



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.1.2006

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2003/0262 (COD)

**COMMUNICATION FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT**

pursuant to the second subparagraph of Article 251 (2) of the EC Treaty

concerning the

**common position of the Council on the adoption of a Regulation of the European
Parliament and of the Council on the addition of vitamins and minerals and of certain
other substances to foods**

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1- BACKGROUND

Date of transmission of the proposal to the European Parliament and the Council 10 November 2003
(document COM(2003) 671 final – 2003/0262 (COD):

Date of the opinion of the European Economic and Social Committee: 31 March 2004

Date of the opinion of the European Parliament, first reading: 26 May 2005

Date of adoption of the common position: 8 December 2005.

2- OBJECTIVE OF THE COMMISSION PROPOSAL

The proposed Regulation covers the addition of vitamins and minerals and of certain other substances to foods.

The main objectives of the proposal are:

- to improve the free movement of goods within the internal market
- to contribute to a high level of protection of human health
- to increase legal security for operators and through proportionate measures, promote innovation
- to ensure fair competition in the area of foods.

The proposed Regulation :

- 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

- provides for certain restrictions regarding the foods to which vitamins and minerals may be added
- sets 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
- provides for the setting of minimum levels of vitamins and minerals through the procedure of the Standing Committee on the Food Chain and Animal Health.
- 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
- enables Member States to require the notification of the marketing of these products in order to facilitate their monitoring
- provides the basis for scrutinising and, where necessary, regulating the addition of certain substances, other than vitamins and minerals, to foods.

3- COMMENTS ON THE COMMON POSITION

3.1 SUMMARY OF THE POSITION OF THE COMMISSION

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.

3.2 AMENDMENTS MADE BY THE EUROPEAN PARLIAMENT AT FIRST READING ACCEPTED BY THE COMMISSION AND INCORPORATED IN THE COMMON POSITION

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.

Restriction on the addition of vitamins and minerals

The common position has included in Article 4 Amendments 49/rev and 54/rev, thus introducing 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 in line the requests of Amendments 34, 35 and 55.

Annex II

The common position has added to annex II of the Regulation, as an allowed mineral source, calcium sulphate, taking into account Amendment 44. Moreover, it has maintained in the same Annex the sodium and the potassium salts of orthophosphoric acid and pyridoxine dipalmitate as a source of vitamin B6. These retentions have the same effect than Amendments 45 and 46.

Other

Amendment 1 (last part) has been considered in the new drafting of recital 8 of the common position. The Commission, even if it has originally indicated that it could not accept Amendment 1, is prepared to support this redrafting related to the effort of simplification of the text of Articles 2 and 3 (deletion of the concepts of “restoration”, “substitute food” and “nutritional equivalence”).

Amendments 2 (first part) has been incorporated in the common position in recital 10.

Amendment 4 has been taken in part and in principle in Recital 2 and in Article 11 paragraph 2, second part.

Amendment 5 and Amendment 25 have been incorporated in principle with the rewording of Article 6 paragraph 6. The Commission recognizes that the Annex of Directive 90/496/EEC on nutritional labelling is not complete therefore can support this redrafting and engages itself in a Declaration to reflect modifications that may be adopted in the future revision of the abovementioned Directive in the Regulation on the addition of vitamins and mineral and of certain other substances to foods.

Amendment 13 and 41 have been partially reflected in Article 3 paragraph 3 which indicates that modification to the Annexes I and II will be adopted taking into account the opinion of the Authority.

Amendment 16 is partially reflected in Articles 17 paragraph 1(b) and in Article 9 paragraph 2(d) according to which during the initial transitional period Member States could allow in 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.

Amendment 17 (first part) has been incorporated in the common position in Article 17 paragraph 2.

Amendment 31 is addressed by Article 9 paragraph 2(d) concerning the publication in the Community Register of information on national provisions on the mandatory addition of vitamins and minerals.

Amendment 38 (first part) has been partially taken into consideration in Article 9 paragraph 2(d) of the common position. In fact information concerning mandatory addition of vitamins and minerals will be included in the Community Register.

Amendment 39 has been partially considered in Article 11 paragraph 2(b) of the common position concerning the notification of national prohibitions or restrictions on the use of certain other substances.

3.3 AMENDMENTS MADE BY THE EUROPEAN PARLIAMENT AT FIRST READING ACCEPTED BY THE COMMISSION AND NOT INCORPORATED IN THE COMMON POSITION

In light of the significant degree of alignment between the Amendments of the Parliament acceptable to the Commission and the common position, the Commission has accepted a compromise which does not include a small number of amendments which it could have, at least in part, accepted (Amendments 11 on the bio-availability of added vitamins and minerals, Amendments 12 and 28 on the necessity that labelling, presentation and advertising should not mislead consumers, Amendment 22 proposing to take into consideration the intakes of vitamins and minerals from food supplements when setting maximum levels, Amendment 40 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 Amendment 42 proposing the communication to the Commission and the publication of the notifications of the placing on the market of foods covered by the Regulation). The Commission would like to remark that the concerns expressed in some of these Amendments are implicitly addressed by the common position and specifically in recital 10 for Amendment 11, in article 7 paragraph 2 for Amendments 12 and 28 and in recital 15 and in Article 6 paragraph 3(b) for Amendment 22.

The Commission would also like to remark that, concerning the modification to the compulsory elements of nutritional labelling, the common position makes implicit reference in Article 6 paragraph 6 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. In the view of the Commission this responds in principle to the aim of Amendments 21, 26 and 30.

3.4 NEW PROVISIONS INTRODUCED IN THE COUNCIL'S COMMON POSITION

The common position has deleted the concepts of “restoration”, “substitute food” and “nutritional equivalence” as purposes for the addition of vitamins and minerals to foodstuffs in Article 2 and consequently the requirements and the conditions for addition of vitamins and minerals to foods in Article 3 and 6. The Commission can accept these changes in the context of a simplification effort.

For the sake of clarity the Commission is ready to accept the grouping of all transitional measures into the new Article 17, with the consequent deletion of Article 4 of the original proposal concerning transitional measures for the addition of vitamins and minerals to foods.

In order to facilitate the monitoring of their market the Commission can accept that Member States can require notification for both the placing and the withdrawal of products to which vitamins and minerals have been added from their market (Article 15).

Finally, the Commission supports the deletion of sodium chloride from Annex II together with the clarification in recital 10 that this substance can continue to be used as an ingredient in the preparation of foods.

4- CONCLUSION

In the light of the above comments, the Commission agrees with the common position by the Council with a view of the adoption of a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

5- DECLARATIONS

The Commission declarations to the minutes of the Council are attached in annex to this communication.

ANNEX

COMMISSION DECLARATIONS

STATEMENT BY THE COMMISSION AND THE COUNCIL

"The Council and the Commission declare that any claim (message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation) related to the addition of vitamins and minerals such as: "with...", "restored in...", "added...", enriched..." should be considered as having the same meaning for consumers as the claim "source of..." as defined in the Annex of the Regulation on nutrition and health claims made on foods."

STATEMENT BY THE COMMISSION

"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."

STATEMENT BY THE COMMISSION

"In the framework of its reflection on the revision of Directive 90/496/EEC on nutrition labelling of foodstuff, the Commission has the intention to consider the following elements in relation to vitamins and minerals:

- revising/updating reference values included in the Annex of Directive 90/496/EEC and the levels that may be considered as significant amounts.
- establishing tolerance levels for acceptable variation from the declared value of added vitamins and minerals on the nutrition label.

Any modification to the compulsory elements of nutritional labelling that may be adapted in the future revision of nutrition labelling Directive will be consequently reflected in Article 7 paragraph 3 of the Regulation on the addition of vitamins and minerals and of certain other substances to foods.

The Commission has the intention to present as soon as possible and in any case within two years following the adoption of the Regulation a proposal for the establishment of maximum/minimum amounts of vitamins and minerals and any conditions for their addition to food as referred to in Article 6 paragraph 2."

STATEMENT BY THE COMMISSION

"The Commission confirms that additional wording for the labelling, designed to draw the attention of particular categories of consumer to the specific risks which certain substances may present for them, can be envisaged as a condition when the maximum content for certain substances listed in Annex I is fixed, if such wording is justified by public-health protection considerations."