Regulation (EC) No 108/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

REGULATION (EC) No 108/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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amending Regulation (EC) No 1925/2006 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) Regulation (EC) No 1925/2006 of the European Parliament and of the Council[(3)] provides that the regulatory procedure established by Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(4)] is to be applied for the adoption of implementing measures concerning that Regulation.

(2) Decision 1999/468/EC has been amended by Decision 2006/512/EC, which introduced the regulatory procedure with scrutiny for the adoption of measures of general scope and designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, *inter alia*, by deleting some of those elements or by supplementing the instrument with new non-essential elements.

(3) The Commission should be empowered to adopt modifications to Annexes I and II to Regulation (EC) No 1925/2006; to establish additional foods to which particular vitamins or minerals may not be added; to take decisions to establish and/or amend the lists of authorised, prohibited or restricted other substances; to define the conditions under which vitamins and minerals may be used, such as purity criteria, maximum amounts, minimum amounts and other restrictions or prohibitions on the addition of vitamins and minerals to food; and to establish derogations from certain provisions of that Regulation. Since those measures are of general scope and are designed to amend non-essential elements of that Regulation, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(4) When, on imperative grounds of urgency, the normal time-limits for the regulatory procedure with scrutiny cannot be complied with, the Commission should be able to use the urgency procedure provided for in Article 5a(6) of Decision 1999/468/EC for the deletion of certain vitamins or minerals listed in the annexes and for the inclusion and amendment of certain other substances in Annex III to Regulation (EC) No 1925/2006.

(5) Regulation (EC) No 1925/2006 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1925/2006 is hereby amended as follows:

1. Article 3(3) shall be replaced by the following:

3. Modifications to the lists referred to in paragraph 1 of this Article shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), taking account of the opinion of the Authority.

On imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(4) in order to remove a vitamin or a mineral from the lists referred to in paragraph 1 of this Article.

Prior to making these modifications, the Commission shall carry out consultations with interested parties, in particular food business operators and consumer groups.;

2. in Article 4, the second paragraph shall be replaced by the following:

Measures determining the additional foods or categories of foods to which particular vitamins and minerals may not be added and designed to amend non-essential elements of this Regulation may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) in the light of scientific evidence and taking into account their nutritional value.;

3. Article 5(1) shall be replaced by the following:

1. Measures determining the purity criteria for vitamin formulations and mineral substances listed in Annex II and designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), except where they apply pursuant to paragraph 2 of this Article.;

4. Article 6 shall be amended as follows:

(a) paragraph 1 shall be replaced by the following:

1. When a vitamin or a mineral is added to foods, the total amount of the vitamin or mineral present, for whatever purpose, in the food as sold shall not exceed maximum amounts. Measures setting that amount and designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3). The Commission may, to this end, submit a draft of measures for the maximum amounts by 19 January 2009. For concentrated and dehydrated products, the maximum amounts set shall be those present

in the foods when prepared for consumption according to the manufacturer's instructions.;

(b) paragraph 2 shall be replaced by the following:

2. Any conditions restricting or prohibiting the addition of a specific vitamin or mineral to a food or a category of foods and designed to amend non-essential elements of this Regulation, *inter alia*, by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

(c) paragraph 6 shall be replaced by the following:

6. The addition of a vitamin or a mineral to a food shall result in the presence of that vitamin or mineral in the food in at least a significant amount where this is defined according to the Annex to Directive 90/496/EEC. Measures determining the minimum amounts, including any lower amounts, by derogation from the significant amounts mentioned above, for specific foods or categories of foods and designed to amend non-essential elements of this Regulation by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3) of this Regulation.;

5. Article 7(1) shall be replaced by the following:

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 and designed to amend non-essential elements of this Regulation by supplementing it may be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).;

6. Article 8 shall be amended as follows:

(a) paragraph 2 shall be replaced by the following:

2. On its own initiative or on the basis of information provided by Member States, the Commission may take a decision designed to amend non-essential elements of this Regulation, following in each case an assessment of available information by the Authority, in accordance with the regulatory procedure with scrutiny referred to in Article 14(3), to include, if necessary, the substance or ingredient in Annex III. In particular:

a if a harmful effect on health has been identified, the substance and/or the ingredient containing the substance shall:

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

(ii) 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;

b if the possibility of harmful effects on health is identified but scientific uncertainty persists, the substance shall be placed in Annex III, Part C.