



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Uimhir an Fhógra : 2016/0257/CZ (Czechia)

Draft Implementing Decree of [date] on food supplements and the composition of foodstuffs

An dáta ar a bhfuarthas é/í : 03/06/2016

Deireadh leis an Tréimhse Neamhghníomhaíochta : 05/09/2016 (05/12/2016) (closed)

Message

Message 002

Communication from the Commission - TRIS/(2016) 01631

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2016/0257/CZ

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késéket - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 201601631.EN)

1. MSG 002 IND 2016 0257 CZ EN 03-06-2016 CZ NOTIF

2. CZ

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4. 2016/0257/CZ - C00A

5. Draft Implementing Decree of [date] on food supplements and the composition of foodstuffs

6. Food supplements, foodstuffs in general

7. - 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

8. The proposed legislation will replace existing Implementing Decree No 225/2008 on food supplements and food



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enrichment, and defines requirements for food supplements and the composition of foodstuffs. It transposes Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements and, pursuant 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, prohibits and restricts the use of some other substances in the production of foodstuffs.

This implementing decree is one of the measures implementing Act No 110/1997 on foodstuffs and tobacco products, as amended, which contains a clause on the mutual recognition of products. It reads as follows:

'It shall not be permitted to refuse the placement on the market in the Czech Republic of foodstuffs produced or placed on the market in a Member State of the European Union or originating in a State party to the Agreement on the European Economic Area, provided that said foodstuffs comply with regulations for their production or placement on the market that are binding in any of these States or production practices and rules of good manufacturing practice applied in any of these States, for which there is sufficiently detailed documentation that can be used as a basis for conducting additional investigations, if necessary.'

In practice, this means that if a particular (specific) area of manufacture, labelling and marketing is not regulated by European legislation, i.e. if this is a non-harmonised area, Member States may address this area according to their specific circumstances, i.e. by means of national legislation, established rules of good manufacturing practice, established food names, etc.

The differences between how a particular issue is addressed in Member States cannot be used as a reason for trade restrictions (suspension, sanctions, return of goods by the supervisory authority, etc.). Naturally, this applies mutually, both to the entry of foodstuffs from Member States into the territory of the Czech Republic and foodstuffs shipped from the Czech Republic into EU countries.

Keywords: food supplement, composition of foodstuffs

9. Existing legislation, i.e. Implementing Decree No 225/2008 of 17 June 2008 stipulating requirements for food supplements and food enrichment, as amended, was found to be unsatisfactory.

The main reason for submitting the new implementing decree is to adapt legislation to directly applicable EU legislation - Commission Regulation (EC) No 1170/2009 of 30 November 2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements. Lists of vitamins and minerals that can be added to food supplements had to be deleted from existing Implementing Decree No 225/2008, as these lists are stipulated by directly applicable Regulation (EC) No 1170/2009.

It was also necessary to align terminology with Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, in particular with regard to the replacement of 'recommended daily dose' with 'reference intake'.

Regarding the prohibition and restriction of some other substances during the production of foodstuffs, including food supplements, stipulated on the basis of Regulation (EC) No 1925/2006, parts of existing Implementing Decree No 225/2008 had to be amended in order to take into account new scientific findings in this area.

The proposed legislation also refers to the following legislation:

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, as amended by Commission Regulation (EC) No 1170/2009, Regulation (EU) No 1161/2011, Regulation (EU) No 119/2014 and Regulation (EU) No 2015/414.

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended.

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of



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vitamins and minerals and of certain other substances to foods, as amended.

Commission Regulation (EU) No 1161/2011 of 14 November 2011 amending Directive 2002/46/EC of the European Parliament and of the Council, Regulation (EC) No 1925/2006 of the European Parliament and of the Council and Commission Regulation (EC) No 953/2009 as regards the lists of mineral substances that can be added to foods.

Commission Regulation (EU) No 119/2014 of 7 February 2014 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards chromium enriched yeast used for the manufacture of food supplements and chromium(III) lactate tri-hydrate added to foods.

Commission Regulation (EU) 2015/414 of 12 March 2015 amending Directive 2002/46/EC of the European Parliament and of the Council as regards (6S)-5-methyltetrahydrofolic acid, glucosamine salt used in the manufacture of food supplements.

Implementing Decree No 113/2005 on the method of labelling foodstuffs and tobacco products, as amended.

Act No 505/1990 on metrology, as amended.

Implementing Decree No 328/2000 on the method used to manufacture certain types of pre-packaged goods whose amount is expressed in units of mass or volume, as amended.

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

Act No 167/1998 on addictive substances and on amendments to certain other acts, as amended

Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors.

10. Reference(s) to basic text(s): Act No 110/1997 on foodstuffs and tobacco products and on amendments to certain related acts, as amended

11. No

12. -

13. No

14. No

15. Yes

16. TBT aspect

No - the draft has no significant impact on international trade.

SPS aspect

No - the draft is neither a sanitary nor phytosanitary measure.

European Commission

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