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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

BACKGROUND

1. The subjects of the addition of vitamins and minerals and of food supplements or diet integrators have often been at the centre of animated discussions among the authorities and representatives of consumers, industry, commerce, the scientific world and other interested parties. Back in 1991 the Commission had circulated a discussion paper on the subject which had served as the stimulus for a debate on the subject. Numerous comments had been received in favour of harmonising legislation at Community level as the best way of overcoming obstacles to intracommunity trade. However during the European Council of 1992 in Edinburgh, it was decided to restrict Community legislation to what was strictly needed, and apply where necessary, the principle of mutual recognition. As a result the development of proposals for harmonisation of legislation on the matter was shelved.

2. This decision had, inevitably, consequences at the national level. Some Member States which had waited for Community-wide rules started working again and adopted national rules on either both or one of the subjects in question. These rules were differing in few or many aspects and resulted in obstacles to intracommunity trade. The application of the principle of mutual recognition did not seem able to solve the problems here since the Member States were evoking reasons of protecting public health for not allowing the marketing of these products. As time passed the number of complaints, received by the responsible services of the European Commission, from economic operators concerning the marketing of these products in various Member States increased substantially.

3. Contacts, as part of the normal procedure of treating complaints, between the Commission, the authorities of Member States, and the economic operators which submitted the complaint and their representatives raised more and more awareness that a problem existed and that it was a substantial one. The subject was discussed at length, at a high level meeting of the heads of the responsible national and European Commission services in April 1995. The vast majority of the Member States asked the Commission to start again work on these subjects. It was specified however that at this stage the work should concern only the addition of vitamins and minerals to foods and food supplements

or diet integrators containing vitamins and minerals (for the purpose of this paper the term minerals includes also trace elements).

4. As a first step it was decided to undertake a task within the framework of Council Directive 93/5/EC on the assistance to the Commission and co-operation by the Member States in the scientific examination of questions relating to food (SCOOP). This task which was co-ordinated by the Netherlands attracted the interest and participation of the great majority of the Member States and had as objective to establish a scientific basis for the development of measures for the protection of public health in respect of the addition of vitamins, minerals and trace elements to foodstuffs. The task gathered a great amount of data concerning the different rules applicable, the differences in attitudes and policies and reviewed and presented together data on intakes of vitamins and minerals and on their safety. The report of this task, which is available to the public, has been a very useful source of information for the Commission services (Scientific considerations for the development of measures on the addition of vitamins and minerals to foodstuffs, Report of SCOOP Task 7.1.1. Working Group, to be published.).

5. The Commission services followed also with great interest discussions and developments on these subjects at the national (within and outside the EU), Community and international level. Within the Community the Commission services were involved in such discussions when the Member States, which adopted or are considering measures for adoption, notified these measures to the Commission in accordance with existing procedures. In assuring the secretariat of the Scientific Committee for Food (SCF) they were fully involved in the preparation of the report of the SCF on Energy and Nutrient Intakes for the European Community (Reports of the Scientific Committee for Food, 31st. series, 1993, Office for Official Publications of the European Communities.).

6. At the international level there was active participation in the discussions on the draft Guidelines for Vitamin and Mineral Supplements which are being considered by the Codex Committee on Nutrition and Foods for Special Dietary Uses (Codex Alimentarius Commission, Alinorm 97/26, Appendix VI) and in a Technical Consultation on Food Fortification convened by the Food and Agriculture Organisation (FAO) of the United Nations (Food fortification, Technology and quality control, Food and Nutrition Paper 60, FAO, 1996).

7. In its Green Paper on Food Law the Commission announced that it intends to initiate technical consultations as soon as possible on the need for, and possible scope of, Community legislation in respect of the addition of vitamins and minerals to foodstuffs and food supplements. Therefore as the second step the Commission Services decided to redraft and update the discussion paper of 1991 taking into account the limits imposed on the work to be done, the data collected by the SCOOP task, and other information which became available through the above mentioned activities and debates. The objective of this paper remains however the same, that is, to identify the points that need to be considered and debated prior to any possible proposals for harmonising Community legislation on the subjects in question. This paper aims further to present these points in the most objective and neutral way without at this stage deciding on any position on the issues raised. It is the comments which will be received that will enable the Commission services to prepare any necessary sensible proposals. Finally it should be pointed out that the list of the points discussed in this paper should not be considered exhaustive. Comments on other relevant points are welcomed.

8. The two subjects to be dealt with in this paper are distinct and concern different products. From the one hand foods to which vitamins and minerals have been added and from the other diet integrators or food supplements containing these same nutrients. However, they are being considered in the same discussion paper for convenience and because there is an important number of issues which are identical or present great similarities for both kinds of products. And it should be absolutely clear that this paper deals with products marketed as foodstuffs.

DEFINITIONS

9. The term diet integrator/food supplement is used here only because it has been used extensively up to now and is fairly well understood. It has appeared in legal Community texts (Council Directive 90/496/EEC on nutrition labelling,) but it has not been defined. This should not however preclude any further discussion as to the terminology to be used in relation to these products. It should be mentioned here that the initial draft Codex Guidelines (see § 6) referred to these products as "dietary supplements". It was argued successfully that the use of the term "dietary" is reserved, in the Codex Standards and in Community legislation, to foods for particular nutritional uses. The term which will be used in the draft at step 5 of the Codex procedure will be "vitamin and mineral supplements".

10. As was said in § 3 the considerations are to be limited to food supplements containing vitamins and minerals. These are generally products marketed as concentrated sources of these nutrients, alone or in combination, whose purpose is to supplement the intake of these nutrients from the normal diet. It is stressed again that only products marketed as food are considered here. During the discussions in the Council which led to the adoption of directive 89/398/EEC on foods for particular nutritional uses the Commission had stated that food supplements, in general, were considered as normal foodstuffs and would be regulated, if necessary, as such, although it cannot be excluded that some of these products, which fulfil the necessary conditions, are considered as dietetic foods and covered by the above directive.

11. The Codex Alimentarius General Principles for the addition of essential nutrients to foods include the following definitions:

Restoration means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

Standardisation means the addition of nutrients to a food in order to compensate for natural variations in nutrient level.

Fortification or enrichment means the addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting demonstrated deficiency of one or more nutrients in the population or specific population groups.

The Codex definition of fortification or enrichment is somehow restrictive in that the purpose should be that of preventing or correcting a demonstrated deficiency, a demonstrated need. However the demonstration of need today is based on a wide range of parameters and factors. The SCOOP report states that "demonstration of need can be based on clinical data, intake data and possible (future) changes of dietary habits". The FAO Consultation accepted that deficiency can be demonstrated by dietary, biochemical, functional and/or clinical data and recognised that micro-nutrients were added to foods taking into account "other considerations such as new scientific findings on the role of micro-nutrients in better health and changes in dietary patterns". For the purposes of this discussion paper therefore and unless it is necessary to use more specific terms, the more general term "addition of ..." is being used.

SCIENTIFIC, LEGISLATIVE AND POLICY CONSIDERATIONS

Scientific aspects

12. A multidisciplinary scientific world would argue that ideally a varied diet should and could, under normal circumstances, provide all the necessary nutrients for normal development and maintenance of a healthy life. However often this same scientific world raises questions as to whether for certain groups of the population "normal circumstances" are applicable. Studies show that changing lifestyles, at the individual and family level, have greatly influenced eating habits. There is less time for selection, purchase and preparation of food at home. There is less time or desire for having full meals and a consequent increase of consumption of snacks and "fast food" products. Other studies reveal that ageing or a more sedentary life result in a reduction of food intake because of reduced energy requirements. Energy reduction can also be the result of, justified or not, dieting over short or prolonged periods. Because of these and other changes in dietary habits concern is often voiced about the adequacy of intakes of vitamins and minerals.

13. In the SCOOP report data are presented on the nutrient intakes based on surveys from a number of Member States. Table A is reproduced from that report. The results suggest that there exist one or more population groups in the different countries which would seem to have intakes below nationally recommended levels for an important number of vitamins and minerals. The report notes that some nutrients are mentioned more often than others such as iron, iodine and vitamins B_2, B_6 and D. [2]However it should be stressed that the results have been based on evaluation at national level and on criteria which differ from country to country e.g. recommended nutrient intakes. The SCOOP report also notes that ideally observations on nutrient intakes should be confronted to data on nutritional status, but that such data are scarce and difficult to evaluate.

14. Over recent years we are also faced with an increasing interest in the relationship between diet and health in general and more specifically in the relationship between specific nutrients and specific diseases or conditions or habits. Considerable resources have been committed to research on the effects, and in particular the benefits to health, of

vitamins and minerals. The antioxidant (and beneficial) effect of some of them is under intense study while the reduction of risk of neural tube defects for children is associated with levels of intake of folic acid by women of child-bearing age. These are only illustrative examples of a vast area of scientific work that has been or is being carried out. This discussion paper cannot expand any further on this matter.

15. The above considerations were without doubt factors which contributed to the proliferation of the products discussed here. Manufacturers developed and marketed more and more of them. But the fact that the market grew continuously and often spectacularly denotes that the products responded to consumer demand and expectations which were formulated and influenced, among others, through public educational campaigns, manufacturers promotional activities, scientific publications and, maybe most important, the mass media. The market structure in the various Member States may however be different. Thus in one single vitamins or minerals might be dominant while in another multivitamins have a greater share of the market of food supplements. The levels of the nutrients present may vary from a fraction to multiples of the amount recommended daily. The range of foods to which vitamins and minerals are added is very big across the Community although substantial differences can be noted between Member States.

Legislation

16. The reasons for some of those differences are also due to national legislation which are to be found across the Community and the underlying attitudes of national authorities. In the most liberal legislation there are no specific limitations concerning the levels of nutrients in products, or the foods to which the nutrients can be added. There is however a legal responsibility imposed on food manufacturers to ensure that all food, including fortified food, which they sell is safe to consume. However this apparently liberal situation often involves codes of practice agreed between manufactures concerning limits and frequent and effective control of the market by the responsible authorities. Then there is legislation where there are no restrictions as to the foods to which nutrients are added but there are limits on the levels of nutrients present ranging from 1-3 times the recommended daily amounts per suggested dose of consumption, in the case of food supplements, or per specified quantity of the food to which nutrients

have been added (100g, 100ml, portion etc.). There are also national rules which although they follow this general principle they prohibit the addition of selected nutrients. Further down the range we find rules which require that all products are subject to prior authorisation. The criteria according to which these authorisations are granted are not always clearly established. In some countries submissions for products are normally granted while in others they are systematically refused.

17. Overall legislation or practices are more liberal towards food supplements, especially in Member States were attitudes are usually restrictive. Food supplements are considered as products which are different than ordinary food. It is, rightly or wrongly, felt that consumers buy them having made a conscious choice. And that provided the necessary rules (which actually differ from country to country), guaranteeing the safety of the product and proper information of the consumer, are there this choice should not be denied to the consumer. Further it is argued that the contribution of these products to the overall intake of vitamins and minerals can be more easily evaluated and monitored.

18. When it comes to the addition of vitamins and minerals to foods the considerations are different. It is necessary here to be precise with the terminology used. The addition of nutrients for the purpose of restoration and standardisation is normally acceptable to the authorities. Then there is a series of statutory additions, whether for the purpose of restoration or fortification, which have been adopted at the national level. Thus in many Member States vitamins A and D have to be added to margarine. In others thiamine, niacin, iron, calcium have to be added to flours other than wholemeal. And still in others iodine has to be added to table salt and/or to salt used in food manufacturing. Folic acid is a nutrient which currently is at the centre of ongoing discussions in some Member States concerning its compulsory addition to certain foods as a public health measure to increase its consumption. These statutory additions have been decided nationally on the basis of national, regional or even local public health considerations which would not be applicable Community wide. They are a good example of application of the principle of subsidiarity and would be rather difficult to harmonise. However relevant national legislation usually includes a mutual recognition clause which generally allows the good functioning of the Internal Market.

Policy considerations

19. In cases others than those mentioned above, attitudes begin to differ substantially. And they have developed over the years into a philosophy, a mentality about the role of the public authorities and a policy in that area. On one side we have safety as the cornerstone of policy. Nutrients can be added as long as the product marketed is safe for the consumer when used in accordance with the instructions of the manufacturer. The factors which determine safety vary and will be discussed in more detail further down in this paper but the important element is the acceptance of safety as the determining principle. An excellent record of good and safe functioning of the system, where it is practised, can be presented.

20. On the opposite side the basic principle guiding the addition of nutrients is nutritional need for the whole population or sectors of it. Safety is of course an important issue which is however considered only after a nutritional need for the addition of the nutrient(s) has been accepted. And it is the responsible authority which decides whether there is nutritional need or not. It is not the consumer or the manufacturer. In some Member States the addition of nutrients forms part of an active food and nutrition policy which involves the planning, control and monitoring of nutrient intakes. The necessary intakes should in principle be achieved through a varied diet, and where there is a need, accepted by the authorities, through compulsory addition as provided for by either Community legislation (e.g. some foods for particular nutritional uses), or national rules (e.g. addition to margarine, etc.).

21. Advocates of this approach argue that liberty to add nutrients voluntarily would lead to undesirable situations. Products with added nutrients, appropriately promoted by manufacturers, would tend to replace ordinary products in the normal diet. As a result the risk to exceed, for some nutrients, levels which could provoke undesirable effects for the population would increase. In a relevant report by the Nordic Council of Ministers (Addition of Nutrients to Food, TemaNord 1995:643) a calculation was made taking into account hypothetical situations where all products in the diet would be products marketed in any one country of the Community, to which the maximum permitted level, again in any country of the Community, would have been added. This extreme scenario situation would result in intakes that could reach for adults 1.5 to 4.5 times recommended intakes.

For children intakes would be of the same magnitude but for vitamins C and B12 they could reach 10 and 11 times recommended intakes respectively. However the SCOOP report, which refers to the above calculation, questions whether this is a realistic scenario and notes that these theoretical calculations and considerations are not supported by data on the present contribution of fortified products to intakes. Table B reproduced from the SCOOP report, admittedly based on limited data, provides an overview on the contribution of fortified products to intakes in some countries in the Community, a contribution that for some nutrients is considered to be important.

22. Another concern is voiced about the consequences for good dietary habits resulting from the increased availability of products to which nutrients have been added. It is feared that good nutritional behaviour by the population, for the development of which many Member States have devoted considerable financial and human recourses, may be upset. People may be led to choose products on the basis of added nutrient content rather than overall nutrient profile. This might affect the intake of other nutrients and in particular fibre and the macronutrients. The latter was a concern which prompted the participants to the SCOOP task to search for relevant data. A lack of such data had to be recorded. Further the addition of nutrients may confer to products an image which is misleading and confusing. This may be the case with products which do not contain naturally the added nutrients. Therefore the question is posed whether this should be allowed.

23. There are other issues which influence attitudes on these subjects. The structure and functioning of the food control services is one. Some authorities claim that the products in question, and in particular food supplements, are so many that it is impossible to control them for safety, labelling requirements, claims, etc. Others are greatly concerned that it would be very difficult to monitor the impact of food supplements and of foods to which nutrients have been added on the intake of these nutrients to the population and act swiftly, where necessary, to prevent undesirable situations developing. In fact structures and methodology for food and nutrition surveillance across the Community vary greatly. This is why 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.

24. The behaviour of manufacturers, importers and sellers of these products is also very important in the shaping of attitudes. In general their seriousness and responsible behaviour is not being called to question. However incidents which are damaging for the image of these operators have occurred. The complaints of the authorities indicate an abuse of claims as a frequent problem. Concern about the safety of substances other than vitamins and minerals included in the composition of food supplements is also often expressed. Although products containing such substances are outside the scope of this discussion paper, it must be said that problems with them have an impact on all similar products including those which concern us here. Other information indicates that the behaviour of the operators concerned may be different depending on the country, the structure and efficacy of the controlling authorities and the fines foreseen for relevant violations of the legislation.

25. At this point it would be very useful to repeat that the aim of this paper is to raise objectively the issues that need to be discussed. Without therefore deciding between safety and nutritional need as the guiding principle of policy and possible harmonising legislation in these subjects it will now go on to raise other relevant issues that have to be considered.

NUTRITIONAL NEED VS. SAFETY

SPECIFIC COMPOSITION CONSIDERATIONS

Foods to which nutrients may be added

26. When discussing the addition of nutrients to foodstuffs one of the first issues to be considered is whether there should be any restrictions or preference as to the foods to which voluntary addition of nutrients should be allowed. Of course an option would be not to have any restrictions or preferences. This is the case in a number of Member States without any apparent problem for public health. This allows manufacturers flexibility to develop different products for different national or local markets in the Community taking into account different culinary habits and consumer preferences. It allows them also freedom to respond to scientific developments or consumer changing attitudes. And, most important, it allows consumers a bigger choice. Some of the arguments for restricting the range of foods have already been mentioned earlier (see para 22). It is often argued that nutrients should not be added to foods which do not naturally contain the nutrient because this could increase the risk of excess intake of the nutrient and could confuse consumers as to the nutritional profile of the food. On the other hand such foods could be very useful vehicles for reaching big segments or vulnerable groups of the population because of their consumption patterns. Therefore there are those who would accept restrictions but would establish their preference list of foods on criteria other than natural presence or absence of the nutrient in the food.

Nutrients to be added or to be contained in food supplements and purity criteria

27. Another issue to be considered is which nutrients may be added to foods or be contained in food supplements. Should there be total liberty for the manufacturers to decide the composition of their products or should the legislator impose, a priori, some restrictions. And if such restrictions were to be, on what criteria should they be based. To begin with, foods should be safe for consumption, therefore substances with inherent toxicity should not be used in their manufacture. Undesirable effects had been associated in the past with a germanium salt. Could one be certain that total liberty would prevent such incidents in the future ? Then there are some vitamins and minerals which are in abundant supply in the foods which are normally included in the daily diet. It is thought unlikely that the consumers would draw any benefit from their addition to foods or their inclusion in food supplements, products for which they pay a certain price. But if the

product is safe should not consumers have the choice to purchase it if they so wish ? The Scientific Committee for Food in its report on energy and nutrient intakes has proposed Population Reference Intakes for some nutrients, ranges of safe and adequate intake for some others and could not make recommendations because of lack of appropriate data for few others. Similar recommendations have been made from other national or international committees. Could these recommendations serve as a guidance on this issue? Finally the question is posed whether on this issue it would be appropriate to treat foods to which nutrients are added and food suppiements in a different manner.

28. There are different chemical forms of a nutrient that can be used in the manufacturing of either food supplements or foods with added nutrients. Again the question is posed whether there should be any restrictions on the use of these different substances. Technological considerations such as physicochemical properties of each substance, colour, smell, etc. would be a natural limiting factor for the manufacturer depending on the product. Manufacturers are looking continuously to the possibilities of using different substances, appropriate to a new product or to any innovative food processing method. Naturally they would prefer to have the least possible restrictions if non at all. However, there are other concerns to be considered. It has already been mentioned that some specific substances may be associated with undesirable effects. Then there is the issue of bioavailability. The consumer would derive no benefit from a product which although it announces the presence of a nutrient does not make it available to the organism. Admittedly the bioavailability of a nutrient from different food sources does not depend only on the sources and it is a rather complex matter.

29. If any mandatory restrictions were judged to be desirable on this point the approach would need to be considered carefully. One approach would be to establish, on the basis of expert scientific advise, an approved list of substances which could be used in the manufacture of the products in question. This would offer guarantees that the substances appearing in the list would be evaluated as safe. Such a list could also ensure that the substances per se included are bioavailable in principle. It should be mentioned here that at Community level there are already positive lists of substances for nutritional purposes which can be used in the manufacture of infant formulae and follow-on formulae and in processed cereal-based foods and baby foods. A list of such substances to be used in the

manufacture of other foods for particular nutritional uses is foreseen to be adopted in the future. The SCF is currently considering this matter in view of preparing an opinion. On the other hand this approach could be considered as unnecessarily restrictive given the rather safe record of the products in question. In fact a recent report on the results of a five year project carried out on behalf of the Ministry and the Department of Health of the UK found that the overall findings on vitamins and minerals in food supplements do not point to their raising serious public health considerations. Further this approach could hamper new product development. An alternative could be to establish a "negative list" of substances. This would mean that substances which appeared on the list could not be used in the manufacture of foods. This list would also be drawn on the basis of expert scientific advice and primarily on safety considerations. It would offer greater flexibility to manufacturers for product development and innovation. The establishment of either list could be coupled to safety clauses and the necessary procedures which would allow to rapidly update it on the basis of new scientific evidence.

30. A very important related issue is the purity criteria for these substances. The great majority of manufacturers claim that vitamins and minerals used either in food supplements or in adding to foods are purchased to the standards given in recognised pharmacopoeia. Such references are also included in Codex Standards (e.g. on infant formulae). However opinions are expressed that the purity criteria for substances used in food manufacture should be even stricter than the ones applicable to substances used in making drugs which are used in the majority of cases occasionally and for a limited period of time. It should be noted here that for a number of vitamin and mineral substances which have been approved at Community level for use as food additives specific purity criteria for that purpose do exist.

Maximum limits

31. Maybe the most controversial single issue on this subject is that of maximum limits for the nutrients added to food or contained in food supplements. It is beyond doubt that 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. The SCOOP report refers to those cases in its Chapter 3. In summary, the report says that adverse effects because of excess intakes are known and documented for vitamins A, D, B_6 and a synthetic form of

vitamin K. Reference is also made to the recent results of a study where high doses of β-carotene in tablets has been shown to increase the risk of lung cancer among smokers. Undesirable effects have been described following high dose intakes of other vitamins such as vasodilatation ("flushing") with niacin and the masking of the effects of vitamin B_{12} deficiency with folate. Among minerals and trace elements the report regards selenium as carrying the highest risk given the narrow margin between recommended levels and levels at which adverse effects may occur. High iodine intakes may adversely affect a small proportion of the population (people with some thyroid disorders and people who are sensitive to iodine), while some researchers report adverse effects from a sharp increase in dietary iron in connection with the possible significance of iron as a catalyst in free-radical reactions. Table C reproduced from the SCOOP report summarises the symptoms occurring with excessive intakes of vitamins and minerals. But perhaps of most concern is the fact that excess intakes of minerals and trace elements may lead to interactions among them and with other nutrients and possibly have an adverse effect on their absorption and metabolism depending on a number of conditions and other parameters (e.g. timing of intake, composition of meals etc.).

The contribution of foods to which nutrients have been added to the intake of vitamins and minerals, as discussed in the SCOOP report has been mentioned earlier (see §21). It should also be added that there are no reports of excessive intakes in those Member States where there are no restrictions to the addition of nutrients to food other than that food should be safe for consumption. In view of the above the questions posed are whether maximum limits should be set for all the vitamins and minerals or only for those for which high intakes could be of concern and whether the same considerations and attitudes should applied to products to which nutrients are added and to food supplements.

32. It would be useful here to mention two important levels for vitamins and minerals which are at the centre of discussions when talking about limits. The first to which different names are attributed is the quantity of the nutrient ingested daily which would cover the normal physiological requirements of 97,5% of the population. Its most common name is Recommended Daily Allowance (RDA) but in its recent report on Energy and Nutrient Intakes in the EEC the Scientific Committee called this quantity

Population Reference Intake (PRI) in order to emphasise that this figure is applicable to populations rather than to individuals and that it should be used accordingly. The second is a higher level which may indicate a level of intake above which undesirable or adverse effects may be observed, or undesirable chronic doses based on some studies, which are limited in humans because of ethical considerations, but also on occasional observations of reported individual cases not being under controlled study conditions. Some scientific bodies after applying a safety factor to these undesirable doses or levels propose maximum safety limits. The different levels or doses that are being used as reference and the different safety factors that may be applied result in widely differing figures proposed for this higher level. This is illustrated in the relevant table of the SCOOP report reproduced here as table D. It should be pointed out though that these levels are not, in strict scientific terms, proper toxicological levels.

33. If maximum limits were to be set at all for some or all vitamins and minerals that could be used in the manufacture of foods the question arises as to how these maxima should be set. The choice of the basic criterion being safety or nutritional need considerations is posed again. There are those fervent believers of allowing consumers freedom to choose among products containing different levels when such levels do not pose any hazard to health. Therefore they believe that any levels should be set solely on safety considerations. It has been suggested that only a certain fraction of the level known to cause adverse health effects should be taken as the maximum level. This idea is based on the fact that some nutrients will be toxic close to their PRI, while others will exhibit no signs of toxicity way above the PRI. Some industry codes of practice would use a similar approach. This would result in allowing relatively high levels of vitamins being present in some products. Certainly there is a market for them. Users of such products forcefully proclaim their belief that they contribute to their overall well being and demand that the wide range of different products be preserved. Others however point to the fact that the nutritional needs of 97,5% of the population would be covered by a daily intake of the PRI for vitamins and minerals. They would prefer therefore that maximum limits for nutrients in the products in question, which, it should be repeated, are foodstuffs, should be based on nutritional needs. Taking into account individual variations and possible health benefits from higher intakes under study from the one hand and the risks associated with excess intakes of some nutrients and the proliferation of

products to which vitamins and minerals are added and of food supplements from the other, they would accept limits which would not exceed one or few multiples of the PRI depending on the nutrient. Again the question is posed here whether different considerations and attitudes should apply to food supplements and to foods with added nutrients on this issue. YES

34. A point that should not be forgotten in this debate, if maximum levels where to be set, is the amount of the product to which they should be related. These could be average daily portions, a standard quantify in terms of weight (100 g) or a standard quantity in terms of calories (100 kcal) for foods to which vitamins and minerals are added. Although some national rules include defined average portions to which nutrient permitted levels are related it has often been argued that average portions of different foods would be rather difficult to define across the Community where culinary habits differ greatly. It was one of the reasons that nutrition labelling was agreed to be declared per 100 g as the rule in the Community. Setting limits per amount of calories can be justified by the fact that average energy intake for the population can be estimated. But equally there are data that would permit the estimation of solid and liquid food consumption in terms of weight. It is worth noting here that the argument used in favour of declaring nutrition labelling per 100 g, namely that declaration per standard weight would facilitate comparison of products by the consumer is not applicable here. Either basis, if used, is likely to result in unfavourable situation for some products. For example, limits set per 100 g would allow the same amount of nutrient to be added in the same weight in low fat and full fat versions of the same kind of food (e.g. yoghurt) while if limits were set per 100 kcal more nutrient could be added to a similar weight or portion of the lower energy product. No matter the basis chosen it might be necessary to consider allowing for some exceptional cases. Therefore comments on this point should bring nutritionally significant cases to light referring to concrete examples. In the case of food supplements which are consumed neither by weight nor for their caloric content those arguing that limits should be set per daily dose as recommended by the manufacturer may have a case.

Minimum limits

35. A final consideration in this point of limits should be whether there may also be a case for setting a lower limit on the amounts of vitamins and minerals to be present in products. Directive 90/496/EEC on nutrition labelling of foodstuffs requires the presence of a significant amount of vitamins and minerals (about 15% of RDA as defined in the Annex of that directive in 100 g of the product) as a prerequisite for their declaration in nutrition labelling. This effectively imposes a lower limit because it would be difficult to imagine that a manufacturer would voluntarily add such nutrients without ensuring that they can be declared. Care should be taken here to assessing the results of combining the hypothetical requirements of setting limits per 100 kcal and declaring nutrition labelling per 100 gr for different products. Directive 90/496/EEC not being applicable to food supplements, there is no lower limit effectively imposed on them. But it is argued that a food supplement, bought specifically by consumers to supplement vitamin and mineral intakes from normal diet should at least contain an appreciable amount in order to fulfil consumer expectations. If that were to be agreed what this appreciable amount should be?

LABELLING ISSUES

36. The provisions of Council Directive 79/112/EEC on the labelling, advertising and presentation of foodstuffs are applicable to both products under consideration in this paper. Council Directive 90/496/EEC on nutrition labelling applies to foods to which vitamins and minerals have been added but not to food supplements. Bearing that in mind there are three labelling issues to which particular attention should be paid namely the declaration of nutrients, the need for specific statements, instructions or warnings concerning these products and claims.

37. As far as foods to which vitamins and minerals are added the rules for nutrient declaration are established in directive 90/496/EEC. A priori there is no reason for differentiating between these products and other foods. However the aim of this paper is to stimulate comments and any comments to the contrary would be given the merited consideration. In any case comments should be restricted to the need of specific rules for such products which should be different from or in addition to those applicable to other foodstuffs. Comments on the need for revision of directive 90/496/EEC in general have been requested in the Green Paper on Food Law.

38. For food supplements the rules will have to be established in specific legislation. Should they differ from those for other foodstuffs and if so to what extent? One characteristic of food supplements is that they are usually presented in the form of tablets, capsules, drops etc., containing a standard quantity of the nutrients and that a number of these tablets, capsules or drops is recommended for daily consumption; their weight is of little relevance. Should therefore their nutrient content be declared per standard weight (100g) as is the rule for other foods, per recommended daily portion or per tablet, capsule or drop? For other foods the declaration of nutrients should be given in absolute numbers and as a percentage of the RDA or PRI. Are there any reasons for departing from this approach for food supplements? For foodstuffs in general, when nutrition labelling is given, the nutrients to be declared include protein, carbohydrate and fat even if the amounts present for these nutrients are negligible or zero. However there are serious arguments advanced that, given the specific nature of food supplements containing only

vitamins and minerals, nutrition labelling should be compulsory, and that only vitamins and minerals should be mandatory to be declared.

39. General labelling rules require that clear instructions for use of products are given. Is there scope for any compulsory statements or warnings to be given in the labels of these products? As examples can be cited statements as to the benefits of having a varied diet for vitamin and mineral intakes, the risks of excessive intakes for specific vitamins and minerals or in general, risks of exceeding doses as recommended by the manufacturer, warnings for specific groups of the population (e.g. pregnant women).

40. Directive 79/112/EEC provides that claims should not mislead the consumers. Further it provides that claims relating to prevention, treatment or cure of disease in the labelling, advertising and presentation of foodstuffs in general is prohibited. There is no apparent reason that different rules should apply to the products considered here. It is known however that the practical interpretation of these general provisions on claims may differ from one Member State to the other thus creating barriers to intracommunity trade. It is pointed out here that the Green Paper on Food Law has specially invited comments on the approach which should be followed at Community level to the regulation of claims. Those comments will be considered in addition to any specific comments on this issue concerning the products covered in this paper.

PACKAGING

41. There are a number of cases each year of children suffering the effects from overdose of food supplements. The vast majority of such cases relate to the consumption by infants of iron supplements prescribed to mothers during pregnancy. The approach to the problem could be to either require child resistant closures (CRCs) to be fitted to containers of supplements with high iron contents, or to limit the total amount of elemental iron per container. Most manufacturers of children's supplements already use CRCs with the majority of these products on a voluntary basis. The labels on many of these products already contain a statement that the container should be kept out of sight and reach of children. There may be a case for the mandatory use of CRCs for those products containing high levels of nutrients. There are however high costs in producing CRCs and research has shown that CRCs have proven more difficult for the elderly to open than children. If there is a case to require the use of CRCs, it may therefore be more practicable to limit this requirement to products containing specific nutrients (e.g. iron, fat soluble vitamins).

PLACING OF PRODUCTS IN THE MARKET

42. Once rules on the products in question have been adopted, products in conformity with these rules will have access to the Community market. Practices of prior authorisation currently existing in some Member States will therefore disappear. However, given the nature of these products, some would consider it desirable to maintain a procedure of notification. This, it is argued, would enable authorities to better control these products and would provide a basis for monitoring the effects of such products to nutrient status of the population. Such a procedure would be burdensome, both for manufacturers and authorities, and any possible benefits should therefore be carefully considered.

REQUEST FOR COMMENTS

43. This discussion paper has attempted to identify and present the most important issues which need to be considered relating to the regulation at Community level of the addition of vitamins and minerals to foods and of food supplements containing vitamins and minerals. Clear, concise and where applicable substantiated comments are invited on the specific issues raised. Comments on other important and relevant issues will be welcome.

Comments should be addressed before 30 September 1997 to:

European Commission
Directorate General for Industry
(Discussion Paper on Vitamins and Minerals)
200 rue de la Loi (RP 11 3/1)
B-1049 Brussels

TABLE A

Table 2.1 Overview of intake of vitamins, minerals and trace elements below recommendations in population groups in European countries as evaluated according to national standards[b].

	Austria	Denmark	Finland	France	Germany	Ireland	Netherlands	Norway	Portugal	Spain	Sweden	UK
vitamin A (as retinol equivalents)							pregnant women, all population groups			elderly, m+f	elderly, m+f	
vitamin D[a]	6-18 y, m + f	15-80 y, m + f	25-64 y, f		15-18 y, m	elderly (status)	elderly (status)	13 y, m+f 18 y, f		elderly, m+f	elderly, m+f	
vitamin E												
thiamin (vitamin B-1)				subgroups >60 y	girls and young women		pregnant women		elderly, f			
	adult women elderly				girls and young women		pregnant women, elderly men		elderly, f			
vitamin B-6	6-18 y, m + f	15-80 y, m + f		subgroups > 14 y	all population groups, except men aged 19-65 y		pregnant women, all other population groups		elderly, m+f			
vitamin B-12					girls and young women							
vitamin C							pregnant women, smokers, growing children					
folic acid	6-18 y, m + f adults, m + f elderly				all population groups		women in child-bearing age			elderly, m+f	women	women in child-bearing age
Calcium	6-18 y, m + f adult women			subgroups > 14 y	several population groups	teenage females			elderly, f	girls, 11 years		women, 16-50
Zinc	6-18 y, m + f		25/64 y, f						elderly, m+f			

[a] It should be noted that the adequacy of vitamin D supply has to be evaluated by status parameters because of the contribution of sunlight to vitamin D status.
[b] Note that the data refer to studies, widely divergent in population groups studied, number of participants, food consumption methods and evaluation criteria. Use of fortified foods included.

EXECUTIVE SUMMARY

Following an increasing number of complaints from economic operators concerning obstacles to trade Member States have asked the Commission to examine the possibilities of harmonising Community legislation relating to the addition of vitamins and minerals to foodstuffs and to food supplements containing vitamins and minerals. A task within the framework of Scientific Co-operation on questions relating to food, aiming to establish a scientific basis for the development of measures for the protection of public health in respect of the addition of vitamins and minerals, has been completed. The Commission in its Green Paper on Food Law announced its intentions to initiate technical consultations on this specific subject.

This discussion paper launches this consultation It presents the points that need to be considered and debated prior to any possible proposals for harmonisation. It invites comments in particular on the following issues :

- terminology/definitions to be used
- the choice of the principles that should guide the addition of vitamins and minerals to foods and the availability of food supplements
- restrictions or preferences, if any, as to the foods to which voluntary addition of vitamins and minerals should be allowed
- restrictions or preferences, if any, as to the vitamins and minerals and their different chemical forms which may be added to foods or be present in food supplements.
- the setting of maximum limits for added nutrients and for nutrients present in food supplements, whether for all nutrients or for selected ones
- if they were to be set, how these maximum limits should be determined
- to what amount of the product should any such limits be related
- the setting of lower limits
- the necessity for specific rules concerning nutrition labelling, particular statements, instructions or warnings and claims
- the necessity for specific rules concerning packaging of food supplements
- the necessity of special procedures for placing products in the market

Where necessary or applicable comments on the above issues should clearly indicate whether they apply to foods to which vitamins and minerals have been added or to food supplements or to both.

Table 2.1 cont. Overview of intake of vitamins, minerals and trace elements below recommendations in population groups in European countries as evaluated according to national standards.

	Austria	Denmark	Finland	France	Germany	Ireland	Netherlands	Norway	Portugal	Spain	Sweden	UK
Iron	6-18 y, m + f	Premeno-pausal wo-men		women 14-30 y	girls and young women	12-60 y, f	1-3 y/13-18 y, m 1-3 y/10-49 y, f	13 y, m+f 18 y, f	elderly, f	elderly, f + m	fertile women	women, 16-50 ye-ars
Iodine	6-18 y, m + f	15-80 y, m + f		18-65 y, f	all population groups		women			school children		
Magnesium				adults > 65 y	girls and young women					elderly, m+f	adults, m + f	women
Selenium											generally low inta-kes	

TABLE B

Table 3.5 Proportional contribution of fortified products to micronutrient intake.

Austria	no data available	
Belgium	no data available	
Denmark	vitamin A 11 - 12% from margarine	
Finland	iodine 20 - 32% from salt	
	vitamin A 18 - 30% from margarine	
	vitamin D 11 - 47% from margarine (% of total dietary vitamin D)	
France*		
Germany no data available		
Ireland	no data available	
Italy	no data available	
Netherlands	iodine from baker's salt in bread 40%	
	vitamin A from margarine 25%	
	vitamin D from margarine 60-70% (% of total dietary vitamin D)	
Norway	vitamin A from margarine 15%	
	vitamin D from margarine 48% (% of total dietary vitamin D; intake from cod liver oil not included)	
	iron from whey cheeses 9%	
Portugal	no data available	
Spain	iodine 20 % from salt	
Sweden	vitamin A 33%	niacin 11%
	vitamin D 75%	vitamin B-6 15%
	thiamin 25%	vitamin C ca. 10 %
	riboflavin 7%	iodine probably > 50%
UK	vitamin A 14%	vitamin B-6 11%
	vitamin D 59%	folate 12%
	thiamin 28%	vitamin B-12 4%
	riboflavin 11%	iron 16%
	niacin 13%	calcium 15%

* 29% of French households consume fortified, mostly restored, foods.

TABLE C

Table 3.1. Vitamins, minerals and trace elements: symptoms of excessive intake.

Nutrient	Symptoms of excessive intake
vitamin A	liver damage; eye and skin disorders; loss of appetite; bone disorders; teratogenic effects
ß-carotene	reversible yellowing of subcutaneous fat; possible other risks still under evaluation
vitamin D	hypercalcaemia; kidney damage
vitamin E	no known effects
thiamin	no known effects (reports of anaphylactic shock after parenteral administration)
riboflavin	no known effects
vitamin B-6	peripheral neuropathy; ataxia
niacin	vasodilatation; pigmentation; liver damage
folate	neurotoxic (in epilepsy patients); mental changes, sleep disturbances, gastrointestinal symptoms; - nephrotoxic effect known in rats; masking of vit. B-12 deficiency
vitamin B-12	no known effects
vitamin C	oxaluria; uricosuria (esp. in renal insufficiency); adv. effect on copper absorption; increased metal toxicity
pantothenic acid	no known effects
biotin	no known effects
iron	gastrointestinal damage; liver necrosis; mainly relevant for genetic disorders; formation of free radicals
calcium	hypercalcaemia; urinary tract stones (in predisposed persons)
phosphorus	hypocalcaemia; diarrhoea
selenium	neurological disorders; hair loss; paralysis; nail and skin disorders
copper	haemolysis; diarrhea
zinc	copper deficiency induction
iodine	thyrotoxicosis
magnesium	diarrhoea; neurological disorders

Table 3.2 Vitamins: maximum daily intake level according to national and EU expert groups and EU population reference intake.

Nutrient	SCF population reference intake for men aged 18+	SCF maximum level, EU (Reports of the SCF, 1993)	Maximum level in the Netherlands (NFNC, 1992)	Maximum level in the UK (Report, 1991)	DGE maximum level, Germany, 1991	France, (CSHPF, 1995)	Nordic countries (preliminary)
Type of maximum		maximum safe level or level above which adverse effects possibly occur	maximum safe level	undesirable doses (chronic dose per day)	maximum safe level or level above which adverse effects possibly occur	maximum safe level	
vitamin A (as retinol,RE)[2]	700 /day	9000 male 7500 female	200 RE/kg body weight. Pregnant women: 3000-7500 RE/day Children: up to 750 RE/kg body weight	6000 RE	2000-3000 RE (infants) > 15000 RE (adults) > 6000 RE (pregnant women)	1000	7500
ß-carotene	no recommendation		-				-
vitamin D	0-10 µg/day[3]	250-1250 µg	25 µg	50 µg	25 µg (infants) 500 µg (adults)	25 µg	50 µg
vitamin E (α-TE)[4]	0.4 x (g pufa) α-TE min. 4 α-TE /day	2000 α-TE	540 α-TE	-	200 α-TE	40 α-TE	-
thiamin	1.1 mg/day		500 mg				500 mg
riboflavin	1.6 mg/day		-				-
vitamin B-6	1.5 mg/day	> 50 mg possibly	500 mg	100 mg	500 mg	5 mg	-

[1] daily intake should be no more than one tenth of the undesirable dose
[2] 1 RE(retinol equivalent)= 3 IU vitamin A =1 µg vitamin A = 6 µg ß-carotene
[3] acceptable range
[4] α-TE = alpha-tocopherol equivalents; 1 mg α-TE = 1 mg RRR-α-tocopherol = 1.49 IU vitamin E

TABLE D cont.

Table 3.2 cont. Vitamins: maximum daily intake level according to national and EU expert groups and EU population reference intake.

Nutrient	SCF population reference intake for men aged 18+	SCF maximum level, EU (Reports of the SCF, 1993)	Maximum level in the Netherlands (NFNC, 1992)	Maximum level in the UK (Report, 1991)	DGE maximum level, Germany, 1991	France, (CSHPF, 1995)	Nordic countries (preliminary)
niacin	18 mg/day	3000-6000 mg 500 mg with delayed release	-	3000-9000 mg 500 mg with delayed release	3000 mg	33 mg	-
folate	200 µg/day	5000 µg	1000 µg	-	-	600 µg	5000 µg
vitamin B-12	1.4 µg/day	> 200 µg not recommended	-	-	-		100 µg
vitamin C	45 mg/day	1000-10,000 mg	10,000 mg	6000 mg	5000 mg	1000 mg	1000 mg
pantothenic acid	3-12 mg/day	-	-	-	-		-
biotin	15-100 mg/day[3]		-				-

[1] daily intake should be no more than one tenth of the undesirable dose
[2] 1 RE(retinol equivalent)= 3 IU vitamin A = 1 µg vitamin A = 6 µg ß-carotene
[3] acceptable range
[4] α-TE = alpha-tocopherol equivalents; 1 mg α-TE = 1 mg RRR-α-tocopherol = 1.49 IU vitamin E