 μ moles/100 kcal).

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<i>Minimum</i>	<i>Maximum</i>
(2.25 g/100 kcal)	(3 g/100 kcal)
<ul style="list-style-type: none"> — Only soya protein isolates may be used in manufacturing these formulae. — The chemical index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule 6). — For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5). — The L-carnitine content shall be at least equal to 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal). 	

(2.4) **In all cases**, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

Lipids

3.

<i>Minimum</i>	<i>Maximum</i>
0.8 g/100 kJ	1.5 g/100 kJ
(3.3 g/100 kcal)	(6.5 g/100 kcal)

(3.1) The use of the following substances is prohibited:

- sesame seed oil;
- cotton seed oil;
- fats containing more than 8% trans isomers of fatty acids.

(3.2) Lauric acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

(3.3) Myristic acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

(3.4) Linoleic acid (in the form of glycerides=linoleates)

<i>Minimum</i>	<i>Maximum</i>
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	1200 mg/100 kcal)

Carbohydrates

4.

<i>Minimum</i>	<i>Maximum</i>
1.7 g/100 kJ	3.4 g/100 kJ
(7 g/100 kcal)	(14 g/100 kcal)

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(4.1) Only the following carbohydrates may be used:

- lactose;
- maltose;
- sucrose;
- malto–dextrins;
- glucose syrup or dried glucose syrup;
- pre–cooked starch) naturally free
- gelatinised starch) of gluten

(4.2) Lactose

<i>Minimum</i>	<i>Maximum</i>
0.85 g/100 kJ	—
(3.5 g/100 kcal)	—

This provision does not apply to formulae in which soya proteins represent more than 50% of the total protein content.

(4.3) Sucrose

<i>Minimum</i>	<i>Maximum</i>
—	20% of the total carbohydrate content

(4.4) Pre–cooked starch and/or gelatinised starch

<i>Minimum</i>	<i>Maximum</i>
—	2 g/100 ml, and 30% of the total carbohydrate content

Mineral substances

5

(5.1) Formulae manufactured from cows' milk proteins

		<i>per 100 kJ</i>		<i>per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Sodium	(mg)	5	14	20	60
Potassium	(mg)	15	35	60	145
Chloride	(mg)	12	29	50	125
Calcium	(mg)	12	—	50	—
Phosphorus	(mg)	6	22	25	90
Magnesium	(mg)	1.2	3.6	5	15
Iron	(mg)(1)	0.12	0.36	0.5	1.5

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

(1) Limit applicable to formulae with added iron.

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		<i>per 100 kJ</i>		<i>per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Zinc	(mg)	0.12	0.36	0.5	1.5
Copper	(µg)	4.8	19	20	80
Iodine	(µg)	1.2	—	5	—

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

(5.2) Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins

— All requirements of paragraph 5.1. are applicable except those concerning iron and zinc, which are as follows:

		<i>per 100 kJ</i>		<i>per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Iron	(mg)	0.25	0.5	1	2
Zinc	(mg)	0.18	0.6	0.75	2.4

Vitamins

6.

		<i>per 100 kJ</i>		<i>per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Vitamin A	(µg-RE)(2)	14	43	60	180
Vitamin D	(µg)(3)	0.25	0.65	1	2.5
Thiamin	(µg)	10	—	40	—
Riboflavin	(µg)	14	—	60	—
Nicotinamide	(µg-NE)(4)	60	—	250	—
Pantothenic acid	(µg)	70	—	300	—
Vitamin B6	(µg)	9	—	35	—
Biotin	(µg)	0.4	—	1.5	—
Folic acid	(µg)	1	—	4	—
Vitamin B12	(µg)	0.025	—	0.1	—
Vitamin C	(mg)	1.9	—	8	—
Vitamin K	(µg)	1	—	4	—
Vitamin E	(mg*-TE)(5)	0.5/g of polyunsaturated fatty acids	—	0.5/g of polyunsaturated fatty acids	—

(2) RE=all trans retinol equivalent.

(3) In the form of cholecalciferol, of which 10 µg=400 i.u. of vitamin D.

(4) NE=Niacin equivalent=mg nicotinic acid+mg tryptophan/60.

(5) *-TE=d*-tocopherol equivalent.

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	<i>per 100 kJ</i>		<i>per 100 kcal</i>	
	<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
	expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ		expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	

SCHEDULE 2

Regulations 9, 11 and 14(e)

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN
RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

(All values refer to the product ready for use)

Energy**1.**

<i>Minimum</i>	<i>Maximum</i>
250 kJ/100 ml (60 kcal/100 ml)	335 kJ/100 ml (80 kcal/100 ml)

Proteins**2.** (Protein content–nitrogen content × 6.38) for cows' milk proteins.

(Protein content–nitrogen content × 6.25) for soya protein isolates.

<i>Minimum</i>	<i>Maximum</i>
0.5 g/100 kJ (2.25 g/100 kcal)	1 g/100 kJ (4.5 g/100 kcal)

The chemical index of the proteins present shall be at least equal to 80% of that of the reference protein (casein as defined in Schedule 6).

The “chemical index” shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.

Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

Lipids**3.**

<i>Minimum</i>	<i>Maximum</i>
0.8 g/100 kJ (3.3 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

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(3.1) The use of the following substances is prohibited:

- sesame seed oil;
- cotton seed oil;
- fats containing more than 8% trans isomers of fatty acids.

(3.2) Lauric acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

(3.3) Myristic acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

(3.4) Linoleic acid (in the form of glycerides=linoleates)

<i>Minimum</i>	<i>Maximum</i>
70 mg/100 kJ (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils	—

Carbohydrates

4.

<i>Minimum</i>	<i>Maximum</i>
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

(4.1) The use of ingredients containing gluten is prohibited.

(4.2) Lactose

<i>Minimum</i>	<i>Maximum</i>
0.45 g/100 kJ (1.8 g/100 kcal)	—

This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50% of the total protein content.

(4.3) Sucrose, fructose, honey

<i>Minimum</i>	<i>Maximum</i>
—	separately or as a whole: 20% of the total carbohydrate content

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Mineral substances

5

		per 100 kJ		per 100 kcal	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Iron	(mg)	0.25	0.5	1	2
Iodine	(µg)	1.2	—	5	—

(5.2) Zinc

(5.2.1) Follow-on formulae manufactured entirely from cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.12 mg/100 kJ	—
(0.5mg/100 kcal)	—

(5.2.2) Follow-on formulae containing soya protein isolates, alone or mixed with cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.18 mg/100 kJ	—
(0.75mg/100 kcal)	—

(5.3) Other mineral substances:

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Schedule 7.

(5.4) The calcium/phosphorus ratio shall not exceed 2.0.

Vitamins

6.

		per 100 kJ		per 100 kcal	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Vitamin A	(µg-RE)(6)	14	43	60	180
Vitamin D	(µg)(7)	0.25	0.75	1	3
Vitamin C	(mg)	1.9	—	8	—
Vitamin E	(mg*-TE)(8)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case	—	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case	—

(6) RE=all trans retinol equivalent.

(7) In the form of cholecalciferol, of which 10 µg=400 i.u. of vitamin D.

(8) *-TE=d*-tocopherol equivalent.

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	per 100 kJ		per 100 kcal	
	<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
	less than 0.1		less than 0.5	
	mg per 100		mg per 100	
	available kJ		available kcal	

SCHEDULE 3

Regulation 11

NUTRITIONAL SUBSTANCES

Vitamins**1.**

<i>Vitamin</i>	<i>Vitamin formulation</i>
Vitamin A	Retinyl acetate
	Retinyl palmitate
	Beta-carotene
	Retinol
Vitamin D	Vitamin D2 (ergocalciferol)
	Vitamin D3 (cholecalciferol)
Vitamin B1	Thiamin hydrochloride
	Thiamin mononitrate
Vitamin B2	Riboflavin
	Riboflavin-5'-phosphate, sodium
Niacin	Nicotinamide
	Nicotinic acid
Vitamin B6	Pyridoxine hydrochloride
	Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium
	D-pantothenate, sodium
	Dexpanthenol
Vitamin B12	Cyanocobalamin
	Hydroxocobalamin

<i>Vitamin</i>	<i>Vitamin formulation</i>
Biotin	D–Biotin
Vitamin C	L–ascorbic acid
	Sodium L–ascorbate
	Calcium L–ascorbate
	6–palmityl–L–ascorbic acid (ascorbyl palmitate)
Vitamin E	Potassium ascorbate
	D–alpha tocopherol
	DL–alpha tocopherol
	D–alpha tocopherol acetate
Vitamin K	DL–alpha tocopherol acetate
	Phylloquinone (Phytomenadione)

Mineral substances

2.

<i>Mineral substances</i>	<i>Permitted salts</i>	
Calcium (Ca)	Calcium carbonate	
	Calcium chloride	
	Calcium salts of citric acid	
	Calcium gluconate	
	Calcium glycerophosphate	
	Calcium lactate	
	Calcium salts of orthophosphoric acid	
	Calcium hydroxide	
	Magnesium (Mg)	Magnesium carbonate
		Magnesium chloride
Magnesium oxide		
Magnesium salts of orthophosphoric acid		
Magnesium sulphate		

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<i>Mineral substances</i>	<i>Permitted salts</i>
	Magnesium gluconate
	Magnesium hydroxide
	Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate
	Ferrous gluconate
	Ferrous lactate
	Ferrous sulphate
	Ferric ammonium citrate
	Ferrous fumarate
	Ferric diphosphate (Ferric pyrophosphate)
Copper (Cu)	Cupric citrate
	Cupric gluconate
	Cupric sulphate
	Copper–lysine complex
	Cupric carbonate
Iodine (I)	Potassium iodide
	Sodium iodide
	Potassium iodate
Zinc (Zn)	Zinc acetate
	Zinc chloride
	Zinc lactate
	Zinc sulphate
	Zinc citrate
	Zinc gluconate
	Zinc oxide
Manganese (Mn)	Manganese carbonate
	Manganese chloride

<i>Mineral substances</i>	<i>Permitted salts</i>
Sodium (Na)	Manganese citrate
	Manganese sulphate
	Manganese gluconate
	Sodium bicarbonate
	Sodium chloride
	Sodium citrate
	Sodium gluconate
	Sodium carbonate
	Sodium lactate
	Sodium salts of orthophosphoric acid
Potassium (K)	Sodium hydroxide
	Potassium bicarbonate
	Potassium carbonate
	Potassium chloride
	Potassium salts of citric acid
	Potassium gluconate
	Potassium lactate
	Potassium salts of orthophosphoric acid
	Potassium hydroxide

Amino acids and other nitrogen compounds

- L-arginine and its hydrochloride
- L-cystine and its hydrochloride
- L-histidine and its hydrochloride
- L-isoleucine and its hydrochloride
- L-leucine and its hydrochloride
- L-lysine and its hydrochloride
- L-cysteine and its hydrochloride
- L-methionine
- L-phenylalanine
- L-threonine

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L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
Taurine

Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

SCHEDULE 4

Regulation 13(3)

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

<i>Claim related to</i>	<i>Conditions warranting the claim</i>
1. Adapted protein	The protein content is lower than 0.6 g/100 kJ (2.5 g/ 100 kcal) and the whey protein/casein ratio is not less than 1.0
2. Low sodium	The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal)
3. Sucrose free	No sucrose is present
4. Lactose only	Lactose is the only carbohydrate present
5. Lactose free	No lactose is present ⁽⁹⁾
6. Iron enriched	Iron is added

SCHEDULE 5

Regulation 8

THE ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK

For the purpose of these Regulations, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	<i>per 100 kJ⁽¹⁰⁾</i>	<i>per 100 kcal</i>
Arginine	16	69
Cystine	6	24

⁽⁹⁾ When determined by a method the detection limits of which will be established at a later stage.

⁽¹⁰⁾ 1 kJ=0.239 kcal.

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	<i>per 100 kJ(10)</i>	<i>per 100 kcal</i>
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29 122	
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

SCHEDULE 6

Regulations 8 and 9

AMINO ACID COMPOSITION OF CASEIN AND BREAST MILK PROTEIN

The amino acid composition of casein and breast milk protein (g/100 g of protein):

	<i>Casein(11)</i>	<i>Breast milk(11)</i>
Arginine	3.7	3.8
Cystine	0.3	1.3
Histidine	2.9	2.5
Isoleucine	5.4	4.0
Leucine	9.5	8.5
Lysine	8.1	6.7
Methionine	2.8	1.6
Phenylalanine	5.2	3.4
Threonine	4.7	4.4
Tryptophan	1.6	1.7
Tyrosine	5.8	3.2
Valine	6.7	4.5

(10) 1 kJ=0.239 kcal.

(11) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383.

(11) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No 24, Rome 1970, items 375 and 383.

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SCHEDULE 7

Regulation 9

THE MINERAL ELEMENTS IN COWS' MILK

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids–non–fat and per g of proteins are the following:

	<i>per 100 g SNF(12)</i>	<i>per g of proteins</i>
Sodium (mg)	550	15
Potassium (mg)	1680	43
Chloride (mg)	1050	28
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3.5
Copper (µg)	225	6
Iodine	NS(13)	NS

(12) SNF: “solids–no fats”.

(13) NS: non specified, varies widely according to season and stock farming conditions.