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| Logo of the European Commission, 12 yellow stars on a blue background arranged in a circle and framed by two light grey graphic elements representing the Berlaymont building, which is the headquarter of the European Commission. | EUROPEAN COMMISSION |

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Her Excellency

Mrs. Hadja Lahbib

Minister of Foreign Affairs, European Affairs and Foreign Trade, and Federal Cultural Institutions

Rue des Petits Carmes, 15

B - 1000 Brussels

Subject: Notification No 2024/289/BE

Draft Royal Decree amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, of 29 August 2021 on the manufacture of and trade in food supplements containing substances other than nutrients and plants or plant preparations, and of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations

Delivery of comments pursuant to Article 5(2) of Directive (EU) 2015/1535

Dear Madam,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services ([[1]](#footnote-1)), on 30 May 2024 the Belgian authorities notified to the Commission the draft Royal Decree amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, of 29 August 2021 on the manufacture of and trade in food supplements containing substances other than nutrients and plants or plant preparations, and of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations (hereinafter, ‘the notified draft’).

According to the notification message, the notified draft aims to amend, harmonise and clarify the current procedure for the notification of food supplements and enriched foods provided for at national level by three Royal Decrees on nutrients, plants and other substances.

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

## General Food Law

Articles 3, 7 and 11 of the notified draft introduce the following definition of ‘foodstuff’in Article 2 of the Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, in Article 2 of the Royal Decree of 29 August 2021 on the manufacture of and trade in food supplements containing substances other than nutrients and plants or plant preparations and in Article 2 of the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations:

*‘foodstuff: any substance or product that is processed, partially processed or unprocessed, intended to be or reasonably expected to be ingested by humans, other than:*

*1° animal feed;*

*2° live animals unless they are prepared for human consumption;*

*3° plants before harvesting;*

*4° medicinal products;*

*5° cosmetics;*

*6° tobacco and tobacco products;*

*7° narcotic drugs and psychotropic substances;*

*8° residues and contaminants.’*

The Commission notes that Regulation (EC) No 178/2002 ([[2]](#footnote-2)) on General Food Law in its Article 2 sets out a definition of ‘food’ or ‘foodstuff’ which is directly applicable in the national legal order for all matters pertaining to food law, including national provisions governing food in general and food safety in particular. As such it is not necessary to repeat this definition in national legislation and a cross-reference to EU legislation would be sufficient.

Furthermore, the Commission notes that the definition of food set out in the national draft does not appear to fully reproduce the directly applicable definition of food, notably as set out in the second subparagraph of Article 2 of Regulation (EC) No 178/2002:

*‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.*’

In particular, Articles 3, 7 and 11 of the notified draft do not specify that food includes drink, chewing gum and any substance, including water intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive (EU) 2020/2184 ([[3]](#footnote-3)).

## Food supplements

Articles 2, 6 and 10 of the notified draft replace the definition of ‘food supplements’ in Article 2(6) of the Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, in Article 2(3) of the Royal Decree of 29 August 2021 on the manufacture of and trade in food supplements containing substances other than nutrients and plants or plant preparations and in Article 2(8) of the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations with the following:

*‘food supplements: foodstuffs whose purpose is to supplement the normal diet and which consist of one or more nutrients, plants, plant preparations or other substances with a nutritional or physiological effect, alone or in combination, marketed in measured doses, namely in forms of presentation such as capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquids, drop bottles and other similar forms of liquid or powder preparations intended to be taken in small measured units.’*

The Commission would like to bring to the attention of the Belgian authorities that, according to the definition of ‘food supplements’ provided in Article 2(a) of Directive 2002/46/EC ([[4]](#footnote-4)), ‘food supplements’ are concentrated sources of ‘nutrients’ or ‘other substances’. Recital 6 of the same Directive also distinguishes between ‘nutrients’, on the one hand, and ‘other ingredients’, including ‘plants and herbal extracts’ on the other:

*Recital 6: ‘There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.’*

However, the notified draft distinguishes between ‘plants and plants preparations’ and ‘other substances’, which could be read as meaning that ‘plants and plants preparation’ are not ‘other substances’.

The Commission invites the Belgian authorities to take into account the above comments.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

Yours faithfully,

For the Commission   
  
  
  
Sandra GALLINA  
Directorate-General for Health and Food Safety

1. () Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1, ELI: <http://data.europa.eu/eli/dir/2015/1535/oj>). [↑](#footnote-ref-1)
2. () Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj). [↑](#footnote-ref-2)
3. () Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1, ELI: http://data.europa.eu/eli/dir/2020/2184/oj). [↑](#footnote-ref-3)
4. () 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 (OJ L 183, 12.7.2002, p. 51, ELI: http://data.europa.eu/eli/dir/2002/46/oj). [↑](#footnote-ref-4)