

Communication from the Commission - TRIS/(2017) 00520  
Directive (EU) 2015/1535  
Notification: 2016/0615/B

Detailed opinion from the Commission (article 6, paragraph 2, second indent of Directive (EU) 2015/1535). This detailed opinion extends the standstill period until 29-05-2017.

Comunicado detallado - Podrobné vyjádření - Udførlig udtalelse - Ausführlichen Stellungnahme - Üksikasjalik arvamus - Εμπειριστικωμένη γνώμη - Detailed opinion - Avis circonstancié - Parere circostanziato - Detalizēts atzinums - Detali nuomonė - Részletes vélemény - Opinioni dettaljata - Uitvoerig gemotiveerde mening - Opinia szczegółowa - Parecer circunstanciado - Podrobný úsudok - Podrobno mnenje - Yksityiskohtainen lausunto - Detaljerat yttrande - Подробно становище - Aviz detaliat - Aviz detaliat.

Amplia el plazo del estatu quo hasta 29-05-2017. - Prodlužuje lhůtu pro stávající stav až do 29-05-2017. - Fristen for status quo forlænges til 29-05-2017. - Die Laufzeit des Status quo wird verlängert bis 29-05-2017. - Praeguse olukorra tähtaega pikendatakse kuni 29-05-2017. - Παρατείνει την προθεσμία του status quo μέχρι την 29-05-2017. - Extends the time limit of the status quo until 29-05-2017. - Prolonge le délai de statu quo jusqu'au 29-05-2017. - Proroga il termine dello status quo fino al 29-05-2017. - Pagarina "status quo" laika periodu līdz 29-05-2017. - Pratešia status quo laiko limitą iki 29-05-2017. - Meghosszabbítja a korábbi állapot határidejét 29-05-2017-ig. - Jestendi t-terminu ta' l-istatus quo sa 29-05-2017. - De status-quo-periode wordt verlengd tot 29-05-2017. - Przedłużenie status quo do 29-05-2017. - Prolonga o prazo do statu quo ate 29-05-2017. - Časový limit momentálneho stavu sa predĺži až do 29-05-2017. - Podaljša rok nespremenjenega stanja do 29-05-2017. - Jatkaa status quo määräaika 29-05-2017 asti - Förlänger tiden för status quo fram till: 29-05-2017 - Удължаване на крайния срок на статуквото до 29-05-2017 - Prelungește termenul status quo-ului până la 29-05-2017.

Die Kommission hat diese ausführliche Stellungnahme am 24-02-2017 empfangen.  
The Commission received this detailed opinion on the 24-02-2017.  
La Commission a reçu cet avis circonstancié le 24-02-2017.

(MSG: 201700520.EN)

1. MSG 315 IND 2016 0615 B EN 27-02-2017 24-02-2017 COM 6.2(2) 27-02-2017

2. Commission

3. DG GROW/B/2 - N105 04/63

4. 2016/0615/B - C00A

5. article 6, paragraph 2, second indent of Directive (EU) 2015/1535

6. Within the framework of the notification procedure laid down by Directive (EU) 2015/1535, the Belgian authorities notified to the Commission on 25 November 2016 the draft "Royal Decree amending the Royal Decree of 3 March 1992 concerning the placing on the market of nutrients and foodstuffs to which nutrients have been added".

It is explained in the notification message that the purpose of the notified draft is to establish maximum levels for vitamins, minerals and trace minerals in food supplements and fortified foods, based on recent scientific data. Examination of the draft has prompted the Commission to issue the following detailed opinion and comments.

#### DETAILED OPINION

Article 9 of the notified draft amends Annex 3(1) to the basic act which specifies substances the marketing of which are prohibited.

Article 9(3) of the notified draft amends point 1.4 of Annex 3 to the basic act as follows:

"3. the provision under 1.4, replaced by the Royal Decree of 15 May 2003, shall be rectified as follows:

"1.4 Nicotinic acid and inositol hexanicotinate (inositol hexaniacinate) as a source of niacin.""

In this respect it should be recalled that Directive 2002/46/EC on food supplements and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods harmonise the addition of vitamins and minerals and of certain other substances to foods and food supplements as applicable.

Article 3(1) of Regulation (EC) No 1925/2006 provides:

"Only vitamins and/or minerals listed in Annex I, in the forms listed in Annex II, may be added to foods, subject to the rules laid down in this Regulation."

Annex I to that Regulation titled "Vitamins and minerals which may be added to foods" in point 1 "Vitamins" lists niacin.

Annex II to that Regulation titled "Vitamin formulations and mineral substances which may be added to foods" states that for niacin the permitted formulations are nicotinic acid and nicotinamide.

The provisions of this Regulation regarding vitamins and minerals do not apply to food supplements covered by Directive 2002/46/EC (Article 1(2)).

Directive 2002/46/EC, Article 4 stipulates:

"1. Only vitamins and minerals listed in Annex I, in the forms listed in Annex II, may be used for the manufacture of

food supplements [...]."

Annex I to that Directive titled "Vitamins and minerals which may be used in the manufacture of food supplements", in point 1 "Vitamins" lists niacin.

Annex II to that Directive titled "Vitamin and mineral substances which may be used in the manufacture of food supplements", Part A "Vitamins", point 7 provides that for niacin such permitted substances are nicotinic acid, nicotinamide and inositol hexanicotinate (inositol hexaniacinate).

Therefore, it follows that Article 9(3) of the notified draft, which amends point 1.4 in Annex 3 to the basic act, does not permit the addition of nicotinic acid and inositol hexanicotinate (inositol hexaniacinate) to foodstuffs, including food supplements.

For these reasons, the Commission delivers a detailed opinion provided for in Article 6(2) of Directive (EU) 2015/1535 to the effect that:

- insofar Article 9(3) of the notified draft does not permit the addition of nicotinic acid to foodstuffs covered by Regulation (EC) No 1925/2004, it would be in breach of Article 3(1) of that Regulation and
- insofar Article 9(3) of the notified draft does not permit the addition of nicotinic acid and inositol hexanicotinate (inositol hexaniacinate) to food supplements covered by Directive 2002/46/EC, it would be in breach of Article 4(1) of that Directive, were this provision to be adopted without giving due consideration to the above remarks.

The Commission would remind the Belgian Government that under the terms of article 6(2) of the above-mentioned Directive (EU) 2015/1535, the delivery of a detailed opinion obliges the Member State which has drawn up the draft technical regulation concerned to postpone its adoption for six months from the date of its notification. This deadline therefore comes to an end on 29 May 2017.

The Commission further draws the attention of your Government to the fact that under this provision the Member State which is the addressee of a detailed opinion is obliged to inform the Commission of the action which it intends to take as a result of the opinion.

The Commission furthermore invites your Government to communicate to it on adoption the definitive text of the draft technical regulation concerned, in accordance with Article 5(3) of Directive (EU) 2015/1535.

In line with the usual procedure under EU law, please be advised that should your Government not comply with the obligations foreseen in Directive (EU) 2015/1535 or should the text of the draft technical regulation under consideration be adopted without account being taken of the above-mentioned objections or be otherwise in breach of European Union law, the Commission may commence proceedings pursuant to Article 258 TFEU.

Comments

The Commission notes that the notified draft describes the general principles that apply as well as certain labelling obligations. It also provides in Article 7 a reference to a general mutual recognition clause, which reads as follows: "The following Article 11/1 is also inserted into the same Decree:

Article 11/1. The provisions of this Decree do not apply to products lawfully placed on the market in other Member States of the European Union or in States party to the Agreement on the European Economic Area, unless the principle of mutual recognition cannot be applied in accordance with Articles 34 to 36 of the Treaty on the Functioning of the European Union."

The Commission appreciates that Belgium has introduced a mutual recognition clause in the notified draft.

However, while the draft mentions only the EU member States and the contracting States of the EEA Agreement the mutual recognition principle should apply also to products that are lawfully manufactured and/or marketed in Turkey.

The requirement to refer to all of them is based on Article 34 and 36 of the Treaty on the Functioning of the European Union (TFEU), the EEA Agreement and the EU-Turkey Customs Union.

According to Article 34 of the TFEU any product imported from another Member State must in principle be admitted to the territory of the importing Member State if it has been lawfully produced and/or marketed. This principle, often referred to by the Court in its jurisprudence, implies that a Member State may not in principle prohibit the sale in its territory of a product lawfully produced and/or marketed according to technical or quality requirements which differ from those imposed on its domestic products if a level of equivalent protection is given (see for example ECJ of 20 February 1979, Case 120/78, Cassis de Dijon, [1979], page 649ff.).

The obligation to apply the principle of mutual recognition to products lawfully manufactured and/or marketed in Turkey is based on Articles 5 to 7 of Decision 1/95 of the EC-Turkey Association Council that provide for the elimination of measures having an effect equivalent to quantitative restrictions between the EU and Turkey. Pursuant to Article 66 of Decision 1/95, Articles 5 to 7 must, for purposes of their implementation and application to products covered by the Customs Union, be interpreted in conformity with the relevant judgments of the Court of Justice of the European Communities. Therefore, principles resulting from the Court of Justice's case-law on issues that relate to Articles 34 and 36 of the TFEU, particularly the "Cassis de Dijon" case, apply to the EU Member States and Turkey.

Furthermore, as far as reference to "lawfully placed on the market in States party to the Agreement on the European Economic Area" is concerned, the Commission would note that the products covered by a standard mutual recognition clause are products lawfully manufactured and/or marketed in another EU Member State or in Turkey or products lawfully manufactured in an EFTA State that is a contracting party to the EEA Agreement. Therefore, the Commission would recommend not extending the scope of the application of the mutual recognition clause also to products that are lawfully marketed in an EFTA State that is a contracting party to the EEA Agreement, but not manufactured there.

For further information, the Belgian authorities may refer to the Commission Communication on mutual recognition ("Commission interpretative Communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition", OJ C 265/02, 4 November 2003).

The partial non-conformity of the mutual recognition clause of the draft with the requirements as specified in the Customs Union with Turkey may create obstacles to the free movement of goods within this Union. It is therefore

necessary to widen the scope of the clause to include Turkey.

In the light of the above considerations, the Belgian authorities are invited to modify the notified draft in order to respect the demands of the mutual recognition principle.

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