

Message 104

Communication from the Commission - TRIS/(2022) 03184  
Directive (EU) 2015/1535  
Translation of the message 103  
Notification: 2022/0395/S

Forwarding of the observations of a Member State (Spain) (article 5, paragraph 2, of Directive (EU) 2015/1535).  
These observations do not have the effect of extending the standstill period.

(MSG: 202203184.EN)

1. MSG 104 IND 2022 0395 S EN 08-09-2022 05-09-2022 COM 5.2 08-09-2022  
2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación  
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3B. Comisión Interministerial para la Ordenación Alimentaria  
Agencia Española de Seguridad Alimentaria y Nutrición.  
Ministerio de Consumo.

4. 2022/0395/S - C80A

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

6. Notification No 2022/395/S

Within the framework of Directive (EU) 2015/535, Sweden notified, on 7 June 2022, the draft Regulation of the Swedish Food Agency on food supplements.

This draft, once adopted, will replace the Regulation currently in force that transposed Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

The Notification states that, in accordance with Directive 2002/46/EC, the Commission is empowered to establish maximum levels of vitamins and minerals in food supplements. However, to date, there has been no decision in this regard. Therefore, on grounds of consumer health protection, the Swedish Food Agency has chosen to introduce national maximum levels of vitamin D and iodine, which have been incorporated in Articles 11 to 13 of the notified draft Regulation. They are expected to apply from 1 January 2024.

Following the analysis of this draft, Spain would like to ask Sweden for clarification on some of the issues contained in the Regulation in question. In particular, it is considered necessary for the Swedish authorities to provide substantiated justification for the reasons why the maximum levels established in this draft are not consistent with those recommended by EFSA. In the case of vitamin D, a maximum permitted limit of 80 µg is set, while EFSA recommends 100 µg. In the case of iodine, the maximum permitted quantity is 200 µg, while the amount recommended by EFSA is 600 µg. In addition, it is noted that the Swedish draft does not contain a Mutual Recognition Clause and therefore an explanation in this regard is also considered necessary.

In Spain's view, the establishment of maximum levels of iodine and vitamin D content in food supplements other than those recommended by EFSA, which are commonly used in many Member States, together with the lack of a mutual recognition clause in this draft Regulation, will de facto constitute an unjustified obstacle to the free movement of goods referred to in Article 34 of the TFEU. In accordance with the current wording of this draft, the only possibility of placing food supplements produced in other Member States on the market in Sweden is to comply with the limits set out therein, which would make it necessary to reformulate their composition and to have labelling expressly adapted to the Swedish market, at the additional cost that this would entail.

The Swedish authorities are therefore urged to take these observations into account and to carry out the appropriate amendments in order to prevent this legislation from becoming an unnecessary obstacle to intra-Community trade in food supplements.

Madrid, 2 September 2022

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European Commission

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