Message 303

Communication from the Commission - TRIS/(2022) 03182
Directive (EU) 2015/1535
Notification: 2022/0395/S

Observations from the Commission (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

Observaciones - připomínky - Bemärkninger - Bemerkungen - Märkused - Παρατηρήσεις - Comments - Observations - Osservazioni - Piezīmes - Komentarai - Megjegyzések - Kummenti - Opmerkingen - Uwagi - Observacoes - Komentáre- Pripombe - Huomautuksia - Synpunkter - Коментари - Comentarii.

Sin plazo de statu quo - Doba pozastavení prací se neaplikuje - Ingen status quo frist - Keine Stillhaltefrist - Ooteaeg ei ole kohaldatav - Δεν υπάρχει statu quo - Standstill period does not apply - Pas de délai de statu quo - Termine di status quo non previsto - Bezdarbības periods netiek piemērots - Atidėjimo periodas netaikomas - A halasztási időszak nem alkalmazandó - Il-perijodu ta' waqfien ma japplikax - Geen status quo-periode - Okres odroczenia nie ma zastosowania - Prazo do statu quo não previsto - Perióda pozastavenia neplatí - Obdobje mirovanja ne velja - Ei status quon määräaikaa - Ingen tidfrist för status quo - Не се прилага период на прекъсване - Perioada de stagnare nu se aplică.

(MSG: 202203182.EN)
1. MSG 303 IND 2022 0395 S EN 08-09-2022 05-09-2022 COM 5.2 08-09-2022

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2022/0395/S - C80A

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

6. Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 , the Swedish authorities notified to the Commission on 7 June 2022 the draft "Swedish Food Agency's regulations on food supplements" (hereafter "the notified draft").

According to the notification message the notified draft will supersede the Swedish Food Agency's current regulations (LIVSFS 2003:9) on food supplements, which transpose 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 (hereinafter "the Directive"). It is also indicated that the notified draft contains updated references to other provisions and is linguistically closer to the wording of the Directive than the regulations currently in force, and that the Swedish Food Agency is also using the possibility provided for in the Directive to introduce maximum levels for certain vitamins and minerals in food supplements.

The examination of the notified draft has prompted the Commission to issue the following comments.

Maximum Amounts

Section 11 of the notified draft

Section 11 of the notified draft, under the Chapter 'Vitamins and minerals', provides that 'the recommended daily dose of

a food supplement placed on the market in Sweden must not contain levels of (1) vitamin D exceeding 80 µg or (2) iodine exceeding 200 µg'.

This draft provision is to be assessed in the light of Directive 2002/46/EC on food supplements (hereinafter the Directive), which aims to protect consumers against potential health risks. Annex I of the Directive lays down a harmonised list of vitamins and minerals that may be added for nutritional purposes to food supplements. Annex II entitled "Vitamins and mineral substances which may be used in the manufacture of food supplements" contains a list of permitted sources (vitamin and mineral substances) from which those vitamins and minerals may be manufactured and be used in food supplements.

Article 5(4) of the Directive empowers the Commission to set the maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption (hereinafter 'Maximum Amounts') taking into account:

(a) the upper safe levels (ULs) of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups (Article 5(1), point (a));

(b) the intake of vitamins and minerals from other dietary sources (Article 5(1), point (b)); and

(c) the reference intakes of vitamins and minerals for the population (Article 5(2)).

Article 5(4) of the Directive does not prescribe any deadline for the adoption of the Maximum Amounts.

To date, the Commission has not made use of the empowerment given by the Directive and therefore, there are no Maximum Amounts set at EU level. In that context, in its judgement in the Solgar case , the Court of Justice of the European Union (CJEU) clarified that so long as the Commission has not laid down Maximum Amounts, the Member States remain competent to adopt legislation relating to those amounts, on the understanding that, in the exercise of that competence, the Member States are required to comply with Articles 34 and 36 TFEU and to be guided by the criteria laid down in Articles 5(1) and 5(2) of the Directive, including the requirement for a risk assessment based on generally accepted scientific data.

Taking this into account, the Commission considers that, in the absence of Maximum Amounts set at EU level for vitamin D and iodine, the Swedish authorities can adopt national measures. Notwithstanding this, in line with the CJEU case law, when adopting national measures to set the Maximum Amounts, the Swedish authorities have to take into account the criteria defined in Articles 5(1) and 5(2) of the Directive. In particular, (i) the ULs of vitamin D and iodine have to be established by scientific risk assessment, based on generally accepted scientific data, taking into account the varying degrees of sensitivity of different consumer groups and (ii) the intake of vitamin D and iodine from other dietary sources have to be taken into consideration.

At the request of the Commission, in 2012, the European Food Safety Authority (EFSA) re-evaluated the safety in use of vitamin D and provided revised ULs for all relevant population groups in a Scientific Opinion. Taking into account the uncertainties associated with the underlying studies, EFSA set the UL of vitamin D for adults, including pregnant and lactating women, at 100 micrograms per day . The EFSA established this limit for vitamin D from all sources (food, beverages, fortified foods and food supplements combined), including the application of an uncertainty factor to cover uncertainties. The EFSA Scientific Opinion also defined ULs for infants (25 micrograms per day) and for children aged 1-10 years (50 micrograms per day) and adolescents aged 11-17 years (100 micrograms per day). EFSA noted that data from European populations (reported from 14 European countries) indicate that vitamin D intakes from all sources in high consumers (95th percentile) are below the UL for all population subgroups (i.e., about 25%, 75%, 30% and 8% of the UL for adults, infants, children and adolescents, respectively).

For iodine daily recommended intake, the Scientific Committee on Food (SCF) derived in its opinion from 2002 a UL of 600 micrograms per day (µg/day) for adults including pregnant and lactating women, of 500 µg/day for adolescents aged

15 to 17 years, and of between 200 and 450 µg/day for 1- to 14-year-old children . The SCF noted in its Opinion that data from European populations indicate that the intakes of iodine from all sources in adults are unlikely to exceed the UL.

In the impact assessment accompanying the notified draft, the Swedish authorities recognize that, for their calculation method for deriving the Maximum Amounts, the Swedish National Food Agency took into account the ULs set, for adults, by EFSA for vitamin D and by the SCF for iodine. By calculating the difference between the UL and the intake of vitamin D and iodine via food in Sweden, the notified draft provides for a recommended daily dose of vitamin D in a food supplement placed on the Swedish market not exceeding 80 micrograms and similarly, recommended the daily dose of iodine not exceeding 200 micrograms.

These Maximum Amounts seem to take into account the risk assessment made by the Swedish authorities based on ULs set only for the adult population. However, Article 5(1) of the Directive requires to take into consideration in particular (i) the scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups in order to prevent that certain groups consume food supplements containing excessive quantities of a given nutrient considering their particular circumstances; and (ii) the intake of vitamin D or iodine from other dietary sources. Moreover, Article 5(2) of the Directive states that, when the maximum levels referred to Article 5(1) of the Directive are set, due account should also be taken of reference intakes of vitamins and minerals for the population.

In that context, in line with the EFSA and SCF Scientific Opinions, the Commission would like to point out that the application of the derivation procedure for determining the Maximum Amounts would result in different values for other population age groups and in particular for children and adolescents due to different ULs and different dietary intakes via the normal diet for those category groups. Furthermore, the Commission understands that with regard to dietary intakes of vitamin D and iodine, intakes from fortified foods were not considered under the notified draft. The Commission also does not see how reference intakes for the population have been taken into account.

In the light of this, the risk management approach proposed by the Swedish authorities may not lead to Maximum Amounts of these substances that ensure safety for all population groups with different dietary habits, such as children and persons consuming foods fortified with vitamin D and iodine.

Considering the above and in the absence of Maximum Amounts set at EU level for vitamin D and iodine, the Commission invites the Swedish authorities to address the safety issues in an appropriate manner, in line with the provisions of Article 5(1) and (2) of Directive 2002/46/EC, the case law cited, and the available to date scientific opinions.

Furthermore, in 2020, the work to set Maximum Amounts was resumed with the aim to harmonise further the compositional requirements of food supplements in accordance with the provisions of Article 5(4) of the Directive. The Commission would therefore like to inform the Swedish authorities that once the Maximum Amounts will be set for vitamin D and iodine at EU level, the national provisions related to the values set in Section 11 of the notified draft shall cease to apply.

Section 12 of the notified draft

Section 12 of the notified draft, also under the Chapter ‘Vitamins and minerals’, empowers the Swedish Food Agency to grant derogations to the Maximum Amounts set in Section 11 (i.e. for vitamin D, 80 micrograms per day and for iodine, 200 micrograms per day) when it considers that the levels of vitamin D or iodine proposed by the applicant in the recommended daily use of the food supplement does not present a risk to human health. Each specific derogation is to be granted for individual products by the National Food Agency and is to be made conditional on compliance with the Maximum Amount set in each approval decision. Section 13 of the notified draft sets out the information that is needed to support the applications for derogation.

Recital 13 of the Directive explains that “the excessive intake of vitamins and minerals may result in adverse effects and therefore necessitate the setting of maximum safe levels for them in food supplements, as appropriate. Those levels

must ensure that the normal use of the products under the instructions of use provided by the manufacturer will be safe for the consumer” .

The exercise by the national authorities of a discretionary power to allow derogations to the Maximum Amounts fixed in Section 11 of the notified draft for vitamin D and for iodine on the basis of a case-by-case assessment could create a contradiction with the criteria established in Articles 5(1) and (2) of the Directive and the case law of the CJEU. Moreover, in practice, the proposed derogations as defined in the notified draft would put into question the effet utile of the Maximum Amounts as would be defined in the Swedish legislation in line with the provisions of Articles 5(1) and (2) of the Directive.

Therefore, pursuant to the provisions of the Directive defining the criteria to be considered when setting maximum amounts of vitamins and minerals present in food supplements and taking into account the strict legal framework applicable, the Commission invites the Swedish authorities to reconsider the possibility for individual derogations provided for by Section 12 of the notified draft.

The notified draft aims, in addition, to update and supersede in their entirety, the current national Regulation on food supplements, LIVSFS 2003:9.In particular, Section 4 to Section 8 of the notified draft, under the Chapter ‘Packaging and labelling’, include the rules regarding the labelling of food supplements marketed in Sweden in general. These provisions apply generally to all food supplements, and not only to vitamin D and iodine.

Articles 6 to 9 of Directive 2002/46/EC on food supplements lay down the legal framework applicable in the Member States for the packaging and labelling of food supplements to ensure that consumers are not provided with misleading information. In that context, the Commission would like to draw the attention of the Swedish authorities to the following aspects:

1. Article 6(1) of Directive stipulates that, for the purposes of Regulation (EU) No 1169/2011 on food information to consumers (the FIC Regulation) , the name under which the products covered by the Directive 2002/46/EC are sold in a Member State has to be "food supplement".

As indicated also in Article 6 (3) (a) of Directive, the “name of the food”, in the context of the FIC Regulation (see Article 9(1)(a)), constitutes a mandatory particular and is subject to particular regulatory requirements, which are directly applicable in EU Member States by virtue of that Regulation. Article 6(1) of Directive 2002/46/EC refers to that notion.

Against this background, the wording of Section 4 of the notified draft does not clarify the scope of that obligation by specifically requiring the indication “food supplement” as being the “name of the food” covered by the notified draft. The Swedish authorities are therefore invited to clarify that provision by using specifically the terminology “name of the food”, which is defined in the FIC Regulation and to underline the cross-reference to that Regulation.

2. Article 6(2) of Directive reads: “The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties”.

The notified draft does not include a provision taking over this requirement.

In those conditions, for the sake of completeness, the Swedish authorities are invited to complete the notified draft by adding a reference to the obligation laid down in Article 6(2) of the Directive.

3. Article 6(3) of the Directive clarifies that the particulars defined specifically for food supplements are without prejudice to the provisions of Regulation (EU) No 1169/2011 on food information to consumers.

Section 5 of the notified draft containing the required particulars for labelling of food supplements does not specify that the provisions of the FIC Regulation on food labelling would also apply, as appropriate, to food supplements.

For the sake of completeness, the Swedish authorities are invited to clarify the notified draft accordingly.

4. Article 11(1) of Directive provides that Member States may not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in food supplements, which comply with the Directive. Moreover, national provisions which are applicable in the absence of EU acts adopted under Directive 2002/46/EC apply without prejudice to the provisions of the TFEU on the free movement of goods.

The notified draft does not include a provision taking over this requirement to guarantee the free movement of food supplements in Sweden.

The Swedish authorities are therefore invited to complete the notified draft in order to guarantee that the EU legal provisions on the free movement of goods are fully respected.

The Swedish authorities are invited to take into account the above-mentioned comments.

The Commission furthermore invites the Swedish Government to communicate the adoption of the definitive text of the notified act, in accordance with Article 5(3) of Directive (EU) 2015/1535.

Kerstin Jorna
Director-General
European Commission

Contact point Directive (EU) 2015/1535
Fax: +32 229 98043
email: grow-dir2015-1535-central@ec.europa.eu