

# **Scientific Advisory Committee on Nutrition**

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## **Subgroup on Maternal and Child Nutrition (SMCN)**

**Paper for information: SCF report on the Composition of Infant Formula**

**Agenda item: 4**

Please see attached paper for discussion.

# Scientific Advisory Committee on Nutrition

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## Subgroup on Maternal and Child Nutrition (SMCN)

### SCF report on the Composition of Infant Formula

#### Paper for information

#### Issue

Recommendations from the Scientific Committee on Food (SCF) for changes to the essential composition of infant formulae and follow-on formulae as set out in its report on the revision of essential requirements of infant formulae and follow-on formulae (SCF/CS/NUT/IF/65 Final 18 May 2003).

#### Background

Harmonised European Community rules on the composition, labelling and certain aspects of the marketing of infant formulae and follow-on formulae are laid down in Commission Directive 91/321/EEC<sup>1</sup>. The compositional requirements are based on a number of opinions from the Scientific Committee on Food<sup>2</sup>.

To inform future amendments to Directive 91/321/EEC and to inform the European Community (EC) position on revision of the Codex Alimentarius standard for infant formula, the European Commission asked the SCF to review and update the scientific basis of the EC legislation and to make recommendations on the compositional criteria that should be applied. The SCF recommendations are contained in its report dated 18 May.

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<sup>1</sup> Directive 91/321/EEC on infant formulae and follow-on formulae as amended by Directive 96/4/EC and Directive 1999/50/EC. Implemented, in England, through The Infant Formula and Follow-on Formula Regulations 1995 SI 1995 No.77 (as amended).

<sup>2</sup> First report on the essential requirements of infant formulae and follow-up milks based on cows' milk proteins (27/04/1983); The minimum requirements for soya-based infant formulae and follow-up milks (09/12/1988); First addendum to the Reports of the Scientific Committee on Food concerning the essential requirements of infant formulae and follow-up milks based on cow's milk proteins (27/04/1983) and the minimum requirements for soya-based infant formulae and follow-up milks (09/12/1988) (27/10/1989); Report on infant formulae claimed to be "hypoallergenic" or "hypoantigenic" (09/12/1991). Second Addendum concerning the essential requirements of infant formulae and follow-up milks based on cows' milk proteins (27/04/01983) and the minimum requirements for soya-based infant formulae and follow-up milks; Report on essential requirements for infant formulae and follow-on formulae (07/06/1993).

Summary tables comparing the SCF's new recommendations with existing requirements in Directive 91/321/EEC are set out in Appendix 1 and Appendix 2. A summary of the SCF's suggestions and recommendations for changes to the presentation of infant formulae and follow on formulae is given in Appendix 3.

The composition of infant formulae will next be discussed at the meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held on 3-7 November 2003. The Commission has indicated that it intends to publish a proposal for an amendment to Directive 91/321/EC, based on the recent SCF opinion, in the first half of 2004 and there will, in due course, be discussions on that proposal.

### **Why are views on the SCF report needed now?**

Unexpectedly, the European Commission has indicated that it aims to call a meeting towards the end of September to discuss Member States views on the SCF report; those views will inform the European Community's initial position at the upcoming meeting of the CCNFSDU.

Food Standards Agency officials will represent the UK at this meeting and have therefore sought views on the SCF report, at short notice, in order to inform the UK's initial position. A list of those individuals and groups consulted is given in Appendix 4. The Agency will consult a wide range of stakeholders in future, in the usual way, as the Codex draft standard and future EC proposal develop.

**The Subgroup is invited to note that The Food Standards Agency has sought the views of a small number of individuals and relevant interest groups on the recommendations contained in the Report of the Scientific Committee on Food on the revision of essential requirements of infant formulae and follow-on formulae.**

- **APPENDIX 3: PRESENTATION OF INFANT FORMULAE AND FOLLOW-ON FORMULAE**

- The SCF made the following suggestions and recommendations:
  - the scientific basis for claims for infant formulae, as laid down in Annex IV of Directive 91/321/EEC, should be reconsidered, based on current scientific knowledge.
  - remove the claim “adapted protein” since the criteria used for this term do not necessarily describe a protein of more superior quality for the feeding of infants.
  - remove the claim “low sodium”. All infant formulae and follow-on formulae have a limitation of sodium contents within well-defined ranges, and no products with high sodium content are recommended or permitted for healthy infants.
  - the claim “lactose free” to be of considerable relevance for the choice of products intended to be fed to infants who do not tolerate lactose. The acceptable maximum amount of residual lactose, if any, in formulae considered “lactose free” should not exceed 10 mg per 100 kcal.
  - remove the claim “sucrose free” or “saccharose free”; the Committee has recommended that sucrose (saccharose) should not be added to infant formulae except for those based on protein hydrolysates where it may be used in limited amounts to achieve an acceptable taste.
  - remove the claim “iron enriched”; the Committee has recommended that all infant formulae should contain iron within the range specified in the report
  - any claim that a formula induces “reduction of risk of allergy to milk proteins” or is “hypoallergenic” should only be allowed if adequate scientific evidence has been accepted by an independent scientific body reviewing such data.
  - the Committee recommends that the source of the protein or proteins used for the production of the hydrolysate should be declared.
  - the Committee recommends not using the term “partial hydrolysate” since there is no agreed definition of “partial” or “extensive” hydrolysates and the effects of protein hydrolysates on prevention of allergic manifestations appear not to be strictly related to the degree of hydrolysis, but may depend also on other properties of the hydrolysates and the formulae produced thereof.
  - mechanisms and criteria should be developed for the communication not only of relevant compositional properties, but possibly also of selected other effects of infant formulae or follow-on formulae if they have been demonstrated beyond doubt in rigorous studies with adequate scientific standards, and the evidence has been accepted by an independent scientific body reviewing such data.
  - the Committee notes that some dietetic products intended for infants with minor and mostly transient health complaints, such as repeated possetting or intestinal discomfort, are currently marketed as Dietary Foods for Special Medical Purposes. Neither the nature of the complaints concerned nor the recently adopted definition of Dietary Foods for Special Medical

Purposes (Directive 1999/21/EC) justifies such presentation for the vast majority of these products. The Committee also notes that such presentation has implications for the labelling and marketing practices of these products. The Committee recommends that the scientific basis for the use, potential benefits and compositional aspects of such products should be reviewed.

#### **APPENDIX 4: LIST OF CONSULTEES**

Professor Peter Aggett (University of Central Lancashire)

Professor Alan Jackson (University of Southampton)

Dr Anthony Williams (St Georges Hospital Medical School)

Maureen Robinson (Royal College of Physicians)

Patti Rundall (Baby Milk Action)

Geraldine Smith (Infant and Dietetic Foods Association)

Jacqueline Wallace (Rowett Research Institute)

Harry McArdle (Rowett Research Institute)

Peter Willatts (Dundee University)

Robert Hume (Dundee University)

Consumers' Association

National Consumers' Council

The Food Commission

Sustain

## APPENDIX 1

SUMMARY TABLE COMPARING RECOMMENDATIONS ON THE COMPOSITION OF INFANT FORMULAE FROM THE SCIENTIFIC COMMITTEE ON FOOD REPORT OF 4 APRIL 2003 WITH EXISTING REQUIREMENTS IN COMMISSION DIRECTIVE 91/321/EEC

*VALUES ARE PER 100 KCAL UNLESS OTHERWISE STATED*

**SHADED CELLS INDICATE A CHANGE COMPARED WITH DIRECTIVE 91/321/EEC**

	SCF April 2003	Directive 91/321/EEC
<b>Energy density</b> (kcal/100 ml)	60 - 70	60 - 75

<b>Protein<sup>3</sup></b>	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
Cows' milk protein	1.8 - 3 g <sup>4, 5</sup>	1.8 - 3 g <sup>6</sup>
Soya protein	2.25 - 3 g <sup>5</sup>	2.25 - 3 g <sup>7</sup>
Protein hydrolysates	2.25 - 3 g <sup>5</sup>	2.25 - 3 g <sup>6, 8</sup>
L-carnitine addition to soya protein and protein hydrolysates formulae	≥ 1.2 mg	≥ 7.5 imoles/100kcal (≥ 1.2 mg)
Addition of taurine	optional addition to any type of infant formula of ≤ 12 mg/100kcal	≥ 42 imoles (≥ 5.3 mg) (applies to protein partial hydrolysates formula only)
Nucleotides, if added <sup>9</sup>	≤ 5 mg	≤ 5 mg
Choline	7-30 mg	ns <sup>10</sup>

### **Other recommendations on protein:**

<sup>3</sup> SCF proposal - calculation of protein content: N x 6.25, and in formulae made from intact protein the non-protein nitrogen should be ≤ 15% of total nitrogen.

Directive 91/321/EEC – calculation of protein content: N x 6.38 for cows' milk proteins; N x 6.25 for soya protein isolates and protein partial hydrolysates.

<sup>4</sup> SCF proposal - infant formulae containing 1.8 g of protein/100 kcal should be clinically evaluated.

<sup>5</sup> SCF proposal – for all types of infant formulae the per energy value amount of indispensable and conditionally dispensable amino acids should at least correspond to the value of human milk shown in Annex 3.

<sup>6</sup> Directive 91/321/EEC – 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 Annex V of 91/321/EEC).

<sup>7</sup> Directive 91/321/EEC – the chemical index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Annex V of 91/321/EEC).

<sup>8</sup> Directive 91/321/EEC – the protein efficiency ratio and net protein utilization must be at least equal to those of casein.

<sup>9</sup> Maximum content per nucleotide as specified in Annex 1.

<sup>10</sup> ns – not specified.

- soy-based formulae and follow-on formulae should be reserved for specific situations only and that cows' milk-based formula should be the standard choice.
- at present there is no documented benefit of milk proteins from animals other than cows, or of plant proteins, over cows' milk protein in the manufacture of infant formula. If other protein sources are to be used, their suitability and safety must be assessed before commercialisation. Data required are amino acid contents and availability, allergenicity, digestibility and technical processing, and constituents other than protein and nitrogenous compounds. Controlled clinical studies are needed to assess the nutritional safety and nutritional value.
- the obligatory request for determining of Protein Efficient Ratio (PER) and Net Protein Utilisation (NPU) of protein hydrolysates in the Directive is not necessary, and that it should be replaced by a requirement for clinical testing of any proteins that have not been evaluated before in the manufacturing of formula. The Committee however emphasizes the importance of pre-clinical testing of new protein sources, hydrolysates and applied new technologies, which may include the evaluation of PER and NPU.
- all formulae that contain new protein sources or protein hydrolysates which have no established use in infant formulae and/or to which processing technologies have been applied that can affect the bioavailability of nitrogen compounds should be clinically tested before their commercialisation.

<b>Fat</b>	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
Total fat	4.4 - 6.0 (6.5?) g	4.4 - 6.5 g
Phospholipids	≤ 1 g/L	ns
Inositol	4 - 40 mg	ns
Lauric and myristic acids	Together ≤ 20% of total fatty acids	Lauric acid ≤ 15% total fat content Myristic acid ≤ 15% total fat content
Linoleic	500 - 1200 mg	300 - 1200 mg
<i>Formulae without added LCPUFA</i>		
α-linolenic	≥ 100 mg	≥ 50 mg
Linoleic/α-linolenic ratio	5 - 15	5 - 15
<i>Formulae with added LCPUFA</i>		
α-linolenic <sup>11</sup>	≥ 50 mg	ns
Linoleic/α-linolenic ratio <sup>11</sup>	5 - 20	ns
n-6 LCPUFA	≤ 2% of fatty acids	≤ 2% of fatty acids
Arachidonic acid	≤ 1% of fatty acids	≤ 1% of fatty acids
n-3 LCPUFA	≤ 1% of fatty acids	≤ 1% of fatty acids
Ratio EPA/DHA (wt/wt)	< 1	≤ 1
Cottonseed/sesame oils	No use of these type of oils	No use of these type of oils
Conjugated linoleic acid (CLA)	No intentional addition	ns
<i>Trans</i> fatty acids	≤ 3% of total fatty acids	≤ 4% of total fatty acids
Erucic acid	≤ 1% of total fatty acids	≤ 1% of total fatty acids

<b>Carbohydrates</b>	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
Total carbohydrates	9 - 14 g	7 - 14 g <sup>12</sup>
Lactose in cows' milk protein- and protein hydrolysates formulae	≥ 4.5 g	≥ 3.5 g
Lactose in soya protein formulae	No requirement	No requirement
Saccharose (Sucrose)	Not permitted in formulae based on intact protein ≤ 20% of total carbohydrates in formulae based on protein hydrolysates <sup>13</sup>	Can be used in all types of formulae up to ≤ 20% of total carbohydrates
Fructose	not permitted	not permitted
Glucose	No intentional addition to formulae based on intact proteins ≤ 2 g in formulae based on protein hydrolysates	ns
Maltose	Unrestricted	Unrestricted
Starches	≤ 30% of total carbohydrates (≤ 2 g/100 ml) as precooked or gelatinised naturally gluten-free starches. No starches modified by enzymatic cross-linking or	precooked or gelatinised naturally gluten-free starches ≤ 2 g/100 ml and 30% of total carbohydrate content

<sup>11</sup> SCF proposal - if DHA content is ≥ 0.2% of total fatty acids.

<sup>12</sup> Directive 91/321/EEC – only lactose, maltose, sucrose, malto-dextrins, glucose syrup or dried glucose syrup, pre-cooked starch or gelatinized starch naturally free of gluten may be used.

<sup>13</sup> Presence must be clearly stated on the label

Other recommendations on carbohydrates:

- locust bean gums, guar gum, pectins and carageenan should not be used in infant formulae
- no major concerns on the inclusion of up to 0.8 g/dl of a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose to infant formulae and follow-on formulae. Further information should be gathered on safety and benefits of this combination as well as other forms of oligosaccharides in infant formulae and follow-on formulae.
- fructans other than oligofructosyl-saccharose should not be included in infant formulae.

<b>Vitamins</b>	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
Vitamin A	60 - 180 µg RE <sup>14</sup>	60 - 180 µg RE <sup>15</sup>
Vitamin D <sup>16</sup>	1 - 2.5 µg	1 - 2.5 µg
Vitamin E <sup>17</sup>	≥ 0.5 mg αTE/g PUFA expressed as linoleic acid (corrected for double bond, see footnote <sup>18</sup> ) but in no case < 0.5 mg/100 available kcal - 5 mg	≥ 0.5 mg αTE/g PUFA expressed as linoleic acid but in no case < 0.5 mg/100 available kcal
Vitamin K	4 - 20 µg	≥ 4 µg
Vitamin B <sub>1</sub> (thiamin)	60 - 300 µg	≥ 40 µg
Vitamin B <sub>2</sub> (riboflavin)	80 - 400 µg	≥ 60 µg
Vitamin B <sub>3</sub> (niacin)	300 - 1200 µg NE <sup>19</sup>	≥ 800 µg NE <sup>20</sup>
Vitamin B <sub>6</sub> (pyridoxine)	35 - 165 µg	≥ 35 µg
Vitamin B <sub>12</sub> (cobalamin)	0.1 - 0.5 µg	≥ 0.1 µg
Pantothenic acid	400 - 2000 µg	≥ 300 µg
Folic acid	10 - 30 µg	≥ 4 µg
Vitamin C (ascorbic acid)	10 - 30 mg	≥ 8 mg
Biotin	1.5 - 7.5 µg	≥ 1.5 µg

<b>Minerals and Trace Elements</b>	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
<b>Iron</b>		
Cows' milk protein and protein hydrolysate formulae	0.3 - 1.3 mg	0.5 - 1.5 mg <sup>21</sup>
Soya protein formulae	0.45 - 1.9 mg	1 - 2 mg
Calcium	50 - 140 mg	≥ 50 mg
Calcium/Phosphorus-Ratio	1.0 - 2.0	1.2 - 2.0
Phosphorus	Cows' milk protein- and protein hydrolysate formulae: 25 - 90 mg Soya protein formulae: 30 - 100 mg (Bioavailable phosphorus, if measured: 20 - 70 mg)	25 - 90 mg
Magnesium	5 - 15 mg	5 - 15 mg
Sodium	20 - 60 mg	20 - 60 mg
Chloride	50 - 160 mg	50 - 125 mg
Potassium	60 - 160 mg	60 - 145 mg
Manganese	1 - 100 µg	ns
Fluoride	≤ 100 µg	ns
Iodine	10 - 50 µg	≥ 5 µg
Selenium	3 - 9 µg	≤ 3 µg <sup>22</sup>

<sup>14</sup> SCF proposal – 1 µg RE = 1 µg all trans retinol. It must be provided in the form of retinol or retinyl esters.

<sup>15</sup> Directive 91/321/EEC – RE = all trans retinol equivalent.

<sup>16</sup> In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

<sup>17</sup> αTE = d-α-tocopherol equivalent.

<sup>18</sup> SCF proposal - 0.5 mg α-TE/1 g linoleic acid (18:2n-6); 0.75 mg α-TE/1 g γ-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-3).

<sup>19</sup> SCF proposal – NE – niacin equivalent - preformed niacin as nicotinamide.

<sup>20</sup> Directive 91/321/EEC – NE= niacin equivalent = mg nicotinic acid + mg tryptophan/60.

<sup>21</sup> Directive 91/321/EEC – limit applicable to formulae with added iron.

<sup>22</sup> Directive 91/321/EEC – Limit applicable to formulae with added selenium.

Copper	35 - 100 µg	20 - 80 µg
Zinc		
Cows' milk protein and protein hydrolysate formulae	0.5 - 1.5 mg	0.5 - 1.5 mg
Soya protein formulae	0.75 - 2.40 mg	0.75 - 2.40 mg

Other recommendations on trace elements:

- there are no biological or nutritional data to define a minimum and maximum content for chromium or molybdenum, in infant formulae.

## **RECOMMENDATIONS ON USE OF PROBIOTICS IN INFANT FORMULAE**

- there is a necessity to come to a decision at Community level on the use of bacteria generally considered as probiotics in infant formulae. The Committee did not have time to perform a full review of the available evidence on the inclusion of probiotic bacteria into infant formulae and follow-on formulae, and it recommends that a full review should be performed in future.
- infant formulae with microorganisms regarded as probiotics should only be introduced into the market if their benefit and safety have been evaluated according to the principles outlined in chapter XI of this report.

## ANNEX 1

**If added the maximum nucleotide contents of nucleotides should be:**

Nucleotide (up to total max 5 mg/100kcal)	mg/100 kcal
cytidine 5'-monophosphate (CMP)	2.50
uridine 5'-monophosphate (UMP)	1.75
adenosine 5'-monophosphate (AMP)	1.50
guanosine 5'-monophosphate (GMP)	0.50
inosine 5'-monophosphate (IMP)	1.00

SCF proposal - Formula based on soya protein isolates should be excluded from the option of further addition of nucleotides because of their high natural contents.

## ANNEX 2

**Amino acid pattern for human milk protein expressed as g/100 g protein to replace Annex VI of the Infant Formulae Directive**

Amino acid	SCF recommendation human milk g/100 g protein	Directive 91/321/EEC Annex VI breast milk g/100g protein
Arginine	ns	3.8
Cystine	2.1*	1.3 <sup>§</sup>
Histidine	2.2	2.5
Isoleucine	5.0	4.0
Leucine	9.2	8.5
Lysine	6.3	6.7
Methionine	1.3*	1.6 <sup>§, #</sup>
Phenylalanine	4.6**	3.4
Threonine	4.3	4.4
Tryptophan	1.8	1.7
Tyrosine	4.2**	3.2
Valine	4.9	4.5

\* Sum of cystine and methionine may be used as basis of calculation if the methionine:cystine ratio  $\leq 2$

\*\* Sum of phenylalanine and tyrosine may be used as basis of calculation if the tyrosine: phenylalanine ratio  $\leq 2$

§ For formula based on cows' milk protein or protein partial hydrolysates for calculation purposes concentration of methionine and cystine may be added together.

# For soya protein isolates the chemical index must be 80% of the reference protein and must contain an available quantity of methionine  $\geq 29$  mg/100 kcal.

### ANNEX 3

Values for indispensable and conditionally indispensable amino acids in human milk expressed as mg/100 kJ or 100 kcal

	SCF recommendation	Directive 91/321/EEC Annex V
	mg/100 kcal	mg/100 kcal
Arginine	ns	69
Cystine	38*	24 <sup>§</sup>
Histidine	40	45
Isoleucine	90	72
Leucine	166	156
Lysine	113	122
Methionine	23*	29 <sup>§, #</sup>
Phenylalanine	83**	62
Threonine	77	80
Tryptophan	32	30
Tyrosine	76**	59
Valine	88	80

\* Sum of cystine and methionine may be used as basis of calculation if the methionine:cystine ratio  $\leq 2$ .

\*\* Sum of phenylalanine and tyrosine may be used as basis of calculation if the tyrosine:phenylalanine ratio  $\leq 2$ .

§ For formula based on cows' milk protein or protein partial hydrolysates for calculation purposes concentration of methionine and cystine may be added together.

# For soya protein isolates the chemical index must be 80% of the reference protein and must contain an available quantity of methionine  $\geq 29$  mg/100 kcal

## APPENDIX 2

### SUMMARY TABLE COMPARING RECOMMENDATIONS ON THE COMPOSITION OF FOLLOW-ON FORMULAE FROM THE SCIENTIFIC COMMITTEE ON FOOD REPORT OF 4 APRIL 2003 WITH EXISTING REQUIREMENTS IN COMMISSION DIRECTIVE 91/321/EEC

*Values are per 100 kcal unless otherwise stated*

SHADED CELLS INDICATE A CHANGE COMPARED WITH DIRECTIVE 91/321/EEC

	<b>SCF April 2003</b>	<b>Directive 91/321/EEC</b>
<b>Energy density</b> (kcal/100 ml)	60 - 70	60 - 80

<b>Protein</b> <sup>23</sup>	<b>SCF APRIL 2003</b>	<b>Directive 91/321/EEC</b>
Cows' milk protein	1.8 - 3 g <sup>24</sup>	2.25 - 4.5 g
Soya protein	2.25 - 3 g	2.25 - 4.5 g
Protein hydrolysates	Optional addition ≤ 12 mg/100kcal	no requirement
Addition of taurine	≤ 5 mg	≤ 5 mg
Nucleotides, if added <sup>25</sup>		

<sup>23</sup>

SCF proposal:

- calculation of protein content: N x 6.25, and in formulae made from intact protein the non-protein nitrogen should be ≤ 15% of total nitrogen.
- for all types of follow-on formulae the per energy value amount of indispensable and conditionally dispensable amino acids should at least correspond to the value of human milk shown in Annex 3.

Directive 91/321/EEC:

- calculation of protein content: N x 6.38 for cows' milk proteins; N x 6.25 for soya protein isolates;
- the chemical index of proteins present shall be at least equal to 80% of that of the reference protein casein or breast milk as defined in Annex VI of Directive 91/321/EEC); and,
- for an equal energy value, the formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Annex V of 91/321/EEC (i.e. 29 mg/100 kcal).

<sup>24</sup> SCF proposal - Infant formulae containing 1.8 g of protein/100 kcal should be clinically evaluated.

<sup>25</sup> Maximum content per nucleotide as specified in Annex 1.

<b>Fat</b>	<b>SCF APRIL 2003</b>	<b>Directive 91/321/EEC</b>
Total fat	4.0 - 6.0 (6.5?) g	3.3 - 6.5 g
Phospholipids	≤ 1 g/L	ns <sup>26</sup>
Lauric and myristic acids	Together ≤ 20% of total fatty acids	Lauric acid ≤ 15% total fat content Myristic acid ≤ 15% total fat content
Linoleic	500 - 1200 mg	≥ 300 mg <sup>27</sup>
<i>Formulae without added LCPUFA</i>		
α-linolenic	≥ 100 mg	Ns
Linoleic/α-linolenic ratio	5 - 15	Ns
<i>Formulae with added LCPUFA</i>		
α-linolenic <sup>28</sup>	≥ 50 mg	Ns
Linoleic/α-linolenic ratio <sup>11</sup>	5 - 20	Ns
n-6 LCPUFA	≤ 2% of fatty acids	Ns
Arachidonic acid	≤ 1% of fatty acids	Ns
n-3 LCPUFA	≤ 1% of fatty acids	Ns
Ratio EPA/DHA (wt/wt)	< 1	Ns
Cottonseed/sesame oils	No use of these type of oils	No use of these type of oils
Conjugated linoleic acid (CLA)	No intentional addition	Ns
<i>Trans</i> fatty acids	≤ 3% of total fatty acids	≤ 4% of total fatty acids
Erucic acid	≤ 1% of total fatty acids	≤ 1% of total fatty acids

<sup>26</sup> ns – not specified.

<sup>27</sup> Directive 91/321/EEC - this limit applies only to follow-on formulae containing vegetable oils.

<sup>28</sup> SCF proposal - if DHA content is ≥ 0.2% of total fatty acids.

<b>Carbohydrates</b>	<b>SCF APRIL 2003</b>	<b>Directive 91/321/EEC</b>
Total carbohydrates	9 - 14 g	7 - 14 g <sup>29</sup>
Lactose in cows' milk protein- and protein hydrolysates formulae	≥ 4.5 g	≥ 1.8 g
Lactose in soya protein formulae	No requirement	No requirement
Saccharose (Sucrose), fructose and honey	Sum of sucrose, fructose, honey ≤ 20% of total carbohydrates	Sum of sucrose, fructose, honey ≤ 20% of total carbohydrates
Glucose	No intentional addition to formulae based on intact proteins  ≤ 2 g in formulae based on protein hydrolysates	ns
Maltose	Unrestricted	Unrestricted
Starches	Gluten-free carbohydrates only	Gluten-free carbohydrates only

Other recommendations on carbohydrates:

- maintain the current maximum level of the use of locust bean gums and guar gums in follow-on formulae of 1 g/L.
- no objection to the use of carrageenan in follow-on formulae up to a maximum level of 0.3 g/L.
- pectins should not be used in follow-on formulae.
- no major concerns on the inclusion of up to 0.8 g/dl of a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose to follow-on formulae. Further information should be gathered on safety and benefits of this combination as well as other forms of oligosaccharides in infant formulae and follow-on formulae.
- fructans other than oligofructosyl-saccharose should not be included in follow-on formulae.

<sup>29</sup> Directive 91/321/EEC – use of ingredients containing gluten is prohibited.

Vitamins	SCF APRIL 2003	Directive 91/321/EEC
Vitamin A	60 - 180 µg RE <sup>30</sup>	60 - 180 µg RE <sup>31</sup>
Vitamin D <sup>32</sup>	1 - 3 µg	1 - 3 µg
Vitamin E <sup>33</sup>	≥ 0.5 mg αTE/g PUFA (corrected for double bond, see footnote <sup>34</sup> ) but in no case < 0.5 mg/100 available kcal - 5 mg	≥ 0.5 mg αTE/g PUFA expressed as linoleic acid but in no case < 0.5 mg/100 available kcal
Vitamin K	4 - 20 µg	ns
Vitamin B <sub>1</sub> (thiamin)	60 - 300 µg	ns
Vitamin B <sub>2</sub> (riboflavin)	80 - 400 µg	ns
Vitamin B <sub>3</sub> (niacin)	300 - 1200 µg NE <sup>35</sup>	ns
Vitamin B <sub>6</sub> (pyridoxine)	35 - 165 µg	ns
Vitamin B <sub>12</sub> (cobalamin)	0.1 - 0.5 µg	ns
Pantothenic acid	400 - 2000 µg	ns
Folic acid	10 - 30 µg	ns
Vitamin C (ascorbic acid)	10 - 30 mg	≥ 8 mg
Biotin	1.5 - 7.5 µg	ns

<sup>30</sup> SCF proposal – 1 µg RE = 1 µg all trans retinol. It must be provided in the form of retinol or retinyl esters.

<sup>31</sup> Directive 91/321/EEC – RE = all trans retinol equivalent.

<sup>32</sup> In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

<sup>33</sup> αTE = d-α-tocopherol equivalent.

<sup>34</sup> SCF proposal - 0.5 mg α-TE/1 g linoleic acid (18:2n-6); 0.75 mg α-TE/1 γ-linolenic acid (18:3n-3); 1.0 mg α-TE/1 g arachidonic acid (20:4n-6); 1.25 mg α-TE/1 g eicosapentaenoic acid (20:5n-3); 1.5 mg α-TE/1 g docosahexaenoic acid (22:6n-3).

<sup>35</sup> SCF proposal – NE – niacin equivalent - preformed niacin as nicotinamide.

Trace Elements	SCF APRIL 2003	Directive 91/321/EEC
Iron		
Cows' milk protein and protein hydrolysate formulae	0.6 - 1.7 mg	1 - 2 mg
Soya protein formulae	0.9 - 2.5 mg	1 - 2 mg
Calcium	50 - 140 mg	min content in cows' milk as reference <sup>36</sup>
Calcium/Phosphorus-Ratio	1.0 - 2.0	≤ 2.0
Phosphorus	Cows' milk protein- and protein hydrolysate formulae: 25 - 90 mg Soya protein formulae: 30 - 100 mg (Bioavailable phosphorus, if measured: 20 - 70 mg)	min content in cows' milk as reference <sup>36</sup>
Magnesium	5 - 15 mg	min content in cows' milk as reference <sup>36</sup>
Sodium	20 - 60 mg	min content in cows' milk as reference <sup>36</sup>
Chloride	50 - 160 mg	min content in cows' milk as reference <sup>36</sup>
Potassium	60 - 160 mg	min content in cows' milk as reference <sup>36</sup>
Manganese	1 - 100 µg	ns
Fluoride	≤ 100 µg	ns
Iodine	10 - 50 µg	≥ 5 µg
Selenium	3 - 9 µg	ns
Copper	35 - 100 µg	min content in cows' milk as reference <sup>36</sup>
Zinc		
Cows' milk protein formulae	0.5 - 1.5 mg	≥ 0.5 mg
Soya protein formulae	0.75 - 2.40 mg	≥ 0.75 mg
Protein hydrolysate formulae	0.5 - 1.5 mg	ns

Other recommendations on trace elements:

- there are no biological or nutritional data to define a minimum and maximum content for chromium or molybdenum, in follow-on formulae.

<sup>36</sup> The concentration should be 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 as guidance in Annex VII of Directive 91/321/EEC.

## RECOMMENDATIONS ON USE OF PROBIOTICS IN FOLLOW-ON FORMULAE

- there is a necessity to come to a decision at Community level on the use of bacteria generally considered as probiotics in follow-on formulae. The Committee did not have time to perform a full review of the available evidence on the inclusion of probiotic bacteria into infant formulae and follow-on formulae, and it recommends that a full review should be performed in future.
- follow-on formulae with added bacteria regarded as probiotics have been marketed for about three years. The Committee has no reason to object to the addition of bacteria regarded as probiotics to follow-on formulae, provided the requirements described below are fulfilled.
- requirements for the use of probiotic bacteria in follow-on formulae:
  - only bacterial strains with identity and genetic stability demonstrated by cultural and molecular methods should be used, if they can be considered as generally safe when added to the individual food and have been shown to survive the gastrointestinal passage, have the capacity to proliferate in the gut for the duration of consumption and can modify the intestinal milieu (for example pH, short chain fatty acids).
  - the identity of the probiotic strain should be described by molecular methods in a dossier and be available to the food control authorities.
  - the content of viable bacteria should be such throughout shelf-life as to achieve  $10^6$  to  $10^8$  colony forming units per gram of formula prepared as ready for consumption.
  - processing, packaging and storage should not impair the viability of the bacteria.
- labelling requirements for follow-on formula with added probiotic bacteria:
  - in case of the addition of microorganisms, it is proposed to allow a label statement on the name of the bacterial strain, the number of microorganisms per g of powder or per 100 ml of the formula as prepared ready for consumption, and the duration of guaranteed microorganism content.
  - the instructions for storage, preparation, heating and handling should take into account the possible impaired viability of probiotic strains when exposed to heat or oxygen.
  - the term “probiotic(s)” should only appear on formula labels if beneficial health effects in recipient infants have been established by adequate clinical trials and the results have been evaluated by an independent scientific body.
  - claims on effects of probiotic bacteria on modification of the risk for specific health disorders are inappropriate unless such effects have been demonstrated by adequate scientific evidence following the guidance outlined in chapter XI of the SCF report.

## Annex 1

**If added the maximum nucleotide contents of nucleotides should be:**

Nucleotide (up to total max 5 mg/100kcal)	mg/100 kcal
cytidine 5'-monophosphate (CMP)	2.50
uridine 5'-monophosphate (UMP)	1.75
adenosine 5'-monophosphate (AMP)	1.50
guanosine 5'-monophosphate (GMP)	0.50
inosine 5'-monophosphate (IMP)	1.00

SCF proposal - Formula based on soya protein isolates should be excluded from the option of further addition of nucleotides because of their high natural content.

## Annex 2

### Amino acid pattern for human milk protein expressed as g/100 g protein to replace Annex VI of the Infant Formulae Directive

Amino acid	SCF recommendation for human milk g/100 g protein	Directive 91/321/EEC Annex VI Breast Milk	Directive 91/321/EEC Annex VI Casein
Arginine	ns	3.8	3.7
Cystine	2.1*	1.3	0.3
Histidine	2.2	2.5	2.9
Isoleucine	5.0	4.0	5.4
Leucine	9.2	8.5	9.5
Lysine	6.3	6.7	8.1
Methionine	1.3*	1.6	2.8
Phenylalanine	4.6**	3.4	5.2
Threonine	4.3	4.4	4.7
Tryptophan	1.8	1.7	1.6
Tyrosine	4.2**	3.2	5.8
Valine	4.9	4.5	6.7

\* Sum of cystine and methionine may be used as basis of calculation if the methionine:cystine ratio  $\leq 2$

\*\* Sum of phenylalanine and tyrosine may be used as basis of calculation if the tyrosine: phenylalanine ratio  $\leq 2$

SCF proposal only includes the amino acid pattern for human milk.

### Annex 3

Values for indispensable and conditionally indispensable amino acids in human milk expressed as mg/100 kJ or 100 kcal

	SCF recommendation	Directive 91/321/EEC Annex V
	mg/100 kcal	mg/100 kcal
Arginine	ns	69
Cystine	38*	24
Histidine	40	45
Isoleucine	90	72
Leucine	166	156
Lysine	113	122
Methionine	23*	29 <sup>§</sup>
Phenylalanine	83**	62
Threonine	77	80
Tryptophan	32	30
Tyrosine	76**	59
Valine	88	80

\* Sum of cystine and methionine may be used as basis of calculation if the methionine:cystine ratio  $\leq$  2.

\*\* Sum of phenylalanine and tyrosine may be used as basis of calculation if the tyrosine: phenylalanine ratio  $\leq$  2.

<sup>§</sup> For an equal energy value, follow-on formulae must contain an available quantity of methionine  $\geq$  29 mg/100 kcal.