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(Twenty-third series)

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Reports of the Scientific Committee for Food

(Twenty-third series)

The minimum requirements for soya-based infant formulae and follow-up milks

(Opinion delivered on 9 December 1988)

Directorate-General
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Abstract

In the present report the Scientific Committee for Food expresses its opinion on the essential requirements of infant formulae and follow-up milks based on soya protein isolates. Reasons for using these products and their basic composition in proteins, lipids, glucides, minerals and vitamins are reviewed. The Committee's opinion is that, in order to meet the nutritional requirements of infants and small children, soya-based products should be required to be supplemented with certain substances.

The recommendations of the Scientific Committee for Food on the essential requirements of infant formulae and follow-up milks based on cows' milk proteins was published in1983 (*Reports of the Scientific Committee for Food*, Fourteenth series, EUR 8752, p. 9).

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First Report of the Scientific Committee for Food on the Minimum Requirements for Soya-based Infant Formulae and Follow-up Milks

(Opinion delivered on December 9, 1988)

Terms of Reference:

To advise on the minimum requirements for soya-based products intended for the feeding of infants and young children.

Introduction

Area of application

1. In 1983 the Committee adopted an opinion on the minimum requirements for infant formulae and follow-up milks based on cows' milk proteins. The Committee was aware at the time that on the Community market there were products based on proteins other than cows' milk proteins, but in view of the deadlines to which the Committee was working, it preferred to postpone specific recommendations on these products*.

The present opinion addresses this issue with regard to soya-based products. The Committee felt that there was no need for the time being to put forward recommendations on the criteria to be applied to products incorporating vegetable proteins other than soya proteins, since that type of product is not marketed in the Community at present. Quite apart from the normal procedures for revising directives, this position will have to be reviewed if new products appear on the market incorporating vegetable proteins other than soya proteins.

In all events, the present opinion is only concerned with products intended to replace breast milk where necessary, i.e. infant formulae and those products intended to form the 'milk' element in food for children over four months old as part of an increasingly diversified diet. Soya-based products which are not presented as 'suitable for infants and young children' are excluded from the area of application. Also excluded are products for infants of low birth weight and for infants and children with nutritional or metabolic disorders.

Definitions

2. In accordance with the Committee's 1983 report the following definitions have been used:

'Infants': children under the age of twelve months.

'Young children': children from the age of one to three years old.

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* *Reports of the Scientific Committee for Food* (Fourteenth series), 1983, p. 9.

'Infant formulae': products intended to replace breast milk where necessary and to satisfy fully the normal nutritional needs of infants during the first four to six months of life.

'Follow-up milks': products intended to form the basic milk element in food for children over four months old as part of an increasingly diversified diet.

Data sources

3. In drawing up this draft report the Committee had the benefit of useful information provided by IDACE (Association of Dietetic Food Industries of the EEC).

Products available in the Community

4. Soya-based infant formulae have been available in the Community for many years. Rightly or wrongly, they are used chiefly as breast milk substitutes in cases where there is a suspicion or evidence of intolerance to cows' milk protein (secondary use) and in new-born babies and infants where there is a risk of allergy (primary use). They are also used, albeit less and less commonly owing to the development of formulae based on hydrolysed protein, for patients recovering from some forms of gastro-enteritis. Because these formulae contain no lactose they are also suitable as substitutes for breast milk and for milk-based formulae for certain cases of lactose intolerance and for children suffering from galactosaemia. Lastly, these formulae are sometimes chosen by consumers who, for various reasons, do not wish to give their children products based on animal protein [1,2].

5. Soya-based infant formulae and follow-up milks are put up in the form of powder, ready-to-feed liquids or concentrated liquids. The methods used to prepare them are similar to those used to manufacture infant products based on cows' milk.

Basic Composition

6. Generally speaking, vegetable proteins have a lower nutritional value than animal proteins. This is partly due to the fact that they contain a limiting amount of one or more essential amino-acids [3]. Moreover, vegetable proteins are often difficult to digest and the bioavailability of the limiting amino-acid(s) can be considerably lower [4]. That is why, according to the Codex Committee on Vegetable Proteins (CCVP), it is the chemical index of a protein, if necessary adjusted to take account of its digestibility and/or the bioavailability of the amino-acids, which nowadays is regarded as the most appropriate method of evaluating the nutritional quality of vegetable proteins [5]. The corrected relative net protein ratio (CRNPR), which is superior to the conventional protein efficiency ratio (PER), could also be chosen as a method of evaluation, particularly where the sulphur amino-acids are limiting, as in the case of soya [6].

7. However, of the vegetable proteins, soya is one of those with the highest nutritional value. Its amino-acid rating is actually 96% of that of casein; even when corrected to allow for the digestibility of the proteins, soya's rating is still 89% and remains above 80% when the bioavailability of each amino-acid is taken into account [5]. Secondly, the CRNPR of soya protein isolates is never more than 10% lower than those of beefmeat or casein, and soya concentrates score even higher (97%), doubtless on account of the slightly higher sulphur amino-acid content in this type of product [6].

8. For adults it is well established that soya protein, correctly treated, is an excellent source of protein, approaching or even on a par with foods of animal origin. It is also well established that soya proteins alone are perfectly capable of supplying an adult's requirements of nitrogen and essential amino-acids as long as the recommended intake of proteins with high nutritional value is covered. Where the protein intake is inadequate, the body's use of soya protein is improved by the addition of L-methionine, but adverse effects on protein use have been observed with methionine

supplements at levels not appreciably higher than the recommended intake. Under normal conditions for soya protein use in adults it is therefore generally accepted that a methionine supplement is unnecessary and probably even undesirable [3]. In fact this has been confirmed by all of the recent short-term and long-term studies with soya protein isolates or soya concentrates; they have shown that the nutritional value of these proteins is comparable to that of eggs, milk and meat, and that their methionine content is not limiting as regards protein maintenance in adults[7-12].

9. For children of pre-school age, soya protein isolates, provided they have undergone proper technological processing, have proved to be an excellent source of protein. Their effect on nitrogen retention, in particular, bears comparison with that of milk protein; depending on the method of comparison chosen, the nitrogen balance ranges from 86% to 107% of that obtained with cows' milk proteins. With an intake of 160 mg N (equivalent to 1 g of protein) per kg of body weight per day, all of the children studied retained sufficient quantities of nitrogen to allow growth and to cover basal losses. Moreover, this level of intake coincides with the level at which plasma protein concentrations are maintained [13].

10. The nitrogen balance results obtained on infants suggest that the same holds true during the first few months of life, provided methionine-supplemented formulae are used. In the case of six infants aged between 3½ and 4 months, at protein intakes accounting for not more than 6.5% of the total energy intake, no difference in nitrogen retention was observed between methionine-supplemented soya protein isolates on the one hand and formulae based on cows' milk or breast milk on the other. At high protein intakes accounting for 8 to 11% and 12 to 16% of energy, there is a high degree of similarity in the nitrogen balance of infants aged between 8 and 120 days, whether they are fed with formulae based on cows' milk or on isolated soya proteins with a methionine supplement. In infants more than 4 months old and in young children, soya protein is even claimed to give better nitrogen retention than milk protein-based products [14]. Moreover, a whole series of studies have shown that formulae based on methionine-supplemented soya protein isolates allow infant growth comparable with that of babies fed with milk based formulae [14, 15].

11. Contrary to what is observed in adults or in pre-school age children, a methionine supplement appears to be necessary for infants, even where the protein intake is not marginal. With protein intakes of the order of 2.25 g/kg body weight, accounting for about 9% of energy, significant differences were observed in terms of the speed of growth, the concentration of albumin in the plasma and the excretion of urea in the urine between a group of infants receiving a non-methionine supplemented formula (26 mg of methionine/100 kcal) and those fed on a supplemented formula (32 mg/100 kcal) [16]. Recent studies in Cebus monkeys have in fact confirmed the beneficial effects on growth and nitrogen retention of supplementing the diet with methionine during the first few weeks of life [17].

The Committee therefore considers that special precautions should be taken to ensure optimum methionine intake from soya-based infant formulae. It therefore decided that for soya-based infant formulae it would not be sufficient to group together the sulphur amino-acids methionine and cystine (as is done for milk-based formulae) for the purpose of calculating the chemical index. Provided that the other requirements applicable to the proteins listed in Annex 1 of the Committee's 1983 report are satisfied, then – energy values being equal – soya protein-based infant formulae should provide an available quantity of methionine not lower than that contained in breast milk.

12. The Committee's attention was also drawn to the possible effects of vegetable protein on the level of cholesterol in the blood (cholesterolaemia). Most of the available data come from studies on laboratory animals. Generally speaking they show that hypercholesterolaemia and atherosclerotic lesions comparable with those caused by a high-cholesterol diet could be induced in rabbits and rats by a casein-based diet, and that these effects could be reversed when vegetable protein, especially soya, was substituted for animal protein [18]. On chickens and turkeys, soya had no effect, but a lessening of cholesterolaemia, mainly affecting LDLs, was observed in pigs and

rhesus monkeys, which suggests that the role of dietary protein in this area is not confined to laboratory animals [19]. Nevertheless, the results in humans are not conclusive.

Studies carried out on healthy volunteers revealed little or no effect as a result of substituting soya protein for casein [20]. Nor was any difference observed in the rate of total cholesterolaemia, LDLs, HDLs or apolipoprotein B in several groups of subjects suffering from varying degrees of hypercholesterolaemia [21,22]. However, in other studies the replacement of animal proteins by soya protein did lead to a certain reduction in cholesterolaemia, particularly in subjects suffering from familial hypercholesterolaemia, in whom soya proteins would appear to cause a very considerable increase in LDL receptor activity [23]. Yet there is virtually no information on the effects of soya protein on cholesterolaemia in infants and nothing to indicate that cholesterolaemia in breast-fed infants is the ideal bench-mark. **The Committee therefore proposes that until indisputable facts are available in this respect, no claims as to the possible favourable effects of these products on the regulation of cholesterolaemia should be accepted.**

13. Soya flour is never used in an untreated form in the preparation of infant formulae in the Community. In the few products where protein isolates are not used, the soya flour is always de-fatted, generally leaving a fat content under 1% [2]. The fatty phase of all products of this type currently marketed in the Community is therefore made up of mixtures of vegetable oils – such as safflower, coconut, corn, palm, soya, and sunflower oils – to which butter fat or destearinized beef fat (oleo oil) may be added. The fat content of these products is generally in the range between 4 and 5.5 g/100 kcal; the linoleic acid content (18:2, n-6), save for exceptions, ranges from 15 to 30% of the fatty acids content, but it can be as high as twice the maximum values permitted for milk-based products (max. = 1200 mg/100 kcal). There is no real justification for these practices. **The Committee therefore agreed to recommend that soya-protein-based formulae must comply with the specifications laid down for lipids and linoleate in milk-based products.**

14. In the 1983 report, for a number of reasons, the Committee felt that the lactose content of milk-based infant formulae should be not less than half of their minimum carbohydrate content. A minimum lactose content of 3.5 g/100 kcal was set for milk-based products. Whilst lactose is an essential constituent of milk, this is not the case for soya and no soya-based product contains lactose. That is precisely why these formulae are recommended when lactose has to be eliminated from the diet, for example in cases of primary lactase deficiency or for the treatment of galactosaemia, or where a temporary exclusion of lactose is considered desirable – as in the case of secondary lactose intolerance induced by an enteral infection or any other condition leading to intestinal lesions [24]. **Consequently, the Committee took the view that the provisions governing the minimum lactose content could not apply to soya-based products and that statements that they contained no lactose, together with any relevant medical indications, should appear on the labelling.**

15. Apart from lactose, for which special provisions should be envisaged, there is no apparent reason for departing from the provisions relating to milk-based products in the Glucides sections of Annexes 1 and 2 to the Committee's 1983 opinion. **Consequently, the Committee took the view that these provisions should also be applied to soya-based products, but that hydrolysed starch products – such as corn syrup solids – should be added to the list of sugars authorized for infant formulae.**

16. Owing to the absence of α-galactosidase in the human upper intestine, galactosido-oligosaccharides such as raffinose, stachyose and verbascose are not digested. De-fatted soya flour contains only traces of verbascose, but raffinose and stachyose each represent about 4 to 5% of the content, accounting for nearly two-thirds of the soluble soya carbohydrates. Their fermentation in the colon by intestinal micro-organisms was responsible for the flatulence and abundant loose and malodorous stools observed so frequently with the first generation of soya-flour-based infant formulae. By and large these problems are not encountered with soya protein isolates whose

carbohydrate content is lower than 0.5%. Stachyose and raffinose are also eliminated, like all soluble carbohydrates, during the manufacture of soya protein concentrates (by definition the minimum protein content is not less than 65% of the dry extract). But all of the insoluble carbohydrates, chiefly cellulose and hemicellulose, remain in the concentrate with the possible risk of fermentation [2, 25]. **The Committee therefore took the view that de-fatted soya flour and soya concentrates were not suitable raw materials for the manufacture of soya-based infant formulae and follow-up milks. Thus only protein isolates from soya should be used for manufacturing these products.**

17. Soya is well-known for its relatively high phytate content (between 1 and 2%). Phytates are only partially eliminated during the preparation of protein isolates. In adults, when meat proteins are replaced by soya proteins, the bioavailability of non-heme iron is lowered chiefly because phytates form highly insoluble complex compounds with ferric salts [26-28]. The inhibiting effect of soya on the bioavailability of iron is shown up again in adults by a comparison of the absorption of iron contained in milk-based infant formulae with the absorption of iron in formulae based on soya protein isolates. At ferrous sulphate intakes of 6 mg per 100 g of powder (1.2 mg/100 kcal), the geometric mean of iron absorption is reduced by more than half in the case of soya. Calculations suggest that, in these formulae, iron concentration should not be less than 2.4 mg/100 kcal in the presence of ascorbic acid when the ascorbic acid/iron ratio is of 4:1 [29]. The very weak absorption (under 2%) of ferrous sulphate which has been added to a soya protein isolate-based formula in a concentration of 12 mg per litre of ready-to-feed product has recently been confirmed in adults. However, it has been shown that there is no difference in iron status between infants who were fed this product up to the age of 9 months and children receiving a milk-based formula with the same iron content (2.2 mg/100 kcal), a level known for its effectiveness in preventing anaemia due to iron deficiency [30]. Despite the limited bioavailability of iron when it is measured in adults, soya-based infant formulae therefore seem to be just as effective as milk-based preparations in preventing iron deficiency, provided the iron content is sufficiently high. **Under these circumstances the Committee proposed that, in contrast to the provisions for milk-based formulae, soya-protein-based infant formulae must be required to be enriched with iron, at concentrations of not less than 1 mg and not more than 2 mg per 100 kcal.**

18. Phytates have an even more pronounced effect on the bioavailability of zinc than on that of iron. Zinc chelation is aggravated by an excess of calcium. Where there are no phytates the excess calcium has no effect on the absorption of zinc. This suggests that calcium, zinc and phytates form highly insoluble complex compounds which reduce zinc absorption to a greater extent than phytates on their own [26]. In addition, inorganic iron seriously inhibits the absorption of zinc where the iron-to-zinc ratio is greater than 2:1 [31]. This inhibiting effect of iron, however, was not found in the case of soya-based products, perhaps because the iron can form a complex compound with the phytates and thus facilitate zinc absorption [32].

At the concentrations normally used in infant formulae (3-4 mg/l), absorption of zinc measured in adults [32] or based on the model of the suckling rat [33] is much lower (nearly 50%) with soya-based than with milk-based formulae. Secondly, the increase in zinc concentrations in milk-based formulae gives an absorption comparable to that of suckling infants, but this objective cannot be achieved to the same extent with soya-based formulae [32]. This suggests that a reduction in phytate content to the sort of level at which the phytate-to-zinc ratio would be less than 10:1 is likely to be more effective than an additional increase in the zinc content of soya-protein-based formulae [32]. However, reducing the phytate content poses a number of as yet unresolved technological problems. **The Committee therefore concluded that soya-based products should be required to have a higher minimum zinc content than infant formulae and follow-up milks based on cows' milk protein (0.3 and 0.5 mg/100 kcal respectively). This minimum zinc content should not be less than 0.75 mg/100 kcal.**

19. The effects of soya-based products on the bioavailability of minerals other than iron and zinc are more doubtful. Poor bone mineralization has been observed in infants receiving this type of product compared with those fed on milk-based products [15, 34]. In one of these studies, these differences, occurring at the age of 3 months, had disappeared at the age of 6 months [34]. In the other, where the differences continued until the age of 1 year, the reduction in bone density was no greater than in breast-fed children receiving vitamin D supplements who were studied earlier [15]. A fall in the absorption or retention of calcium and/or phosphorus might explain these differences, the long-term significance of which has not yet been determined [35].

20. There is very little information about the bioavailability of other minerals and trace elements contained in soya-based products. Experiments in chickens with EDTA indicate that soya can bind copper and manganese, but adverse effects are only observed if the intake of one or other of these elements is limiting [26]. It has also been demonstrated in growing rats that copper was absorbed as efficiently from soya protein isolates as from a copper carbonate solution [36]. However, although the bioavailability of manganese is reduced in the case of soya-based products, concentrations of manganese in these formulae are in most cases so much higher than those found in breast milk that there is very little likelihood of a deficiency [37]. Lastly, although there are a number of findings to indicate that phytates might reduce the bioavailability of magnesium, it would appear that soya proteins have no significant effect on its bioavailability [26]. **The Committee therefore took the view that there was no need, in the case of minerals other than iron and zinc, to alter the specifications for milk-based infant formulae laid down in Annex 1 of the Committee's 1983 opinion. The Committee was not presented with any findings to warrant amending the specifications on vitamins.**

21. Particular attention must be paid to L-carnitine, which is indispensable to the transport of long-chained fatty acids within the mitochondria and plays a key role in the oxidation of fatty acids, thermogenesis of brown adipose tissue and initiation of cetogenesis. It is synthesized in the body from lysine and methionine (which is a methyl group donor). The ability of a newborn infant to synthesize carnitine, however, is extremely limited, even though this product is critical to it during its first few hours of life. The newborn infant therefore has to rely chiefly on its prenatal reserves from the mother and exogenous intakes [38, 39]. Its reserves, estimated at around 2 mmoles at birth, are certainly sufficient to cover its needs during the first few weeks; if no exogenous supplies are forthcoming, it has been calculated that reserves fall by around 25% in 15 days and that they are liable to be completely exhausted after two and a half months [40,41]. The concentration of carnitine in colostrum is close to 10 μmoles, stabilizing at an average of between 4 and 5 μmoles/100 ml in the milk of a mature female from the first month onwards [42]. Cows' milk is also a good source of carnitine and milk-based preparations have naturally-occurring concentrations of carnitine which are as high as those in breast milk.

Soya, on the other hand, like all plants, contains practically none and the content of soya-based formulae, unless they are supplemented with carnitine, is close to zero [42,43]. Instances of hypoglycaemia, vomiting, hypothermia, accompanied by hepatomegalia and steatosis have been reported in an infant fed with one of these soya-based formulae [44] but it has still to be conclusively demonstrated that reduced carnitine intake during the first few weeks of life has harmful effects [38]. **In any case, the Committee took the view that soya-based products should be systematically enriched with L-carnitine. Given the carnitine content of breast milk and its higher bioavailability in human milk than in infant formulae, the L-carnitine content of soya-based formulae must not be less than 7.5 μmole/100 kcal. For the purposes of implementing this measure, L-carnitine should be added to the list of nutritional substances (the section dealing with amino-acids and other nitrogenous compounds) in Annex 4 of the Committee's previous 1983 opinion.**

22. On the question of technological additives, particular attention should be paid to thickeners, a number of which are essential to the stability of the milk-based (ready-to-use) liquids and soya-based formulae. Several of these are on the list of additives in the Codex standard for infant formulae (CODEX STAN 72-1981). **The Committee therefore recommended the holding**

of consultations with the IDACE to review the lists, in accordance with the principles established in § 43 of the Committee's previous 1983 opinion.

23. Vegetables and vegetable products eaten as foods contain a number of minor chemical compounds which can have undesirable effects. Soya is no exception to this rule, containing in particular trypsin inhibitors, phytohemagglutinins (lectins), goitrogenic substances, oestrogens and galactosido-oligosaccharides (see § 16 above) [25, 45]. **The Committee therefore pointed out that every effort should be made to reduce the concentrations of these substances to the lowest level compatible with good manufacturing practice.**

24. The antigenic potential of soya protein is lower than that of milk protein, particularly lactoserum (whey) protein. That is why some thirty years ago soya proteins were recommended for children who were allergic to cows' milk protein. However, there are very well documented reports of severe gastro-intestinal reactions in the form of vomiting, diarrhoea, weight loss, villose atrophy and even characteristic allergy symptoms as a result of feeding with soya protein. Intolerance associated with milk and soya protein or intolerance caused by these proteins has also been reported. This multi-sensitization could be ascribed to the increase in the permeability of the intestine to foreign proteins induced by the intestinal lesions which the foreign proteins may cause. The idea was also put forward that these proteins – which were thought to be non-antigenic – could cause allergy-type reactions if they are ingested at a time when there are clinical signs of an intolerance to cows' milk. Less antigenic formulae (e.g. protein hydrolysates) should therefore be used in preference to soya-based protein for infants who are allergic or who show signs of intolerance to dietary protein [24].

The possibility of preventing the appearance of allergy symptoms in families at risk and in the population at large through the use of soya-based formulae has also been called into question. Even extremely well controlled studies have not revealed any difference in the development of an allergy that could be ascribed to the type of food administered to infants [46]; other studies have, on the contrary, highlighted the protective effect of breast feeding and 'elementary' food compared with milk or soya-protein-based formulae [24, 47]. **Under these circumstances, the Committee felt that soya-based products might possibly be regarded as substitutes for cows' milk in children suffering from an intolerance to these proteins, but that no reference should be made to the possible protective role of soya-based products as regards allergy.**

25. Lastly, the question of the minimum requirements for products combining milk protein and soya protein was discussed. The possibility that this type of formula might eventually be marketed in the Community cannot be ruled out. **Taking all of the issues into account, the Committee held that all of the provisions proposed in § § 11, 12, 15, 16, 17, 18, 20, 21, 22, 23, and 24 should apply equally to soya-protein-based products and to those combining milk protein and soya protein. The provisions of § 14 are, clearly, the only ones which cannot be applied to 'combined' products. Finally, it should be mentioned on the packaging of these products that in spite of partial replacement of milk by soya proteins, they do contain lactose and cows' milk protein.**

26. As mentioned above (see § 1), this opinion supplements the opinion expressed previously in 1983 by the Committee on the minimum requirements for infant formulae and follow-up milks based on cows' milk proteins. The relevant annexes of the 1983 report have been modified in order to take into account the recommendations expressed here, and to make them applicable to preparations covered by both opinions. For the sake of clarity, all the annexes are included in the present document.

A N N E X E S

Annex 1

Infant Formulae –

Essential Composition of the Product Ready for Use when Reconstituted as Instructed by the Manufacturer

1. Energy

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

2. Proteins

(Protein content = nitrogen content x 6.38) for cows' milk proteins.
(Protein content = nitrogen content x 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 Annex 7); 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 Annex 6).

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
(2.25 g/100 kcal)	(3 g/100 kcal)

- Only soya protein isolates must 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 Annex 7).
- 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 Annex 6).
- The L-carnitine content shall be equal to at least 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.

3. Lipids

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

3.1 *The use of the following substances is prohibited*

- sesame oil;
- cotton 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 (300 mg/100 kcal)	285 mg/100 kJ (1200 mg/100 kcal)

4. Carbohydrates

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

4.1 *Only the following carbohydrates may be used*

- lactose;
- maltose;
- sucrose;
- malto-dextrins;
- corn syrup solids;
- pre-cooked starch (naturally free of gluten)
- gelatinized starch (naturally free 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

5. Mineral substances

5.1 Formulae manufactured from cows' milk proteins

	Per 100 kJ		**Per 100 kcal**	
	Minimum	*Maximum*	*Minimum*	*Maximum*
Sodium (mEq)	0.25	0.6	1	2.6
Potassium (mEq)	0.4	0.9	1.6	3.8
Chlorine (mEq)	0.35	0.8	1.4	3.5
Calcium (mg)	12	—	50	—
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)[a]	0.12	0.36	0.5	1.5
Zinc (mg)	0.07	—	0.3	—
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 protein isolates, 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	—	0.75	—

[a] Limit applicable to formulae with added iron.

6. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	*Maximum*	*Minimum*	*Maximum*
Vitamin A (μg RE)[b]	14	43	60	180
Vitamin D (μg)[c]	0.25	0.5	1	2
Thiamine (μg)	10	—	40	—
Riboflavin (μg)	14	—	60	—
Nicotinamide (μg NE)[d]	60	—	250	—
Pantothenic acid (μg)	70	—	300	—
Vitamin B_6 (μg)	9	—	35	—
Biotin (μg)	0.4	—	1.5	—
Folic acid (μg)	1	—	4	—
Vitamin B_{12} (μg)	0.025	—	0.1	—
Vitamin C (mg)	1.9	—	8	—
Vitamin E (mg α-TE)[e]	0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	—	0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	—

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[b] RE = all-trans retinol equivalent.

[c] In the form of cholecalciferol, of which 10 μg = 400 i.u. of vitamin D

[d] NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60

[e] α-TE = D-α-tocopherol equivalent

Annex 2

Follow-Up Milks –

Essential Composition of the Product Ready for Use when Reconstituted as Instructed by the Manufacturer

1. Energy

Minimum	*Maximum*
250 kJ/100ml (60 kcal/100 ml)	335 kJ/100ml (80 kcal/100 ml)

2. Proteins

(Protein content = nitrogen content x 6.38) for cows' milk proteins.
(Protein content = nitrogen content x 6.25) for soya protein isolates.

Minimum	*Maximum*
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 equal to at least 85% of that of the reference protein (casein, as defined in Annex 7).
- 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-up milks manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used and the L-carnitine content shall be at least equal to 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal).
- Amino-acids may be added to follow-up milks for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.

3. Lipids

Minimum	*Maximum*
0.8 g/100 kJ (3.3 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

3.1 *The use of the following substances is prohibited:*

- sesame oil;
- cotton 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 (300 mg/100 kcal): this limit applies only to follow-up milks containing vegetable oils	—

4. Carbohydrates

Minimum	*Maximum*
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

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

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

4.3 Sucrose, Fructose, Honey

Minimum	*Maximum*
—	separately or as a whole: 20% of the total carbohydrate content.

5. Mineral substances

5.1 Iron

Minimum	*Maximum*
0.25 mg/100 kJ (1 mg/100 kcal)	0.5 mg/100 kJ (2 mg/100 kcal)

5.2 Zinc

5.2.1 Follow-up milks manufactured entirely from cows' milk

Minimum	*Maximum*
0.12 mg/100 kJ (0.5 mg/100 kcal)	—

5.2.2 Follow-up milks manufactured from soya protein isolates, alone or mixed with cows' milk

Minimum	*Maximum*
0.18 mg/100 kJ (0.75 mg/100 kcal)	—

5.3 Other mineral substances

- Their concentrations should be at least the concentrations normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-up milk to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Annex 8.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

6. Vitamins

	Per 100 kJ		**Per 100 kcal**	
	Minimum	*Maximum*	*Minimum*	*Maximum*
Vitamin A (µg RE)[a]	14	43	60	180
Vitamin D (µg)[b]	0.25	0.5	1	2
Vitamin C (mg)	1.9	—	8	—
Vitamin E (mg α-TE)[c]	0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ	—	0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	—

[a] RE = all trans retinol equivalent.
[b] In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.
[c] α-TE = D-α-tocopherol equivalent.

Annex 3

Specific Compositional Criteria for Infant Formulae, Warranting a Corresponding Claim

Composition criterion	*Conditions warranting a claim*
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
Sodium	The sodium content is lower than 0.4 mEq/100 kJ (1.7 mEq/100 kcal)
Sucrose	No sucrose is present
Lactose	Lactose is the only carbohydrate used
Lactose	No lactose is present
Iron	Iron is added

Annex 4

Nutritional Substances

1. Vitamins

Vitamin	*Vitamin formulation*
Vitamin A	Vitamin A acetate Vitamin A palmitate Beta-carotene (Provitamin A)
Vitamin D	Vitamin D_2 (ergocalciferol) Vitamin D_3 (cholecalciferol) Vitamin D_3 cholesterol
Vitamin B_1	Thiamine hydrochloride Thiamine mononitrate
Vitamin B_2	Riboflavin Riboflavin 5'-sodium phosphate
Nicotinamide	Niacinamide Nicotinic acid (niacin)
Vitamin B_6	Pyridoxine hydrochloride Pyridoxal 5'-phosphate
Folic acid	Folic acid
Pantothenic acid	D-calcium pantothenate D-sodium pantothenate D-panthenol
Vitamin B_{12}	Cyanocobalamin Hydroxycobalamin
Vitamin H	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate L-ascorbyl 6-palmitate Potassium ascorbate
Vitamin E	D-α-tocopherol DL-α-tocopherol D-α-tocopherol acetate DL-α-tocopherol acetate
Vitamin K	Vitamin K_1

Special vitamin formulations

- For reasons of stability and handling, some vitamins have to be converted into suitable preparations, for example stabilized oily solutions, gelatine-coated products and fat-coated preparations. For this purpose, edible substances and additives recommended in the present document may be used. In addition, the following substances are permitted:

  Gelatine, gum arabic (acacia gum), silicon dioxide (as an anti-caking agent): maximum level 10 g/kg in the vitamin preparation.

2. Mineral substances

Mineral substances	*Permitted salts*
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium citrate Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium phosphate, monobasic Calcium phosphate, dibasic Calcium phosphate, tribasic Calcium hydroxide
Phosphorus (P)	Calcium phosphate, monobasic Calcium phosphate, dibasic Calcium phosphate, tribasic Magnesium phosphate, dibasic Magnesium phosphate, tribasic Potassium phosphate, monobasic Potassium phosphate, dibasic Sodium phosphate, dibasic
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium phosphate, dibasic Magnesium phosphate, tribasic Magnesium sulphate Magnesium gluconate
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferrous ammonium citrate
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper Lysine Complex Copper carbonate
Iodine (I)	Potassium iodide Sodium iodide Potassium iodate

Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate
Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium phosphate, monobasic Sodium phosphate, dibasic Sodium phosphate, tribasic Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium gluconate Potassium lactate Potassium phosphate, monobasic Potassium phosphate, dibasic Potassium phosphate, tribasic Potassium hydroxyde

3. Amino-acids and other nitrogen compounds

L- arginine and its hydrochloride
L- cystine and its hydrochloride
L- histidine and its hydrochloride
L- isoleucine
L- leucine
L- lysine
L- and DL-methionine
L- phenylalanine
L- threonine
L- tryptophan
L- tyrosine
L- valine

L- carnitine
Taurine

4. Others

Choline (choline chloride)
Inositol

Annex 5

Technological Additives

Thickening agents	*Maximum level in 100 ml of the product ready for use when reconstituted as instructed by the manufacturer*
E 407 Carrageenan	0.03 g in follow-up milks
E 410 Gum carob	0.1 g in follow-up milks
E 412 Gum guar	0.1 g in follow-up milks
Emulsifiers	
E 322 Lecithin	0.5 g in infant formulae and follow-up milks
E 471 Mono- and di-glycerides	0.4 g in infant formulae and follow-up milks
Antioxidants	
E 300 L-ascorbic acid	1 mg in infant formulae and follow-up milks
E 301 Sodium L-ascorbate	1 mg in infant formulae and follow-up milks
E 302 Calcium L-ascorbate	1 mg in infant formulae and follow-up milks
E 304 Ascorbyl palmitate	1 mg in infant formulae and follow-up milks
E 306 Tocopherol-rich extracts of natural origin	1 mg in infant formulae and follow-up milks
E 307 α-tocopherol	1 mg in infant formulae and follow-up milks
E 308 γ-tocopherol	1 mg in infant formulae and follow-up milks
E 309 δ-tocopherol	1 mg in infant formulae and follow-up milks

Acidified milks

For the manufacture of acidified milks, the addition of citric acid, L(+)-lactic acid or the culture method, producing lactic acid *in situ*, can be used.

Annex 6

The Essential and Semi-Essential Amino-Acids in Breast Milk

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

	Per 100 kJ*	Per 100 kcal
Arginine	16	69
Cystine	6	24
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

* 1 kJ = 0.239 kcal.

Annex 7

Amino-acid Composition of Casein and Breast Milk Protein

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

	Casein*	Breast Milk*
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

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

Annex 8

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 gram of proteins are the following:

	Per 100 g SNF[a]	Per g of proteins
Sodium (mEq)	24	0.65
Potassium (mEq)	43	1.1
Chlorine (mEq)	30	0.8
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3.5
Copper (µg)	225	6
Iodine	NS[b]	NS

[a] SNF: solids–non-fat.

[b] NS: non specified, varies widely according to season and stock farming conditions.

R E F E R E N C E S

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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ L 136, 20.5.1974, p. 1) to advise the Commission on any problem relating to the protection of the health and safety of persons arising from the consumption of food, and in particular the composition of food, processes which are liable to modify food, the use of food additives and other processing aids as well as the presence of contaminants.

The members are independent persons, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

The Secretariat of the Committee is provided by the Directorate-General for Internal Market and Industrial Affairs of the Commission. Recent Council directives require the Commission to consult the Committee on provisions which may have an effect on public health falling within the scope of these directives.

The present report deals with the minimum requirements for soya-based infant formulae and follow-up milks.