Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2003/0262(COD)
Protection of human health: addition of nutrients to food Amended by 2006/0193(COD) Amended by 2008/0028(COD) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PSE SCHEELE Karin	27/07/2004
Former committee responsible		
ENVI Environment, Public Health, Consumer Policy	PSE LUND Torben	02/12/2003
ENVI Environment, Public Health and Food Safety	PSE SCHEELE Karin	27/09/2004
Former committee for opinion		
ITRE Industry, External Trade, Research, Energy	PPE-DE KHANBHAI Bashir	02/12/2003
IMCO Internal Market and Consumer Protection	PPE-DE STUBB Alexander	31/08/2004
JURI Legal Affairs and Internal Market	PPE-DE KAUPPI Piia-Noora	22/01/2004
JURI Legal Affairs and Internal Market	ELDR WALLIS Diana	18/02/2004
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
Former committee for opinion on the legal basis		
JURI Legal Affairs	PSE MEDINA ORTEGA Manuel	20/09/2004

Council of the European Union

Council configuration	Meeting	Date
Transport, Telecommunications and Energy	2754	12/10/2006
Employment, Social Policy, Health and Consumer Affairs	2733	01/06/2006
Employment, Social Policy, Health and Consumer Affairs	2699	08/12/2005
Employment, Social Policy, Health and Consumer Affairs	2663	02/06/2005
Employment, Social Policy, Health and Consumer Affairs	2627	06/12/2004

European Commission	Employment, Social Policy, Health and Consumer Affairs2586		01/06/2004
	Commission DG	Commissioner	
	Health and Food Safety	KYPRIANOU Markos	

Key events

09/11/2003	Legislative proposal published	COM(2003)0671	
17/11/2003	Committee referral announced in Parliament, 1st reading		
01/06/2004	Debate in Council	2586	
16/09/2004	Committee referral announced in Parliament, 1st reading		
06/12/2004	Debate in Council	2627	
26/04/2005	Vote in committee, 1st reading		Summary
29/04/2005	Committee report tabled for plenary, 1st reading	A6-0124/2005	
25/05/2005	Debate in Parliament		
26/05/2005	Decision by Parliament, 1st reading	T6-0202/2005	Summary
07/12/2005	Council position published	09857/3/2005	Summary
19/01/2006	Committee referral announced in Parliament, 2nd reading		
21/03/2006	Vote in committee, 2nd reading		Summary
23/03/2006	Committee recommendation tabled for plenary, 2nd reading	A6-0078/2006	
15/05/2006	Debate in Parliament		
16/05/2006	Results of vote in Parliament		
16/05/2006	Decision by Parliament, 2nd reading	T6-0199/2006	Summary
01/06/2006	Debate in Council	2733	
12/10/2006	Act approved by Council, 2nd reading		
20/12/2006	Final act signed		
20/12/2006	End of procedure in Parliament		
30/12/2006	Final act published in Official Journal		

Technical information

Procedure reference	2003/0262(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by 2006/0193(COD) Amended by 2008/0028(COD)

Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/32907

Documentation gateway

For information		COM(2003)0671	10/11/2003	EC	Summary
Economic and Social Committee: opinion, report		CES0084/2004 OJ C 112 30.04.2004, p. 0044-0046	31/03/2004	ESC	
Economic and Social Committee: opinion, report		CES0512/2004	31/03/2004	ESC	
Committee draft report		PE353.331	07/01/2005	EP	
Amendments tabled in committee		PE353.662	02/03/2005	EP	
Committee opinion	JURI	PE355.786	01/04/2005	EP	
Committee opinion	IMCO	PE353.489	21/04/2005	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0124/2005	29/04/2005	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0202/2005 OJ C 117 18.05.2006, p. 0023-0205 E	26/05/2005	EP	Summary
Council statement on its position		14793/2005	23/11/2005	CSL	
Council position		09857/3/2005 OJ C 080 04.04.2006, p. 0027-0042 E	08/12/2005	CSL	Summary
Commission communication on Council's position		COM(2006)0001	13/01/2006	EC	Summary
Committee draft report		PE367.862	19/01/2006	EP	
Amendments tabled in committee		PE370.025	22/02/2006	EP	
Committee recommendation tabled for plenary, 2nd reading		A6-0078/2006	23/03/2006	EP	
Text adopted by Parliament, 2nd reading		T6-0199/2006	16/05/2006	EP	Summary
Commission response to text adopted in plenary		SP(2006)2902	22/06/2006	EC	
Commission opinion on Parliament's position at 2nd reading		COM(2006)0369	12/07/2006	EC	Summary
Draft final act		03617/7/2006	20/12/2006	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2006/1925

OJ L 404 30.12.2006, p. 0026 Summary

Protection of human health: addition of nutrients to food

The committee adopted the report by Karin SCHEELE (PES, AT) amending the proposal under the 1st reading of the codecision procedure:
- the regulation should also apply to drinking water;
- although the committee agreed that there was no need to draw up a positive list of 'certain other substances' along the lines of the lists of vitamins and minerals in Annexes I and II, it said that there should at least be a definition of 'certain other substances' in the regulation;
- the regulation should contain a definition of the 'recommended daily intake', taking into account the maximum amounts set in Article 7(1) and the recommended daily allowances (RDAs) for nutrients laid down in Directive 90/496/EEC;
- the Commission should establish, no later than the entry into force of the regulation, RDAs for all the vitamins and minerals listed in Annexes I and II, "taking into account the latest scientific knowledge and international recommendations". Upper safe levels and RDAs should also be set for certain other substances;
- on the question of labelling, manufacturers should be obliged to provide information on vitamins and minerals per serving size, as a percentage of the RDA. In addition, information should be expressed per 100g or per 100 ml. Manufacturers should also state a recommended daily intake and put a warning not to exceed the stated RDA;
- in the interests of legal certainty and effective consumer protection, the purity criteria and the maximum and minimum amounts should be established before the regulation enters into force;
- the reference levels should be aligned to the Codex Alimentarius guidelines, so that different levels apply to solid products and liquid products;
- the opinion of the European Food Safety Authority must be obtained and consultations held with interested parties (such as food business operators and consumer groups) before setting the implementing rules for the regulation;
- although the regulation bans the addition of vitamins and minerals to beverages containing more than 1.2% by volume of alcohol, MEPs adopted an amendment which would allow the continued production and marketing of tonic wine (sold primarily in the United Kingdom), as well as the addition of certain substances, in very small quantities, as "authenticity markers" to help combat the trade in counterfeit spirits. They also extended the ban to foods containing more than 1.2% by volume of alcohol, pointing out that nowadays foods, such as ice-cream, may also contain alcohol;
- Member States should notify the Commission of the substances or ingredients used in their territory to enrich foodstuffs and the substances other than vitamins or minerals that these may contain. The Commission should publish these reports;
- the provisions governing the procedure for evaluating substances were redrafted to make them clearer and more consistent.

Protection of human health: addition of nutrients to food

The European Parliament adopted a resolution based on the report drafted by Karin SCHEELE (PES, AT) by 516 votes in favour, 69 against and 6 abstentions. The principal amendments were as follows:

- there is a new definition of 'certain other substances' in the regulation;

- the regulation should contain a definition of the 'recommended daily intake', taking into account the maximum amounts set in Article 7(1) and the recommended daily allowances (RDAs) for nutrients laid down in Directive 90/496/EEC;

- the Commission should establish, no later than the entry into force of the regulation, RDAs for all the vitamins and minerals listed in Annexes I and II, "taking into account the latest scientific knowledge and international recommendations". Upper safe levels and RDAs should also be set for certain other substances;

- on the question of labelling, manufacturers should be obliged to provide information on vitamins and minerals per serving size, as a percentage of the RDA. In addition, information should be expressed per 100g or per 100 ml. Manufacturers should also state a recommended daily intake and put a warning not to exceed the stated RDA;

- the opinion of the European Food Safety Authority must be obtained and consultations held with interested parties (such as food business operators and consumer groups) before setting the implementing rules for the regulation;

- Member States should notify the Commission of the substances or ingredients used in their territory to enrich foodstuffs and the substances other than vitamins or minerals that these may contain. The Commission should publish these reports;

- The addition of vitamins and minerals to foods shall not be used to mislead or deceive the consumer as to the nutritional merit of the food, whether by means of labelling, presentation, advertising or the additive itself;

- until three 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 under certain conditions. (The Commission had proposed seven years);

- Member States must inform the Commission about the use of vitamins and minerals allowed in their territory although they are not listed in Annex I, or in forms not listed in Annex II. The Commission will make this information available to the public;

- to clarify, no vitamins and minerals may be added to beverages containing more than 1.2% by volume of alcohol, except to products: referred to in Article 44(6) and (13) of Council Regulation 1493/1999/EC on the common organisation of the market in wine and that were marketed prior to the adoption of the Regulation and which have been notified to the Commission by a Member State within six months from the entry into force of the Regulation, and provided no nutrition or health claim is made;

- Recommended daily allowances and upper safe levels shall be set for certain other substances as listed in Annex III, Parts B and C;

- 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, i.e. 15% of the Nutrient Reference Value (NRV) per 100g (solids) or 7.5% of NRV per 100ml (liquids) or 5% of

NRV per 100kcal (12% of NRV 1MJ) or 15% of NRV per serving;

-the provisions governing the procedure for evaluating substances were redrafted;

- If the Commission or a Member State considers that the addition of a substance other than vitamins or minerals or an ingredient containing a substance other than vitamins or minerals may lead to the intake of amounts of that substance exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet, it must notify the Commission without delay.

- Within 18 months of the entry into force of this Regulation, the Member States shall notify theCommission of the substances or ingredients which are used in their territory to enrich foodstuffs and the substances other than vitamins or minerals that these may contain. The Commission shall forward this information to the Authority and shall publish the reports received;

- certain amendments were made to Annexes I and II with regard to fluoride, calcium sulphate potassium phosphate, and sodium phosphate.

Protection of human health: addition of nutrients to food

The Council's common position, adopted by qualified majority, conforms to the objectives of the Commission proposal while introducing a limited number of modifications. These include:

- removing the definitions in Article 2 on the purposes of the addition of vitamins and minerals to food in favour of explaining the circumstances in which vitamins and minerals may be added to food in Article 3 (Requirements);

- a more precise description of derogations applicable to Article 4 (outlining the cases where the addition of vitamins and minerals may not take place) in relation to alcoholic beverages;

- streamlining the provisions applicable to substances other than vitamins and minerals (merging Articles 10 and 11 of the original proposal);

- clarifying the procedures for notification of existing and new national provisions (new Article 11 and deletion of Article 9 of the original text).

The common position reflects the spirit of all or part of 17 of the 23 amendments which were acceptable by the Commission in full, in part, in principle or subject to drafting changes and of 3 amendments which the Commission had originally indicated it was unable to accept. The amendments refer to :

- Restriction on the addition of vitamins and minerals : the common position has introduced a derogation for the addition of vitamins and minerals to well specified traditional beverages containing more than 1.2% by volume of alcohol;

- Other substances : the common position has merged Articles 10 and 11 of the original Commission proposal on the addition of certain other substances to foods into Article 8 simplifying the text and specifying the procedure for evaluation of these substances;

- Annex II : the common position has added to annex II of the Regulation, as an allowed mineral source, calcium sulphate. Moreover, it has maintained in the same Annex the sodium and the potassium salts of ortophosphoric acid and pyridoxine dipalmitate as a source of vitamin B6.

- Other : modifications have been made to Annexes I and II so that the opinion of the Authority shall be taken into account; allowing Member States, during an initial transition period, to authorise on to their territory vitamins and minerals not listed in the annexes of the Regulation provided a dossier is submitted to the Commission. The list of these substances will then be published in the Community register which will be available to the public; the publication in the Community Register of information on national provisions on the mandatory addition of vitamins and minerals; the notification of national prohibitions or restrictions on the use of certain other substances.

It should be noted that the Council has not incorporated the amendments concerning : the bio-availability of added vitamins and minerals; the necessity that labelling, presentation and advertising

should not mislead consumers; proposing to take into consideration the intakes of vitamins and minerals from food supplements when setting maximum levels; making compulsory the consultation of the Standing Committee on the Food Chain and Animal Health when Member States notify the Commission on the adoption of new provisions and proposing the communication to the Commission and the publication of the notifications of the placing on the market of foods covered by the Regulation.

Other innovations introduced in the common position include:

- the grouping of all the applicable transitional measures in a new Article 17, with the deletion of Article 4 of the original proposal;

- a revision of Articles 6 (on conditions on the addition of vitamins and minerals) and 7 (on labelling, presentation and advertising) following the deletion of the definitions in Article 2;

- a modification of Article 15 on monitoring, so that when a notification of placing on the market is required, information on the withdrawal of the product from the market can also be required;

- a reference to implementation rules for the application of Article 16;

- the deletion of sodium chloride from Annex II and with a corresponding modification of Recital 11 explaining this change.

Protection of human health: addition of nutrients to food

The Commission supports the common position as adopted by the Council at qualified majority. It is in line with the aims and the approach taken in the Commission?s original proposal and takes into account several amendments proposed by the European Parliament. The common position reflects the spirit of all or part of 17 of the 23 amendments which were acceptable by the Commission in full, in part, in principle or subject to drafting changes and of 3 amendments which the Commission had originally indicated it was unable to accept.

The Commission would also like to remark that, concerning the modification to the compulsory elements of nutritional labelling, the common

position makes implicit reference to the incompleteness of the Annex of Directive 90/496/EEC. Moreover, it includes a statement by the Commission indicating its intention to revise the Annex of Directive 90/496/EEC on nutritional labelling and consequently reflect these modifications in the Regulation on the addition of vitamins and minerals and of certain other substances to foods. The Commission also engages itself to present within two years following the adoption of the Regulation a proposal for the establishment of maximum/minimum amounts of vitamins and minerals and of any related condition.

Lastly, it should be noted that in the framework of Article 4 on Restrictions on the addition of vitamins and minerals (second indent) the Commission will examine the possible addition of food categories such as confectionery.

Protection of human health: addition of nutrients to food

The committee adopted the report by Karin SCHEELE (PES, AT) amending the Council's common position under the 2nd reading of the codecision procedure. It reinstated, sometimes in slightly modified form, a number of amendments adopted by Parliament at 1st reading which had not been taken up by the Council:

- the regulation should contain a definition of 'certain other substances' (meaning a substance other than a nutrient that has a nutritional or physiological effect) and of 'recommended daily intake';

- to ensure that information for consumers is easy to understand and useful for them, nutrition labelling of products should give information on vitamins and minerals expressed not only per 100g or per 100 ml but also per serving size (amount per serving) in absolute numbers and as a percentage of the Recommended Daily Allowance (RDA). The label should also mention the manufacturer's Recommended Daily Intake of the product (RDI), together with a warning not to exceed the stated RDA;

- it should be stipulated that vitamins and minerals may only be added to foods "in a form that is bio-available to the human body" (i.e. they can be absorbed by the body);

- the Commission must hold consultations with interested parties (such as the food industry and consumer groups) before setting the implementing rules for the regulation.

The committee also sought to reach a compromise with the Council on the question of setting a date for establishing maximum amounts for vitamins or minerals added to foods. Although at 1st reading Parliament had called for such amounts to be established before the regulation's entry into force, the Council did not stipulate any date in its common position. By way of a compromise, MEPs in the committee therefore proposed that the Commission should put forward proposals for the maximum amounts not later than two years after the regulation entered into force.

In another attempt to strike a deal with Council, the committee slightly modified Parliament's 1st reading amendment (rejected by Council) on aligning reference levels with international standards so that different levels apply to solid products and liquid products. It proposed using the term 'RDA' (Recommended Daily Allowance) rather than 'NRV' (Nutrient Reference Value) as Parliament had initially suggested, on the grounds that this was appropriate in order to harmonise this requirement with existing EU legislation on food labelling.

Lastly, MEPs wanted to introduce a degree of flexibility about the cut-off date for selling products which do not comply with the regulation. Whereas the Council had proposed that such products could only be marketed for a maximum of 29 months after the regulation's entry into force, the committee proposed that they be marketed "until all stocks have been sold off", in order to take into account products with a longer shelf life.

Protection of human health: addition of nutrients to food

The European Parliament adopted a resolution drafted by Karin SCHEELE (PES, AT) and voted to adopt the compromise text agreed by Parliament, Council and Commission. The compromise focuses primarily on three elements: the definition of ?other substances?, the setting of vitamin and mineral ratios, and the extension of marketing deadlines for foods after the entry into force of the legislation. The main amendments were as follows:

- ?Other substance? means a substance other than a vitamin or a mineral that has a nutritional or physiological effect. The Council had ignored this amendment in its common position.

- The compromise text includes the notion of ?bioavailability? in its operative clauses. Nutrients added must be capable of being used by the body. Otherwise it would be misleading for the consumer and in extreme cases ?can cause damage to health?.

- The positive list attached to the regulation listing more than 100 formulae for vitamins and minerals that can be added to food has been removed from the compromise.

- The Commission may submit proposals for the maximum amounts of vitamins and minerals in the food as sold, within years of entry into force of the Regulation.

- Finally, foods present on the market prior to the entry into force of the Regulation may be sold up to 35 months after its entry into force.

Protection of human health: addition of nutrients to food

The Commission can accept all 8 amendments adopted by the European Parliament in full. They are the result of a compromise agreement reached between the European Parliament, Council and Commission during the second reading.

The main modifications introduced by these amendments are the following:

- introduce a definition of other substances in line with the one present in the draft Regulation on nutritional and health claims (refer to COD/2003/0165);
- provide that substances put under scrutiny in accordance with the procedure described in Article 8 and then generally allowed are listed in the Community register;
- underline that vitamins and minerals added to foods have to be bioavailable to the human body;
- provide that, prior to making modification to the Annexes, the Commission has to carry out consultations with interested parties;
- foresee that the Commission may submit a proposal for the maximum amounts of vitamins and minerals added to foods by two years from the date of entry into force of the Regulation;
- provide that foods placed on the market or labelled prior to the date of application of the Regulation and which do not comply with it, may be marketed until thirty-fifth months following the date of entry into force of the Regulation;
- give into a recital an example of restrictions regarding the food to which vitamins and minerals can be added and specify that such restrictions should concern particular vitamins and minerals.

The amendments are in line with the Commission?s objectives for the proposal and maintain the balance of interests achieved in the common position.

Protection of human health: addition of nutrients to food

PURPOSE: to adopt Community rules harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods.

LEGISLATIVE ACT: Regulation 1925/2006/EC of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

CONTENT: the Council adopted, with a qualified majority, the Regulation on the addition of vitamins and minerals and of certain other substances to foods, after approving all of the amendments adopted by Parliament at second reading. The Danish delegation voted against the Regulation.

There is a wide range of nutrients and other ingredients that might be used in food manufacturing, including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibres and various plants and herbal extracts. Their addition to foods is regulated in the Member States by differing national rules that impede the free movement of these products and creates unequal conditions of competition. This has a direct impact on the functioning of the internal market. The purpose of this Regulation, therefore, is to adopt Community rules harmonising national provisions relating to the addition of vitamins and minerals and of certain other substances to foods.

It does so by harmonising 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. At the same time the Regulation seeks to provide a high level of consumer protection.

The provisions of this Regulation will not apply to ?food supplements? as set out in Directive 2002/46/EC. It does, however, refer to:

- food for particular nutritional uses;
- novel food and novel food ingredients;
- genetically modified food;
- food additives and flavourings;
- authorised oenological practices and processes.

The provisions specify that only those vitamins and/or minerals listed in Annex I and Annex II of the Regulation may be added to foods. Vitamins and minerals in a form that is bio-available to the human body may be added to food to take account of:

- a deficiency of vitamins and/or minerals in the population;
- the potential to improve the nutritional status of the population; and
- the evolving acceptable scientific knowledge on the role of vitamins and minerals in nutrition.

Vitamins and minerals will not be allowed in unprocessed foodstuffs nor beverages containing more than 1,2% by volume of alcohols.

The purity criteria for vitamin formulations and mineral substances listed in Annex II will be adopted in accordance with the procedures laid down in this Regulation. In cases where a vitamin and mineral is added to foods, the total amount of the vitamin and mineral present, in the food as sold, will not be allowed to exceed the maximum amounts laid down in accordance with this Regulation.

The labelling, presentation and advertising of foods to which vitamins and minerals may have been added will not include any mention that a balanced and varied diet cannot provide the appropriate quantities of nutrients; nor must the labelling be misleading. The Commission will be responsible for establishing and maintaining a Community Register on the addition of vitamins and minerals and of certain other substances to foods.

On a final point transitional measures are foreseen. They state:

- Member States will be allowed to use vitamins and minerals not listed in Annex I and Annex II until 19 January 2007 provided that the substance in question is used for addition to foods marketed in the Community on 19 January 2007.
- Member States may 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.

ENTRY INTO FORCE: 19 January 2007.

APPLICATION: 1 July 2007.