

Commission Decision of 30 July 2008 concerning a draft Decree from the Czech Republic laying down requirements for food supplements and the enrichment of foodstuffs (notified under document number C(2008) 3963) (Only the Czech text is authentic) (Text with EEA relevance) (2008/864/EC)

COMMISSION DECISION

of 30 July 2008

concerning a draft Decree from the Czech Republic laying down requirements for food supplements and the enrichment of foodstuffs

(notified under document number C(2008) 3963)

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(Text with EEA relevance)

(2008/864/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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⁽¹⁾, and in particular Articles 11(2)(b) and 12 thereof,

Whereas:

- (1) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods, in the absence of Community provision, provides for the notification and the assessment of national new provisions concerning, *inter alia*, the prohibition or restriction on the use of certain other substances in the manufacture of specified foods.
- (2) In accordance with the procedure provided for in Article 12 read in conjunction with Article 11(2)(b) of Regulation (EC) No 1925/2006, the Czech authorities notified the Commission on 30 November 2007 of a draft Decree laying down requirements for food supplements and the enrichment of foodstuffs, and in particular Articles 2(3) and 4 as well as the Annexes 4 and 5 thereto.
- (3) Article 2(3) of the draft Decree establishes by means of Annex 4 thereto a list of other substances in the sense of Article 2(2) of Regulation (EC) No 1925/2006, as well as the respective conditions under which these substances may be used in the manufacture of food supplements.
- (4) Articles 2(3) and 4 of the draft Decree establish by means of Annex 5 thereto a list of plants and other substances that are prohibited in the manufacture of food supplements and foodstuffs in general.

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- (5) In accordance with the provisions of Article 12(2) of Regulation (EC) No 1925/2006, the Commission consulted the other Member States via the Standing Committee on the Food Chain and Animal Health.
- (6) The draft Decree, as it currently stands, does not indicate why the substances contained in Annex 4 have to comply with the thresholds thereof based on public health reasons.
- (7) In the absence of harmonised Community legislation, Member States retain their competence to regulate the production and marketing of goods in their territory without prejudice to the Articles 28 and 30 of the EC Treaty.
- (8) In particular, Article 2(3) of the draft Decree read in conjunction with Annex 4 thereto appears to suggest that substances other than those listed therein are not permitted to be used in the manufacture of food supplements.
- (9) Even if were demonstrated that Annex 4 is justified on the basis of public health reasons, the draft decree does not indicate how products, lawfully produced and/or marketed in other Member States that do not comply with the requirements laid down in Articles 2(3) and 4 thereof will be treated.
- (10) The draft Decree does not contain any provision ensuring the free movement of food supplements lawfully produced and/or marketed in other Member States which contain substances that are included in Annex 4 thereto but not in accordance with the conditions laid down therein, or substances other than those included in Annex 4 thereto either in the form of a mutual recognition clause or in the form of an approval procedure enabling economic operators to have such substances included on the national list of authorised substances.
- (11) Pursuant to Articles 2(3) and 4 of the notified Decree read in conjunction with Annex 5 thereto, food supplements and foodstuffs in general shall contain no narcotic or psychotropic substances, nor precursors of Category 1, nor any other substance demonstrated to have a toxic, genotoxic, teratogenic, hallucinogenic, narcotic or other unfavourable effects on the human body, nor any of the substances contained in Annex 5 thereto. The prohibition of certain other substances for the manufacture of food supplements and foodstuffs in general may be justified on grounds of the protection of health and life of humans within the meaning of Article 30 EC Treaty.
- (12) Since the latter article provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health.
- (13) The Czech authorities have not provided any evidence that would justify the establishment of a list containing prohibited substances to be used in the manufacture of food supplements and foodstuffs in general.
- (14) Even if such evidence were provided, the draft Decree does not contain any provision ensuring the free movement of food supplements and foodstuffs in general lawfully

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produced and/or marketed in other Member States which contain substances not permitted thereby.

- (15) Therefore, the draft Decree fails to provide adequate guarantees that the rights of the economic operators deriving from Articles 28 and 30 of the EC Treaty.
- (16) In light of these observations, the Commission has delivered a negative opinion pursuant to Article 12(3) of Regulation (EC) No 1925/2006.
- (17) The Czech authorities should accordingly be requested not to adopt the draft Decree in question and modify it in accordance with Articles 28 and 30 of the EC Treaty taking into account the observations of the Commission in its negative opinion.
- (18) The measures provided for in this Decision are in line with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

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- (1) [OJ L 404, 30.12.2006, p. 26.](#)

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