FEDERAL PUBLIC SERVICE FOR PUBLIC HEALTH, SAFETY OF THE FOOD CHAIN AND THE ENVIRONMENT

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

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to of the Law of 24 January 1977 on the protection of the health of consumers with regard to foodstuffs and other products, Articles 1, 2, 6 and 10 amended by the Law of 22 March 1989;

Having regard to the Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, Articles 2(6) and (7) and 5;

Having regard to 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, Articles 2(3) and (6) and 5;

Having regard to the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations, Articles 2(8) and (10) and 3, as amended by the Royal Decree of 12 December 2023;

Having regard to 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;

Having regard 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;

Having regard to 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, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004;

Having regard to the communication to the European Commission of (date of transmission), pursuant to Article 5(1) of 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;
Having regard to the opinion of the High Council for Health issued on xxx;
Having regard to the opinion of the Inspector of Finance, issued on 7 May 2024;
Having regard to the opinion xxx of the Council of State, issued on (date), pursuant to Article 84(1), subparagraph 1(2), of the laws on the Council of State, consolidated on 12 January 1973;
Following the proposal of the Minister for Agriculture and the Minister for Public Health, and the opinion of the Ministers who deliberated thereon in the Council,
WE HAVE DECREED AND HEREBY DECREE:
CHAPTER 1: Amendments to the Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added
Article 1. In the Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, an Article 1a is inserted, worded as follows:
‘Article 1a. This Decree shall apply to foodstuffs intended for human consumption as defined in Article 2 of 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.’.
Article 2. Article 2(6) of the same Decree is replaced by the following:
‘6° 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;’.
Article 3. Article 2 of the same Decree is supplemented by point 7 worded as follows:
‘7° 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.’.
Article 4. Article 5 of the same Decree is replaced by the following:
‘Article 5. § 1. It shall be prohibited to place on the market food supplements consisting of or containing one or more nutrients if prior notification to the Service has not been made in accordance with the following provisions. .
A notification file must be submitted in one copy or via the FOODSUP application on the website of the FPS Health, Safety of the Food Chain and the Environment (www.santé.belgique.be).
The notification file must contain the following data:
1° the nature of the foodstuff;
2° the list of ingredients of the product (qualitative and quantitative);
3° the list of nutrients added per recommended portion of the foodstuff to be consumed daily on the labelling or per quantity of the foodstuff equal to the average daily intake of that foodstuff provided for in Annex 2 for the foodstuffs referred to in Article 4;
4° if applicable, the nutritional analysis of the product;
5° the final version of the labelling as marketed;
6° the data necessary to assess the nutritional value;
7° the commitment to carry out frequent analyses at different times of the product and to make the results available to the Service.
Payment of a fee per notified product in pre-dosed form to the account of the Budget Fund for Raw Materials and Products in accordance with Article 10(1) of the Royal Decree of 13 November 2011 laying down the fees and contributions due to the Budget Fund for Raw Materials and Products and meeting the conditions set out in the request to pay is necessary for the submission of the notification file.
Products shall be marketed in accordance with Article 17(1) of 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.
§ 2. Within 30 days of receipt of the notification file, the Service shall send an acknowledgement of receipt to the applicant.
Within 90 days of receipt of the file and if the product falls within the scope of this Decree and meets the requirements laid down in this Decree, the Service may make comments and recommendations, inter alia, to adapt the labelling,

in particular by requiring the indication of warnings. The Service shall send a letter containing these comments within the specified time limit.

A notification number shall be assigned if the product meets the definition of food supplement as provided for in this Decree, with the exception of the provisions laid down in subparagraph 7 of this Article.

This notification number serves as the national reference number between the declarant, the Service and the Federal Agency for the Safety of the Food Chain;

This notification number is not:
- a Belgian marketing authorisation;
- proof of conformity of the product;
- recognition of the status of the product.

This notification number cannot be used in the context of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State.

However, no notification number shall be assigned:

1° in case of doubt as to the status of the product as a food supplement or enriched foodstuff, or if the product contains claims that attribute to the product preventive, treating or curing properties for a disease or indicate similar properties. In such cases, the file shall be sent to the following opinion bodies or competent administrations that determine the status of the product:
- the Joint Commission as defined by the Royal Decree of 28 October 2008;
- the Service;
- the Federal Agency for the Safety of the Food Chain;

2° to products intended for children under three years of age in the absence of an opinion from the High Council for Health;

3° if the safety of products or ingredients is to be studied by advisory bodies such as:
- the Advisory Committee on Plant Preparations;
- the High Council for Health;
- the Service'.

CHAPTER 2: Amendments to 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

Article 5. Article 1a, worded as follows, is inserted in 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:

'Article 1a. This Decree shall apply to
foodstuffs intended for human consumption as defined in Article 2 of 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.'.

Article 6. Article 2(3) of the same Decree is replaced as follows:
‘3° 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;’.
Article 7. Article 2 of the same Decree is supplemented by point 6, worded as follows:
‘6° 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 products and tobacco; 7° narcotic drugs and psychotropic substances; 8° residues and contaminants.’.
Article 8. Article 3 of the same Order is replaced by the following:
“ Article 3. § 1. It shall be prohibited to place on the market food supplements consisting of or containing one or more other substances if prior notification to the Service has not been made in accordance with the following provisions.
A notification file must be submitted in one copy or via the FOODSUP application on the website of the FPS Health, Safety of the Food Chain and the Environment (www.santé.belgique.be).
The notification file must contain the following data:
1° the nature of the foodstuff;
2° the list of ingredients of the product (qualitative and quantitative);
3° the list of qualitative and quantitative data on other substances, per unit and per daily portion, as well as data on their toxicity and stability;
4° if applicable, the nutritional analysis of the product;
5° the final version of the labelling as marketed;
6° the data necessary to assess the nutritional value;
7° the commitment to carry out frequent analyses at different times of the product and to make the results available to the Service.

Payment of a fee per notified product in pre-dosed form to the account of the Budget Fund for Raw Materials and Products in accordance with Article 10(1) of the Royal Decree of 13 November 2011 laying down the fees and contributions due to the Budget Fund for Raw Materials and Products and meeting the conditions set out in the request to pay is necessary for the submission of the notification file.
Products shall be marketed in accordance with Article 17(1) of 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.
§ 2. Within 30 days of receipt of the notification file, the Service shall send an acknowledgement of receipt to the applicant.
Within 90 days of receipt of the file and if the product falls within the scope of this Decree and meets the requirements laid down in this Decree, the Service may make comments and recommendations, inter alia, to adapt the labelling, in particular by requiring the indication of warnings. The Service shall send a letter containing these comments within the specified time limit.
A notification number shall be assigned if the product meets the definition of food supplement as provided for in this Decree, with the exception of the provisions laid down in subparagraph 7 of this Article.
This notification number serves as the national reference number between the declarant, the Service and the Federal Agency for the Safety of the Food Chain;
This notification number is not: - a Belgian marketing authorisation; - proof of conformity of the product; - recognition of the status of the product.
This notification number cannot be used in the context of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State.
However, no notification number shall be assigned:
1° in case of doubt as to the status of the product as a food supplement or enriched foodstuff, or if the product contains claims that attribute to the product preventive, treating or curing properties for a disease or indicate similar properties. In such cases, the file shall be sent to the following opinion bodies or competent administrations that determine the status of the product: - the Joint Commission as defined by the Royal Decree of 28 October 2008; - the Service; - the Federal Agency for the Safety of the Food Chain;
2° to products intended for children under three years of age in the absence of an opinion from the High Council for Health;
3° if the safety of products or ingredients is to be studied by advisory bodies

such as:

- the Advisory Committee on Plant Preparations;
- the High Council for Health;
- the Service'.

CHAPTER 3: Amendments to the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing plants or plant preparations

Article 9. Article 1a, worded as follows, is inserted in the Royal Decree of 31 August 2021 on the manufacture of and trade in foodstuffs consisting of or containing substances other than nutrients and plants or plant preparations:

'Article 1a. This Decree shall apply to
foodstuffs intended for human consumption as defined in Article 2 of 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.

Article 10. Article 2(8) of the same Decree is replaced by the following:

'8° 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'.

Article 11. Article 2 of thee same Decree is supplemented by point 10, worded as follows:

'10° 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 products and tobacco;
7° narcotic drugs and psychotropic substances;
8° residues and contaminants.'.

Article 12. In Article 5 of the same Decree, paragraphs 1, 2 and 3 are replaced by the following:

'§ 1. It shall be prohibited to place on the market food supplements consisting of or containing one or more plants which are listed in List 2 and List 3 in the Annex to this Decree and which meet the conditions and restrictions, if prior notification to the Service has not been made in accordance with the following provisions.

A notification file must be submitted in one copy or via the FOODSUP application on the website of the FPS Health, Safety of the Food Chain and the

Environment (www.santé.belgique.be).
The notification file shall include the following data:
1° the nature of the foodstuff;
2° the list of ingredients of the product (qualitative and quantitative);
3° the list of qualitative and quantitative data on known significant active substances or markers, per unit and per daily portion, toxicity and stability;
4° if applicable, the nutritional analysis of the product;
5° the final version of the labelling as marketed;
6° the data necessary to assess the nutritional value;
7° the commitment to carry out frequent analyses at different times of the product and to make the results available to the Service.
Payment of a fee per notified product in pre-dosed form to the account of the Budget Fund for Raw Materials and Products in accordance with Article 10(1) of the Royal Decree of 13 November 2011 laying down the fees and contributions due to the Budget Fund for Raw Materials and Products and meeting the conditions set out in the request to pay is necessary for the submission of the notification file.
Products shall be marketed in accordance with Article 17(1) of 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'.
§ 2. It shall be prohibited to place on the market food supplements consisting of or containing one or more plants which: 1° are not included in List 2 and List 3 annexed to this Decree; or 2° are included in List 2 and List 3 annexed to this Decree, but which do not meet the conditions and restrictions, if prior notification to the Service is not made in accordance with § 1 of this Article. The notification file must contain the data listed in § 1(2) and all necessary data relating to the nature, toxicity and quantities of the most important active substances, as far as they are known and detectable.
§ 3. Within 30 days of receipt of the notification file, the Service shall send an acknowledgement of receipt to the applicant.
Within 90 days of receipt of the file and if the product falls within the scope of this Decree and meets the requirements laid down in this Decree, the Service may make comments and recommendations, inter alia, to adapt the labelling, in particular by requiring the indication of warnings. The Service shall send a letter containing these comments within the specified time limit.

A notification number shall be assigned if the product meets the definition of food supplement as provided for in this Decree, with the exception of the provisions laid down in subparagraph 7 of this Article.
This notification number serves as the national reference number between the declarant, the Service and the Federal Agency for the Safety of the Food Chain;
This notification number is not: - a Belgian marketing authorisation; - proof of conformity of the product; - recognition of the status of the product.
This notification number cannot be used in the context of Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State.
However, no notification number shall be assigned:
1° in case of doubt as to the status of the product as a food supplement or enriched foodstuff, or if the product contains claims that attribute to the product preventive, treating or curing properties for a disease or indicate similar properties. In such cases, the file shall be sent to the following opinion bodies or competent administrations that determine the status of the product: - the Joint Commission as defined by the Royal Decree of 28 October 2008; - the Service; - the Federal Agency for the Safety of the Food Chain;
2° to products intended for children under three years of age in the absence of an opinion from the High Council for Health;
3° if the safety of products or ingredients is to be studied by advisory bodies such as: - the Advisory Committee on Plant Preparations; - the High Council for Health; - the Service'.
4° encapsulated essential oils which must be approved by the Advisory Committee on Plant Preparations'.
CHAPTER 4: Final provisions
Article 13. The Minister in charge of food chain safety and the Minister in charge of public health are responsible, each one insofar as it concerns them, for the execution of this Decree.
(Place), (date).
By the King:

The Minister for Agriculture,
David CLARINVAL
The Minister for Public Health,
Frank VANDENBROUCKE