

Society for the Promotion of Nutritional Therapy

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Addition of Vitamins and Minerals to Foods and Food Supplements

A discussion paper prepared by DG III of the European Commission

Reply

from the

Society for the Promotion of Nutritional Therapy

INTRODUCTION

The Society for the Promotion of Nutritional Therapy aims to improve public understanding of the benefits of nutritional therapy. It has 2,000 direct members and more than 50,000 supporters in 12 countries, including the UK, France, Germany, Belgium, Italy, Greece, the Netherlands and Cyprus. Its members include doctors, nurses, dietitians, clinical scientists, nutritional therapists, acupuncturists, homoeopaths and other health professionals, as well as many consumers who have a special interest in this field.

Nutritional therapy is a healthcare system which recognises the role of increased nutritional needs and also of food intolerances and other environmental factors in the development of poor health. Food supplements are frequently used *in addition to* a balanced diet to meet these higher nutritional needs. Since these needs may go unrecognised by doctors and other health professionals, consumers are forced to fall back on their own resources. The society's members therefore have a special interest in the free availability of these products to the consumer.

The society's members are generally not in favour of legislation at EU level since:

- a) Since the majority of EU governments seek to restrict the consumer's rights in this area, this restrictive attitude would therefore form the basis of any federal EU legislation (or "harmonisation" as it is termed).
- b) The cost of lobbying throughout the EU for the type of legislation they would support is prohibitive.

Any curtailment of the consumer rights currently prevailing in the liberal Member States would be considered completely unacceptable.

COMMENTS ON THE DISCUSSION PAPER

1. Title and Scope

1.1 We do not consider it practical to create a directive covering both food fortification and food supplements. For example, while the ingredients may be the same, the definitions are different.

Food supplements are defined by us as follows:

a) Preparations of vitamins, minerals, amino acids, essential fatty acids, enzymes, fibre and other factors which fulfil a useful or necessary physiological function and are found in food or synthesised within the body from food. These preparations may be chemically synthesised or natural extracts.

b) Concentrated plant- or animal-source preparations such as fish oils, yeast, probiotics, spirulina, kelp, royal jelly and plant or herb extracts, used to supplement the diet with the nutrients they contain, or for their health-giving properties.

1.2 Labelling issues will also be completely different. Nutrients added to food are normally labelled as quantity per 100 g of food, whereas for food supplements the quantity of nutrient is measured per tablet, capsule or other unit of presentation.

1.3 Grouping the two types of product together is confusing and unnecessary. If food supplements are subjected to federal EU legislation at all, they should have their own directive. There are many special considerations which apply to them and not to ordinary foodstuffs. Since our members advocate the consumption of a wholefood diet wherever possible, we do not see food fortification as within our area of special interest and we will therefore be confining our comments only to food supplements.

Paragraph 8 (page 3)

“It should be absolutely clear that this paper deals with products marketed as foodstuffs.”

1.4 This is also confusing for the consumer. Food supplements are used to supplement foodstuffs by those who believe they have special needs. They do not need to be referred to as foodstuffs, although they may be governed by food legislation as far as safety and labelling issues are concerned. They are simply food supplements and should be marketed and referred to as such.

2. Need for legislation

Executive Summary (page iii)

“Following an increasing number of complaints from industry concerning obstacles to trade Member States have asked the Commission to examine the possibilities of harmonising Community legislation relating to ... food supplements containing vitamins and minerals.”

2.1 The industry is clearly keen for a “level playing field”, but consumers in the more liberal countries are extremely concerned that under the current law-making system the resulting federal EU legislation would be modelled on the highly restrictive attitude which prevails towards food supplements in most EU governments. The enactment of federal laws which would interfere with the consumer’s cultural rights in order to accede to industry’s demands for measures that will help it to sell more products is contrary to basic human rights legislation and is by definition corrupt.

2.2 Consumers in the UK, Sweden and Holland are happy with their national legislation. Many consumers in the restrictive countries want to have the same laws. Until the Commission can prove to consumers that any federal legislation would extend the current laws in these three countries throughout the EU, they do not want federal legislation.

3. Policy considerations

Paragraph 20 (page 9)

“It is the officials who decide whether there is nutritional need or not. It is not the consumer or manufacturer.”

3.1 We do not agree that the content of food supplements should be determined on the basis of theoretical figures of nutritional need calculated for the population as a whole or for sectors of the population.

Paragraph 21 (page 9)

The risk of exceeding, for some nutrients, levels which could provoke undesirable effects for the population would increase.

3.2 This may be true for fortified foods since consumers generally eat these with little regard for possibly exceeding safe intakes of certain nutrients. However, this does not apply to food supplements, which are consumed deliberately to increase the intake of certain nutrients in a controlled manner. No demonstrable problems have occurred in countries where food supplements have been freely available for decades.

Paragraph 23 (page 10)

“... many authorities insist on either prior authorisation of each product or on a notification at the time of placing the product into the market in order to enable the creation of a register of these products.”

3.4 We would have no objection to the creation of such a register.

4. Nutrients, compounds, bioavailability and purity

Paragraph 27 (page 12)

Which nutrients may be contained in food supplements?

4.1 It would be a simple matter to determine what nutrients are at present legally contained in food supplements in the EU, and to authorise them all. We would support this measure as the only one which is fair to consumers since the alternative would be to ban products that have already been approved as safe and form part of the consumer culture in one or more Member States.

Should there be total liberty for the manufacturers to decide the composition of their products? If restrictions are imposed, on what criteria should they be based?

4.2 Many governments have an advisory committee on novel foods and processes. If such a body does not exist at EU level then it could be created in order to evaluate the safety and health value of any future new ingredients proposed for use in food supplements.

It is thought unlikely that the consumer could draw any benefit from the inclusion in food supplements of vitamins and minerals which are in abundant supply in foods normally included in the daily diet.

4.3 If this was so unlikely, the consumer would also be unlikely to buy the products. Not only do consumers buy them, but they also report deriving many benefits from them. The Commission has received many letters to this effect, and, as pointed out in the discussion paper, there is now also much research to corroborate these personal accounts. Consumers should be free to buy whatever products they wish as long as the products are safe.

Paragraph 27 (page 13)

Could the Population Reference Intakes serve as a guidance on which nutrients should be contained in food supplements?

4.4 See our Para. 3.1 above.

Would it be appropriate to treat foods to which nutrients are added and food supplements in a different manner?

4.5 Foods are generally consumed with little regard for possibly exceeding safe intakes of certain nutrients. On the other hand food supplements are consumed deliberately to increase the intake of certain nutrients in a controlled manner. They should naturally be treated differently.

Paragraph 28 (page 13)

Should there be any restrictions on the use of different chemical forms in the manufacturing of food supplements?

4.6 Chemical forms which are already legally on the market in any EU country are presumed safe and should be automatically placed on an approved list. New forms which may subsequently arise could be submitted for approval to a novel substances and procedures advisory committee.

Should bioavailability be a requisite?

4.7 Yes.

Paragraph 29 (page 13)

Should a positive list or a negative list system be used to decide what chemical forms may be marketed?

4.8 A positive list system would not be acceptable unless it began by including all forms now legally sold in any Member State. Otherwise to maintain current product availability a negative list system would have to be applied.

Paragraph 30 (page 14)

Should purity criteria be set for substances included in food supplements?

4.9 We are not experts on specific purity criteria and have no comment beyond being in favour of high standards in this area.

5. Maximum and minimum limits in products

Paragraph 31 (page 14)

“Intakes above a certain level of some vitamins and minerals for a long period of time can lead to undesirable or adverse health/physiological effects.”

5.1 While this is undoubtedly true, it is almost impossible to find cases of people who have suffered adverse effects from taking food supplements. This is because the products are not currently sold at levels which pose a risk to health. The worry which authorities experience over this issue is often caused by poor communication. For instance in the UK vitamin B6 has recently created a scare because three statements were juxtaposed in a press release from the Government’s Food Advisory Committee: (a) “High doses of

vitamin B6 taken for lengthy periods can cause nerve damage”, (b) “The daily intake of vitamin B6 should not be more than 10 mg per day”, (c) “Supplements of 100 mg vitamin B6 or more are currently on sale”. The statement failed to make it clear that the high doses which have caused nerve damage are in the range of 500-3,000 mg per day, a dose considerably in excess of the level of likely intake.

Paragraph 31 (page 15)

Should maximum limits be set for all the vitamins and minerals or only for those for which high intakes could be of concern?

5.2 We are aware that the industry has researched the literature extensively, and has come up with a set of recommendations (*Shrimpton, DH 1997: Essential Nutrients in Supplements. European Federation of Associations of Health Product Manufacturers, Thames Ditton, UK*) which includes the setting of limits for vitamins and minerals which do not pose a problem at high intakes. We consider that these limits are generally responsible and adequate. For the reasons given in our paragraph 4.5 above, upper limits used in foods and in food supplements should be determined differently.

Paragraph 33 (page 16)

If maximum limits were to be set for some or all vitamins and minerals that could be used in the manufacture of food supplements, how should these maxima be set?

5.3 For nutrients known to be toxic in excess, we support a maximum level based on the known safe dose, with a safety margin appropriate for that nutrient. For nutrients with no known unsafe dose, we suggest an upper limit based on what is currently the highest dose currently available to consumers. See Appendix I for the set of values which we would support. It will be noted that we give two sets of figures: one for long-term and one for short-term use.

5.4 We do not agree with taking only a certain fraction of the level known to cause adverse health effects, since the toxicity of nutrients is not linear.

5.5 The use of the PRI (RDA) to set upper limits for food supplements is not a consumer-friendly method and is extremely unpopular. There is no real proof that the needs of 97.5% of the population are served by the PRI (RDA). Nutrition is not an exact science. Many people have testified to the health benefits they have derived from increasing their nutrient intake considerably beyond the PRI (RDA).

Paragraph 35 (page 18)

It is argued that a food supplement, bought specifically by consumers to supplement vitamin and mineral intakes from the normal diet should at least contain an appreciable amount in order to fulfil consumer expectations. If that were to be agreed what should this appreciable amount be?

5.6 This is a difficult question, since some food supplements, such as spirulina, contain very small quantities of nutrients per tablet or capsule. This should not preclude the sale of the product. It is really a labelling issue and we would, for instance, support a system whereby a nutritional claim could not be made unless the product contained a significant amount of that nutrient.

6. Labelling issues

Paragraph 38 (page 19)

Should nutrient content be declared per standard weight (100 g) as is the rule for other foods, per recommended daily portion or per tablet, capsule or drop?

6.1 Since food supplements are sold as tablets, capsules, drops, etc, it seems logical that the nutrient content should be declared per tablet etc. For ordinary foods consumers may find it most helpful to be given the nutrient content both per portion and per 100 g. For fortified foods, it would also be helpful to give the percentage of RDA for the added nutrients.

Given the specific nature of food supplements containing only vitamins and minerals, should only the vitamin and mineral content be required to be declared?

6.2 All ingredients added to the vitamin and minerals should also be declared since consumers may be sensitive to colourings, excipients etc. or wish to avoid them.

Paragraph 39 (page 20)

Is there scope for any compulsory statements or warnings to be given in the labels of food supplements? E.g. statements as to the benefits of a varied diet for vitamin and mineral intakes, the risks of excessive intakes for specific vitamins and minerals or in general, risks of exceeding the manufacturer's recommended dose, or warnings for specific groups of the population (e.g. pregnant women)?

6.3 We would be in favour of all such labelling policies.

7. Claims

Paragraph 40 (page 20)

Directive 79/112/EEC provides that claims should not mislead the consumer... Claims relating to prevention, treatment or cure of disease in the labelling, advertising and presentation of foodstuffs in general are prohibited.

7.1 We agree that manufacturers should not make misleading claims or medicinal claims about products sold as food supplements.

Appendix I

Society for the Promotion of Nutritional Therapy

Guidelines for the Safe Use of Food supplements¹

Nutrient	RDA ²	Recommended upper limit for daily short-term use (up to 3 months)	Recommended upper limit for daily long-term use (more than 3 mths)
Vitamin A (retinol)	700 mcg (2,300 iu)	7,500 iu (in pregnancy) 10,000 iu (in others)	7,500 iu
Beta carotene (synthetic forms)		15 mg	6 mg
Vitamin B1	1 mg	200 mg	100 mg
Vitamin B2	1.3 mg	200 mg	100 mg
Vitamin B3 (Nicotinic acid) (Nicotinamide)	18 mg	50 mg 100 mg	50 mg 100 mg
Vitamin B6 (Pyridoxine) (Pyridoxal)	1.5 mg	100 mg 100 mg	50 mg 100 mg
Vitamin B12	1.5 mcg	500 mcg	500 mcg
Biotin	100-200 mcg ³	500 mcg	500 mcg
Folic acid	200 mcg	800 mcg	400 mcg
Pantothenic acid	4.7 mg USA	1,000 mg	500 mg
Vitamin C	40 mg	5,000 mg	2,000 mg
Vitamin D	5 mcg (200 iu)	800 iu	400 iu
Vitamin E	10 mg USA	800 iu	400 iu
Calcium	700 mg	1,000 mg	800 mg
Magnesium	300 mg	500 mg	200 mg
Iron	15 mg	25 mg	15 mg
Zinc	9 mg	30 mg	15 mg
Copper	1.2 mg	4 mg	2 mg
Manganese	4.6 mg	10 mg	5 mg
Selenium	60 mcg	200 mcg	100 mcg
Chromium	50-200 mcg ³	200 mcg	100 mcg
Molybdenum	150-500 mcg ³	200 mcg	100 mcg

¹ On the basis of a careful analysis of the scientific literature and available knowledge and experience, it is extremely unlikely that harmful adverse reactions could occur if these supplementation levels are applied. All values are for adults and should be adjusted in proportion to body weight for children. The society's qualified nutritional therapists use a different set of guidelines which take into account the practitioner's training in safety considerations.

² Where possible the UK Reference Nutrient Intake values are used. In the absence of these, United States RDAs have been taken.

³ United States Food and Nutrition Board range of safe, adequate intake.