



The Legal Department informs ...

New Developments in Food Law



Date: February 05, 2007

From: Armin Behringer

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



On 30 December 2006, REGULATION (EC) NO. 1925/2006 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL DATED 20 DECEMBER 2006 ON THE ADDITION OF VITAMINS AND MINERALS AND OF CERTAIN OTHER SUBSTANCES TO FOODS, the so-called Enrichment Regulation, was published in the Official Journal of the European Union. Even though this regulation has often been pushed somewhat into the background in the face of the discussions about the Health Claims Regulation, it still represents an important building block for the functioning of the internal market of the European Community.

The considerations on which the Regulation is based duly state that there is a broad range of nutrients and other ingredients that may be added to foodstuffs during manufacturing, amongst other things vitamins, minerals (including trace elements), amino acids, essential fatty acids, fibre, various plants and herb 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 certain other substances to foods.

However, the objectives pursued by the Regulation have at this point not yet been achieved in full. At present the Regulation is restricted to specifying which vitamins and minerals, including trace elements, that may be added to foods. The more precise conditions of use will not be specified until later on, as is also the case with the “other substances” referred to, the names of which have not yet even been put on record.

The Enrichment Regulation does not apply to dietary supplements, for which there are special provisions, as there are for dietetic foods, provided the dietetic purpose sets different requirements for the composition of such foods. This regulation also does not apply, amongst other things, to food additives and flavourings. This is also important in that some vitamins and minerals can also have a technological function; in this respect the provisions of the Directive on the authorisation of food additives still apply. Where plant and herb extracts are used exclusively for the purpose of flavouring, in other words for the taste, then they, too, will in future no longer come within the scope of this Regulation.

Only vitamins and/or minerals listed in Annex I may be added to foods, and only in the forms listed in Annex II, in order to guarantee that the substances are safe and also bio-available, that is able to be used by the body. Sodium chloride does not appear in this list, it can, however, still be used as an ingredient in the manufacture of foods. Both Annexes are attached.



Vitamins and minerals in a form that is bio-available to the human body may be added to a food, whether or not they are usually contained in that food, in order to take into account, in particular:

- 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
- the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or
- evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

The above criteria must therefore form the basis for the addition of vitamins and minerals.

Vitamins and minerals may not be added to unprocessed foodstuffs, including, for example, fruit and vegetables, as well as beverages containing more than 1.2 % vol. of alcohol. This means, for instance, that ascorbic acid may only be added to a mixed beer drink to prevent oxidation, that is for technological purposes, but not as Vitamin C.

As excessive intakes of vitamins and minerals may result in adverse health effects, it is therefore necessary to set maximum amounts for them that must be observed when they are added to foods for the consumer. Both the vitamins and minerals present naturally in the food and/or added to the food should be taken into account. It is intended that the appropriate maximum amounts will have been stipulated by 19 January 2009.

Furthermore any conditions prohibiting or restricting the addition of a specific vitamin or mineral will be stipulated.

The addition of a vitamin or mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount, as defined in the Directive on nutritional labelling. The practice observed occasionally in the past of adding smaller quantities of vitamins to a food and, as a countermove, refraining from making any claims, is therefore no longer possible.



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.

Whereas according to previous laws, nutrition labelling for foods to which vitamins or minerals had been added was only necessary when a corresponding advertising claim was being made, nutrition labelling will in future be compulsory, i.e. regardless of whether or not any claim is made. This must – again in contrast to the previous ruling – be in the form of the so-called Big 8. Details must be given of the total amount, after any additions, of vitamins and minerals present in the food.

An independent chapter in the Enrichment Regulation deals with the addition of “certain other substances”. “Other substances” within the meaning of the Regulation are substances other than vitamins and minerals that have a nutritional or physiological effect. These include for example amino acids, essential fatty acids, fibre and also herb and plant extracts.

If “another substance” of this type is directly or indirectly added to foods or used in the manufacture of foods under 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/or would otherwise represent a potential risk to consumers, then the procedure described below shall be implemented.

If after testing by the European Food Safety Authority (EFSA) the use of a substance is found to have a harmful effect on health, then this substance shall be placed in Annex III Part A (“Prohibited Substances) and the addition of this substance to foods shall be prohibited. Alternatively the substance may also be placed in Annex III Part B (“Restricted substances”) and its addition to foods shall only be allowed under the conditions specified therein.

If the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C (“Substances Under Community Scrutiny”). Members of the food industry may therefore submit for evaluation to the EFSA at any time scientific data demonstrating the safety of a substance and explaining the purpose of its use. Within four years from the date a substance has been listed in Part C, a decision shall be taken on the basis of the data submitted whether to generally allow the use of this substance, or to list it in Annex III, Part A or B.

As has already been stressed at the start, Annex III does not yet contain the names of any substances.

To facilitate the efficient monitoring of foods to which vitamins and minerals have been added, and of foods containing substances listed in Annex III, Parts B and C, Member States may require the manufacturer of the product or the person placing it on the market in their territory to



notify the competent authority of that placing on the market by providing a sample of the label used for the product. In such cases, information on the withdrawal of the product from the market may also be required. It has not yet been decided whether the Federal government will avail itself of this option.

As the authorisation for the use of vitamins and minerals in the manufacture of foods was subject to vastly differing controls in the Member States of the European Community, various transitional measures were put in place. Amongst other things, Member States have the option of continuing to apply existing national provisions on maximum and minimum amounts of vitamins and minerals listed in Annex I and added to foods, and on the conditions applicable to this addition, until corresponding conditions have been adopted on a Community level. However, in this regard too, it is still unclear whether, and, if so, in what way the Federal government will avail itself of this option.

The Enrichment Regulation came into force on **19 January 2007**. However, it shall not apply until **1 July 2007**.

Foods placed on the market or labelled prior to 1 July 2007 which do not comply with this Regulation may be marketed until their expiry date, but not later than **31 July 2009**. This means that a food that does not comply with the Enrichment Regulation may continue to be manufactured until 30 June 2007 and may then be marketed until its best-before date. This means that the deadline of 31 July 2009 is only relevant to products with a best-before date more than 24 months ahead.

Copies of the text of the Enrichment Regulation may be requested from the Legal Department.



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. Vitamin formulations

VITAMIN A
 retinol
 retinyl acetate
 retinyl palmitate
 beta-carotene

VITAMIN D
 cholecalciferol
 ergocalciferol

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

VITAMIN K
 phyloquinone (phytomenadione)

VITAMIN B1
 thiamin hydrochloride
 thiamin mononitrate

VITAMIN B2
 riboflavin
 riboflavin 5'-phosphate, sodium

NIACIN
 nicotinic acid
 nicotinamide

PANTOTHENIC ACID
 D-pantothenate, calcium
 D-pantothenate, sodium
 dexpanthenol

VITAMIN B6
 pyridoxine hydrochloride
 pyridoxine 5'-phosphate
 pyridoxine dipalmitate

FOLIC ACID
 pteroylmonoglutamic acid

VITAMIN B12
 cyanocobalamin
 hydroxocobalamin

BIOTIN
 D-biotin

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

2. Mineral 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
 calcium sulphate
 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	manganese sulphate
ferrous sulphate	sodium bicarbonate
ferric diphosphate (ferric pyrophosphate)	sodium carbonate
ferric saccharate	sodium citrate
elemental iron (carbonyl + electrolytic + hydrogen reduced)	sodium gluconate
cupric carbonate	sodium lactate
cupric citrate	sodium hydroxide
cupric gluconate	sodium salts of orthophosphoric acid
cupric sulphate	sodium selenate
copper lysine complex	sodium hydrogen selenite
sodium iodide	sodium selenite
sodium iodate	sodium fluoride
potassium iodide	potassium fluoride
potassium iodate	potassium bicarbonate
zinc acetate	potassium carbonate
zinc chloride	potassium chloride
zinc citrate	potassium citrate
zinc gluconate	potassium gluconate
zinc lactate	potassium glycerophosphate
zinc oxide	potassium lactate
zinc carbonate	potassium hydroxide
zinc sulphate	potassium salts of orthophosphoric acid
manganese carbonate	chromium (III) chloride and its hexahydrate
manganese chloride	chromium (III) sulphate and its hexahydrate
manganese citrate	ammonium molybdate (molybdenum (VI))
manganese gluconate	sodium molybdate (molybdenum (VI))
manganese glycerophosphate	