COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.11.2003
COM(2003) 671 final

2003/0262 (COD)

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

(presented by the Commission)

EXPLANATORY MEMORANDUM

EXECUTIVE SUMMARY

The proposed Regulation aims to harmonise divergent national rules concerning the addition of vitamins and minerals and of certain other substances to foods in order to ensure a high level of consumer protection and the free circulation of goods within the Community.

The proposed Regulation

(1) defines the purposes for which vitamins and minerals are allowed to be added

(2) lists in Annex I the vitamins and minerals that may be added and in Annex II the vitamin preparations and mineral salts that may be used and refers to their purity criteria

(3) provides for certain restrictions regarding the foods to which vitamins and minerals may be added

(4) set the criteria for the establishment of maximum levels of vitamins and minerals in foods through the procedure of the Standing Committee on the Food Chain and Animal Health

(5) provides for the setting of minimum levels of vitamins and minerals to be established through the procedure of the Standing Committee on the Food Chain and Animal Health

(6) provides for appropriate specific rules on labelling, presentation and advertising of products to which vitamins and minerals have been added in addition or by derogation to other such horizontal rules applicable to all foods

(7) enables Member States to require the notification of the marketing of these products in order to facilitate their monitoring

Finally, the proposed Regulation provides the basis for scrutinising and, where necessary, regulating the addition of certain substances, other than vitamins and minerals, to foods.

INTRODUCTION

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.

BACKGROUND

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 at this stage, although the possibility of adopting harmonised specific rules on the compulsory addition of certain nutrients to certain foods or food categories should not be excluded. This proposal aims to harmonise the rules on the voluntary addition of nutrients in the European Union. 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.

3. 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.

4. As already mentioned, national rules on the voluntary addition of vitamins and minerals vary widely. For example addition is allowed without any restrictions in one Member State provided the food is not posing any risk to health while in another the addition is only allowed if it could be demonstrated that there was a nutritional need for the addition of the nutrient. In between, some Member States allow the addition of vitamins and minerals specified in a list but allow different maximum levels to be present in the food. Yet some others prohibit the addition of a few specific vitamins. 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.

5. 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 an 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.

6. It is widely recognised that different groups of the population may be affected. The report of the Scientific Co-operation (SCOOP) task No. 7.1.1., published in April 1997, 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 Community to another.

7. 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 to the 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.

SPECIFIC ISSUES OF THE PROPOSAL

ADDITION OF VITAMINS AND MINERALS

8. 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 Regulation. The definition of fortification merits more careful consideration in the context of European Community legislation on the subject.

9. 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 restrictive regime of fortification and would be difficult to retain for the European Community 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 Community today. They would not concern the whole of the EC 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 EC 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.

10. 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. Changes taking place in food habits may also indicate risk for insufficient intakes as mentioned in point 5. These indicators of "deficiencies" of vitamins and minerals should therefore be taken into account today. This would be supported by the Codex General Principles which, in the case of fortification programs, accepts that a demonstration of the need for increasing intakes “may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits”. 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.

11. 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 Community level.

12. 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.

13. Instead of severe restrictions on fortification across the board some would advocate selective restrictions on 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 for public comment, suggested 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)". On the basis of the comments received, Health Canada revised the policy recommendations and put them forward again for further comment. In the new recommendations, among other, the amount of total fat as a “disqualifying” nutrient level has been dropped. No rules have yet been adopted by Canada following the publication of the above policy document.

14. Consumer organisations in the European Community consider that products that do not have a "desirable" nutrient 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. This view is shared by a number of Member States. This argument has been taken into consideration in the proposed rules regarding nutrition and health claim made for foods. The nutrient profile of a food is proposed to be a criterion for allowing a food to bear claims. In the vast majority of cases manufacturers that add vitamins and minerals to foods wish to make a claim about that addition. Preventing such a claim for a food will be dissuasive for such addition to be effected. It is therefore not necessary to establish nutrient profiles also as a criterion for the foods to which the addition of vitamins and minerals should be allowed.

15. Restrictions 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. 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 in order to preserve the original content of these nutrients and avoid any confusion for the consumer.

16. 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.

17. Given the modification of nutrient content through the addition of vitamins and minerals, the information for the consumer about the overall 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 on a voluntary basis. 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.

18. However, there should be vigilance regarding the evolution of the situation once the harmonised rules begin to apply in the European Community. 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. It is up to the Member States to decide whether existing means of monitoring, for example regular food intake surveys or other, are sufficient or whether notification should be required for the purpose of monitoring. 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 Community, 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 Community 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.

19. 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 (SCF), following a request from the Commission, established upper safe levels for a number of vitamins and minerals based on scientific risk assessment. The European Food Safety Authority that took over the advisory role on scientific matters from the SCF will complete this task for the remaining vitamins and minerals. 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. These maximum levels should also take into account the use of some vitamins or minerals as food additives and flavourings. 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.

20. 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. In this context another useful criterion would be the nutrient profile of the food that is proposed to be a criterion for allowing a food to make nutrition and health claims in the relevant proposed Regulation under discussion in the European Parliament and the Council. 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.

ADDITION OF CERTAIN OTHER SUBSTANCES

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. Because of their presence in foods or their use as food ingredients prior to the entry into force of Regulation (EC) 258/97 of the European Parliament and of the Council concerning novel foods and novel food ingredients these substances or ingredients would not fall under the scope of that Regulation. 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. For the sake of transparency a *Community Register on addition of vitamins and minerals and of certain other substances to foods* shall be established and regularly updated. It shall include information regarding vitamins and minerals and the vitamin formulations and mineral salts that may be added to foods and the maximum and minimum amounts permitted and information regarding the mandatory addition of vitamins and minerals in Member States, as the case may be. It shall also include information on the status of substances other than vitamins and minerals and, where necessary, ingredients containing them mentioned in point 21.

23. There are no budgetary implications for the Commission.

- The above-mentioned « Register » will be established as a section of DG SANCO's Web-site, using existing budgetary and human resources

- The regulatory committee mentioned in Article 16 is the existing Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 ; decisions under this Proposal will be dealt with by the Section on General Food Law of the Committee, which currently meets 6 times a year ; implementation of this proposal will not result in more meetings of this Section being organised

– The management of the Community procedures foreseen in this proposal will not require additional staffing as current infringement procedures should be significantly reduced.

CONSULTATION

24. In preparing this proposal the Commission considered carefully relevant rules that are applicable or are under preparation in third countries. It also took into account the relevant Codex Guidelines. The Commission consulted extensively with Member States and interested stakeholders. To that effect a preliminary draft of the measures to be proposed was discussed with stakeholders in July of 2000 and with the Member States in September 2000. This initial consultation highlighted the wish of Member States and of the stakeholders to harmonise the rules in this area, the similarities with certain issues included in the proposal concerning food supplements that was discussed at the time by the European Parliament and the Council and the strong link that the proposal on the addition of vitamins and minerals to foods should have with the proposal on nutrition and health claims made on foods also under elaboration at the time. Following the adoption of Directive 2002/46/EC of the European Parliament and of the Council on food supplements and taking into account progress in the preparation of the proposals on claims an updated draft proposal was prepared and discussed in February 2003 with the stakeholders and in March 2003 with the Member States. The various views expressed on the individual issues that are covered by the proposal have been considered very carefully. The positions and arguments put forward are reflected in this explanatory note although not necessarily attributed to specific interested parties.

CONCLUSION

25. 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.

2003/0262 (COD)

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

(Text with EEA relevance)

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 Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

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. Their addition to foods is regulated in Member States by differing national rules that impede the free movement of these products, 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 harmonising national provisions which relate to the addition of vitamins and minerals and of certain other substances to foods.

(2) In accordance with the principle of proportionality, as set out in Article 5 of the Treaty, this Regulation confines itself to those measures which are necessary in order to achieve the internal market objectives pursued, taking as a base a high level of consumer protection.

(3) 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 that are added to foods or used in the manufacture of foods at conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet.

(4) 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 today

---

1 OJ
2 OJ

harmonisation of the mandatory addition of nutrients across the Community. However, if and when this became appropriate, such provisions could be adopted at Community level. Meanwhile, it would be useful that information on such national measures be compiled.

(5) Vitamins and minerals may be added to foods voluntarily by food manufacturers or must be added as nutritional substances as provided by specific Community legislation. They may also be added for technological purposes as additives, colourings, flavourings or other such uses including authorised oenological practices and processes provided by relevant 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 or their addition for purposes other than those covered by this Regulation.

(6) Given that detailed rules on food supplements containing vitamins and minerals have been adopted by Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[3], provisions of this Regulation regarding vitamins and minerals should not apply to food supplements.

(7) 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 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.

(8) 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.

(9) 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”. The Codex definition for “fortification” or “enrichment” allows the addition of nutrients to food for the purpose of preventing or correcting a deficiency of one or more nutrients in the population or specific population groups that can be demonstrated by existing scientific evidence or indicated by estimated nutrient intakes due to changing dietary habits.

(10) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist today in the Community. 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

---

[3] OJ L 183, 12.7.2002, p. 51

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 include but also be extended beyond what is provided in the relevant Codex Alimentarius General Principles.

(11) 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.

(12) 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 of safety and bioavailability, 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 appear in this positive list.

(13) 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.

(14) Food to which vitamins and minerals are added are in most cases promoted by manufacturers and may be perceived by consumers as products having a nutritional, physiological or other health advantage over similar or other products without such nutrients added. This may induce consumer choices that may be otherwise undesirable. To counter this potential undesirable effect, it is considered appropriate to impose some restrictions to the products to which vitamins and minerals can be added, in addition to those that would result naturally from technological considerations or become necessary for safety reasons when maximum limits of vitamins and minerals in such products are set. The content in the product of certain substances, like alcohol, would, in this context, be an appropriate criterion for not allowing vitamins and minerals to be added to it. In order to avoid any confusion for the consumer as to the natural nutritional value of fresh foods, vitamins and minerals should also not be allowed to be added to them.

(15) For vitamins and minerals excessive intakes may result in adverse effects and therefore necessitate the setting of maximum safe levels for them when they are 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. Therefore they should be total maximum safe levels of the vitamins and minerals present in the food naturally and/or added to the food for whatever purpose, including for technological uses.

(16) 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.

(17) 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. Otherwise the presence of too small and insignificant amounts in these fortified foods would not offer any benefit to consumers and would be misleading. The same principle underlines the requirement that these nutrients should be present in a significant amount in the food in order to be allowed to be declared in nutrition labelling. Therefore it would be appropriate that the minimum amounts of vitamins and minerals in foods resulting from fortification should be the same as those significant amounts that should be present for those nutrients to be declared in nutrition labelling.

(18) The adoption of maximum levels and any conditions of use based on the application of the principles and criteria stipulated in this Regulation and the adoption of minimum levels would be implementing measures of technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

(19) 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[4] as amended by Directive 2001/101/EC. This Regulation should therefore be confined to the necessary additional provisions. Those additional provisions should also apply without prejudice to Regulation (EC) No ../.. of the European Parliament and of the Council of ……. On nutrition and health claims made on foods[5]

(20) 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 of 24 September 1990 on nutrition labelling for foodstuffs[6], should be compulsory.

(21) A normal and varied diet contains many ingredients which in turn contain many substances. The intake of these substances or ingredients resulting from their normal and traditional use in current diets would not cause concern and does not need to be regulated. Some substances other than vitamins and minerals or ingredients containing them are added to foods as extracts or concentrates and may result in intakes that are significantly higher than those that could be ingested through eating an adequate and varied diet. The safety of such practices is in some cases seriously contested and the

---

4 OJ L 109, 6.5.2000, p. 29

5 OJ […]

6 OJ L 276, 6.10.1990, p. 40

benefits are unclear; therefore they should be regulated. It is appropriate, in such cases, that food operators, responsible for the safety of the food products they place in the market, assume the burden of proof of the safety of them.

(22) 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.

(23) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred to the Commission[7].

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation is intended to harmonise the provisions laid down by law, regulation or administrative action in Member States which relate to the 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:

   (a) to specific provisions laid down in Community legislation concerning foods for particular nutritional uses and, in the absence of specific provisions, compositional requirements of such products rendered necessary by the particular nutritional requirements of the persons for whom they are intended;

   (b) to specific provisions laid down in Community legislation concerning novel foods and novel food ingredients;

   (c) to specific provisions laid down in Community legislation concerning food additives and flavourings;

   (d) to specific provisions laid down in Community legislation concerning authorised oenological practices and processes.

---

7 OJ L 184, 17.7.1999, p.23

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) "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;

(2) "nutritional equivalence" means being of similar nutritive value in terms of quantity and bio-availability of vitamins and minerals;

(3) "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;

(4) "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) a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients or,

(b) the potential to improve the nutritional status of the population and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits or,

(c) evolving generally accepted scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health;

(5) "Authority" means the European Food Safety Authority as set by Regulation (EC) No 178/2002 of the European Parliament and the Council.

CHAPTER II

ADDITION OF VITAMINS AND MINERALS

Article 3

Conditions for the addition of vitamins and minerals

1. Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II may be added to foods subject to the rules laid down in this Regulation.

2. Vitamins and minerals may be added to foods only for the purpose of:

(a) restoration and/or,

(b) nutritional equivalence of substitute foods and/or,

(c) fortification or enrichment.

3. Implementing rules for the addition of vitamins and minerals to foods for the purpose of restoration and nutritional equivalence of substitute foods may be adopted, as necessary, in accordance with the procedure referred to in Article 16(2).

4. Modifications to the lists referred to in paragraph 1 shall be adopted in accordance with the procedure referred to in Article 16(2).

Article 4

Transitional measures

By way of derogation from Article 3 paragraph 1 and until (seven years from the entry into force of this Regulation), Member States may allow in their territory the use of vitamins and minerals not listed in Annex I, or in forms not listed in Annex II, provided that:

a) the substance in question is used for addition to foods marketed in the Community on the date of entry into force of this Regulation,

b) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form, in the manufacture of food, on the basis of a dossier supporting use of the substance in question to be submitted to the Commission by the Member State not later than (three years from the entry into force of this Regulation).

Member States may, in compliance with the rules of the Treaty, continue to apply existing national restrictions or bans on trade in foods to which vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II are added.

Article 5

Restrictions on the addition of vitamins and minerals

Vitamins and minerals may not be added to:

a) fresh non-processed produce, including, but not limited to, fruits, vegetables, meat, poultry 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 16(2) and in the light of scientific evidence.

Article 6

Purity criteria

1. The purity criteria for substances listed in Annex II shall be adopted in accordance with the procedure referred to in Article 16(2), except where they apply pursuant to paragraph 2.

2. Purity criteria for substances listed in Annex II, 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 II 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 7

Maximum and minimum amounts

1. When a vitamin or a mineral is added to foods for the purposes specified in Article 3(2), the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed amounts that shall be set. For concentrated and dehydrated products the maximum amounts that shall be set shall be those present in the foods when prepared for consumption according to the manufacturers instructions.

   The maximum amounts of vitamins and minerals referred to in the first sub-paragraph and any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods shall be adopted in accordance with the procedure referred to in Article 16(2).

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.

   c) the nutrient profile of the product established as foreseen by Regulation (EC) No ../2003 on nutrition and health claims made on foods.

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. The minimum amounts, including any lower amounts, by derogation to the significant amounts mentioned above, for specific foods or categories of foods shall be adopted in accordance with the procedure referred to in Article 16(2).

Article 8

Labelling, presentation and advertising

1. 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. Where appropriate a derogation concerning a specific nutrient may be adopted in accordance with the procedure referred to in Article 16(2).

2. 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.

3. 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.

4. Nutrition labelling of products to which vitamins and minerals have been added and covered by this Regulation 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.

5. This Article shall apply 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.

6. Rules for implementing this Article may be specified in accordance with the procedure referred to in Article 16(2).

Article 9

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 unless specific derogations are provided.

2. Where there are no Community provisions, Member States may make provisions for the mandatory addition of vitamins and minerals to specified foods 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 10

Restricted and prohibited substances

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 in each case an assessment of available information by the Authority, a harmful effect on health resulting from such use has been identified, the substance and/or the ingredient containing the substance, where necessary, shall, in accordance with the procedure referred to in Article 16(2):

   (a) either be placed in Annex III, Part A and its addition to foods or its use in the manufacture of foods shall be prohibited;

   (b) or be placed in Annex III, Part B and its addition to foods or its use in the manufacture of foods shall only be allowed under the conditions specified therein.

2. 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.

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 in each case an assessment of available information by the Authority, the possibility of harmful effects on health resulting from such use is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C, in accordance with the procedure referred to in Article 16(2).

2. Food business operators, or any other interested parties, may at any time submit for evaluation to the Authority, a file containing the scientific data demonstrating the safety of a substance listed in Annex III, Part C under the conditions of its use in a food or in a category of foods and explaining the purpose of that use.

3. Within four years from the date a substance has been listed in Annex III, Part C, a decision shall be taken, in accordance with the procedure referred to in Article 16(2) and taking into account the opinion of the Authority on any files submitted for evaluation as mentioned in paragraph 2, to generally allow the use of a substance listed in Annex III, Part C or to list it in Annex III, Part A or B, as appropriate.

CHAPTER IV

GENERAL AND FINAL PROVISIONS

Article 12

Community Register

1. The Commission shall establish and maintain a Community Register on addition of vitamins and minerals and of certain other substances to foods, hereinafter referred to as 'the Register'.

2. The *Register* shall include the following:

   a) The vitamins and minerals which may be added to foods in accordance with Annex I.

   b) The vitamin formulations and mineral substances which may be added to foods in accordance with Annex II.

   c) The maximum and minimum amounts of vitamins and minerals which may be added to foods set in accordance with Article 7.

   d) The information regarding mandatory addition of vitamins and minerals referred to in Article 9.

   e) The substances for which dossiers have been submitted as provided in Article 4 first paragraph, point (b).

   f) Information about the substances referred to in Annex III and the reasons for their inclusion therein.

3. The Register shall be made available to the public.

Article 13

National provisions

Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in foods which comply with this Regulation and Community acts adopted for its implementation by the application of non-harmonised national provisions governing the addition of vitamins and minerals to foods.

Article 14

Notification procedure

1. Where reference is made to this Article, the procedure laid down in paragraphs 2, 3 and 4 shall apply.

2. If a Member State considers it necessary to adopt new legislation, it 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 Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, if it considers such consultation to be useful or if a Member State so requests and shall give an opinion on the envisaged measures.

4. The Member State concerned may take the envisaged measures only six months after the notification referred to in paragraph 2, and provided that the Commission's opinion is not negative.

   If the Commission's opinion is negative, it shall determine, in accordance with the procedure referred to in Article 16(2) and before the expiry of the period referred to in the first subparagraph of this paragraph, whether the envisaged measures may be implemented. The Commission may require certain amendments to be made to the envisaged measure.

Article 15

Safeguard measures

1. Where a Member State has serious grounds for considering that a product endangers human health though it complies with this Regulation, 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. In accordance with the procedure referred to in Article 16(2), a decision shall be taken, where appropriate after obtaining an opinion from the Authority.

   The Commission may initiate this procedure on its own initiative.

3. The Member State referred to in paragraph 1 may maintain the suspension or restriction until the decision referred to in paragraph 2 has been notified to it.

Article 16

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 (1) of Regulation (EC) No 178/2002, hereafter referred to as the "Committee".

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 17

Monitoring

To facilitate efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Part B and Part C, 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 18

Evaluation

By … at the latest [*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. In this context Member States shall provide the necessary relevant information to the Commission by [*first day of sixth month following date of publication + 5 years*]

Article 19

Entry into force

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

It shall apply from [*first day of sixth month following publication*].

Foods placed on the market or labelled prior to [*first day of sixth month following publication*] which do not comply with this Regulation may be marketed until [*last day of the seventeenth month following publication*].

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

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 II

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

- phylloquinone (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

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 III

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

Part A - Prohibited substances

Part B – Restricted substances

Part C - Substances under Community scrutiny

BASIC IMPACT ASSESSMENT STATEMENT

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.

1. WHAT PROBLEM THE POLICY/PROPOSAL IS EXPECTED TO TACKLE ?

Nutrients and other substances are often added to foods voluntarily in order to restore what is lost during processing, to produce foods that would be nutritionally equivalent to an important food item or to enrich foods with particular nutrients or other substances having a nutritional or physiological effect. The nutrients most commonly added to foods for the purposes mentioned above are vitamins and minerals.

The practice of adding vitamins and minerals has attracted attention in recent years because of the increasing scientific evidence of the relationship between diet and health. Manufacturers have developed more products to which vitamins and minerals are added and they tend to promote those as products that would confer a health benefit to consumers. This has lead to increasing concern of authorities regarding the practice and its consequences for public health and to attempts to regulate it by a number of Member States at he national level. It is widely recognised today that relevant national rules vary widely and very often result in obstacles to intra-community trade in such products. Some of these national rules have been considered by the Commission as contrary to the provisions of the Treaty and have resulted in a number of cases currently in front of the European Court. Therefore, it is necessary to harmonise these rules. In its White Paper on Food Safety (COM (1999) 719, adopted on 12 January 2000) 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).

In addition, 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 use of certain such substances or ingredients is increasingly cause for concern from the public health point of view. 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. Again attitudes and rules to such practices vary in the different Member States resulting in obvious problems for the free circulation of products. Member States have asked with insistence the Commission to act on this issue.

2. WHAT MAIN OBJECTIVE IS THE POLICY/PROPOSAL SUPPOSED TO REACH?

The overall policy objectives of the proposal are the basic objectives of food law, namely:

- to contribute to a high level of protection of human health and promote the protection of consumer interests
- to improve the free movement of goods within the internal market
- to increase legal security for operators and through proportionate measures, promote innovation

- to ensure fair competition in the area of foods

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.

The importance of improving the functioning of the internal market for the products concerned is obvious. The proposed rules take also 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.

3. WHAT ARE THE MAIN POLICY OPTIONS AVAILABLE TO REACH THE OBJECTIVE?

The issues arising in the case of addition of vitamins and minerals and of certain other substances to foods concern from the one hand the functioning of the internal market but also the protection of public health. The latter is the main reason put forward by certain Member States for taking certain measures which, however, the Commission has considered as contrary to the provisions of the Treaty. However, the issues concerning public health were mostly relevant to all EU citizens. Therefore, their regulation could not be considered as a matter of subsidiarity and be left to the Member States.

Some of the issues to be regulated are real issues of safety of the products. As examples can be cited the vitamin and mineral substances to be used in the manufacture of these products, that need to be selected on the basis of opinions of the scientific advisory bodies (the Scientific Committee for Food in the past and the European Food Safety Authority in the future) and the maximum levels for certain vitamins and minerals that need to be set again on the basis of scientific advice. The promotion of voluntary Codes of practice by the industry or the adoption of non binding Community measures were, therefore, not a viable option.

The nature of the rules was appropriate for them to be tackled through a Regulation.

4. WHAT ARE THE IMPACTS – POSITIVE AND NEGATIVE – EXPECTED FROM THE DIFFERENT OPTIONS IDENTIFIED?

There are two important elements to bear in mind when considering the impact of the proposed rules on the addition of vitamins and minerals and of certain other substances to foods. First, the addition of these substances is practised on a voluntary basis, that is, no such addition is imposed on the food manufacturers. Second, products to which the nutrients or other substances in question are added are perceived by the consumer and promoted by the manufacturers as of "better" nutritional quality and as conferring certain benefits to those who consume them and as such constitute a developing and promising segment.

Bearing the above in mind it can be said that the proposed rules will have a substantial positive impact both for the economic operators concerned and for consumers. Manufactures will not only benefit from the establishment of common rules in the relevant area which will facilitate the free circulation of the products but will benefit from the opening of certain

national markets which currently are severely restricted by very strict national rules. In fact, the food industry is a strong supporter of harmonising this area. The benefits are likely to be felt by both the big companies and the small and medium enterprises.

Consumers are becoming increasingly conscious of the important relationship between diet and health and are very much attracted by products to which vitamins and minerals and other substances are added. The proposed Regulation will ensure that the products when consumed under normal conditions and as part of a varied diet will pose no risk to public health, an issue closely related to the setting of maximum levels for certain vitamins and minerals in such products. The rules relating to specific labelling requirements will ensure that the consumer disposes of adequate and appropriate information that will help him/her to make informed choices among these products. Consumer organisations are also in favour of this Regulation for this reason.

There are some restrictions concerning certain foods to which vitamins and minerals may be added that may be perceived as having a negative impact for some operators. Such restrictions are based on health considerations like the increasing incidence of obesity and of other chronic diseases for which diet is emerging as a very important factor. However, they concern a very limited number of products to which vitamins and minerals are added today. Food manufacturers, as important players in the shaping of dietary habits for the population, are aware of their responsibilities and the role they are expected to play in promoting health through improved dietary choices and they are expected to adapt accordingly without serious consequences. In any case the great majority of the products marketed today are thriving without any added vitamins and minerals.

There are no particular effects that can be expected for Candidate Countries. The rules would not be contrary to existing Codex Alimentarius Guidelines and, therefore, are not expected to pose any problem at international level. It should also be noted that that important trading partners like the USA, Canada and Australia/New Zealand are either having or are consulting on similar rules or recommendations.

5. HOW TO MONITOR AND EVALUATE THE RESULTS AND IMPACTS OF THE PROPOSAL AFTER IMPLEMENTATION?

One particular concern from the public health point of view is the effect of the rules on the availability of foods to which vitamins and minerals and certain other substances have been added. This is expected to increase in particular in those Member States where national rules were particularly restrictive. Many Member States requested the possibility to monitor consequences for the ingested amounts of certain vitamins and minerals and also for the variation in consumer habits, that may result from the penetration in the market of more such products, through the notification of these products to the competent authorities when they are placed on the market. Such a notification has been foreseen. It is a simple notification that announces the marketing of the product and includes a model of the label of the product and as such does not constitute a burden for the economic operators.

6. WHAT ACTIONS ARE EXPECTED TO FOLLOW-UP?

There has been extensive consultation with Member States and interested stakeholders over the past year in preparing the proposed Regulation through specifically organised meeting and subsequent submission of written comments. The different views and suggestions have been

taken on board to the extent possible and necessary to produce a balanced proposal. An extended assessment on this proposal is not recommended.