Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods

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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 Commission,

Having regard to the Opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[(2)],

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, various plants and herbal extracts. 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 relating to the addition of vitamins and minerals and of certain other substances to foods.

(2) This Regulation aims to regulate the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals that are added to foods or used in the manufacture of foods under 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 and/or would otherwise represent a potential risk to consumers. In the absence of specific Community rules regarding prohibition or restriction of use of substances or ingredients containing substances other than vitamins or minerals under this Regulation or under other specific Community provisions, relevant national rules may apply without prejudice to the provisions of the Treaty.

(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 reasons may be pertinent at national or even regional level, but would not currently justify harmonisation of the mandatory addition of nutrients across the Community. However, if and when this became appropriate, such provisions could be adopted at

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Community level. Meanwhile, it would be useful for information on such national measures to be compiled.

(4) Vitamins and minerals may be added to foods voluntarily by food manufacturers or must be added as nutritional substances as provided for 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 for by relevant Community legislation. This Regulation should apply without prejudice to the specific Community rules concerning the addition of vitamins and minerals to or their use in specific products or groups of products or their addition for purposes other than those covered by this Regulation.

(5) 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.

(6) Vitamins and minerals are added to foods by manufacturers for a number of purposes including to restore their content where this has been reduced during manufacturing, storage or handling procedures or to provide a similar nutritional value to foods for which they are intended as alternatives.

(7) An adequate and varied diet can, under normal circumstances, provide all necessary nutrients for normal development and maintenance of a healthy life in quantities such as those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is being achieved neither for all vitamins and minerals nor by all groups of the population across the Community. Foods to which vitamins and minerals have been added appear to make an appreciable contribution to the intake of these nutrients and as such may be considered to make a positive contribution to overall intakes.

(8) Some nutrient deficiencies, although not very frequent, can be demonstrated to exist at present 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 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.

(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 to foods although this does not mean that their addition thereto is necessary. Controversy as to the identity of these essential nutrients that could potentially arise should be avoided. It is therefore appropriate to establish a positive list of these vitamins and minerals.

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(10) The chemical substances used as sources of vitamins and minerals which may be added to foods 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 on Food in an Opinion expressed on 12 May 1999, on the basis of the above criteria of safety and bio-availability, and can be used in the manufacture of foods intended for infants and young children, other foods for particular nutritional uses or food supplements should appear in this positive list. Although sodium chloride (common salt) does not appear among the substances in this list, it may continue to be used as an ingredient in the preparation of food.

(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 a technical nature and their adoption should be entrusted to the Commission in order to simplify and expedite the procedure.

(12) Foods 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 on 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, such as alcohol, would, in this context, be an appropriate criterion for not allowing vitamins and minerals to be added to it. Any derogation from banning the addition of vitamins and minerals to alcoholic beverages should be limited to protecting traditional wine recipes, with the relevant products being notified to the Commission. No claims about any nutritional or health benefits of the additions should be made. Moreover, in order to avoid any confusion for the consumer as to the natural nutritional value of fresh foods, the addition of vitamins and minerals thereto should not be allowed.

(13) This Regulation is not intended to cover the use of vitamins and minerals in trace quantities as authenticity markers used with the objective of combating fraud.

(14) Excessive intakes of vitamins and minerals may result in adverse health effects and it is therefore necessary to set maximum amounts for them when they are added to foods, as the case may be. These amounts must ensure that the normal use of the products, under the instructions for use provided by the manufacturer and in the context of a diversified diet, will be safe for the consumer. Therefore those amounts should be total maximum safe levels for the vitamins and minerals present in the food naturally and/or added to the food for whatever purpose, including for technological uses.

(15) For that reason those maximum amounts 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

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necessary, for certain vitamins and minerals, to establish restrictions regarding the foods to which they can be added (e.g. the addition of iodine to salt), priority should be given to the purposes of restoring their content where this has been reduced during manufacturing, storage or handling procedures and of providing a similar nutritional value to foods for which those foods are intended as alternatives.

(16) Vitamins and minerals added to foods 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 underlies 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 to which those vitamins and minerals have been added should be the same as those significant amounts that should be present for those nutrients to be declared in nutrition labelling unless otherwise provided for by appropriate derogations.

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

(18) 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)]. This Regulation should therefore be confined to the necessary additional provisions. Those additional provisions should also apply without prejudice to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[(5)].

(19) 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 the global nutritional quality of those products. Therefore, by derogation from Article 2 of Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs[(6)], nutrition labelling should be compulsory.

(20) 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 benefits are unclear; therefore they should be regulated. It is appropriate, in such cases, that food business operators, responsible for the safety of the foods they place on the market, assume the burden of proof in relation to their safety.

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(21) Given the particular nature of foods to which vitamins and minerals are added, means additional to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of those products.

(22) Since the objective of this Regulation, namely to ensure the effective functioning of the internal market as regards the addition of vitamins and minerals and certain other substances to foods whilst providing a high level of consumer protection, cannot be sufficiently achieved by the Member States, and can therefore be better achieved at Community level, the Community may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(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 on the Commission[7],

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1 This Regulation harmonises 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 to specific provisions laid down in Community legislation concerning:

a 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 novel foods and novel food ingredients;

c genetically modified food;

d food additives and flavourings;

e authorised oenological practices and processes.