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First addendum

(Opinion expressed on 27 October 1989)

to the reports of the Scientific Committee for Food concerning

The essential requirements of infant formulae and follow-up milks based on cows' milk proteins

(Opinion expressed on 27 April 1983)

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

(Opinion expressed on 9 December 1988)

First report

of the Scientific Committee for Food concerning

The essential requirements for weaning foods

(Opinions expressed on 27 October 1989 and 30 March 1990)

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First Addendum

(Opinion expressed 27th October 1989)

to the Reports of the Scientific Committee for Food

concerning

Essential Requirements of Infant Formulae and Follow-up Milks based on Cows' Milk Proteins

(Opinion delivered 27th April 1983)

The Minimum Requirements for Soya-based Infant Formulae and Follow-up Milks

(Opinion delivered 9th December 1988)

Introduction

The Committee has as already adopted two reports on infant formulae and follow-up milks based on cows' milk proteins and soya proteins respectively [1,2].

The Committee has subsequently been asked to reconsider its recommendations relating to the maximum levels of the vitamin D content of these products, and to give its opinion on a limited extension to the list of nutritional substances which may be used in the manufacture of these products.

Increase in vitamin D content

The recommended daily allowance for vitamin D is 1 µg (40 IU). If this quantity is ingested regularly, then, in general, neither rickets nor a reduction in the reserves of 25(OH) D are observed. On the other hand, no signs of overdosage are observed with doses four to five times higher, which are needed for the prevention of rickets in infants of low birthweight and in those of black race. Moreover, requirements have increased because of atmospheric pollution, are more important in winter than in summer, and are higher the further the distance from the equator.

Until now the Committee has accepted values between 1 and 2 µg/100 kcal for infant formulae and follow-up milks. Breast-fed infants consume daily on average 600-700 ml of milk. Bottle-fed infants consume about the same quantitites until the age of 2-3 months, and slightly higher quantities up to 4-6 months. However, milk consumption rarely exceeds half a litre per day once nutrition has become diversified. In these different age periods, the amounts of energy derived from milk are of the order of 500, 600, and 350 kcal per day, which correspond respectively to vitamin D intakes of 200, 250, and 150 IU per day for the minimum value (1 µg/100 kcal) or 400, 500, and 300 IU per day for the maximum value (2 µg/100 kcal).

The appropriate Codex Alimentarius Committee (FSDU) has proposed raising the maximum value to 2.5 µg for infant formulae, and to 3 µg for follow-up milks at the request of the Scandinavian countries and the Netherlands. This proposal has been approved by the Codex Alimentarius Commission and was inserted into the respective standards in 1987. Under those conditions no risk of overdosage exists and the Committee sees no reason not to accept the recommendations of the Codex Alimentarius.

Additions to the list of nutritional substances

The Committee has examined the list of additional nutritional substances from the nutritional and safety viewpoints. It considered that the additional nutritional substances requested did not pose any nutritional or toxicological problems but were alternative preparations to some of the nutritional substances already approved. The approved further nutritional substances are listed in the Annex.

References

1. First Report of the Scientific Committee for Food on the Essential Requirements of Infant Formulae and Follow-up Milks Based on Cows' Milk Proteins (1983). *Food — Science and Techniques*, Commission of the European Communities, Luxembourg : 14th Series, EUR 8752.

2. First Report of the Scientific Committee for Food.on the Minimum Requirements for Soya-based Infant Formulae and Follow-up Milks, (1989). *Food — Science and Techniques*, Commission of the European Communities, Luxembourg : 23rd Series, EUR 12536.

Annex

Approved Further Nutritional Substances

Vitamins

Vitamin A

retinol

Special Vitamin Formulations

mannitol: as a diluent in preparations of vitamin B_{12} to a maximum dilution of 1:1000

Amino Acids and Other N-Containing Compounds

L-isoleucine)
L-leucine) HCL salts
L-lysine)

L-cysteine and its HCL salt

choline citrate
choline bitartrate
L-carnitine hydrochloride

Salts of Minerals and Trace Elements

Magnesium

tri-magnesium dicitrate
magnesium hydrogen citrate
magnesium hydroxide

Iron

ferrous fumarate
ferric diphosphate

Zinc

zinc oxide
zinc gluconate

First Report of the Scientific Committee for Food on the Essential Requirements for Weaning Foods

(Opinion expressed on 27th October 1989 and on 30th March 1990)

Abstract

In the present report, the Scientific Committee for Food expresses its opinion on the requirements of weaning foods, i.e. foods suitable for infants and young children during the transition from a diet of milk or milk substitutes to adult food. The variety of weaning foods commercially available in the Community is examined. Recommendations are given for various categories of weaning foods (cereals and other starchy foods, and baby foods, i.e. complete or incomplete dishes or meals in cans, jars or, if dehydrated, packets, soups, desserts and puddings, juices, etc., regarding, inter alia, the required amounts of proteins, carbohydrates, fats, minerals and vitamins.

Terms of Reference

To advise on essential requirements for weaning foods for infants and young children

I. Introduction

1. The Committee has published two reports concerned with foods for infants and young children: *Essential Requirements of Infant Formulae and Follow-up Milks based on Cow's Milk Protein* in 1983, and *Minimum Requirements for Soya-based Infant Formulae and Follow-up Milks* in 1989 [1]. The present report is concerned with the foods consumed at a later stage in the child's development, i.e. during weaning, when other foods in addition to breast milk, an infant formula, or a follow-up milk begin to be offered.

Definitions

2. The following definitions have been adopted in line with the previous reports:

'Infants': Children aged less than 12 months.

'Young children': Children aged between 1 and 3 years.

'Infant formulae': Products intended where necessary to replace human milk and to meet by themselves the normal nutritional needs of infants during the first 4-6 months of life, labelled as suitable for infants from birth to one year of age if enriched in iron, or as suitable for infants from birth to six months of age if not enriched in iron.

'Follow-up milks': Products intended to constitute the basic milk element in the progressively diversified diet of infants over the age of 4 months, labelled as suitable for infants over the age of four months and young children.

The following definitions were also adopted in line with current custom:

'Weaning': The process of introducing semi-solid or solid foods to the infants' diet *in addition* to breast milk, infant formula or follow-up milk.

'Weaning foods': Foods specially prepared for the weanling child, either from family foods in the home or by manufacturers in various forms. This is similar to the meaning of the German *Beikost* adopted by Fomon [2] and the European Society of Paediatric Gastroenterology and Nutrition (ESPGAN) [3].

Documents consulted

3. In drafting this opinion the Committee considered the views of other bodies who have reported on this topic as well as information provided by the Association of Dietetic Foods Industries of the EEC (IDACE). It also had the benefit of access to the relevant standards laid down by the Codex Alimentarius and of legal provisions existing in Member States of the European Community. In addition the Committee took into account the fact that Council Directive 79/112/EEC on *Labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer* and 89/398/EEC on *Foods for particular nutritional uses* are applicable to the products under consideration.

Plan of the report

4. This report considers the nutritional background to weaning, the types of weaning foods available in the European Community, and the food and nutrient intakes of weanlings, and then gives the Committee's conclusions and recommendations. These appear in five separate sections. Section V gives the Committee's general conclusions and recommendations. Section VI gives the Committee's conclusions and recommendations on cereals and other starchy foods, with two related annexes. Section VII gives the Committee's conclusions and recommendations on baby foods, with one related annex. Section VIII gives the Committee's recommendations on nutritional substances and technological additives, with two related annexes. Section IX discusses hygienic standards.

II. Nutritional background

5. There is common agreement in Europe and North America that weaning should occur between the ages of 3-4 and 6 months [3-10]. Opinion against early introduction of solid foods has focused on concerns about renal solute load, obesity, and coeliac disease. Solid foods, particularly those high in protein, given to a baby receiving unmodified cow's milk (or worse, skimmed milk) will result in a substantial renal solute load and higher plasma concentrations of sodium and urea. Quite apart

from the problems that these changes may lead to if there are excessive water losses during an illness, the introduction of solid foods may, even in a healthy baby, increase thirst, causing the baby to drink more milk.

Far from reducing the infant's reliance on milk or formula, solid foods may increase it and so contribute to obesity [11]. Epidemiologically, however, it has proved difficult to demonstrate that the early introduction of solids is associated with obesity [12]. The reduced incidence of rapid weight gain that has been reported to occur in infants may be due more to the widespread introduction of low solute milks than to a delay in the time of weaning [13].

6. The few children destined to acquire coeliac disease may do so earlier if they receive foods containing gluten early in life. As coeliac disease in the young infant is more troublesome than in the older child, any delay in the development of the disease is worthwhile [14]. The fact that coeliac disease is now less prevalent in European countries may perhaps be related to an altered immunological milieu of the young infant's gut induced by the increased prevalence of breast-feeding and the later introduction of gluten [15, 16].

7. There are physiological arguments, however, against weaning too late. Lactation may be unable to meet the infant's recommended energy and nutrient intake. The question is whether the recommended dietary allowances indeed reflect the physiological requirements (even for populations) or whether they are set too high [17].

8. Some breast-fed infants experience very low weight gains. Human milk provides little iron and copper, and for some months the baby relies on the initial stores in haemoglobin (iron) and the liver (copper and iron) to meet the apparent requirements calculated by the factorial method. Most formulae contain added copper and added iron so that most bottle-fed babies receive plenty of both minerals.

9. When the bottle-fed baby is given whole cow's milk or a formula containing only cow's milk fat, the intake of linoleic acid is 0.5% to 1% of energy. It has been suggested that clinical signs of deficiency in essential fatty acids do not develop because weaning cereals are introduced early. Since wheat flour provides only 2% energy as polyunsaturated fatty acids, and rice less than 1%, this argument has always been doubtful; but, as most formulae now have a minimum recommended content of linoleic acid, events have overtaken it. Previous recommendations of this Committee are 300-1200 mg of linoleic acid per 100 kcal, i.e. 2.7% of energy [1].

10. An argument against late weaning, based on developmental aspects, is that some infants who have not started to take food from the spoon by the age of six months subsequently show delay in adapting from a suckling action to the chewing and tongue-rolling action of the weanling. Finally, although studies of polysaccharide digestion have reached varying conclusions [18], generally the infant should be 3 to 4 months of age before the more complex carbohydrates are introduced in significant amounts.

11. Some children of certain subgroups of ethnic minorities who live in EEC countries have special problems [19,20,26]. Iron deficiency anaemia and rickets are common occurrences. Food policies intended for a whole population should not be dictated by the problems of a minority. Nevertheless, subclinical deficiencies of iron may be widespread. Rickets is more common in the northern European countries, but does also occur in the urban areas of the sunny Mediterranean countries.

III. Available weaning foods

12. The aim in all prepared weaning foods is to produce a product in a suitable form for this age group, so that the food can be a link from the wholly liquid diet of breast- or formula-feeding to family-type meals.

Some products are designed so that they can be used as a complete meal, viz. those prepared from meat, fish, eggs and vegetables, while others are intended to be a supplement to the main meal, e.g. only meat – to be used with cereal products or vegetables, or only vegetables and/or fruit. Certain vitamin and mineral additions are made to various products as appropriate for the type. In some countries, the addition of all or some vitamins is restricted. When additions are made, the compounds of vitamins and minerals are to be selected from a list of approved compounds. Each type of product will have different uses and therefore will need different formulations.

13. Other considerations will be the physical characteristics of the food, so that the weaning process can be followed through from a smooth mixture (puree), through junior and toddler food with larger particles, and thence on to adult food for the whole family.

14. Companies have specifications for the raw materials used which depend on national legislation, their own internal standards, the formulation, the process and the type of baby food to be prepared. In general, these specifications are more restrictive and severe than those used for adult foodstuffs in order to meet the special requirements of infants and young children.

15. There are four broad types of weaning foods:

a) Cereal-Based Weaning Foods

Cereal-based weaning foods are composed of one or more cereals either alone, or with the addition of other ingredients, for example, vegetables, fruit, egg, milk products, etc. These weaning foods are often fortified with vitamins and minerals (particularly iron), and contain technological additives such as emulsifiers (e.g. lecithin and mono- and diglycerides) or a raising agent for rusks and biscuits.

There are six varieties:

- Uncooked and partially cooked cereals which require cooking before use.
- Pre-cooked cereals which require no further cooking before use.
- Enzyme-treated cereals in which the starch of the cereal has been degraded into dextrin, maltodextrin, maltose and/or dextrose.
- Pasta prepared from milled cereal products using extrusion technology.
- Rusks and biscuits produced by a baking or similar process, which may be consumed as such or, after pulverization, as a gruel with the addition of water, milk or other suitable liquid.
- Milk biscuits consisting primarily of cereals with added whole milk or milk components.

b) Baby Foods in Jars and Cans

Baby foods in jars and/or cans are available in all EEC countries, either as homogeneous purees for young infants or as preparations with larger particles for older infants ('Junior' foods).

Each country has its own particular methods for weaning babies and many different types of weaning foods are in use. For example, in the United Kingdom, traditional beef dishes are adapted for infants, so one has 'Beef Casserole', 'Braised Beef and Vegetables', and so on. In Italy, many meat-only varieties are marketed as an addition to cooked pasta and rice. In Germany, traditional dishes with meat, carrots and vegetables are used. In Holland, brown beans and strained apples are a traditional dish. Soups and broths are available in a ready-to-feed form after warming, or as concentrated liquids to be diluted with water.

c) Dehydrated Baby Foods

Products with contents similar to those presented in cans and jars are also available in a dried form (usually roller-dried). These products are prepared from meats, fish, vegetables, fruits, eggs, cereals, and milk products, either alone or as complex mixtures; hundreds of different varieties are produced throughout the EEC, and they are available in most countries.

d) Fruit and/or Vegetable Drinks or Nectars

Fruit and vegetable drinks and nectars are marketed in most EEC countries, either as ready-to-feed liquids or concentrated liquids. Most are based on a fruit juice or a fruit puree. Many contain added sugars and vitamin C. Production methods are similar to those used for adult fruit and vegetable drinks.

Foods included in this report

16. In this report, recommendations are made concerning both cereals and other baby foods. The latter include baby foods in jars and cans, dehydrated baby foods, soups, fruit juices and nectars.

IV. Food and Nutrient Intakes of Weanlings

17. There have been a number of investigations describing the diet of the weanling in Europe [21-27] and North America [28-30]. In the early weanling months, formulae provide a substantial proportion of the total energy and nutrient intake. In later infancy and beyond, this role is taken over by cow's milk which provides about a quarter of the total energy and a third of protein intakes. Any recommendation concerning the composition of suitable weaning foods must be made against this background. Total energy intakes studied mostly met the recommended allowances, but not in one of the Canadian studies [29]. In general, boys ate more than girls, and energy intakes tended to be a little higher in less-favoured social groups [25]. If the child was not taking vitamin preparations, the intake of vitamin D was frequently below 10 µg (400 IU) per day. The intake of most other nutrients met the recommended dietary allowances (RDA) of the regions studied except for iron, and the British report noted that children who drank little milk had intakes of calcium and riboflavin well below the average. The RDAs for protein are set to provide about a tenth of the energy intake, but the observed protein intake exceeds this in most countries, particularly in later infancy, reflecting the contribution of cow's milk to the total diet.

18. The average diet of the American one-year-old contains iron-enriched formula and cereals. This explains the higher intakes of iron which they achieved. The changes in nutrient intake in the United States from 1972 to 1979 are interesting. While total energy intake showed little change, the type of food eaten to provide this energy changed substantially. In 1972, the average four-month-

old received a third of his energy from weaning foods, a fifth from cow's milk and less than a half from breast milk or formula; in 1979, 60% of the child's energy came from breast milk or formula. These changes over the years, in addition to the reduction of salt added to commercial weaning foods, have led to a reduction in intake of protein, sodium and calcium. Similar changes in infant feeding practices have occurred in Europe, with some reduction in protein and calcium intake [24, 25], but we are unaware of any objective evidence of a reduction in sodium intake since this nutrient has often not been recorded in the published data. Similarly, there is little data concerning intakes of zinc and copper.

V. General Conclusions and Recommendations on Weaning Foods

19. The Committee endorses the widely accepted opinion that up to the age of 4-6 months the infants' diet should consist solely of breast milk, or in those cases in which breastfeeding is not advised, sufficient or possible, or in which the mother chooses not to breastfeed, of an approved infant formula complying with the recommendations of the Committee.

Products covered by this document are those foods manufactured or marketed for consumption by infants from the age of 4-6 months and also for progressive adaptation of infants and children to the usual diet of their families.

20. In making recommendations the Committee has adopted the position that as the infant becomes progressively less dependent on single foods or a small number of foods for the satisfaction of its nutritional needs it is the energy and nutrient quality of the diet as a whole rather than the nutritional composition of individual items that is of greatest importance.

The recommendations are presented in a general section (§§ 19 - 21) and in three specific sections: Cereals and Other Starchy Foods (§§ 22 - 30), Baby Foods (§§ 31 - 39), and Nutritional Substances and Technological Additives (§§ 40 - 41). Each specific section is followed by annexes giving the Committee's definitive recommendations. Hygienic standards are discussed in the final paragraph (§ 42).

21. The recommendations are intended to ensure that the mother (or other care giver) is in no doubt as to the constituents of the product and to the nutrient composition of the preparation as offered to the child. The Committee therefore recommends that in all products designed and marketed specifically for the weanling:

1. The name or product description should give the mother a reasonable idea of the foods which it contains.
2. The nutrient composition and ingredients of the preparation should not differ substantially from that of the constituent foods indicated in the name or product description.
3. No novel food ingredients should be used in their manufacture. This view may change if more extensive nutritional and toxicological evidence concerning their value and safety becomes available.
4. The foods should contain only those nutritional substances and technological additives that are specifically approved for use in their manufacture.
5. The strictest microbiological standards must be observed and contamination by potentially dangerous substances (heavy metals, aflatoxins, pesticide residues, hormones, etc.) must be avoided.

VI. Cereals and Other Starchy Foods: Conclusions and Recommendations

22. Traditionally the first weaning foods offered throughout most of Europe have been cereals; in some countries a cereal 'pap' (i.e. with milk or water) is offered for many months. Cereals are used as weaning foods in many ways, e.g. alone, mixed with milk or water, baked as biscuits and rusks, or combined with other foods. In addition the infant may consume some of the wide selection of cereal foods available for older children and adults, e.g. breakfast cereal, bread, etc.

    The Committee has been concerned only with those cereal products designed and marketed specifically for the weanling. In respect of specific nutrients the following points have been considered:

Protein

23. If high protein foods are added to cereals, the quality of the added protein should be defined, since if mothers or their professional advisers wish to choose an 'added protein' product its quality should be assured. There are many ways of defining protein quality. In its previous reports [1], the Committee used the chemical index and for follow-up milks adopted a figure of 0.8 (reference protein: casein). The Committe has recommended therefore that the chemical index of the added protein should not be less than 0.8, or that the Protein Efficiency Ratio (PER) * of the protein mixture should not be less than 0.7.

    If the product is marked as 'with milk' or its equivalent, the mother and her professional adviser should reasonably expect that the amount of milk protein provided in the mixture is not substantially less than the minimum amount found in a follow-up milk, i.e. 2.25 g per 100 kcal. The Committee has rounded this down to 2.0 g per 100 kcal. The same figure applies to other added proteins, e.g. soya. The Committee also recommends that the total amount of milk protein should not exceed the amount found in whole cow's milk, i.e. 5.5 g per 100 kcal.

Carbohydrates

24. Many weaning cereals in Europe have by tradition contained considerable amounts of added carbohydrate, particularly sucrose. Indeed sucrose is often necessary to achieve the crunchy texture of certain products, particularly biscuits and rusks, and simple sugars or oligosaccharides must be added to flour and water in order to achieve a suitable consistency for feeding to an infant.

    Nevertheless there are some concerns about simple sugars in the diets of young children. They are conducive to dental caries. They may lead to the development of a 'sweet tooth' so affecting eating patterns in later life, and they may add unduly to the total energy intake. The Committee considers therefore that limits are desirable.

Fat

25. The Committee saw no need to add fat to cereal mixtures, except for baking biscuits. Mothers and their professional advisers in many countries regard cereals as starchy foods and it could be misleading for any cereal mixture to contain substantial amounts of fat, e.g. the mother would not expect them to contain as much fat as milk. The Committee has therefore recommended that the maximum amount of fat in *simple cereals which are to be reconstituted with milk* (see definition in Annex 1) should be set at the minimum amount of fat previously recommended for a follow-up milk, i.e. 3.3 g per 100 kcal.

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* The definition of PER is as in *Energy and Protein Requirements* (FAO/WHO, 1973)

However, both breast and bottle-fed babies consume a food in which about 50% of the energy is provided by fat and some paediatricians are wary of too rapid a reduction in the fat intake of weanling infants. For this and other reasons, cereals with added fat above 3.3 g per 100 kcal are available in some countries of the Community. The Committee therefore did not object to allowing larger amounts of fat to be added to *cereals enriched with high protein foods* (see definition in Annex 1) so long as (a) the total fat in the product did not exceed 4.5 g per 100 kcal, and (b) the quality of the fat in the final mixture was satisfactory.

Sodium

26. Mixtures of cereals and added protein may replace milk in the weanling's diet. Milk contains more than adequate amounts of sodium and the Committee considers that the cereal mixture should not provide much more than that found in cows' milk, i.e. 80 mg per 100 kcal. This figure is rounded up to 100 mg per 100 kcal. It allows mixtures of cereals with vegetables with relatively high sodium contents, such as carrots and celery.

The Committee understands this figure also allows the traditional use of sodium bicarbonate as a raising agent. In the Committee's opinion it is unlikely that a sodium intake at this level would adversely affect the health of young children. The Committee notes, however, that raising agents not containing sodium are used by some manufacturers. The Committee also notes that many biscuits on general sale contain considerably less than 100 mg sodium per 100 kcal.

Calcium

27. Products consisting of cereals with milk should provide no less calcium than is provided by a follow-up milk, i.e. 80 mg per 100 kcal.

The Committee is unable to give any exact compositional guidelines concerning calcium in cereals with added soya protein isolate because there is insufficient knowledge about the bio-availability of calcium from food to food and from salt to salt. Nevertheless, the calcium content should be at least the same amount as in a follow-up milk, i.e. at least 80 mg per 100 kcal.

Iron

28. Scientific opinion is divided on whether the fortification of cereals with iron is useful or desirable. Since absorption of iron from cereals is uncertain, the Committee reluctantly concluded that there was insufficient knowledge on which to base a firm recommendation.

Vitamins

29. Cereals are an important source of thiamin and therefore a minimum content is prescribed equal to that found in unfortified brown wheat flour. The addition of other water soluble vitamins is possible, but no claims should be based on that fact; no minimum value shall be established for them.

30. There is no absolute justification for adding vitamins A and D to simple cereals (either alone or in a mixture with vegetables or fruits) which are to be reconstituted with milk. However it is possible to add them to these products, without it being obligatory, under the same conditions as for water soluble vitamins except thiamine. If vitamins A and D are added, they should be within the limits applying to fortified cereals.

Cereals fortified with milk or other high protein foods may replace an infant formula or follow-up milk, both of which contain added vitamins A and D. It therefore seems reasonable to impose the addition of these vitamins to such fortified cereals. The recommendations are based on the limits for follow-up milk and therefore regarded as safe. A child receiving as many as 1000 kcal from follow-up milk and vitamin fortified cereal would receive 30 µg (1200 units) of vitamin D daily.

Annex 1

Specific Recommendations on Cereals and Other Starchy Foods

(These recommendations refer to products in the ready-to-eat form, marketed as such or reconstituted as instructed by the manufacturer.)

1. Definitions

These recommendations apply to those products where the name of a cereal appears first in the name or description of a product, e.g. 'Rice and milk' – but not to 'Pears and rice'. Cereals are as botanically defined, e.g. rice, wheat, maize, oats, etc.

Reference is made to four categories:

A. The *simple cereals* – either alone or in a mixture with vegetables or fruits – which are to be reconstituted with milk;

B. The *cereals with an added high protein food*, such as milk, soya, etc., which are to be reconstituted with water. In this case, where the amount of the high protein food added, on a dry weight basis, is greater than the amount of cereals, the name of the added protein source shall appear first in the name of the product.

C. *Infant pastas*: foods prepared from milled cereal products, suitable for the weaning period, and used after cooking in boiling water or other appropriate liquids.

D. *Rusks and biscuits*: cereal-based foods for infants and young children, produced by a baking process, used either directly or, after pulverization, with the addition of water, milk or other suitable liquids. Milk biscuits consist primarily of cereals with added whole milk or milk components.

The recommendations also apply to products where the name of a root or another starchy food. (e.g. tapioca, arrowroot, buckwheat) is the food first mentioned.

2. Cereal content

In any case the amount of cereal should not be less than 25% of the final mixture on a dry weight-for-weight basis.

3. Protein *

In a product whose name implies the addition of a high protein food, e.g. 'with milk' or 'with soya':

3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein (casein as defined in Annex 2), or the PER of the protein in the mixture shall be equal to at least 70% of that of the reference protein.

* The definition of chemical index, PER, and the factors for converting nitrogen content into protein content as in *Energy and Protein Requirements* (FAO/WHO, 1973).

The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and then only in the proportions necessary for that purpose.

3.2 Total protein from all sources:

not more than 1,3g/100 kJ (5.5g/100 kcal).

3.3 Added protein:

(i) for products of category B: not less than 0.48g/100 kJ (2.0g/100 kcal).

(ii) for products of category D: not less than 0.36g/100 kJ (1.5g/100 kcal)

4. Added carbohydrates

4.1 If sucrose, fructose, honey, glucose or glucose syrups are added to products of categories A and D:

the product should not contain more than 1.8g/100 kJ (7.5g/100 kcal) of carbohydrate from these added sources and not more than 0.9g/100 kJ (3.75g/100 kcal) of added fructose.

4.2 If any of the above-mentioned carbohydrates is added to a cereal with added protein (i.e. products of category B):

the product should not contain more than 1.2g/100 kJ (5.0g/100 kcal) of carbohydrate from these sources and not more than 0.6g/100 kJ (2.5g/100 kcal) of added fructose.

The variety of added carbohydrates must be indicated on the label.

5. Fat

5.1 If fat (e.g. butter, cream, vegetable oils, etc) is added to cereals of category A and D:

the total fat in the final product should not exceed 0.8g/100 kJ (3.3g/100 kcal).

5.2 If fat is added to cereals of category B:

(i) the total fat in the final product should not exceed 1g/100 kJ (4.5g/100 kcal).

(ii) If the total fat exceeds 0.8g/100 kJ (3.3g/100 kcal):

(a) the percentage of lauric acid must not exceed 15% of the total fat

(b) the percentage of myristic acid must not exceed 15% of the total fat

(c) the content of linoleic acid (in the form of glycerides = linoleates) must not be less than 70mg/100 kJ (300mg/100 kcal) nor more than 285mg/100 kJ (1200mg/100 kcal) in the final product.

6. Sodium

No sodium salts should be added to these products except for technological purposes during manufacture. The total sodium content from all sources including the constituents, technological agents, etc. should not exceed 25mg/100 kJ (100mg/100 kcal)

7. Calcium

7.1 ***For products of category B:*** the calcium content should be not less than 20mg/100 kJ (80mg/100 kcal).

7.2 ***For products of category D:*** the calcium content should be not less than 12mg/100 kJ (50mg/100 kcal).

8. Vitamins

8.1 Water soluble vitamins:

The concentration of thiamin should not be less than 25µg/100 kJ (100µg/100 kcal) of ready-to-eat product.

8.2 Vitamins A and D:

These must be added to products of category B. They may be added to other cereal-based foods, but it is not compulsory.

	Per 100 kJ		**Per 100 kcal**	
	Min	*Max*	*Min*	*Max*
Vitamin A (RE)*	14	43	60	180
Vitamin D (µg)**	0.25	0.75	1	3

8.3 There are no compulsory minimum concentrations for the other vitamins included in Annex 4 of this report.

* RE = all trans retinol equivalent

** In the form of cholecalciferol, of which 10 µg = 400 I.U. of vitamin D

9. Claims and labelling

9.1 The following claims on the label are allowed:

'No added salt'	if no sodium salt has been added.
'No added sugar'	if no sucrose, fructose, glucose syrup, glucose or honey has been added
'Gluten free'	

9.2 In addition to the list of ingredients, the label should give the available energy value, the content of proteins, lipids, total and added carbohydrates, and values for total and added sodium of the product ready-for-use.

Annex 2

Amino acid Composition of Casein

	g per 100 of protein
Arginine	3.7
Cystine	0.3
Histidine	2.9
Isoleucine	5.4
Leucine	9.5
Lysine	8.1
Methionine	2.8
Phenylalanine	5.2
Threonine	4.7
Tryptophan	1.6
Tyrosine	5.8
Valine	6.7

(taken from the *Report of the Scientific Committee for Food* [1])

VII. Baby Foods : Conclusions and Recommendations

31. Baby foods sold in cans or jars or as a dehydrated powder vary considerably in their form and in their nutritional content because they mimic the diversified diet of an adult. Furthermore, these manufactured foods form a very variable part of the child's total diet. It is difficult therefore to give comprehensive guidelines.

In addition to the general principles regarding weaning foods, a number of specific observations have been made concerning these products, which have led to the recommendations given in Annex 3 at the end of section VII.

Definition

32. The Codex definition has been adopted by the Committee (see Annex 3, §1).

Energy density

33. It is difficult to define an energy density for baby foods since some are presented 'ready to feed' while others are in a dehydrated form requiring the addition of water. Moreover, some dishes are complete while others are vegetables only. Therefore no specific recommendation on energy density is given.

Protein

34. The exact uses of weaning foods containing meat, poultry or fish also vary considerably from one country to the other within the European Community. Some mothers use a meat only preparation as the basis of a dish, adding vegetables, etc. themselves. Others give their babies a 'complete dish' to start with, e.g. lamb and vegetables, and then a second dish or course - dessert, pudding or fruit. Yet others use a 'complete meal' from one can or jar. Clearly, a meat-only dish would be relatively high in protein, a complete dish might rely on the second course for various nutrients and energy, while a 'complete meal' would contain reasonable amounts of many nutrients, reasonably balanced.

After extensive discussions and consultations the Committee have made three recommendations concerning protein aiming to cover the three situations where the high protein foods (meat, fish, poultry and offal) are used in weaning practice as described above.

In each case a minimum amount of protein by weight as well as per unit energy has been given. Specifications by weight of individual foods is a departure from our usual practice, but the Committee considered that the consumer would reasonably expect that dishes labelled meat, fish, poultry, etc. would contain some minimum amount of these foods. The protein/energy ratio recommended for meat-only dishes (7g per 100 kcal) is above the value for a dressed beef carcass (5g per 100 kcal) but is much below that for chicken, poultry and fish (15 g per 100 kcal). However the minimum chicken content (40%) and maximum fat content (4.5 g per 100 kcal) ensure that a very dilute chicken preparation cannot be offered. For complete meals the minimum amount of animal protein (2.2 g per 100 kcal) is similar to the minimum amount of milk protein recommended in an infant formula, while the minimum amount of total protein (3 g per 100 kcal, 12% of energy) is similar to the average mixed European diet. The recommendations for the 'complete dish' are set at an intermediate value of 4 g per 100 kcal.

The Committee has no firm evidence which would lead it to prohibit the use of novel proteins (e.g. produced by micro-organisms, algae, etc.). Nevertheless, experience with them is limited and well tried natural alternatives are available. The Committee considers, therefore, that they should not be used.

Carbohydrates

35. In the section on cereals the Committee has explained its concern about simple sugars, particularly when added during the manufacture of processed foods.

Fruit juices (with or without added sugar), nectars (diluted fruit juices, usually with added sugar) and fruit-only dishes have traditionally been a part of the weanling's diet throughout Europe. Natural fruit juices contain carbohydrates at approximately 10 g per decilitre. However, the Committee is aware that natural sweetness varies from fruit to fruit and also in particular crops of the same fruit, and that this may affect palatability. The Committee's recommendation allows a moderate augmentation of the natural carbohydrate content (up to a total of 15 g per decilitre in fruits and nectars, up to 20 g per 100 g in a fruit-only dish), which should be adequate for palatability.

Many traditional desserts and puddings which will be eaten by older members of the family contain large amounts of sugar. The dry matter content of these products increases steadily from fruit juices to puddings. The latter products consist almost entirely of carbohydrates and it is difficult to distinguish analytically between those carbohydrates deriving from the fruits and those added during processing. The quantities of starch present also vary with the product. This however is not a good reason for allowing substantial quantities of added carbohydrates in baby foods. Therefore the Committee wished to limit the quantity of carbohydrates in dessert and pudding dishes to 25g/100 g.

Fat

36. Throughout Europe recommendations have been made to reduce the overall consumption of fat, particularly saturated fat. However, the infant naturally consumes foods in which fat contributes a substantial proportion of the energy (e.g. in breast milk 6 g per 100 kcal, i.e. approximately 50% of total energy content). Strict limitation of fat in the diet (e.g. down to 30% as advised for adults) is therefore inappropriate for weanlings. The Committee suggests that in most preparations no more than 40% energy should be provided by fat (i.e 4.5 g per 100 kcal). The Committee is aware that some traditional dinners, desserts and puddings eaten by older children and adults have higher fat contents (e.g. up to 9 g per 100 kcal); nevertheless, the Committee regards 4.5 g per 100 kcal as a sensible upper limit for most preparations. However, where the preparation is meat-only this limit may be too low, e.g. the fat content of many cuts of beef is about 7 g per 100 kcal. Therefore for these meat-only dishes the upper limit of fat has been set higher than 4.5 g per 100 kcal; the Committee recommends 6.0 g per 100 kcal.

The Committee has not been able to make specific recommendations concerning the fatty acid composition of baby foods. Nevertheless, manufacturers will be aware of current opinion concerning the contribution of saturated, monounsaturated and polyunsaturated fat to the diet and may be able to bear this in mind when formulating recipes for their products.

Sodium

37. The Committee's views on sodium in baby foods are similar to those made for cereals (see Annex 1, §6 for details). However, some soups have traditionally contained relatively large amounts of sodium per unit energy. An amount of sodium greater than in cereal products is therefore allowed (up to 200 mg per 100 kcal) to accommodate this food custom. In order to allow for the low energy content of some baby foods, a content of up to 200 mg per 100 g is also allowed.

Some mothers will wish to choose foods that have no added salt. This should be clearly indicated on the label. The Committee is not convinced of any compelling reason to add a sodium salt to a baby food.

Vitamin C

38. Fruit juices and nectars have traditionally been used as a vehicle for vitamin C supplementation in Europe, and this practice may have helped to eliminate almost completely infantile scurvy from Europe. Most mothers regard fruit and vegetables as a good source of vitamin C. If necessary, vitamin C should be added to these products so that the final concentration is not less than that found in many fruits (25 mg per 100 kcal, or 25 mg per 100 g). Vegetable juices may be used instead of fruit juices and the Committee therefore also recommends a minimum vitamin C content in them.

Vitamin A

39. Many vegetable juices naturally contain vitamin A precursors such as carotene, particularly tomatoes and carrots. The Committee has therefore recommended that the vitamin A content of these preparations should not be below the amount found in an average source of carotene, e.g. peas, i.e. 100 retinol equivalents per 100 kcal (1 retinol equivalent = 6 μg beta carotene). The maximum level should not be greater than twice this amount, i.e. 200 retinol equivalents per 100 kcal.

The addition of vitamins A and D should not be allowed in the other baby foods.

Annex 3

Specific Recommendations on Baby Foods

(These recommendations refer to products in the ready-to-eat form, marketed as such or reconstituted as instructed by the manufacturer.)

1. Definition

'Baby Foods' are foods intended primarily for use during the normal infant's weaning period and also for the progressive adaptation of infants and children to ordinary food. They may be either in ready-to-eat form or in dry form requiring reconstitution with water only. They do not include infant formulae, follow-up milks and cereals for infants and children.

'Baby Foods' include :

(a) complete or incomplete meals sold in cans, jars, or if dehydrated, in packets:

e.g. 'lamb and vegetable dinner', 'spinach and carrots', etc.

(b) soups

(c) desserts and puddings

(d) fruit juices, nectars and vegetable juices

This is not an exhaustive list.

2. Protein

2.1 If meat, poultry, fish or offal are the only ingredients mentioned in the name of the product, then

- the named meat, poultry, fish or offal should constitute not less than 40% by weight of the total product.
- the protein from the named source should not be less than 1.7g/100 kJ (7g /100 kcal).

2.2 If meat, poultry, fish or offal are mentioned first in the name of the product, then

- the named meat, poultry, fish or offal should constitute not less than 10% by weight of the total product.
- the protein from the named source should not be less than 1g/100kJ (4g/per 100kcal).

2.3 If the product is designated in the label as a 'complete meal' or if meat, poultry, fish or offal are present in the product but are not mentioned first in the name of the product, then:

- the named meat, poultry, fish or offal should constitute not less than 8% by weight of the total product.
- the protein from the named source should not be less than 0.5g/100 kJ (2.2 g per 100 kcal).
- the total protein in the product from all sources should not be less than 0.7 g/100 kJ (3 g per 100 kcal).

2.4 'Novel' proteins (e.g. from microorganisms or algae) should not be included in these foods.

3. Carbohydrates

The quantities of total carbohydrates present in fruit juices and nectars, fruit-only dishes, and desserts or puddings should not exceed:

- 15g/100 ml for fruit juices and nectars
- 20g/100g for fruit-only dishes
- 25g/100g for desserts and puddings

4. Fat

4.1 If meat is the only ingredient mentioned in the name of a product , then

the total fat in the product from all sources should not exceed 1.4 g/100 kJ (6 g per 100 kcal).

4.2 For all other products:

the total fat in the product from all sources should not exceed 1.1 g/100 kJ (4.5 g/100 kcal).

5. Sodium

5.1 The final sodium content in the product should be either not more than 48mg/100 kJ (200mg/100 kcal) or not more than 200 mg per 100 g.

5.2 Sodium salts may not be added to products based on fruit, nor to desserts, puddings, etc.

6. Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product should be either not less than 6mg/100 kJ (25mg/100 kcal) or not less than 25 mg per 100 g.

7 Vitamin A

In vegetable juices only, the final content of Vitamin A in the product should be not less than 25 RE/100 kJ (100 RE/100 kcal).

8. Claims and labelling

8.1 The following claims on the label are allowed:

'No added salt'	if no sodium salt has been added.
'No added sugar'	if no sucrose, fructose, glucose syrup, glucose or honey has been added
'Gluten free'	

8.2 The available energy value and the content of proteins, lipids, carbohydrates and sodium of the product ready-for-use should be given on the label.

* RE = all trans retinol equivalent

VIII. Nutritional Substances and Technological Additives: Recommendations

40. The Committee examined the list of proposed nutritional substances and technological additives from the nutritional and safety point of view. It reiterates the opinion expressed in its report on infant formulae and follow-up milks [1] that the amount of additives in foods for infants and young children should be limited as far as possible to those required for technological reasons. The Committee recognises however that weaning foods comprise a large and diversified variety of products and acknowledges that manufacturers require some choice of these substances to meet the requirements of technological production and nutritional adequacy, and to maintain the quality of nutrients and the characteristics of the food. The approved nutritional substances are given in Annex 4, and the approved technological additives in Annex 5.

41. The Committee is currently reviewing the subject of the use of enzymes and flavouring substances in foodstuffs in general.

At this stage the Committee was therefore not able to include such substances in Annex 5.

Annex 4

Approved nutritional substances

1. Vitamins

Vitamin A

Retinol
Retinyl acetate
Retinyl palmitate
beta Carotene

Vitamin D

Vitamin D_2 (= ergocalciferol)
Vitamin D_3 (= cholecalciferol)

Vitamin B1

Thiamine hydrochloride
Thiamine mononitrate

Vitamin B2

Riboflavine
Riboflavine-5'-phosphate, sodium

Niacin

Nicotinamide
Nicotinic acid

Vitamin B6

Pyridoxine hydrochloride
Pyridoxine-5-phosphate
Pyridoxine dipalmitate

Pantothenic acid

D-pantothenate, calcium
D-pantothenate, sodium
Dexpanthenol

Folate

Folic acid

Vitamin B12

Cyanocobalamine
Hydroxocobalamine

Biotin

D-biotin

Vitamin C

L-Ascorbic acid
Sodium L-ascorbate
Calcium L-ascorbate
6-Palmityl-L-ascorbic acid (ascorbyl palmitate)

Vitamin K

Phylloquinone (Phytomenadione)

Vitamin E

D-alpha tocopherol
DL-alpha tocopherol
D-alpha tocopherol acetate
DL-alpha tocopherol acetate

2. Amino acids

L-arginine)
L-cystine)
L-histidine)
L-isoleucine) and their hydrochlorides
L-leucine)
L-lysine)
L-cysteine)
L- and DL-methionine
L-phenylalanine
L-threonine
L-tryptophane
L-tyrosine
L-valine

3. Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol
L-carnitine
L-carnitine hydrochloride

4. Salts of minerals and trace elements

Calcium

Calcium carbonate
Calcium chloride
Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium oxide
Calcium hydroxide
Calcium salts of orthophosphoric acid

Magnesium

Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium oxide
Magnesium hydroxide
Magnesium salts of orthophosphoric acid
Magnesium sulphate
Magnesium lactate
Magnesium glycerophosphate

Potassium

Potassium chloride
Potassium salts of citric acid
Potassium gluconate
Potassium lactate
Potassium glycerophosphate

Iron

Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous lactate
Ferrous sulphate
Ferrous fumarate
Ferric diphosphate
Elemental iron (carbonyl + electrolytic + hydrogen-reduced)
Ferric saccharate
Sodium ferric diphosphate
Ferrous carbonate

Copper

Copper-lysine complex
Cupric carbonate
Cupric citrate

Cupric gluconate
Cupric sulphate

Zinc

Zinc acetate
Zinc chloride
Zinc citrate
Zinc lactate
Zinc sulfphate
Zinc oxide
Zinc gluconate

Manganese

Manganese carbonate
Manganese chloride
Manganese citrate
Manganese gluconate
Manganese sulphate
Manganese glycerophosphate

Iodine

Sodium iodide
Potassium iodide
Potassium iodate
Sodium iodate

Annex 5

Approved technological additives

Name		*Maximum level in the product ready for use when reconstituted as instructed by the manufacturer*
Antioxidants		
E 300	L-Ascorbic acid	30mg/100ml in fruit and vegetable based drinks, juices and baby foods.
E 301	Sodium L-ascorbate	
E 302	Calcium L-ascorbate	20mg/100g in fat containing cereal based foods
E 304	6-Palmityl -L-ascorbic acid (ascorbyl palmitate)	10mg/100g in fat containing cereals, biscuits baby foods
E306	Tocopherol-rich extract of natural origin	
E 307	Synthetic alpha-tocopherol	
E 308	Synthetic gamma-tocopherol	
E 309	Synthetic delta-tocopherol	
Acidity regulators		
E 170	Calcium carbonates	GMP (good manufacturing practice)
E 260	Acetic acid	
E 261	Potassium acetate	
262	Sodium acetate	
E 263	Calcium acetate	
E 270	Lactic acid {L-(+) isomer only}	
296	Malic acid	
E 325	Sodium lactate)	
E 326	Potassium lactate){L-(+) isomer	
E 327	Calcium lactate)only }	
E 330	Cítric acid	
E 331	Sodium citrates	
E 332	Potassium citrates	
E 333	Calcium citrates	
500	Sodium carbonates	
501	Potassium carbonates	
507	Hydrochloric acid	
524	Sodium hydroxide	
525	Potassium hydroxide	
526	Calcium hydroxide	

Name		*Maximum level in the product ready for use when reconstituted as instructed by the manufacturer*
E 339	Sodium orthophosphates	)
E 340	Potassium orthophosphates	) 150mg/100g singly or in combination
E 341	Calcium orthophosphates	) in simple cereals
E 338	Orthophosphoric acid	) 150mg/100g

Emulsifiers, stabilisers, thickeners

E 322	Lecithins	) 1g/100g in biscuits, cereal based and baby foods
E 471	Mono-and diglycerides of fatty acids	)
E 472a	Acetic acid esters of mono- and diglycerides of fatty acids	) 0,5g/100g singly or in combination ,) for biscuits, cereal based and baby foods
E 472b	Lactic acid esters of mono- and diglycerides of fatty acids	)
E 472c	Citric acid esters of mono- and diglycerides of fatty acids	)
E 400	Alginic acid	) 50mg/100 singly or in combination in
E 401	Sodium alginate	) desserts and puddings
E 402	Potassium alginate	)
E 404	Calcium alginate	)
E 410	Locust bean gum	) 1g/100g singly or in combination in
E 412	Guar gum	) all weaning foods
E 414	Acacia (gum arabic)	) 2g/100g singly or in combination in
E 415	Xanthan gum	) gluten free cereal based foods
E 440	Pectin	)
E 460a	Microcrystalline cellulose	)

Modified starches

White or yellow dextrin, Roasted or dextrinated starch	) GMP
Starch modified by acid treatment	)
Starch modified by alkali treatment	)

Name			*Maximum level in the product ready for use when reconstituted as instructed by the manufacturer*
Bleached starch		)	
Oxidized starch		)	
Monostarch phosphate		)	
Acetylated starch		)	
Acetylated distarch adipate		)	5g/100 singly or in combination
Distarch phosphate		)	
Acetylated distarch phosphate		)	
Phosphated distarch phosphate		)	
Anticaking agents			
551	Silicon dioxide	)	0,2g/100g in dry cereals
Raising agents			
503	Ammonium carbonates	)	GMP
E 330	Citric acid	)	
E 334	L(+)- Tartaric acid	)	
E 335	Sodium L(+)- tartrate	)	
E 336	Potassium L(+)- tartrate	)	Residue 0,5g/100g in biscuits and rusks
E 450ai	Disodium dihydrogen diphosphate	)	
500	Sodium carbonates	)	
501	Potassium carbonates	)	
575	Glucono-delta-lactone	)	

Additives for 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 this report may be used. In addition, the following substances are permitted:

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

- Mannitol as a diluent in preparations of vitamin B_{12} to a maximum dilution of 1:1000.

IX Hygienic standards

42. The Committee acknowledges the great need for protecting infants and young children against adverse health effects or diseases arising from inadequate hygienic standards of commercial weaning foods manufactured according to the standards outlined in this report.

The adverse health effects or diseases might arise from transmissible microbial agents or from toxicants of natural or man-made origin. Examples are Salmonella, mycotoxins (e.g. aflatoxins), heavy metals, residues of industrial and agricultural chemicals, as well as naturally occuring compounds such as nitrates.

The Committee will deal with these matters at a later stage.

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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 the 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:

(a) the first addendum to the reports of the Scientific Committee for Food (opinion expressed on 27 October 1989) concerning:

  (i) the essential requirements of infant formulae and follow-up milks based on cows' milk proteins (opinion expressed on 27 April 1983),

  (ii) the minimum requirements for soya-based infant formulae and follow-up milks (opinion expressed on 9 December 1988),

and with

(b) the first report of the Scientific Committee for Food concerning the essential requirements for weaning foods (opinions expressed on 27 October 1989 and 30 March 1990).

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