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.

Minimum	*Maximum*
250 kJ	315 kJ
(60 kcal/100 ml)	(75 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.

(2.1) Formulae manufactured from unmodified cows' milk proteins

Minimum	*Maximum*
0.56 g/100 kJ	0.7 g/100 kJ
(2.25 g/100 kcal)	(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)

Minimum	*Maximum*
0.45 g/100 kJ	0.7 g/100 kJ
(1.8 g/100 kcal)	(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

Minimum	*Maximum*
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 µmoles/100 kJ (7.5 µmoles/100 kcal).

Minimum	*Maximum*
(2.25 g/100 kcal)	(3 g/100 kcal)

— 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.

Minimum	*Maximum*
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

Minimum	*Maximum*
—	15% of the total fat content

(3.3) Myristic acid

Minimum	*Maximum*
—	15% of the total fat content

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

Minimum	*Maximum*
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	1200 mg/100 kcal)

Carbohydrates

4.

Minimum	*Maximum*
1.7 g/100 kJ	3.4 g/100 kJ
(7 g/100 kcal)	(14 g/100 kcal)

(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

Minimum	*Maximum*
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

Minimum	*Maximum*
—	20% of the total carbohydrate content

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

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

Mineral substances

5

(5.1) Formulae manufactured from cows' milk proteins

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
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.

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
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:

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
Iron	(mg)	0.25	0.5	1	2
Zinc	(mg)	0.18	0.6	0.75	2.4

Vitamins

6.

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
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	—
VitaminB12	(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.

	per 100 kJ		*per 100 kcal*	
	Minimum	*Maximum*	*Minimum*	*Maximum*
	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	