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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.01.2003
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Preliminary Draft Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the addition of vitamins and minerals and of certain other substances to foods

EXPLANATORY MEMORANDUM

1. In its White Paper on Food Safety, the Commission announced that it would put forward a proposal for harmonising rules on the addition of nutrients to food in the European Union (Action no. 61). It is widely recognised today that relevant national rules vary widely and very often result in obstacles to intra-community trade in such products. Therefore it is necessary to harmonise these rules in order to facilitate the free circulation of these products within the Community. At the same time harmonisation would ensure a high level of consumer protection across the Community in general and notably ensure that products concerned do not present any risk for public health.
2. Addition of nutrients is generally practised by manufactures either voluntarily or because it is compulsory under national or Community rules. Thus, addition of vitamins and/or minerals is compulsory for a number of foods for particular nutritional uses (dietetic foods) by Community law. At national level, in some Member States, the addition of vitamins and/or minerals is mandatory in margarine (Vitamins A and D), flour (B complex vitamins, iron, and calcium), and salt (iodine). These national rules are dictated by public health considerations that are relevant to national or regional level and the rationale for their mandatory nature cannot be applied at Community level. Therefore, this proposed Regulation does not affect the existing Community rules on addition of nutrients and is not intended to harmonise existing national rules on compulsory addition of nutrients to foods. This proposal aims to harmonise the rules on the voluntary addition of nutrients in the European Union.
3. The nutrients most commonly added to foods for the purposes mentioned above are vitamins and minerals. For this reason it is considered appropriate for this proposed Regulation to cover only the addition of vitamins and minerals to foods. Some other nutrients are specifically allowed by Community legislation to be added to foods for particular nutritional uses (dietetic foods). Thus amino acids may be added to foods such as infant formulae and follow-on formulae based on soya for improving the quality of the protein. Certain fatty acids also are added to such products for satisfying the particular nutritional requirements of the persons for whom they are intended. However, as said above, rules concerning such products are not the subject of this proposed Regulation.
4. Vitamins and minerals are added to food for three purposes. Firstly, for restoring in the final product offered to the consumer the amount of nutrient(s) lost during the various stages of the storage, handling and manufacturing of foods. Such losses are very often inevitable and may occur even when the latest state of the art in manufacturing process is applied. Secondly, for producing substitute foods that resembles common food in appearance, organoleptic properties and nutritive value. The most well-known of such products is margarine, which was originally produced as a substitute to butter. Thirdly, vitamins and minerals are added to foods for the purpose of fortifying or enriching foods with them, irrespective of whether or not the nutrients are originally present in the food.
5. As already mentioned, national rules on the voluntary addition of vitamins and minerals vary widely. This is the result of a differing appreciation of the various arguments that are being considered when regulating their addition to foods. Food has two basic functions. One is to provide pleasure and the other is to provide nutrition, that is all the necessary elements for growth, development and

maintenance of a healthy life. In addition, food must be safe. Most would agree that in the context of the addition of vitamins and minerals for the purposes outlined above, products to which vitamins and minerals are added should offer to consumers a plausible beneficial nutritional or physiological effect and should be safe when consumed as part of a varied diet.

6. European Union citizens in general have at their disposal a variety of safe foods at affordable prices. Ideally, they should be able to choose a diet that provides all necessary nutrients in adequate quantities according to their individual needs. However, many studies have demonstrated that all individuals do not achieve this ideal situation across the European Union. This may be due to a variety of reasons. Changes to economic and social situations, such as increased proportion of working women and changes in family structures, affect food purchasing, meal preparation and the number and nature of meals eaten at home. The application of technological progress, both at work and at home, and changes to other life-style factors have contributed to changing dietary needs, in particular a reduction in energy requirements. For example, the UK National Food Survey of 1998 showed that in UK households there has been a 30% decline in the average energy intakes of adults, from 2700 calories in 1960 to 1800 calories in 1998. As a result substantial modifications of eating habits and dietary behaviour have occurred that would place substantial importance on the micronutrient density (amount of vitamins and minerals per given amount of energy) of individual foods and overall diets. In addition, scientific progress has led to a reappraisal of dietary needs for certain nutrients because their effect on specific conditions or diseases has been established or because the baseline that determines need is moving from preventing deficiencies towards ensuring optimal health.
7. It is widely recognised that different groups of the population may be affected. The report of the Scientific Co-operation (SCOOP) task on the scientific considerations for the development of measures on the addition of vitamins and minerals to foods states: "The results suggest that for almost all vitamins, minerals and trace elements there exist one or more population groups with intakes below nationally recommended levels. However, some nutrients are mentioned more often than others: iron, iodine and vitamins B2, B6 and D". The population groups may include adolescents or children, particularly "picky" ones, women, women during the periconceptual period, the elderly, people on a diet for losing weight, people on vegetarian diets, an increasing number of people having allergies to foods, persons eating a high proportion of "fast foods" or "junk foods" and others. The combinations of the specific groups of the population and the nutrients for which the intake may be deficient vary from one Member State of the Union to another. (Should examples be given?).
8. Foods to which vitamins and minerals have been added voluntarily can make a contribution, sometimes significant, to achieving adequate intakes of them and consequently reducing the risk of deficiencies. It is estimated that in general margarine and spreadable fats to which vitamin A and D are added, voluntarily in the great majority of the Member States, contribute about 20% of the Population Reference Intake (PRI) of vitamin A intake and about 30% of the PRI of vitamin D intake for very important groups of the EU population. Fortified breakfast cereals have become, in the 1990s, the principal source of iron in young children's diets in the UK, replacing meat that was the principle source in the 1950s. The same products can also contribute 20% of vitamin D intake and about 20% of intakes of B vitamins in the diets of children. (Fortified fruit juices contribute about ... of

calcium and Vitamin C intakes of German adolescents?). Therefore, in general, the availability and consumption of these foods can make a significant contribution to nutrient intakes.

9. At international level General Principles for the addition of essential nutrients to foods were adopted by the Codex Alimentarius in 1987. These General Principles provide definitions for the three cases of addition of nutrients to foods mentioned above, namely restoration, nutritional equivalence of substitute foods and fortification or enrichment. The Codex definitions in the first two cases remain valid to a large extent today and could be therefore included in this proposed Directive. The definition of fortification merits more careful consideration in the context of European Union legislation on the subject.
10. The Codex General Principles, according to the definition of fortification, would allow addition of nutrients to foods "for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific groups of the population". This is a definition that was adopted fifteen years ago having in mind the nutritional situation worldwide at the time. It gives emphasis to preventing or correcting a demonstrated deficiency of a vitamin or a mineral, a situation that was likely to occur, particularly in developing countries. This definition would result in a very restrictive regime of fortification and would be difficult to retain for the European Union for a number of reasons. Nutrient deficiencies for specific vitamins and minerals demonstrated by agreed clinical symptoms or other biomarkers are very few, if any, in the European Union today. They would not concern the whole of the EU population but rather specific groups which would not necessarily exist or be the same in all the Member States. Therefore, acceptance of fortification only for such restricted purposes would eliminate the basis for harmonising the EU rules on voluntary addition of nutrients to foods and give reason to those advocating that rules for the addition of nutrients to foods, voluntary or mandatory, should remain the responsibility of national authorities.
11. On the other hand, intakes below the recommended intakes for various vitamins and minerals, as defined at national level, have been reported in many Member States for different groups of the population as mentioned above. Various physiological parameters indicate a poor nutritional status for them too. These indicators of "deficiencies" of vitamins and minerals should therefore be taken into account today. Further, it is very important to take note of the evolution of scientific thinking with regard to recommended intakes. In the very recent past these would aim to cover the needs of the vast majority of the population in order to avoid deficiencies. Today more recent recommendations from scientific bodies of Member States and of third countries are aimed at providing intakes that would contribute to "optimal health" for the population. These take into account evolving scientific knowledge on the role and the beneficial effects of certain vitamins and minerals on certain physiological processes and conditions. It is true that many of the beneficial relationships between vitamin and mineral intakes and health are put forward as plausible benefits based on scientific evidence rather than proof. But many would point out that proof may take yet some time. Thus although evidence about the relationship between folic acid and neural tube defects existed for some time, proof came only a few years ago. Selenium was shown to be essential in animals in 1958 whilst it was accepted as essential to humans in 1980 and similar stories can be told for zinc and chromium. There have been reports about boron, silicon, molybdenum, tin, vanadium and other trace elements having a function in animals but because there are no deficiencies or

reduced biochemical activity demonstrated in humans the potential beneficial effects of their intake for man remain very much in doubt.

12. The above arguments, which would be in favour of a less strict approach on the addition of vitamins and minerals to foods, are often countered by arguments as to the potential risks that such an approach may entail. Such risks could be the result of two possible effects of fortification. First, it is feared that voluntary fortification practised by the manufacturers in a liberal environment would result in a substantial proliferation of fortified foods. These could progressively replace non-fortified foods in the diet and thus result in excessive intakes of certain nutrients that would represent a risk to the health of consumers. This is a legitimate concern. However, evidence from Member States and third countries, where voluntary fortification is allowed without many or any restrictions, show that the feared proliferation of fortified foods has been fairly limited. Today in these countries, according to data provided by the manufacturers, such foods represent 1-6% of the food supply, a percentage that has remained stable in recent years. In any case, there are measures to be adopted that would avoid risks of excess consumption of vitamins and minerals. Therefore, prohibiting or severely restricting fortification to avoid risk of excess consumption of vitamins and minerals would be considered a disproportionate measure to take at European Union level.
13. Another serious concern is that the proliferation of fortified foods may undermine consumer knowledge of basic nutritional principles and perception of foods. Some national authorities and consumer organisations claim that after substantial efforts they have succeeded in educating consumers about the nutritional value of the different foods and the importance of having a varied diet for ensuring the necessary intakes of the essential nutrients. Fortification could result in diminishing the current importance, in consumers' minds, of certain categories of foods such as fruits, vegetables, dairy products and red meat as sources of vitamins and minerals. People could turn to fortified foods for their vitamin and mineral intakes, change their dietary patterns and thus jeopardise good dietary habits. This, it is feared, could have a detrimental effect on the quantity, quality and ratio of intakes of certain nutrients and other substances, such as fibre, protein, fat and carbohydrate, and constitute a long-term risk for the population. This is also a legitimate concern which, however, at this stage is based on a hypothesis for future market evolution, supported by the observation that often the fortification of foods is used as a promotional tool by the manufacturers. It is not supported by any evidence for such adverse effects in any Community Member State or third countries having experience with voluntary addition of nutrients. Therefore, again, there are measures that can be taken which would be more proportionate than a prohibition or severe restriction of fortification.
14. Instead of severe restrictions to fortification across the board some would advocate selective restrictions to the foods or categories of foods that can be fortified. Practices in some third countries are cited as examples. Thus the USA Food and Drug Administration "does not encourage indiscriminate addition of nutrients to foods, nor does it consider it appropriate to fortify fresh produce; meat, poultry or fish products; sugars or snack foods such as candies and carbonated beverages". The Australia and New Zealand regulatory principles for voluntary addition of vitamins and minerals to general foods allow the addition "to some basic foods providing the vitamin or mineral is present in the nutrient profile, prior to processing, of a closely associated reference food in the food group to which the basic food belongs". However they allow the addition of some nutrients to certain categories of foods, even if the criteria are not met, where such additions are historically established (e.g.

calcium and vitamin C added to breakfast cereals). They also set certain specific "nutritional quality" limits for allowing some categories of foods to be fortified (biscuits containing up to 200 g/kg fat and not more than 50g/kg sugar). Health Canada, in policy recommendations on the addition of vitamins and minerals to foods, put forward in 1999 criteria for selecting foods to which vitamins and minerals should be allowed to be added. Such foods would be those that provide 10 % or more of the Canadian recommended nutrient intake for at least one nutrient and that would not contain "disqualifying" nutrient levels (proposed for total fats, saturates and trans fatty acids, and sodium). However it was recognised that "foods of low nutritional value and foods with high levels of those nutrients for which reduced intake is desirable could also be potential vehicles for reaching specific groups in certain circumstances (e.g. fruit-flavoured drinks and whole milk)". No rules have yet been adopted by Canada following the publication of the above policy document.

15. Some consumer organisations in the European Union consider that products that do not have a "desirable" nutritional profile, such as candies, high salt and high fat snacks or high fat and sugar biscuits and cakes should not be allowed to be fortified. Such foods, they consider, would become more attractive because of their fortification and they would be consumed in greater quantities by many consumers who are currently eating them in moderation. This, they consider, would have a more immediate negative effect in the dietary habits of certain particularly vulnerable sections of the population, like children and adolescents.
16. Such restrictions, although based on understandable concerns and important arguments, would be challenged by a number of scientific and policy arguments. The concept of prohibiting the addition of vitamins and minerals to certain foods on the basis of their "nutritional profile" is contrary to the basic principle in nutrition that there are not "good" and "bad" foods but rather "good" and "bad" diets. Such advice certainly recommends judicious food choices and moderation in consumption of certain products but accepts that, in a long-term varied diet, all foods could be included in appropriate frequency and quantities. The examples of recommendations, policy proposals and applicable rules mentioned in point 15 amply demonstrate that there is a lack of consistently defined and widely acceptable criteria for selecting the products or categories of products that should be allowed to be fortified or not. Permission to add vitamins and minerals only to foods that originally contain them is strongly contested because such a criterion would unnecessarily deprive certain groups of the population of valuable intakes of some nutrients. For example, consumption of fruit juices or fruit-flavoured soft drinks fortified with calcium may contribute to reaching desirable levels of calcium intakes by persons who cannot drink milk for physiological, taste or social reasons. Cultural and culinary traditions in the different Member States would further complicate the choice of different foods or groups of foods as appropriate or inappropriate for fortification. Total fat, saturates, trans fatty acids, sugars, sodium or salt, at variable levels, are commonly cited as criteria for the "nutritional profile" of products. More complicated schemes involving many more parameters may be under study. But all these proposals are currently far from meeting with the required consensus. The exception would be alcoholic beverages. Given the efforts made against alcohol abuse, addition of vitamins and minerals to these products should be prohibited as is proposed to prohibit any claims for them. It should also be clear that the above considerations apply to manufactured foods and that vitamins and minerals should not be added to fresh and non-transformed produce such as fruits, vegetables, meat, poultry, fish etc.

17. It is worth mentioning a few other points that would be relevant for the complete consideration of the issue. Consumers are becoming more and more conscious about the relationship between nutrition in general and intakes of certain nutrients in particular and health. Therefore, rightly or wrongly, they are increasingly seeking products to which vitamins and minerals have been added. As mentioned in the Nordic Council of Ministers report on the Addition of Nutrients to Foods, in a study conducted in the Nordic countries on behalf of a food company, 78% of consumers in those countries believed that consumers should have the possibility and choice to buy foods fortified with vitamins and minerals although not as many would choose the fortified version (only 33% would choose it). The above figures indicate that it is important for consumers to have choice between fortified and non-fortified foods. Therefore, all those concerned should ensure that allowing voluntary fortification should not lead to the disappearance of the non-fortified versions from the mass distribution chain. This will be a substantial responsibility of the food industry who, on the other hand, requests that the rules on the addition of vitamins and minerals to foods are not unduly restrictive. This would enable it to develop innovative products, beneficial for the consumers, and remain competitive not only at the Community and wider European level but also worldwide. This will be of particular importance now that the obligation has been established, through the recently adopted general principles and requirements of food law, that food exported from the Community for placing on the market of a third country shall comply with the relevant requirements of Community law.
18. In view of the above, it is considered that measures that would be more proportionate than a prohibition or severe restriction of fortification should be taken at Community level. The information for the consumer about the nutritional profile of the product could be improved through the labelling. Thus nutrition labelling should become mandatory for all foods to which vitamins and minerals are added. It should also be complete in order to give a better overall picture of the food. Specific statements relevant to the importance of a diversified diet can serve to remind and reinforce consumer knowledge on this specific point. As said above, the issue of claims made for fortified products is very important. Claims can give an improved image to fortified foods and hence their potential value as a promotional tool is considerable. Proposals for the harmonisation of claims for foods in general are being put forward by the Commission in parallel with the present proposal on the addition of vitamins and minerals to foods. Appropriate control of relevant claims would be another measure for controlling the impact of fortified foods on the choices of consumers. In parallel efforts to inform and educate consumers on nutritional issues and the importance of good dietary habits for better health and overall well-being should be maintained and, where possible, reinforced.
19. However, there should be vigilance regarding the evolution of the situation once the harmonised rules begin to apply in the European Union. In order to identify any adverse developments that may appear to occur and take the necessary action to prevent or minimise them Member State authorities should be able to monitor the marketing of products to which vitamins and minerals are added as best they can. For this reason they should be able, if they consider it necessary, to require those responsible for the marketing of these products to notify their marketing. Authorities, scientific bodies and interested stakeholders should co-operate as much as possible in order to best gather data concerning food intakes that are comparable across the European Union, identify intakes of foods to which vitamins and minerals have been added and estimate with the best possible accuracy the intake of these nutrients. In addition, the gathering of data on relevant indicators should be given

priority at national and at European Union level. The Commission should proceed, after a reasonable period following the effective application of the adopted rules, to analyse and report on their effect on the issues mentioned above and any others that may become relevant and to propose any appropriate measures that may be deemed necessary.

20. As said before, it is necessary to adopt measures to ensure that there will be no risk from excessive consumption of nutrients from a varied diet that includes also foods to which vitamins and minerals have been added. It is well known that excessive intakes of some vitamins and minerals would present greater risks to public health than others. A classification to categories according to the potential risk has been proposed by the Nordic Nutrition Recommendations, the French Food Safety Authority and other scientific sources and they tend to coincide. The Scientific Committee for Food, following a request from the Commission, is currently working to establish upper safe levels for vitamins and minerals based on scientific risk assessment. On the basis of these upper levels and taking into account certain other parameters, maximum levels of vitamins and minerals in foods to which they have been added should be set in order to ensure that the consumption of these foods in the context of a diversified diet will not result in any risk for the consumer. Therefore intakes from all potential food sources, including those naturally present in foods and food supplements, should be taken into account. It should be noted, however, that it is not possible to fortify all foods. This may be due to technological reasons that render addition of vitamins and minerals impossible or would result in products that would not be appealing to the consumer because of the resulting taste, colour, odour or consistency. For others the costs involved would be dissuasive. The population reference intakes or safe and adequate intakes established by the Scientific Committee for Food in 1992 and, more recently, by other authoritative scientific bodies should also be given due consideration. For some vitamins and minerals the amounts that could be permitted to be added, potentially to a wide range of foods, would be limited by safety considerations. Allowing their addition to all foods, on the basis of energy (calorie) content or specific quantity of weight or volume, could result in allowing only insignificant amounts to be added in the different foods. This would be misleading for the consumer and jeopardise the nutritional value of some traditional substitute foods (e.g. margarine) or others that have become an important part of certain meals (e.g. breakfast cereals). It might be therefore necessary in such cases to preferentially limit the addition of a certain vitamin or mineral to only one or a few products or categories of products, taking into account the importance of their contribution to the intake of the vitamin or mineral by the population. Given the technical and complex nature of setting these maximum levels it is appropriate that they should be adopted through the procedure of the Regulatory Committee when all the technical and scientific data become available.
21. In recent years we note the increasing appearance in the composition and labelling of foods of substances or ingredients other than vitamins and minerals that are used in an “innovative” way. The majority of these substances or ingredients are used on the basis of adequate scientific data supporting a demonstrated or plausible beneficial effect and have permitted the food industry to put forward innovative products for an increasingly health conscious and demanding consumer. The use of certain substances or ingredients though is increasingly cause for concern. This is largely due to the absence of sufficient scientific data to demonstrate that their use in large quantities, often far in excess of the quantities in which these substances would be ingested with a normal diet, do not pose any risks to health. These substances or

ingredients would not fall under the scope of Regulation (EC) 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients. Sometimes their use and presentation in the labelling may lead to questions as to whether they should be treated as ingredients used in the manufacture of foods or whether they should be considered as “added”. Irrespective of the answer to this question, it would be opportune to regulate the safe use of such substances or ingredients, and where necessary prohibit their use, under this proposed Regulation.

22. In conclusion, the proposed rules would contribute to a high level of protection of human life and health and promote the protection of consumer interests by ensuring that the marketed foods to which vitamins and minerals are added or in which certain ingredients are used, are safe and labelled in an adequate and clear manner, allowing consumers to make informed choices. Thus they would be in line with the general principles and requirements of food law as stipulated in Articles 5-8 of the recently adopted Regulation (EC) 178/2002 of the European Parliament and of the Council and with Article 153 of the Treaty. They would also take into account the importance for the food industry to have a regulatory environment that will allow them to innovate and remain competitive at Community and international level. Finally, they would allow monitoring and the possibility to take action if a risk to health or other consumer interests was to appear.

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the addition of vitamins and minerals and of certain other substances to foods

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission¹,

Having regard to the Opinion of the Economic and Social Committee²,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

- (1) There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals including trace elements, amino acids, essential fatty acids, fibre and many others. This Regulation restricts itself in regulating the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing them.
- (2) Vitamins and minerals may be added to foods voluntarily by food manufacturers or must be added as provided by specific Community legislation. This regulation shall apply without prejudice to the specific Community rules concerning addition to or use of vitamins and minerals in specific products or groups of products already in force.
- (3) Some Member States require the mandatory addition of some vitamins and minerals to certain ordinary foods, for reasons dictated by public health considerations. These may be pertinent at national or even regional level and as such would not support harmonisation of the mandatory addition of these nutrients across the Community.
- (4) Voluntary addition of vitamins and minerals to foods is regulated in Member States by differing national rules that may impede the free movement of these products, may create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market; it is therefore necessary to adopt Community rules on this subject.
- (5) Voluntary addition of vitamins and minerals to food is carried out by manufacturers for three purposes: for restoration of the vitamin or mineral levels reduced during

¹ OJ

² OJ

processing of foods, ensuring nutritional equivalence of products replacing common foods in the diet and for fortifying or enriching foods with vitamins or minerals they do not usually contain or contain at lower levels.

- (6) An adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all vitamins and minerals and by all groups of the population across the Community. Foods to which vitamins and minerals have been added appear to contribute a non-negligible amount of these nutrients and as such may be considered to make a positive contribution to overall intakes.
- (7) At international level Codex Alimentarius adopted in 1987 General Principles for the addition of nutrients, including vitamins and minerals, to foods. Due consideration is given to the definitions included therein for “restoration”, “nutritional equivalence”, and “substitute food”. However the Codex definition for “fortification” or “enrichment” only allows the addition of nutrients to food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.
- (8) Changes in the socio-economic situation prevailing in the Community and the life styles of different groups of the population have led to different nutritional requirements and to changing dietary habits. This in turn has led to changes in the energy and nutrient requirements of various groups of the population and to intakes of certain vitamins and minerals for these groups that would be below those recommended in different Member States. In addition, progress in scientific knowledge indicates that intakes of some nutrients for maintaining optimal health and well being could be higher than those currently recommended. Taking into account the above it is considered that in Community rules the definition on fortification should be extended beyond that provided in the relevant Codex Alimentarius General Principles.
- (9) Only vitamins and minerals normally found in and consumed as part of the diet and considered essential nutrients should be allowed to be added in foods although this does not mean that their addition therein is necessary; controversy as to the identity of these essential nutrients that could potentially arise should be avoided; therefore it is appropriate to establish a positive list of these vitamins and minerals.
- (10) The chemical substances used as sources of vitamins and minerals to be added to food should be safe and also be bio-available i.e. available to be used by the body. For this reason a positive list of these substances should also be established. Such substances that have been approved by the Scientific Committee for Food (opinion expressed on 12 May 1999), on the basis of the above criteria, and can be used in the manufacture of foods intended for infants and young children, in other foods for particular nutritional uses or in food supplements should at least appear in this positive list.
- (11) In order to keep up with scientific and technological developments it is important to revise the above lists promptly, when necessary. Such revisions would be implementing measures of technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

- (12) For vitamins and minerals excessive intakes may result in adverse effects and therefore necessitate the setting of maximum safe levels for them when added to foods, as the case may be. These levels must ensure that the normal use of the products, under the instructions of use provided by the manufacturer and in the context of a diversified diet, will be safe for the consumer.
- (13) For that reason these maximum levels and any other conditions restricting their addition to foods, where necessary, should be adopted taking into account their upper safe levels established by scientific risk assessment based on generally acceptable scientific data and their potential intake from other foods. Due account should also be taken of the population reference intakes of vitamins and minerals. Where it is necessary, for certain vitamins and minerals, to establish restrictions regarding the foods to which they can be added, priority should be given according to the purpose of the addition and the contribution of the food to the overall diet.
- (14) Minimum amounts of vitamins and minerals added for the purpose of restoration or for nutritional equivalence of substitute foods would depend on the levels in the unprocessed food or the food being substituted. However, their addition for the purpose of fortification should result in a minimum amount being present in the food in order to avoid the consumer being misled. The adoption of maximum levels and any conditions of use based on the application of the principles and criteria stipulated in this directive would be implementing measures of technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.
- (15) General labelling provisions and definitions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer³ as last amended by Directive 2001/101/EC of the European Parliament and of the Council⁴ and do not need to be repeated. This Directive can therefore be confined to the necessary additional provisions.
- (16) Given the nutritional importance of products to which vitamins and minerals have been added and their potential impact on dietary habits and overall nutrient intakes the consumer should be able to evaluate their global nutritional quality. Therefore, nutrition labelling, by derogation to Article 2 of Council Directive 90/496/EEC on nutrition labelling⁵, should be compulsory and should be extensive.
- (17) Given the particular nature of foods to which vitamins and minerals are added, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.
- (18) Since the measures necessary for the implementation of this Regulation are measures of general scope within the meaning of Article 2 of Council Decision 1999/468/EC of June 1999 laying down the procedures for the exercise of implementing powers

³ OJ L 124, 25.5.2000, p. 29

⁴ OJ L 310, 26.9.2001, p. 19

⁵ OJ L 276, 6.10.1990, p. 40

conferred to the Commission⁶, they should be adopted by the use of the regulatory procedure provided for in Article 5 of that Decision.

HAVE ADOPTED THIS REGULATION

⁶ OJ L 184, 17.7.1999, p.23

CHAPTER I

AIM, SCOPE AND DEFINITIONS

Article 1

Aim and scope

1. The aim of this Regulation is the approximation of the provisions laid down by law, regulation or administrative action in Member States which relate to the voluntary addition of vitamins and minerals and of certain other substances to foods, with the purpose of ensuring the effective functioning of the internal market whilst providing a high level of consumer protection.
2. The provisions of this Regulation regarding vitamins and minerals shall not apply to food supplements covered by Directive 2002/46/EC.
3. This Regulation shall apply without prejudice to specific provisions concerning foods for particular nutritional uses, novel foods and novel food ingredients laid down in Community legislation.

Article 2

Definitions

For the purpose of this Regulation:

- a) “restoration” means the addition to a food of vitamins and minerals 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 vitamins and minerals present in the edible portion of the food before processing, storage or handling;
- b) “nutritional equivalence” means being of similar nutritive value in terms of quantity and bio-availability of vitamins and minerals;
- c) “substitute food” is a food which is designed to resemble a common food in appearance, texture, flavour and odour and is intended to be used as a complete or partial replacement for the food it resembles;
- d) “fortification” or “enrichment” means the addition of one or more vitamins and/or minerals to a food whether or not it is usually contained in the food in order to take into account:
 - a demonstrated deficiency of one or more vitamins and/or minerals in the population or specific population groups,
 - potential to improve the nutritional status of the population and dietary intakes of vitamins or minerals due to changes in dietary habits,
 - evolving generally accepted scientific knowledge on the role of vitamins and minerals in health.

CHAPTER II

ADDITION OF VITAMINS AND MINERALS

Article 3

Conditions for the addition of vitamins and minerals

1. No person shall place on the market a food to which vitamins and/or minerals are added unless it complies with the rules laid down in this Regulation.
2. Vitamins and minerals may be added to foods for the purpose of
 - restoration,
 - nutritional equivalence of substitute foods,
 - fortification or enrichment.
3. Only the vitamins and minerals listed in Annex 1, in the forms listed in Annex 2 may be used for addition to foods.
4. Modifications to the lists referred to in paragraph 4 shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 4

Restrictions on the addition of vitamins and minerals

1. Vitamins and minerals may not be added to:
 - a) fresh produce, including, but not limited to, fruits, vegetables, meat, and fish;
 - b) beverages containing more than 1.2% by volume of alcohol.

Additional foods or categories of foods to which vitamins and minerals may not be added may be determined in accordance with the procedure laid down in Article 13(2).

2. Community provisions applicable to specified foods may provide for restrictions or prohibitions on the addition of vitamins and minerals in addition to those laid down in this Regulation. In the absence of such Community provisions, Member States may make provisions for such restrictions or prohibitions, in accordance with the procedure laid down in Article 14, in well-defined cases where they can demonstrate that the provisions of Article 3.3 are not fulfilled.

Article 5

Purity criteria

1. The purity criteria for substances listed in Annex 2 shall be adopted in accordance with the procedure referred to in Article 13(2), except where they apply pursuant to paragraph 2.
2. Purity criteria for substances listed in Annex 2, specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by this Regulation, shall apply.
3. For those substances listed in Annex 2 for which purity criteria are not specified by Community legislation, and until such specifications are adopted, generally acceptable purity criteria recommended by international bodies shall be applicable and national rules setting stricter purity criteria may be maintained.

Article 6
Maximum amounts

1. Maximum amounts of vitamins and minerals present in foods as sold shall be set for vitamins and minerals that have been added to those foods. For concentrated and dehydrated products the maximum amounts shall be those for foods when prepared for consumption according to the manufacturers instructions.
2. The maximum amounts referred to in paragraph 1 shall be set taking the following into account:
 - a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally acceptable scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
 - b) intakes of vitamins and minerals from other dietary sources
3. When the maximum levels referred to in paragraph 1 are set, due account should also be taken of reference intakes of vitamins and minerals for the population.
4. When the maximum levels referred to in paragraph 1 are set for vitamins and minerals whose reference intakes for the population are close to the upper safe levels, the following will also be taken into account, as necessary:
 - a) the requirements for addition of certain vitamins or minerals to foods for the purpose of restoration and/or for the purpose of nutritional equivalence of substitute foods;
 - b) the contribution of individual products to the overall diet of the population in general or of sub-groups of the population.
5. The addition of a vitamin or a mineral to food for the purpose of fortification shall result in the presence of this vitamin or mineral in the food in at least a significant amount as this is defined in the Annex of Directive 90/496/EEC.
6. The maximum and minimum amounts of vitamins and minerals referred to in paragraphs 1 and 5 of this Article and any conditions restricting their addition to foods shall be adopted in accordance with the procedure referred to in Article 13(2).

Article 7

Labelling, presentation and advertising

1. This Article applies without prejudice to Directive 2000/13/EC, Regulation (EC) No .../2003 on nutrition and health claims made on foods, and other provisions of food law applicable to specified categories of foods.
2. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients.
3. The labelling, presentation and advertising of foods to which vitamins and minerals have been added shall not mislead or deceive the consumer as to the nutritional merit of the food that may result from the addition of these nutrients.
4. The labelling of products to which vitamins and minerals have been added may bear a statement indicating such addition under the conditions laid down in Regulation (EC) No .../2003 on nutrition and health claims made on foods.
5. By derogation to Article 2 of Council Directive 90/496/EEC, nutrition labelling of products to which vitamins and minerals have been added shall be compulsory. The information to be provided shall consist of that specified in Article 4, paragraph 1, Group 2 of that Directive and of the total amounts present of the vitamins and minerals added to the food.
6. Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 13(2).

Article 8

Free movement of goods

1. Member States shall not forbid or restrict trade in foods which comply with the rules laid down in this Regulation and in Community acts adopted for its implementation by the application of national provisions governing the addition of vitamins and minerals to foods.
2. Paragraph 1 shall not affect national provisions which are applicable in the absence of Community acts adopted in implementation of this Regulation or which are justified on grounds of:
 - protection of public health,
 - prevention of fraud, unless such provisions are liable to impede the application of the definitions and rules laid down by this Regulation,
 - protection of industrial and commercial property rights, indications of provenance, registered designations of origin and prevention of unfair competition.

Article 9

Safeguard measures

1. Where a Member State, as a result of new information or of a reassessment of existing information made since this Regulation or one of the implementing Community acts was adopted, has detailed grounds for establishing that a product to which vitamins or minerals have been added endangers human health though it complies with those Community acts, that Member State may temporarily suspend or restrict application of the provisions in question within its territory. It shall immediately inform the other Member States and the Commission thereof and give reasons for its Decision.
2. The Commission shall examine as soon as possible the grounds adduced by the Member State concerned and shall consult the Member States within the Standing Committee on the Food Chain and Animal Health, and shall then deliver its opinion without delay and take appropriate measures.
3. If the Commission considers that amendments to this Regulation or to the implementing Community acts are necessary in order to remedy the difficulties mentioned in paragraph 1 and to ensure the protection of human health, it shall initiate the procedure laid down in Article 13(2) with a view to adopting those amendments. The Member State that has adopted safeguard measures may in that event retain them until the amendments have been adopted.

Article 10

Mandatory addition of vitamins and minerals

1. Community provisions applicable to specified foods or categories of foods may provide for the mandatory addition of vitamins and minerals. Such provisions shall otherwise conform with the provisions laid down in this Regulation.
2. Where there are no Community provisions, Member States may make provision for the mandatory addition of vitamins and minerals to specified or categories of foods, in accordance with the procedure laid down in Article 14.

Within six months from the entry into force of this Regulation, Member States shall inform the Commission of existing relevant national provisions.

CHAPTER III

ADDITION OF CERTAIN OTHER SUBSTANCES

Article 11

Substances under Community scrutiny

1. Where a substance, or an ingredient containing a substance other than vitamins or minerals, is added to foods or used in the manufacture of foods at conditions that would result in the ingestion of amounts of this substance greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet, and where, following an assessment of available information, it appears that such use gives rise to concerns about risks to public health, the substance shall be placed in Annex 3, Part A, in accordance with the procedure referred to in Article 13(2).
2. Food business operators, or any other interested parties, may at any time submit to the European Food Safety Authority, hereafter referred to as ‘the Authority’, a file containing the scientific data demonstrating the safety of a substance listed in Annex 3, Part A under the conditions of its use in a food or in a category of foods and explaining the purpose of that use.
3. If, within three years from the date of entry into force of this Regulation or from the date a substance has been listed in Annex 3, Part A, whichever comes last, a decision has not been taken in accordance with the procedure referred to in Article 13(2) to generally allow the use of a substance listed in Annex 3, Part A or to list it in Annex 3, Part B, the concerned substance shall be automatically transferred to Annex 3, Part C.

Article 12

Restricted and prohibited substances

1. The addition to foods and the use in the manufacture of foods of the substances, or of ingredients containing them, listed in Annex 3, Part B is allowed only under the conditions specified therein.
2. The addition to foods and the use in the manufacture of foods of the substances, or of ingredients containing them, listed in Annex 3, Part C, shall be prohibited.
3. Modification to Annex 3, Part B or Part C, other than under the circumstances referred to in Article 9(3), shall be adopted in accordance with Article 13(2), where appropriate after having obtained an opinion from the Authority and taking into account the circumstances referred to in Article 9(1).
4. Community provisions applicable to specified foods may provide for restrictions or prohibitions on the use of certain substances in addition to those laid down in this Regulation. Where there are no Community provisions, Member States may make

provision for such prohibitions or restrictions, in accordance with the procedure laid down in Article 14.

CHAPTER IV

PROCEDURES AND FINAL PROVISIONS

Article 13

Implementing powers of the Commission

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) 178/2002.
2. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7 (3) and Article 8 thereof.
3. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 14

Notification procedure

1. Where reference is made to this Article, the following procedure shall apply should a Member State deem it necessary to adopt new legislation.
2. The Member State concerned shall notify the Commission and the other Member States of the envisaged measures and give the reasons justifying them.
3. The Commission shall consult the Committee referred to in Article 13(1) if it considers such consultation to be useful or if a Member State so requests and give an opinion on the envisaged measures.
4. Member State concerned may take the envisaged measures only six months after the notification and provided that the Commission's opinion is not negative. In the latter event, and before the expiry of the abovementioned period, the Commission shall initiate the procedure provided for in Article 13(2) in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate modifications.

Article 15

Emergency measures

The provisions of this Regulation shall apply without prejudice to the adoption of emergency measures under Article 53 or 54 of Regulation (EC) No 178/2002.

Article 16

Monitoring

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex 3, Part A and Part B, Member States may require the manufacturer or the person placing such foods on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.

Article 17
Evaluation

Not later than [*first day of sixth month following date of publication + 6 years*], the Commission shall submit to the European Parliament and the Council a report on the effects of implementing this Regulation, in particular concerning the evolution of the market of foods to which vitamins and minerals have been added, their consumption, nutrient intakes for the population and changes in dietary habits, accompanied by any proposals for amendment to this Regulation which the Commission deems necessary.

Article 18
Entry into force and application

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Communities*.

It shall apply from [*first day of sixth month following date of publication*]. However, products placed on the market or labelled prior to that date and packages which do not comply with this Regulation may be marketed until [*same + 2 years*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX 1

Vitamins and minerals which may be added to foods

1. VITAMINS

Vitamin A
Vitamin D
Vitamin E
Vitamin K
Vitamin B1
Vitamin B2
Niacin
Pantothenic acid
Vitamin B6
Folic acid
Vitamin B12
Biotin
Vitamin C

2. MINERALS

Calcium
Magnesium
Iron
Copper
Iodine
Zinc
Manganese
Sodium
Potassium
Selenium
Chromium
Molybdenum
Fluoride
Chloride
Phosphorus

ANNEX 2

Vitamin formulations and mineral substances which may be added to foods

1. VITAMINS FORMULATIONS

VITAMIN A

- retinol
- retinyl acetate
- retinyl palmitate
- beta-carotene

VITAMIN D

- cholecalciferol
- ergocalciferol

VITAMIN E

- D-alpha-tocopherol
- DL-alpha-tocopherol
- D-alpha-tocopheryl acetate
- DL-alpha-tocopheryl acetate
- D-alpha-tocopheryl acid succinate

VITAMIN K

- phyloquinone (phytomenadione)

VITAMIN B1

- thiamin hydrochloride
- thiamin mononitrate

VITAMIN B2

- riboflavin
- riboflavin 5'-phosphate, sodium

NIACIN

- nicotinic acid
- nicotinamide

PANTOTHENIC ACID

- D-pantothenate, calcium
- D-pantothenate, sodium
- dexpanthenol

VITAMIN B6

- pyridoxine hydrochloride
- pyridoxine 5'-phosphate
- pyridoxine dipalmitate

FOLIC ACID

- pteroylmonoglutamic acid

VITAMIN B12

- cyanocobalamin
- hydroxocobalamin

BIOTIN

- D-biotin

VITAMIN C

- L-ascorbic acid
- sodium-L-ascorbate
- calcium-L-ascorbate
- potassium-L-ascorbate
- L-ascorbyl 6-palmitate

2. MINERALS SUBSTANCES

calcium carbonate
calcium chloride
calcium salts of citric acid
calcium gluconate
calcium glycerophosphate
calcium lactate
calcium salts of orthophosphoric acid
calcium hydroxide
calcium oxide
magnesium acetate
magnesium carbonate
magnesium chloride
magnesium salts of citric acid
magnesium gluconate
magnesium glycerophosphate
magnesium salts of orthophosphoric acid
magnesium lactate
magnesium hydroxide
magnesium oxide
magnesium sulphate
ferrous carbonate
ferrous citrate
ferric ammonium citrate
ferrous gluconate
ferrous fumarate
ferric sodium diphosphate
ferrous lactate
ferrous sulphate
ferric diphosphate (ferric pyrophosphate)
ferric saccharate
elemental iron (carbonyl + electrolytic + hydrogen reduced)
cupric carbonate
cupric citrate
cupric gluconate
cupric sulphate
copper lysine complex
sodium iodide
sodium iodate
potassium iodide
potassium iodate
zinc acetate
zinc chloride
zinc citrate
zinc gluconate
zinc lactate
zinc oxide
zinc carbonate
zinc sulphate
manganese carbonate
manganese chloride
manganese citrate

manganese gluconate
manganese glycerophosphate
manganese sulphate
sodium bicarbonate
sodium carbonate
sodium chloride
sodium citrate
sodium gluconate
sodium lactate
sodium hydroxide
sodium salts of orthophosphoric acid
potassium bicarbonate
potassium carbonate
potassium chloride
potassium citrate
potassium gluconate
potassium glycerophosphate
potassium lactate
potassium hydroxide
potassium salts of orthophosphoric acid
sodium selenate
sodium hydrogen selenite
sodium selenite
chromium (III) chloride and its hexahydrate
chromium (III) sulphate and its hexahydrate
ammonium molybdate (molybdenum (VI))
sodium molybdate (molybdenum (VI))
potassium fluoride
sodium fluoride

ANNEX 3

Substances and whose use in foods is prohibited or subject to conditions

Part A - Substances under Community scrutiny

Glucoronolactone

Taurine

Guarana

Part B – Restricted substances

Caffeine: its content in soft drinks shall not exceed.... mg/l

Quinine: its content in soft drinks shall not exceedmg/l

Part C - Prohibited substances and ingredients containing them

Ephedrine and its alcaloids

Hormones

Kava - kava

Nicotine

Aristolochic acid

St John's wort