Comments on Initial Assessment Report (New proposal – S21 of the ANZFA Act) Proposal P. 242.

Foods for Special Medical Purposes (FSMPs)

This initial assessment report has been put together extremely well particularly from a health professional point of view and all avenues of implications explored. I do feel the input at stakeholder forums is very necessary. The Medicines Act, the Health Professionals Competency Insurance (HPCA) Act and discussion documents from MOH on credentialling, should be considered in conjunction with this document as there may be ramifications in that legislation which impinge on this document.

Preferred Option is 2

It allows FSMP to be considered lawful without introducing too many changes and cost implication and fulfils the objectives as set out by the ANZFA criteria.

The costs of these products are already expensive and minimal cost increases to the government need to be considered. The cost to the industry would be ultimately passed onto the consumer. The protection of public health and safety are met by adopting the "Codex Standard to be used only under medical supervision" or other wording that is as meaningful but incorporates other relevant health professionals.

This option maintains the same costs to all those involved i.e. government, industry, consumer and health professionals. In NZ the risk of new competition coming in and compromising product quality and standards is offset by health professionals i.e. dietitians deciding on hospital contracts for FSMPs and Pharmac having experts co-opted to a Foods Sub Committee who make informed decisions about products and this includes public health risk and benefits.

New products are not accepted without evidence based data to support their use.

This option allows for generic and exemption from generic prohibitions. There is likely to be an increase in FSMPs which may have nutrients added for pharmacological value. Too stringent criteria for FSMPs will prevent specific products from being used in NZ which ultimately may be detrimental to the health care of that person deemed to benefit from that product.

Option 2 infers a government responsibility which lessens public health risk. If industry is kept to comply or not (as option 3) then there is a cost to the consumer with direct costs and indirect costs to health professional with provision of product information and access to that information.

The outline as in Attachment 5 is well reviewed and in keeping with my opinions.

I cannot comment fully on what measures industry would be prepared to take. Currently NZ is a very small slice of their market and should huge increases in costs be

imposed with new legislation they may well choose to withdraw from the market place which would hugely disadvantage the consumer and health professional.

Should FSMP be regulated as a special purpose foods and why.

Primarily special purpose foods is providing legislation for these products and defining their nutritional content. It also defines their usage which protects the public from risk of misuse.

Should FSMP be required to conform to the existing standards as listed above?

Again both safety and efficacy protect industry, the consumer and health professional as criteria for their formulation are covered by legislation.

Other regulatory principles may require further examination as to implications these regulations may have on FSMPs.

The Codex definition of FSMP is appropriate for Australia and NZ. It is an international definition and if it fulfils the ANZFA criteria why adopt something else?

Products which would be encompassed by a definition of FSMP would include:

- complete enteral products which may be standard or specialised
- all specialised paediatric formulas/foods for metabolic diseases
- specialised dietary supplement formulas
- specialised foods modified to meet the needs of specific disease states.

Should '*use under medical supervision*' be a defining feature ensures that the public are aware of the safety of its use, however some of these products are recommended by dietitians as experts in the nutritional care of patients and comments from a wider audience, would be recommended, particularly as there is a plan in situ to have dietitians apply to Pharmac for FSMPs.

I feel that FSMP is a good term and by using the word medical infers to the public that its use is restricted.

Are there significant health and safety risks to the composition of FSMP. This may occur if persons are incorrectly or inadvertently recommended a product to use which may affect their underlying medical condition or a pre-existing allergy e.g a person who has an allergy to soy products is recommended to use a soy containing product to increase their energy intake or a person with end stage renal failure is recommended to use a high protein product. The consumer safety will be protected by the HPCA Act which infers that persons recommending an FSMP are appropriately qualified or credentialled to do so.

Should FSMP have compositional regulations, currently all products are designed to meet regulations set out in their country of origin and all companies are "reasonably consistent with product meeting recommendations of intake. If these guidelines are necessary then they should utilise international standards.

Nutritive substances are added to enteral product for their pharmaceutical benefit. Product is not imported to NZ until it has met the legislation imposed by the F.D.A. Again to legislate against adding nutrients would be detrimental to the patient outcome.

The definition of nutritive substances being added to FSMPs should include '*an added health benefit*' or '*improved outcome*'. This is a really difficult area to address, but it needs to be kept reasonably broad as with new discoveries, nutrient benefits a too restrictive legislation can outright their use.

There are significant health and safety risks to consumers if the consumer had ready access to product over the counter e.g. a patient with end stage renal disease choosing a high protein formula or the poorly controlled diabetic choosing a product with a high glucose content.

The paediatric patient having access to a metabolic product low in an essential amino acid when they don't need it.

Are there situations in which ANZFA should restrict the sale of FSMP and in particular those designed for very specific needs e.g. inborn errors of metabolism. These particular products are also expensive and should not be accessible to the general public and in my view should be a "Pharmacy only product". Other products which are more generic e.g. nutritional supplements could be more available to the public e.g. sold in supermarkets.

The current labelling of FSMPs is reasonably adequate and in fact includes many of the "*generic or horizontal*" labelling requirements already.

The industry is diligent already with keeping health professionals informed on product information and health professionals likewise inform the public. The industry could and already do make 'easy to read' information available for the local market. I'm sure they feel it is a good marketing tool to inform as many people as possible about their 'generic' products.

FSMPs are labelled with their specialist use. They are more expensive than the non specialised formulae and would therefore restrict use. I feel they should be labelled e.g. use only under guidance of doctor or dietitian or similar statement.

FSMPs which are for specific diseases e.g. PKU should be permitted to make reference to particular disease's states. This infers a protection for the public in preventing misuse. However if there is limited availability of these products then this issue doesn't arise. The definition of 'convincing' is acceptable however a stronger implication would be better.

Clinical Nutrition (2001) **20(Supplement 1)**: 47–59

doi:10.1054/clnu.2001.0426

European Union legislation and enteral nutrition

C. A. RUSSELL,* C. J. GREEN†

**Head of Nutrition, Nutricia Clinical Care, Trowbridge, UK, † International Nutritional Sciences Manager, Nutricia Healthcare, Zoetermeer, The Netherlands (Correspondence to: CJG, Nutricia Healthcare, PO Box 1, 2700 MA Zoetermeer, The Netherlands)*

Abstract—The Commission Directive on Dietary Foods for Special Medical Purposes (1999/21/EC), which defines and categorises the products covered, also includes guidelines on the micronutrient content and labelling requirements for enteral nutrition products. The legislation was to be implemented into national law by 1 May 2000, from which date products complying with the directive should be allowed on the market throughout the European Union. All products must comply with the directive by 1 November 2001. In order to comply with the directive, all enteral nutrition products (tube feeds, sip feeds and supplements) will need to change, even if it is only changes to the labels. This paper summarises not only the provisions and requirements of the directive but also the measures taken by Nutricia to reformulate their products to be both in line with the new legislation and with more recent scientific thinking. © 2001 Harcourt Publishers Ltd.

Key words: enteral nutrition; legislation; European Union; EC directive; micronutrients; labelling

Introduction

Until recently, there have been no comprehensive European legal guidelines for the composition and labelling of tube feeds, sip feeds and oral nutritional supplements. The Codex Alimentarius includes a standard for the labelling and claims for foods for special medical purposes (Codex STAN 180-1991) (1), but there has been no specific European legislation covering foods for special medical purposes. These products were covered in the general provision set out in the directive for foods for particular nutritional uses (PARNUTS) (89/398/EEC) that was implemented in May 1991 (2). This framework or 'horizontal' directive covers nine categories of products for special nutritional purposes, of which dietary foods for special medical purposes is one. Specific 'vertical' directives for most of these categories are already in place or are in the process of being prepared and implemented. In April 1999, the Commission Directive on Dietary Foods for Special Medical Purposes (FSMPs) (1999/21/EC)[1] was published (3). This directive defines and categorises the products covered, includes compositional guidelines for the micronutrient content of FSMPs, sets out labelling requirements for such products, and states dates of implementation of these new regulations.

[1]The directive can be found in all EU languages on the internet (http://europe.eu.int/eur-lex/nl/lif/dat/1999/nl_399L0021.html).

Definition of FSMPs: scope of the directive

FSMPs are defined in the directive as 'a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically determined nutrient requirements, whose dietary management cannot be achieved only by the modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two'. This definition is taken from the Codex Alimentarius Standard for labelling and claims for FSMPs (1).

Product categorization

FSMPs include tube feeds, drink feeds and oral nutritional supplements.[2] The directive categorises these into three groups:

Article 1.3 (a): Nutritionally complete, standard formulas

These products can be used to provide total (i.e. must be appropriate as a sole source of nutrition) or partial

[2]Specialised infant formulas, low protein products and products for inborn errors of metabolism are also included within the scope of the directive. Gluten-free products may be positioned as FSMPs but discussion regarding gluten free claims are ongoing. Low birthweight formulas are not covered by this directive.

192

nutrition. They must comply with the compositional guidelines for micronutrients set out in the directive. Examples of products[3] in this category are Nutrison Standard, Nutrison Multi Fibre, Nutrison Energy, Nutridrink/Fortisip and the Nutrini/Nutrison Paediatric range.

Article 1.3 (b): Nutritionally complete, nutrient-adapted/ disease-specific formulas

These products can be used to provide total (i.e. must be appropriate as a sole source of nutrition) or partial nutrition and are designed to meet the needs of patients with a specific disease or disorder. They must comply with the compositional guidelines for micronutrients set out in the directive, unless there are good reasons for deviation in the micronutrient composition that can be supported by generally accepted scientific data. Examples of products in this category are Nutrison Low Sodium, Nutrison MCT, Peptisorb (formerly Nutrison Pepti), Nutrison Diabetes and Stresson.

Article 1.3 (c): Nutritionally incomplete standard or nutrient-adapted disease-specific formulas

These products are not appropriate as a sole source of nutrition. They are nutritionally incomplete either because they do not contain all macronutrients or micronutrients, or because they contain all macro- and micronutrients but not in a ratio to make them appropriate for use as a sole source of nutrition. If products in this category are designed to deliver all or some micronutrients, then levels should not exceed the maximum levels set in the directive unless there are good reasons for deviation that can be supported by generally accepted scientific data. As the products in this category are not designed to be used as a sole source of nutrition, minimum levels do not apply. Examples of products in this category include Fortimel, Fortijuce/Ensini, Forticreme, Nutrical/Polycal and Protifar.

Compositional guidelines for micronutrient content of FSMPs

From a compositional point of view, the directive defines minimum and maximum levels of vitamins, minerals and trace elements, expressed on a per 100 kcal basis. Two lists are given: ranges intended for FSMPs for infants (<1 year) and ranges intended for FSMPs other than those intended for use by infants (>1 year). In the latter list, the range for calcium and vitamin D is modified for children aged 1–10 years. The ranges for infants are given in Table 1 and for all other ages in Table 2.

For infants, the minimum levels and certain maximum levels follow the provisions of the infant milk formula/follow-on formula directive (4). For persons >1 year of age, the minimum figures are based on recommendations made by the Scientific Committee for Food (SCF) (5) which in turn were based on recommendations for healthy populations. The European Population Reference Intake (PRI) for adult males was used where possible (6), and for nutrients for which a PRI or 'acceptable range of intakes' has not been proposed, the US recommended daily allowance (RDA) from 1989 for adult males was used (7). On the assumption that 2000 kcal is the average daily energy intake of these age groups, the PRIs (or RDAs) were divided by 20 to arrive at a minimum level per 100 kcal. The maximum figures in the directive are based to some extent on levels in existing FSMPs on the market and on safety data.

Labelling requirements

A number of mandatory statements must be included on the label of products (Table 3). Some of these statements must be preceded by the words 'Important Notice'. One such statement is that the product must be used under medical supervision. Whilst this may be provided with the assistance of other competent health care professionals (e.g. dietitians, nurses and pharmacists), hospital physicians and general practitioners have the overall legal responsibility for the use of clinical nutrition products. A number of other statements must be given on the label if appropriate (Table 4) and some other non-mandatory information (Table 5) may also be given if desired.

Dates of implementation of the directive

All Member States were expected to implement the directive into national law by 1 May 2000, and after that date should allow products that comply with the directive on their markets. By 1 November 2001 (30 months after publication), all FSMPs on the market must comply with the directive, and the legislation will supersede previous (national) legislation in relation to FSMPs.

In all cases, notification by the industry to the national authorities of EU countries of the intention to market an FSMP product (submission of a model of the product label) should be given.[4] This simple procedure is designed to replace the more complex process of product registration in each country within

[3]It is up to individual companies to interpret the directive with respect to their own product range. Therefore, only examples of products marketed by Nutricia are given here.

[4]Member states may choose not to impose this obligation.

Table 1 Values for minerals, trace elements and vitamins in nutritionally complete foods intended for use by infants

Micronutrient	Unit	Per 100 kJ		Per 100 kcal	
Min		Minimum	Maximum	Minimum	Maximum
Sodium	mg	5	14	20	60
Potassium	mg	15	35	60	145
Chloride	mg	12	29	50	125
Calcium	mg	12	60	50	250
Phosphorus[2]	mg	6	22	25	90
Magnesium	mg	1.2	3.6	5	15
Trace elements					
Iron	mg	0.12	0.5	0.5	2
Zinc	mg	0.12	0.6	0.5	2.4
Copper	ug	4.8	29	20	120
Manganese	mg	0.012	0.05	0.05	0.2
Fluoride	mg	—	0.05	—	0.2
Molybdenum	ug	—	2.5	—	10
Selenium	ug	0.25	0.7	1	3
Chromium	ug	—	2.5	—	10
Iodine	ug	1.2	8.4	5	35
Vitamins					
Vitamin A	ugRE	14	43	60	180
Vitamin D	ug	0.25	0.75	1	3
Vitamin E	mgαTE	0.5[2]	0.75	0.5[4]	3
Vitamin K	ug	1	5	4	20
Thiamin	mg	0.01	0.075	0.04	0.3
Riboflavin	mg	0.014	0.1	0.06	0.45
Niacin	mgNE	0.2	0.75	0.8	3
Pantothenic acid	mg	0.07	0.5	0.3	2
Vitamin B6	mg	0.009	0.075	0.035	0.3
Folic acid	ug	1	6	4	25
Vitamin B12	ug	0.025	0.12	0.1	0.5
Biotin	ug	0.4	5	1.5	20
Vitamin C	mg	1.9	6	8	25

[1]Children under the age of 12 months
[2]The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0
[3]Per gram polyunsaturated fatty acid expressed as linoleic acid but in no case less than 0.1 mg/100 available kJ
[4]Per gram polyunsaturated fatty acid expressed as linoleic acid but in no case less than 0.5 mg/100 available kcal
Source: The Commission Directive on Dietary Foods for Special Medical Purposes (1999/21/EC) (3)

Europe. In case of deviation of micronutrient levels per 100 kcal compared with the directive, a written nutritional and/or technical justification together with a label should be available.[5]

As an aid to common interpretation of the directive by member states, guidelines have been prepared by the European body representing the European dietetic food industries (Association of the food industries for particular nutritional uses of the European Union; IDACE) (8). Competent authorities in all member states and the European Commission have received a copy of these guidelines.

Implications of the directive for industry

Every company in the clinical nutrition market in Europe will have to make some changes to all of their products, even if it is just a label change. All products must comply with the legislation by 1 November 2001, and companies will need to communicate product changes to their customers to avoid unnecessary confusion.

Nutricia's approach to the directive

Almost all of our products deviated in some way from the new legislation. Therefore, there was a need to make at least minor adjustments to most products to ensure that they would be legally acceptable. However, instead of only rectifying these minor deviations, it was decided to review the micronutrient composition of all products, last revised in the early 1990s. The new directive has thus been a great opportunity to update, harmonize and rationalize the complete product range. The decision has been taken not only to bring products in line with the directive, but also to improve the micronutrient profile in line with more recent scientific thinking and findings.

Patients are frequently malnourished on admission to hospital, and it is these patients who are most at risk of deterioration during their hospital stay (9, 10). In addition, there is growing awareness that a wide variety of patients outside the hospital, living at home, in institutions or in sheltered accommodation, are also at risk of disease-related malnutrition (DRM) (9, 10). Most

[5]This is not stated in the directive, but it is our belief that the rationale should be available in case requested. In some cases, depending on the national authority in question, it may be appropriate to submit the rationale together with the label for products that deviate from the directive in order to avoid delays that may be incurred following a request from the authorities for a written rationale.

Table 2 Values for minerals, trace elements and vitamins in nutritionally complete foods other than those intended for use by infants

Micronutrient	Unit	Per 100 kJ		Per 100 kcal	
Minerals		Minimum	Maximum	Minimum	Maximum
Sodium	mg	7.2	42	30	175
Potassium	mg	19	70	80	295
Chloride	mg	7.2	42	30	175
Calcium[1]	mg	8.4/12	42/60	35/50	175/250
Phosphorus	mg	7.2	19	30	80
Magnesium	mg	1.8	6	7.5	25
Trace elements					
Iron	mg	0.12	0.5	0.5	2.0
Zinc	mg	0.12	0.36	0.5	1.5
Copper	ug	15	125	60	500
Manganese	mg	0.012	0.12	0.05	0.5
Fluoride	mg	—	0.05	—	0.2
Molybdenum	ug	0.72	4.3	3.5	18
Selenium	ug	0.6	2.5	2.5	10
Chromium	ug	0.3	3.6	1.25	15
Iodine	ug	1.55	8.4	6.5	35
Vitamins					
Vitamin A	ugRE	8.4	43	35	180
Vitamin D[3]	ug	0.12	0.65/0.75	0.5	2.5/3
Vitamin E	mgαTE	0.5[4]	0.75	0.5[5]	3
Vitamin K	ug	0.85	5	3.5	20
Thiamin	mg	0.015	0.12	0.06	0.5
Riboflavin	mg	0.02	0.12	0.08	0.5
Niacin	mgNE	0.22	0.75	0.9	3
Pantothenic acid	mg	0.035	0.35	0.15	1.5
Vitamin B6	mg	0.02	0.12	0.08	0.5
Folic acid	ug	2.5	12.5	10	50
Vitamin B12	ug	0.017	0.17	0.07	0.7
Biotin	ug	0.18	1.8	0.75	7.5
Vitamin C	mg	0.54	5.25	2.25	22

[1]Persons over the age of 12 months.
[2]Higher values denote levels for products intended for children of 1 to 10 years of age
[3]Higher values denote levels for products intended for children of 1 to 10 years of age
[4]Per gram of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ
[5]Per gram of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal.
Source: The Commission Directive on Dietary Foods for Special Medical Purposes (1999/21/EC) (3).

Table 3 Statements that must be included on the label (obligatory)

- Product must be described as Food(s) for Special Medical Purposes
- Nutritional information must be expressed per 100 g or per 100 ml of the product as sold
- Information on the origin and nature of the protein and/or protein hydrolysates contained in the product
- A statement that the product is 'For the dietary management of . . .' (the relevant disease, disorder of medical condition for which the product is intended)
- A description of the properties and/or characteristics of the product
- Instructions for the appropriate preparation, use and storage of the product after opening
- The words 'Important Notice', followed by statements that the product:
  - Must be used under medical supervision
  - Is or is not suitable as the sole source of nutrition
  - Is intended for a specific age group (if appropriate)
  - Could be a hazard to health if taken by a person without the specific disease or disorder for which the product is intended (if appropriate)

Table 4 Statements that must be included on the label if appropriate

- Osmolarity or osmolality
- Nutritional information expressed per 100 g or per 100 ml of the product ready for use in accordance with the manufacturer's instructions
- The content of components of protein, carbohydrate and fat and/or of other nutrients, the declarations of which would be necessary for the intended use of the product
- A statement concerning adequate precautions and contraindications
- A warning that the product is not for parenteral use

Table 5 Information that can be included on the label (not obligatory)

- Nutritional information expressed per serving, provided that the number of servings contained in the package is stated

attention has been paid to body weight and anthropometry as indices of DRM, but a number of studies suggest that micronutrient status is also poor in patients in hospitals, long-stay institutions and those receiving long-term enteral feeding (11–28). This is still frequently overlooked. Although this situation may be related in part to inflammation, both due to increased requirements and to the interpretation of the analyses (29), and

to malabsorption (30), poor intake also seems to be a major factor (31–34).

Furthermore, we have acknowledged the need to address recommendations from non-European countries, particularly important for those marketing units outside the immediate reach of the EC (e.g. Australia, New Zealand, South Africa). These countries tend to use US or Australian nutrient reference values, rather than European recommendations.

Table 6 Factors taken into account in the determination of a desirable daily intake of micronutrients for adult patients

- The EC directive on Dietary Foods for Special Medical Purposes (1999/21/EC) minimum and maximum levels (which supersedes the need to look at individual national recommendations for healthy populations in EU member states)
- The United States dietary reference intakes (DRI)[1]
- The Australian recommended dietary intake (RDI) values (1991)
- Potential poor status of some or all micronutrients in individuals who require nutritional support (i.e. requiring repletion as well as maintenance)
- Possible reduced bioavailability of some micronutrient sources, e.g. non-haem iron
- Possible increased requirements of some micronutrients in disease compared with dietary recommendations for healthy population groups
- Normal dietary intakes
- Safe upper levels
- Technological issues (e.g. stability)
- Taste issues (for complete drink feeds and oral supplements)
- Quality assurance issues (tolerances, overages and allowance for analytical error)

[1]At the time of preparing the Nutricia Internal Micronutrient Standard, not all revised US RDAs (2000, 2001) were available. Where necessary, the values from 1989 were used instead.

Nutricia internal micronutrient standard (NIMS)

There are many different public health recommendations for intakes of micronutrients in healthy populations, with many countries having their own set of guidelines. Often these recommendations vary quite markedly from country to country. Requirements in individuals with disease may differ from recommendations for healthy populations, either because requirements may be increased and/or because there is a need to replete an already depleted state. No recommendations based on established patient needs have been made. In order to try to overcome these difficulties, and in order to define a logical basis for application across the complete product range, we have developed an internal standard for daily micronutrient intake in adults (the so called Nutricia Internal Micronutrient Standard, or NIMS). This will be used as the basis for the micronutrient composition of all products for adults that are intended as a source of micronutrients, unless there is good reason for deviation. This standard takes into account a number of factors, including the FSMP directive (3) and dietary recommendations for healthy groups from the US and Australia (7, 35–39), as summarised in Table 6.

In addition to the micronutrients listed in the directive, the NIMS also includes some other micronutrients. Choline has always been included in Nutricia tube and sip feeds, and as there is growing recognition of the importance of choline (36, 40), it was decided to continue to include this nutrient. In addition, the opportunity has been seized to introduce a new innovation into all clinical products that are suitable as a sole source of nutrition (and some disease-specific supplements), namely the incorporation of a mixture of carotenoids from natural plant extracts. Several studies have demonstrated carotenoid deficiencies in patients receiving tube feeding (13, 16, 20, 23, 41, 42), which is unsurprising as most clinical nutrition products are devoid of carotenoids. The importance of these substances for maintaining health is gaining general acceptance as a result of demonstrated associations between intakes and status of carotenoids with decreased risk of certain chronic diseases, including macular degeneration (43), some cancers (44–46) and cardiovascular disease (37, 46, 47). With the continuing increased use of enteral tube feeds in the community (48), representing more and more long-term use of these products, this is a timely introduction. Not only will this be expected to improve the status of these nutrients in patients who require nutritional support, it will also have a positive influence on the colour of products. This is especially important for the tube feeds, which without carotenoids have often been described by customers as having a rather off-putting greyish colour. The new products will all have a yellow/beige appearance that may even aid compliance in some cases. The added advantage is that this is of course achieved without the need for any artificial colouring agents. A complete nutritional rationale for the addition of carotenoids to enteral tube and sip feeds is available (49).

As part of the process of defining the target micronutrient intake for adult patients, it was necessary to consider the typical energy intake required by the majority of patients. It is known that the SCF assumed a daily energy intake of 2000 kcal when setting minimum levels of micronutrients (5). Although this may be appropriate for normal, healthy free-living persons, a daily intake of 1500 kcal per day is more reflective of the typical intakes of patients. Surveys in long-term fed patients have shown mean intakes of 1500 kcal/day from enteral formulas (M. Elia, personal communication). Overall, mean daily intake was slightly higher than this (1750 kcal), representing a small contribution from oral intake (mean of 250 kcal per day). However, the type and nutritional content of the oral foods consumed is variable and sometimes unusual, and cannot be relied on

to provide a reasonable source of micronutrients. Most adult patients receiving long-term enteral nutrition are inactive and many are housebound (50), factors that will serve to lower energy requirements (51–53). In addition, the majority of these patients are elderly, with lower resting energy expenditure than younger individuals of the same height and weight. Some of them, particularly elderly women, have a low body-mass index and have even lower resting energy expenditure.

It was therefore decided that products that are suitable as a sole source of nutrition should be complete in micronutrients (according to the NIMS) in 1500 kcal whilst ensuring that levels per 100 kcal fell within the minimum and maximum levels defined in the directive, unless there were good reasons for deviation. However, if patients consume more than 1500 kcal/day (e.g. up to 2500 kcal/day) there is no reason to believe that the micronutrient levels provided will be in any way detrimental.

An overview of the NIMS for adults in comparison with several national dietary recommendations for healthy groups (6, 35–39, 54), other recommendations for mineral intake (55), and recognised tolerable upper intake levels for adults (6, 35–38, 54, 56–65) is given in Tables 7–10. The EC directive does not set minimum or maximum values for total daily intake. However, an arbitrary upper level of intake can be calculated by multiplying the maximum value per 100 kcal by 20, based on the knowledge that an assumption of a daily adult intake of 2000 kcal was used in setting the EC directive minimum levels (5). It would seem logical to apply this calculation to maximum levels.

Application of NIMS to FSMPs

Article 1.3 (a) products: Nutritionally complete standard tube and drink feeds

Since it is usual practice to base formula choice on the calculation of patients' energy requirements, and the EC directive gives micronutrient levels on a per 100 kcal basis, application of the NIMS to nutritionally complete standard tube and drink feeds that are suitable as a sole source of nutrition is based on *energy rather than volume*. In order to reflect the typical intake for the majority of patients, core range tube feeds are 'complete' (100% NIMS) in micronutrients in 1500 kcal, irrespective of energy density of the product.[6]

Energy-dense nutritionally complete drink feeds will contain the same micronutrient levels per 100 kcal as the energy-dense nutritionally complete tube feeds, except for some modification of the mineral profile for taste reasons. Thus they will also be complete in 1500 kcal. Nutritionally complete drink feeds with an energy density of 1.0 kcal/ml will also be complete in 1500 kcal.

Following this approach, nutritionally complete tube feeds have comparable micronutrient levels when expressed on an energy basis (except for some minor variations in mineral levels) but will differ if comparisons are made on a volume basis.

No additional increment in micronutrient levels was deemed necessary for fibre-containing formulas. Therefore fibre-containing products will have the same micronutrient profile as their fibre-free counterparts.

Article 1.3 (b) products: Nutritionally complete, nutrient adapted disease-specific tube feeds

These products will have the same profile of micronutrients as the nutritionally complete standard tube feeds (i.e. will provide 100% NIMS in 1500 kcal) unless there is a sound nutritional (or technological) reason for deviation e.g. low Na, K, and P levels for products intended for renal patients. Products with an energy density of greater than 1.0 kcal/ml will have some modification of the mineral levels for technological reasons.

Article 1.3 (c) products: Nutritionally incomplete standard or nutrient-adapted disease-specific formulas

In contrast to nutritionally complete products which can be used as a sole source of nutrition, and for which expression of micronutrients on an energy basis may be appropriate, products that fall into this category are not suitable as sole sources of nutrition. In many products in this category, and depending on their purpose, the energy content may be quite low relative to the content of other nutrients. In this case, expression of micronutrient content on an energy basis may be inappropriate. For this reason, for those supplements intended to be a significant source of micronutrients, it is more appropriate to consider micronutrient levels on a serving basis rather than on an energy basis. The principle followed for liquid oral supplements intended as a source of micronutrients is that one serving should provide 25% of the NIMS, with the exception of minerals for technological and taste reasons. This means that when expressed on a per 100 kcal basis, levels of some micronutrients for products with an energy density of 1 kcal/ml may exceed the maximum levels of the EC directive. With the same amount of micronutrients per serving, products with a higher energy density will deviate to a much lesser extent from the directive. A micronutrient level of 25% of the NIMS per serving of an oral supplement represents a reasonable contribution to micronutrient intake and is in line with recommendations by experts (66). Furthermore, an intake of three servings per day (the maximum recommended), providing 75% of NIMS, does not exceed the maximum daily amount allowed according to the EC directive, if an

[6]For complete formulas with an energy density of > 1.0 kcal/ml, some modification of the mineral levels (Na, K, Cl and Ca) was necessary for technological reasons, but the remaining micronutrients follow the same principle per 100 kcal as for lower energy density products.

Table 7 Minerals. Comparison of dietary recommendations for healthy populations (US, Australia, Europe and UK), suggested requirements for patients, minimum and maximum EC levels (multiplied by 20), recognised tolerable upper intake levels for adults and Nutricia internal micronutrient standard (NIMS) for adults

Micronutrient	Unit	US RDA/AI 1997–2001 /day (35–38)	Australian RDI 1991 /day (39)	European PRI 1993 /day (6)	UK RNI 1991 /day (54)	Suggested adult patient requirements/day (55)	EC directive minimum and maximum (1999/21/EC) /2000 kcal	UL for adults/day	NIMS for adults/day
Na	mg	n/s	**320–1150** (1–3y) **460–1730** (4–7y) **600–2300** (8–15y) **920–2300** (>16y)	575–3500*	**500** (1–3y) **700** (4–6y) **1200** (7–10y) **1600** (>11y)	1380–2300	600–3500	3500 (6,60)	1500
K	mg	n/s	**980–2730** (1–3y) **1560–3900** (4–7y) **950–5460** (>8y)	**800** (1–3y) **1100** (4–6y) **2000** (7–10y) **3100** (>11y)	**800** (1–3y) **1100** (4–6y) **2000** (7–10y) **3100** (11–14y) **3500** (>19y)	1955–3910	1600–5900	5900 (6) 17,500 (54)	2250
Cl	mg	n/s	n/s	n/s	800 (1–3y) 1100 (4–6y) 1800 (7–10y) 2500 (>11y)	2130–3550	600–3500		1875
Ca	mg	500* (1–3y) 800* (4–8y) 1300* (9–18y) 1000* (19–50y) 1200* (>51y)	**700** (1–3y) **800** (4–11y)[1] **1200** (12–15y) **1000** (>16y)	**400** (1–3y) **450** (4–6y) **550** (7–10y) **1000** (11–17y) **700** (>18y)	**350** (1–3y) **450** (4–6y) **550** (7–10y) **1000** (11–18y) **700** (>19y)	800	700/1000–3500/5000[2]	1500 (57) 2000 (61) 2500 (6, 35, 56, 58, 59)	1200
P	mg	**460** (1–3y) **500** (4–8y) **1250** (9–18y) **700** (>19y)	**500** (1–3y) **700** (4–7y) **800** (8–11y) **1200** (12–15y) **1100** (16–18y) **1000** (>19y)	**300** (1–3y) **350** (4–6y) **450** (7–10y) **775** (11–17y) **550** (<18y)	**270** (1–3y) **350** (4–6y) **450** (7–10y) **775** (11–18y) **550** (>19y)	773	600–1600	1100 (57) 2500 (60) 3000 (56) 3000 (>70y); 4000 (19–70y) (35) 4500 (54) 5000 (58)	1080
Mg	mg	**80** (1–3y) **130** (4–8y) **240** (9–13y) **410** (14–18y) **400** (19–30y) **420** (>31y)	**80** (1–3y) **110** (4–7y) **180** (8–11y) **260** (12–15y) **320** (>16y)	150–500*	**85** (1–3y) **120** (4–6y) **200** (7–10y) **280** (11–14y) **300** (>15y)	292–340	150–500	350 from extra sources (35, 61) 700 (56, 57) <3000 (60) 3000–5000 (64)	338

AI: adequate intake; RDA: recommended dietary allowance; RDI: recommended dietary intake; PRI: population reference intake; RNI: reference nutrient intake; *UL: tolerable upper intake level; NIMS: Nutricia internal micronutrient standard; y: years; n/s: not set.

Values in bold type represent RDAs, RDIs, PRIs or RNIs for males. All of these levels are set to meet the needs of nearly all (97–98%) of healthy people in a group. Values in normal type followed by an asterisk (*) are AIs or acceptable ranges of intakes. These levels are thought to cover the needs of all individuals within a group but lack of data or uncertainty in the data do not allow these levels to be given the status of RDAs

[1]900 mg for girls aged 8–11 years

[2]Higher levels are for children aged 1–10 years

Table 8 Trace elements. Comparison of dietary recommendations for healthy populations (US, Australia, Europe and UK), minimum and maximum EC levels (multiplied by 20), recognised tolerable upper intake levels for adults (UL) and Nutricia internal micronutrient standard (NIMS) for adults

Micronutrient	Unit	US RDA/AI 1997–2001 /day (35–38)	Australian RDI 1991 /day (39)	European PRI 1993 /day (6)	UK RNI 1991 /day (54)	EC directive minimum and maximum (1999/21/EC) /2000 kcal	UL for adults /day	NIMS for adults /day
Fe	mg	**7** (1–3y) **10** (4–8y) **8** (9–13y) **11** (14–18y)[1] **8** (>19y)[2]	**6–8** (1–11y) **10–13** (12–18y) **7** (>19y)[3]	**4** (1–6y) **6** (7–10y) **10** (11–14y)[4] **13** (15–17y)[5] **9** (>18y)[6]	**6.9** (1–3y) **6.1** (4–6y) **8.7** (7–10y) **11.3** (11–18y)[7] **8.7** (>18y)	10–40	20 (57) 45 (38) 60 (56, 58) 50–75 (59) 30–110 (6)	24
Zn	mg	**3** (1–3y) **5** (4–8y) **8** (9–13y) **11** (>14y)	**4.5** (1–3y) **6** (4–7y) **9** (8–11y) **12** (>12y)	**4** (1–3y) **6** (4–6y) **7** (7–10y) **9** (11–7y) **9.5** (>18y)	**5** (1–3y) **6.5** (4–6y) **7** (7–10y) **9** (11–14y) **9.5** (>15y)	10–30	30 (6, 56, 57, 61) 45 (58) 40 (38) <50 (60)	18
Cu	ug	**340** (1–3y) **440** (4–8y) **700** (9–13y) **890** (14–18y) **900** (>19y)	n/s	**400** (1–3y) **600** (4–6y) **700** (7–10y) **800** (11–14y) **1000** (15–17y) **1100** (>18y)	**400** (1–3y) **600** (4–6y) **700** (7–10y) **800** (11–14y) **1000** (15–18y) **1200** (>19y)	1200–10000	500 ug/kg (59) 9000 (56) 8000 (57) 10,000 (6, 38)	2700
Mn	mg	1.2* (1–3y) 1.5* (4–8y) 1.9* (9–13y) 2.2* (14–18y) 2.3* (>19y)	n/s	1–10*	>0.016 mg/kg *(paeds) >1.4 *(adults)	1–10	1–10 (6) 11 (38) 20 (56, 57)	4.95
F	mg	0.7* (1–3y) 1.0* (4–8y) 2* (9–13y) 3* (14–18y) 4* (>19y)	n/s	n/s	0.12 mg/kg *(0.5–6y) 0.05 mg/kg *(>6y)	0–4	10 (35, 61)	1.5
Mo	ug	**17** (1–3y) **22** (4–8y) **34** (9–13y) **43** (14–18y) **45** (>19y)	n/s	n/s	0.5–1.5 ug/kg *(1–18y) 50–400 *(>18y)	70–360	300 (56, 57) 450 (6) 600 (62) 2000 (38)	150
Se	ug	**20** (1–3y) **30** (4–8y) **40** (9–13y) **55** (>14y)	**25** (1–3y) **30** (4–7y) **50** (8–11y) **85** (>12y)	**10** (1–3y) **14** (4–6y) **25** (7–10y) **35** (11–14y) **45** (15–17y) **55** (>18y)	15 (1–3y) 20 (4–6y) 30 (7–10y) 45 (11–14y) 70 (15–18y) 75 (>19y)	50–200	200 (57, 59) 300 (58, 63) 200–400 (61) 400 (37) <450 (60) 450 (6, 54, 56) 600 (39)	85.5
Cr	ug	11 *(1–3y) 15 *(4–8y) 25 *(9–13y) 35 *(14–50y) 30 *(>51y)	n/s	n/s	0.1–1.0 ug/kg *(1–18y) >25 *(>18y)	25–300	200 (56, 57) >200 (61)	100
I	ug	**90** (1–8y) **120** (9–13y) **150** (>14y)	**70** (1–3y) **90** (4–7y) **120** (8–11y) **150** (>12y)	**70** (1–3y) **90** (4–6y) **100** (7–10y) **120** (11–14y) **130** (>15y)	**70** (1–3y) **100** (4–6y) **110** (7–10y) **130** (11–14y) **140** (>15y)	130–700	500 (61) 1000 (54,56–58) 1100 (38) 1000–2000 (6)	200

AI: adequate intake; RDA: recommended dietary allowance; RDI: recommended dietary intake; PRI: population reference intake; RNI: reference nutrient intake; *UL: tolerable upper intake level; NIMS: Nutricia internal micronutrient standard; y: years; n/s: not set.

Values in bold type represent RDAs, RDIs, PRIs or RNIs for males. All of these levels are set to meet the needs of nearly all (97–98%) of healthy people in a group. Values in normal type followed by an asterisk (*) are AIs or acceptable ranges of intakes. These levels are thought to cover the needs of all individuals within a group but lack of data or uncertainty in the data do not allow these levels to be given the status of RDAs

[1] 15 mg for females aged 14–18 years
[2] 18 mg for females aged 19–50 years
[3] 12–16 mg for females aged over 19 years
[4] 22 mg for females
[5] 21 mg for females
[6] 20 mg for pre-menopausal females; 8 mg for post-menopausal females
[7] 14.8 mg for females 11–50 years

186

Table 9 Fat soluble vitamins, carotenoids and choline. Comparison of dietary recommendations for healthy populations (US, Australia, Europe and UK), minimum and maximum EC levels (multiplied by 20), recognised tolerable upper intake levels for adults and Nutricia internal micronutrient standard for adults

Micronutrient	Unit	US RDA/AI 1997–2001 /day (35–38)	Australian RDI 1991 /day (39)	European PRI 1993 /day (6)	UK RNI 1991 /day (54)	EC directive minimum and maximum (1999/21/EC) /2000 kcal	UL for adults /day	NIMS for adults /day
Vit A	ug RE	**300** (1–3y) **400** (4–8y) **600** (9–13y) **900** (>14y)	**300** (1–3y) **350** (4–7y) **500** (8–11y) **725** (12–15y) **750** (>16y)	**400** (1–6y) **500** (7–10y) **600** (11–14y) **700** (>15y)	**400** (1–6y) **500** (7–10y) **600** (11–14y) **700** (>15y)	700–3600	200 ugRE/kg (59) 3000 (38, 57) >3000 (61) 3300 (56) 7500 (58, 60) 9000 (6)	1500, of which 270 ugRE from carotenoids[1]
Carotenoids	mg	n/s	n/s	n/s	n/s	n/s	Beta-carotene: 10 (61) 25 (56, 57)	3[2]
Vit D	ug	5* (1–50y) 10* (51–70y) 15* (>70y)	n/s	0–10*	**7** (1–3y) –(4–64y) **10** (>65y)	10–50/60[3]	20 (57) 25 (56, 59) 50 (6, 35, 58, 60, 61)	10.5
Vit E	mgα-TE	**6** (1–3y) **7** (4–8y) **11** (9–13y) **15** (>14y)	**5** (1–3y) **6** (4–7y) **8** (8–11y) **10.5** (12–15y) **11** (16–18y) **10** (>19y)	0.4 mgα-TE/g PUFA	>4*	10–60	200 (61) 100–800 (58) 540 (59) 800 (57) 900 (56) 1000 (37) <2000 (6) 2000 (60)	18.75
Vit K	ug	30* (1–3y) 55* (4–8y) 60* (9–13y) 75* (14–18y) 120* (>19y)	n/s	n/s	1 ug/kg/day*	70–400		80
Choline	mg	200* (1–3y) 250* (4–8y) 375* (9–13y) 550* (>14y)	n/s	n/s	n/s	n/s	3500 (36)	550

AI: adequate intake; RDA: recommended dietary allowance; RDI: recommended dietary intake; PRI: population reference intake; RNI: reference nutrient intake; *UL: tolerable upper intake level; NIMS: Nutricia internal micronutrient standard; y: years; n/s: not set.

Values in bold type represent RDAs, RDIs, PRIs or RNIs for males. All of these levels are set to meet the needs of nearly all (97–98%) of healthy people in a group. Values in normal type followed by an asterisk (*) are AIs or acceptable ranges of intakes. These levels are thought to cover the needs of all individuals within a group but lack of data or uncertainty in the data do not allow these levels to be given the status of RDAs

[1]Conversion factors: 6 ug beta-carotene = 1 ugRE; 12 ug other provitamin A carotenoids = 1 ugRE

[2]Mixed carotenoids from natural plant extracts

[3]Higher level is for children aged 1–10 years

185

Table 10 Water soluble vitamins. Comparison of dietary recommendations for healthy populations (US, Australia, Europe and UK), minimum and maximum EC levels (multiplied by 20), recogn[illegible] tolerable upper intake levels for adults and Nutricia internal micronutrient standard for adults

Micronutrient	Unit	US RDA/AI 1997–2001 /day (35–38)	Australian RDI 1991 /day (39)	European PRI 1993 /day (6)	UK RNI 1991 /day (54)	EC directive minimum and maximum (1999/21/EC) /2000 kcal	UL for adults /day	NIMS for adults /day
Thiamin	mg	**0.5** (1–3y) **0.6** (4–8y) **0.9** (9–13y) **1.2** (>14y)	**0.5** (1–3y) **0.7** (4–7y) **0.9** (8–11y) **1.2** (12–18y) **1.1** (19–64y) **0.9** (>64y)	0.1 mg/MJ	**0.5** (1–3y) **0.7** (4–10y) **0.9** (11–14y) **1.1** (15–18y) **1** (19–50y) **0.9** (>50y)	1.2–10	50 (57) 50–200 (61) <500 (6) 500 (58, 59) No limit (56)	2.25
Riboflavin	mg	**0.5** (1–3y) **0.6** (4–8y) **0.9** (9–13y) **1.3** (>14y)	**0.8** (1–3y) **1.1** (4–7y) **1.4** (8–11y) **1.9** (12–15y) **1.9** (16–18y) **1.7** (19–64y) **1.3** (>64y)	**0.8** (1–3y) **1** (4–6y) **1.2** (7–10y) **1.3** (11–14y) **1.6** (>15y)	**0.6** (1–3y) **0.8** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.3** (>15y)	1.6–10	200 (57) >400 (61) No limit (56)	2.4
Niacin	mg NE	**6** (1–3y) **8** (4–8y) **12** (9–13y) **16** (>14y)	**10** (1–3y) **12** (4–7y) **15** (8–11y) **20** (12–15y) **21** (16–18y) **19** (19–64y) **16** (>64y)	1.6 mg/MJ	8–12 (1–10y) 12–18 (11–18y) 12–17 (>19y)	18–60	35 [from supplements](36, 61) 200 (acid); 500 (amide) (56) 500 (acid); 1500 (amide) (57) 500 (acid) (58) 500 (60)	27
Pantothenic acid	mg	2* (1–3y) 3* (4–8y) 4* (9–13y) 5* (>14y)	—	3–12*	3–7*	3–30	No limit (56) 1000 (57) >1200 (60)	8.0
Vit B_6	mg	**0.5** (1–3y) **0.6** (4–8y) **1.0** (9–13y) **1.3** (14–50y) **1.7** (>51y)	**0.6–0.9** (1–3y) **0.8–1.3** (4–7y) **1.1–1.6** (8–11y) **1.4–2.1** (12–15y) **1.5–2.2** (16–18y) **1.3–1.9** (19–64y) **1.0–1.5** (>64y)	**0.015** mg/g protein	**0.7** (1–3y) **0.9** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.5** (15–18y) **1.4** (>19y)	1.6–10	25 (64) 50 (6,58,60) 100 (36,61) 200 (56, 57, 59)	2.55
Folic acid	ug	**150** (1–3y) **200** (4–8y) **300** (9–13y) **400** (>14y)	**100** (1–7y) **150** (8–11y) **200** (>12y)	**100** (1–3y) **130** (4–6y) **150** (7–10y) **180** (11–14y) **200** (>15y)	**70** (1–3y) **100** (4–6y) **150** (7–10y) **200** (>11y)	200–1000	400 (6) 700 (56) 1000 (36, 57–59, 61, 65)	400
Vit B_{12}	ug	**0.9** (1–3y) **1.2** (4–8y) **1.8** (9–13y) **2.4** (>14y)	**1.0** (1–3y) **1.5** (4–11y) **2.0** (>12y)	**0.7** (1–3y) **0.9** (4–6y) **1** (7–10y) **1.3** (11–14y) **1.4** (>15y)	**0.5** (1–3y) **0.8** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.5** (>15y)	1.4–14	100 (58) 200 (6,60) >1000 (59) 3000 (57) >5000 (61) No limit (56)	3.15
Biotin	ug	8* (1–3y) 12* (4–8y) 20* (9–13y) 25* (14–18y) 30* (>19y)	—	15–100*	10–200*	15–150	200 (54) 2500 (57) >10,000 (60) No limit (56)	60
Vit C	mg	**15** (1–3y) **24** (4–8y) **45** (9–13y) **75** (14–18y) **90** (>19y)	**30** (1–15y) **40** (>16y)	**25** (1–6y) **30** (7–10y) **35** (11–14y) **40** (15–17y) **45** (>18y)	**30** (1–10y) **35** (11–14y) **40** (>15y)	45–440	1000 (57, 58) 2000 (37, 56) 500–5000 (61) 10,000 (6, 59)	150

AI: adequate intake; RDA: recommended dietary allowance; RDI: recommended dietary intake; PRI: population reference intake; RNI: reference nutrient intake; *UL: tolerable upper intake level; NIMS: Nutricia internal micronutrient standard; y: years; n/s: not set

Values in bold type represent RDAs, RDIs, PRIs or RNIs for males. All of these levels are set to meet the needs of nearly all (97–98%) of healthy people in a group. Values in normal type followed by an asterisk (*) are AIs or acceptable ranges of intakes. These levels are thought to cover the needs of all individuals within a group but lack of data or uncertainty in the data do not allow these levels to be given the status of RDAs

Table 10 Water soluble vitamins. Comparison of dietary recommendations for healthy populations (US, Australia, Europe and UK), minimum and maximum EC levels (multiplied by 20), recogr``` tolerable upper intake levels for adults and Nutricia internal micronutrient standard for adults

Micronutrient	Unit	US RDA/AI 1997–2001 /day (35–38)	Australian RDI 1991 /day (39)	European PRI 1993 /day (6)	UK RNI 1991 /day (54)	EC directive minimum and maximum (1999/21/EC) /2000 kcal	UL for adults /day	NIMS for adults /day
Thiamin	mg	**0.5** (1–3y) **0.6** (4–8y) **0.9** (9–13y) **1.2** (> 14y)	**0.5** (1–3y) **0.7** (4–7y) **0.9** (8–11y) **1.2** (12–18y) **1.1** (19–64y) **0.9** (> 64y)	0.1 mg/MJ	**0.5** (1–3y) **0.7** (4–10y) **0.9** (11–14y) **1.1** (15–18y) **1** (19–50y) **0.9** (> 50y)	1.2–10	50 (57) 50–200 (61) < 500 (6) 500 (58, 59) No limit (56)	2.25
Riboflavin	mg	**0.5** (1–3y) **0.6** (4–8y) **0.9** (9–13y) **1.3** (> 14y)	**0.8** (1–3y) **1.1** (4–7y) **1.4** (8–11y) **1.9** (12–15y) **1.9** (16–18y) **1.7** (19–64y) **1.3** (> 64y)	**0.8** (1–3y) **1** (4–6y) **1.2** (7–10y) **1.3** (11–14y) **1.6** (> 15y)	**0.6** (1–3y) **0.8** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.3** (> 15y)	1.6–10	200 (57) > 400 (61) No limit (56)	2.4
Niacin	mg NE	**6** (1–3y) **8** (4–8y) **12** (9–13y) **16** (> 14y)	**10** (1–3y) **12** (4–7y) **15** (8–11y) **20** (12–15y) **21** (16–18y) **19** (19–64y) **16** (> 64y)	1.6 mg/MJ	8–12 (1–10y) 12–18 (11–18y) 12–17 (> 19y)	18–60	35 [from supplements](36, 61) 200 (acid); 500 (amide) (56) 500 (acid); 1500 (amide) (57) 500 (acid) (58) 500 (60)	27
Pantothenic acid	mg	2* (1–3y) 3* (4–8y) 4* (9–13y) 5* (> 14y)	—	3–12*	3–7*	3–30	No limit (56) 1000 (57) > 1200 (60)	8.0
Vit B_6	mg	**0.5** (1–3y) **0.6** (4–8y) **1.0** (9–13y) **1.3** (14–50y) **1.7** (> 51y)	**0.6–0.9** (1–3y) **0.8–1.3** (4–7y) **1.1–1.6** (8–11y) **1.4–2.1** (12–15y) **1.5–2.2** (16–18y) **1.3–1.9** (19–64y) **1.0–1.5** (> 64y)	**0.015** mg/g protein	**0.7** (1–3y) **0.9** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.5** (15–18y) **1.4** (> 19y)	1.6–10	25 (64) 50 (6,58,60) 100 (36,61) 200 (56, 57, 59)	2.55
Folic acid	ug	**150** (1–3y) **200** (4–8y) **300** (9–13y) **400** (> 14y)	**100** (1–7y) **150** (8–11y) **200** (> 12y)	**100** (1–3y) **130** (4–6y) **150** (7–10y) **180** (11–14y) **200** (> 15y)	**70** (1–3y) **100** (4–6y) **150** (7–10y) **200** (> 11y)	200–1000	400 (6) 700 (56) 1000 (36, 57–59, 61, 65)	400
Vit B_{12}	ug	**0.9** (1–3y) **1.2** (4–8y) **1.8** (9–13y) **2.4** (> 14y)	**1.0** (1–3y) **1.5** (4–11y) **2.0** (> 12y)	**0.7** (1–3y) **0.9** (4–6y) **1** (7–10y) **1.3** (11–14y) **1.4** (> 15y)	**0.5** (1–3y) **0.8** (4–6y) **1** (7–10y) **1.2** (11–14y) **1.5** (> 15y)	1.4–14	100 (58) 200 (6,60) > 1000 (59) 3000 (57) > 5000 (61) No limit (56)	3.15
Biotin	ug	8* (1–3y) 12* (4–8y) 20* (9–13y) 25* (14–18y) 30* (> 19y)	—	15–100*	10–200*	15–150	200 (54) 2500 (57) > 10,000 (60) No limit (56)	60
Vit C	mg	**15** (1–3y) **24** (4–8y) **45** (9–13y) **75** (14–18y) **90** (> 19y)	**30** (1–15y) **40** (> 16y)	**25** (1–6y) **30** (7–10y) **35** (11–14y) **40** (15–17y) **45** (> 18y)	**30** (1–10y) **35** (11–14y) **40** (> 15y)	45–440	1000 (57, 58) 2000 (37, 56) 500–5000 (61) 10,000 (6, 59)	150

AI: adequate intake; RDA: recommended dietary allowance; RDI: recommended dietary intake; PRI: population reference intake; RNI: reference nutrient intake; *UL: tolerable upper intake level; NIMS: Nutricia internal micronutrient standard; y: years; n/s: not set

Values in bold type represent RDAs, RDIs, PRIs or RNIs for males. All of these levels are set to meet the needs of nearly all (97–98%) of healthy people in a group. Values in normal type followed by an asterisk (*) are AIs or acceptable ranges of intakes. These levels are thought to cover the needs of all individuals within a group but lack of data or uncertainty in the data do not allow these levels to be given the status of RDAs

183

arbitrary calculation is made to determine this level (EC maximum multiplied by 20).

Paediatric products

Although the EC directive does not set separate levels for children over the age of one year (with the exception of calcium and vitamin D), it is in fact very difficult to apply one micronutrient standard across the whole age range from toddlers to the elderly. Even within the age range of 1–12 years, it is difficult to apply one micronutrient mix that will be optimal for all ages within this group, because of the changing energy and nutrient requirements with age. A review of the paediatric product range is currently underway, in order to ensure that tube and sip feeds used in paediatric patients are not only in line with the EC directive, but also best match the changing requirements across this age range.

Implications of the directive on clinical practice

In general, the directive will not have a great impact on clinical practice, although dietitians and other health care professionals should be aware of the compositional changes, and the fact that there is now a greater emphasis on micronutrient levels in relation to energy rather than volume for nutritionally complete products. Medical supervision does not necessarily mean prescribable, and protocols for the appropriate use of FSMPs should be agreed with clinicians and/or general practitioners who may then delegate the provision of advice on their use to a dietitian or other suitably qualified health care professional.

Future EC directives

A new directive that will also have an influence on FSMPs has recently been published in early 2001. This directive (67) encompasses foods covered by the directive on foodstuffs intended for particular nutritional uses (PARNUTS) (2) including FSMPs, low calorie diets, sports foods, but excluding infant formulas, follow-on formulas, processed cereal-based foods and baby foods intended for infants and young children. The draft directive lists six categories, each containing a selection of nutritional substances. The suitability for inclusion of a substance in the directive is based on safety, availability for use by humans, and organoleptic and technological properties. The categories are vitamins, minerals, amino acids, carnitine/taurine, nucleotides and choline/inositol. Some countries market products which contain nutritional substances that are not yet included in the directive, and which do not fall under one of the six categories mentioned. This directive should thus be seen as an 'open list', and does not necessarily mean that substances cannot be used if they are not included. It will be possible to request that additional nutrients are included in future revisions of the directive. This will involve submission of a dossier of information per additional nutrient for review by the Scientific Committee on Food and approval by the European Commission.

Conclusion

The publication of the Commission Directive on Dietary Foods for Special Medical Purposes (1999/21/EC) sets out, for the first time, specific European guidelines on the micronutrient composition and labelling requirements for this diverse range of products. Whilst the inclusion of both minimum and maximum levels for all micronutrients might be restrictive in some instances, the legislation provides certain safeguards towards consumer protection. The impact of the directive on the clinical nutrition industry has been significant. All companies will need to make some changes to their products, even if it is just label changes. However, the legislation provides benefits such as harmonization across Europe, reduced barriers to trade and a simple notification procedure replacing the current registration processes required by each member state before placing a product on the market.

Nutricia has taken the opportunity to thoroughly review the composition of all of its products, going beyond the directive, to reformulate them in line not only with the new guidelines but also with the latest scientific thinking.

Furthermore directives such as the Nutritional Substances directive are likely to impose additional controls on the manufacture and composition of products in the future. If patients requiring enteral feeding, particularly long-term enteral feeding, are to gain maximum benefit from the products they receive, more research is required to support the addition of other nutritional substances which may be present in the normal diet but which hitherto are not added to foods for special medical purposes.

Acknowledgements

The authors would like to thank Dr. Jaap Schrijver and Professor Marinos Elia for their valuable comments during the preparation of this manuscript.

References

1. CODEX STAN 180–1991. Codex Standard for the labelling of and claims for foods for special medical purposes. In: Foods for special dietary uses, including foods for infants and young children. Codex Alimentarius Volume 4, 2nd ed. Joint FAO/WHO Food Standards programme of the Codex Alimentarius Commission. Rome: FAO/WHO, 1994: 104–107

2. Council Directive on Foodstuffs intended for Particular Nutritional Uses 89/398/EEC OJ L 186, 30.06.89: 27
3. Commission Directive on Foods for Special Medical Purposes 1999/21/EC. OJEC L 91, 7.4.99; 42: 29–36
Commission Directive on Infant Milk Formulae and Follow on Formulae 91/321/EC as modified by directive 96/4/EC
5. Scientific Committee for Food. Opinion on Foods for Special Medical Purposes (expressed on 13 December 1996). Annex 4 to document III/5156/97
6. Scientific Committee for Food. Report of the Scientific Committee for Food of the Commission for the EEC on Nutrient and Energy Intakes for the European Community. Brussels: Commission of the European Communities, 1993
7. National Research Council, Subcommittee on the 10th Edition of the RDAs, Food and Nutrition Board, Commission on Life Sciences. Recommended Dietary Allowances. 10th Ed. Washington DC: National Academy Press, 1989
8. IDACE. Guidelines on the interpretation of the provisions of the Commission Directive (1999/21/EC) of 25 March 1999 on dietary foods for special medical purposes. Adopted by the Praesidium on 30 November 1999. IDACE, 194 Rue de Rivoli, F-75001 Paris
9. Green C J. Existence, causes and consequences of disease-related malnutrition in the hospital and the community, and clinical and financial benefits of nutritional intervention. Clin Nutr 1999; 18 (Suppl 2): 3–28
10. Green C J. The cost-effectiveness of nutritional support. In: Grimble G K, Payne-James J J, Silk D B A. (eds). Artificial nutritional support in clinical practice, 2nd ed. Greenwich Medical: London, 2001, in press
11. Hill G L, Blackett R L, Pickford I, Burkinshaw L, Young G A, Warren J V, Schorah C J, Morgan D B. Malnutrition in surgical patients. Lancet 1977; I: 689–692
12. Abad-Lacruz A, Fernandez-Banres F, Cabre E et al. The effect of total enteral tube feeding on the vitamin status of malnourished patients with inflammatory bowel disease. Int J Vitam Nutr Res 1988; 58: 428–435
13. Berner Y, Morse R, Frank O, Baker H, Shike M. Vitamin plasma levels in long-term enteral feeding patients. J Parenter Enteral Nutr 1989; 13: 525–528
14. Park R H R, Galloway A, Shenkin A, MacKenzie J F, Russell R I. Magnesium deficiency in patients on home enteral nutrition. Clin Nutr 1990; 9: 147–149
15. Brown K M, Seabrook N A. Nutritional influences on recovery and length of hospital stay in elderly women following femoral fracture. Proc Nutr Soc 1992; 51: 132A
16. Henderson C T, Trumbore L S, Mobarhan S, Benya R, Miles T P. Prolonged tube feeding in long-term care: nutritional status and clinical outcomes. J Am Coll Nutr 1992; 11: 309–325
17. McWhirter J P, Hambling C E, Pennington C R. The nutritional status of patients receiving home enteral feeding. Clin Nutr 1994; 13: 207–211
18. Palmo A, Gavassa L, Protta F, Fontanesi G. Blood micronutrients during total enteral nutrition. Clin Nutr 1994; 13: 53–54
19. Fenton J, Eves A, Kipps M, O'Donnell C C. Menu changes and their effects on the nutritional content of menus and nutritional status of elderly, hospitalised, mental health patients. J Hum Nutr Dietet 1995; 8:395–409
20. Olmedilla B, Granado F, Blanco I, Rojas-Hidalgo E. Evaluation of retinol, α-tocopherol and carotenoids in serum of men with cancer of the larynx before and after commercial enteral formula feeding. J Parenter Enteral Nutr 1996; 20: 145–149
21. Gariballa S E, Parker S G, Taub N, Castleden C M. A randomized, controlled, single-blind trial of nutritional supplementation after acute stroke. J Parenter Enteral Nutr 1998; 22: 315–319
22. Baldwin C, Shaw J, Dewit O, Elia M. Circulating concentrations of vitamins D and C in a cross-sectional group of patients on long-term tube feeding at home or in residential care. Proc Nutr Soc 1998; 57: 109A
23. Baldwin C, Shaw C J, Dewit O, Elia M. Nutrient deficiencies during home enteral feeding. Proc Nutr Soc 1998; 57: 95A
24. Murphy M C, New S A, Patel L S, Pither C A R, Creedon M H, Older M W J, Lumbers M. Biochemical indicators of nutritional status in elderly patients with a fractured neck of femur: comparison with age-matched controls. Proc Nutr Soc 1998; 57: 62A
25. Thomas M K, Lloyd-Jones D M, Thadhani R I, Shaw A C, Deraska D J, Kitch B T et al. Hypovitaminosis D in medical inpatients. New Engl J Med 1998; 338: 777–783
26. Jamieson C P, Obeid O A, Powell-Tuck J. The thiamin, riboflavin and pyridoxine status of patients on emergency admission to hospital. Clin Nutr 1999; 18: 87–91
27. Volkert D, Stehle P. Vitamin status of elderly people in Germany. In J Vitam Nutr Res 1999; 69: 154–159
28. Essama-Tjani J C, Guilland J-C, Fuchs F, Lombard M, Richard D. Changes in thiamin, riboflavin, niacin, beta-carotene, vitamins C, A, D and E status of French elderly subjects during the first year of institutionalisation. Int J Vitam Nutr Res 2000; 70: 54–64
29. McMillan D C, Sattar N, Talwar D, O'Reilly D S J, McArdle C S. Changes in micronutrient concentrations following anti-inflammatory treatment in patients with gastrointestinal cancer. Nutrition 2000; 16: 425–428
30. Feranchak A P, Sontag M K, Wagener J S et al. Prospective, long-term study of fat-soluble vitamin status in children with cystic fibrosis identified by newborn screen. J Pediatr 1999; 135: 601–610
31. Holmes S, Dickerson J W T. Food intake and quality of life in cancer patients. J Nutr Med 1991; 2: 359–368
32. Lewis B K, Hitchings H, Bale S, Harding K G. Nutritional status of elderly patients with venous ulceration of the leg – report of a pilot study. J Hum Nutr Dietet 1993; 6: 509–515
33. Klipstein-Grobusch K, Reilly J J, Potter J, Edwards C A, Roberts M A. Energy intake and expenditure in elderly patients admitted to hospital with acute illness. Br J Nutr 1995; 73: 323–334
34. Lumbers M, Murphy M C, Pither C A R, Creedon M H, Older M W J, New S A. Differences in dietary intake and food selection between hospital patients and day-centre visitors: implications for supplementation. Proc Nutr Soc 1998; 57: 56A
35. Institute of Medicine. Dietary reference intakes for calcium, phosphorus, magnesium, vitamin D and fluoride. Washington DC: National Academy Press, 1997
36. Institute of Medicine. Dietary reference intakes for thiamin, riboflavin, niacin, vitamin B6, folate, vitamin B12, pantothenic acid, biotin and choline. Washington DC: National Academy Press, 1998
37. Institute of Medicine. Dietary reference intakes for vitamin C, vitamin E, selenium and carotenoids. Washington DC: National Academy Press, 2000
38. Institute of Medicine. Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium and zinc. Washington DC: National Academy Press, 2001
39. National Health and Medical Research Council recommended dietary intakes for use in Australia. Australian Government Publishing Service, 1991
40. Zeisel S H. Choline: an essential nutrient for humans. Nutrition 2000; 16: 669–671
41. Bowen P E, Mobarhan S, Henderson C, Stacewicz-Sapuntzakis M, Friedman H, Kaiser R. Hypocarotenemia in patients fed enterally with commercial liquid diets. J Parenter Enteral Nutr 1988; 12: 484–489
42. Wust B, Stahelin H B, Seiler W O. Beta-carotene in tube feeding. Int J Vit Nutr Res 1990; 60: 19–25
43. Eye Disease Case-Control Study Group. Antioxidant status and neovascular age-related macular degeneration. Arch Opthalmol 1993; 111: 104–109
44. Hughes D A. Effects of carotenoids on human immune function. Proc Nutr Soc 1999; 58: 713–718
45. Ziegler R G, Mayne S T, Swanson C A. Nutrition and lung cancer. Cancer Causes Control 1996; 7: 157–177
46. Cooper D A, Eldridge A L, Peters J C. Dietary carotenoids and certain cancers, heart disease and age-related macular degeneration: a review of recent research. Nutr Rev 1999; 57: 201–214
47. Biesalski H K, Bohles H, Esterbauer H, Furst P, Gey F, Hundsdorfer G et al. Antioxidant vitamins in prevention. Clin Nutr 1997; 16: 151–155
48. Elia M E, Stratton R J, Holden C et al. Home artificial nutritional support: the value of the British Artificial Nutrition Survey. Clin Nutr 2001; this supplement
49. Stratton R. Rationale for the addition of carotenoids to enteral tube and sip feeds. Nutricia Healthcare, 2000, on file

50. Elia M, Russell C, Shaffer J et al. Report of the British Artificial Nutrition Survey (BANS), August 1999. Maidenhead:BAPEN, 1999
Elia M. Changing concepts of nutrient requirements in disease: implications for artificial nutritional support. Lancet 1995; 345: 1279–1284
52. Jebb S A. Energy metabolism in cancer and human immunodeficiency virus infection. Proc Nutr Soc 1997; 56: 763–775.
53. Gibney E R. Energy expenditure in disease: time to revisit? Proc Nutr Soc 2000; 59: 199–207
54. Department of Health. Dietary reference values for food energy and nutrients for the United Kingdom. HMSO, London, 1991. (Report on health and social subjects; 41)
55. McAtear C A, ed. Current perspectives on enteral nutrition in adults. Maidenhead: BAPEN, 1999. Available from BAPEN, PO BOX 922, Maidenhead, Berks SL6 4SH
56. Shrimpton D H. Essential Nutrients in Supplements. A review of the safety of vitamins and minerals provided in nutritional supplements for free sale by self-selection by consumers. Commissioned by the European Federation of Associations of Health Product Manufacturers, 1995
57. Shrimpton D H. Vitamins and minerals. A scientific evaluation of the range of safe intakes. Commissioned by the European Federation of Health Product Manufacturers Associations, 1997
58. Nordiske Näringsrekomendationer. (Dietary recommendations for Nordic countries). Nordic Council of Ministers, Denmark. Haaksbergen: De Lindeboom – Inorpublikaties, 1996
59. Voedingsraad. Nederlandse Voedingsnormen 1989: advies opgesteld door de Commissie Voedingsnormen (Dietary recommendations for The Netherlands). s'Gravenhage: Voorlichtingsbureau voor de Voeding, 1989
60. Nationale Raad voor de Voeding, Ministerie van Sociale Zaken, Volksgezondheid en Leefmilieu. Voedingsaanbevelingen voor België (Dietary recommendations for Belgium). Sint Martens Latem: G De Backer, 1996
61. DGE, ÖGE, SGE/SVE. Referenzwetre für die Nährstoffzufuhr. 1. Auflage. (Dietary recommendations for Germany, Austria and Switzerland). Frankfurt am Main: Umschau Braus GmbH, 2000
62. European Commission. Opinion of the Scientific Committee on Food on the tolerable upper intake level of molybdenum. Expressed on 19 October 2000. See website at the internet address http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html
63. European Commission. Opinion of the Scientific Committee on Food on the tolerable upper intake level of selenium. Expressed on 19 October 2000. See website at the internet address http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html
64. European Commission. Opinion of the Scientific Committee on Food on the tolerable upper intake level of vitamin B6. Expressed on 19 October 2000. See website at the internet address http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html
65. European Commission. Opinion of the Scientific Committee on Food on the tolerable upper intake level of folate. Expressed on 19 October 2000. See website at the internet address http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html
66. Silk D B A. Formulation of enteral diets. Nutrition 1999; 15: 626–632
67. Commission Directive on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. 2001/15/EC. OJEC L52, 22.2.01; 19–25