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TRIS notification 2024/0289/BE

Royal Decree amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foods to which nutrients have been added, and of 29 August 2021 on the manufacture and marketing of food supplements

(notified on 30th of May 2024)

Lasne, 11 July 2024

Opinion from the Belgian Association of the Consumer Healthcare Industry ('BACHI')

I am writing to you in my capacity as representative of BACHI, the Belgian Association of the Consumer Healthcare Industry which represents companies active in the industry of over-the-counter (OTC) and pharmacy-based health products. BACHI asbl has its registered seat in Belgium, Chaussée de Louvain 431, 1380 Lasne and is registered at the Crossroad Bank for Enterprises under number 809.465.691.

Our Association wishes to submit an opinion on the Draft Royal Decree *amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foods to which nutrients have been added, and of 29 August 2021 on the manufacture and marketing of food supplements, notified by Belgium* on the 30th of May 2024 under notification number 2024/0289/BE[1] (see Annex 2 – the "Draft Royal Decree") as we believe that it creates barriers to the professional activities of our Members.

In what will be detailed hereinafter, we set out that two main aspects of the notified Draft Royal Decree are found incompatible with EU law. The purpose of this opinion is to bring to the

[1] See Annex 1 to this opinion for the details of this TRIS notification.

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attention of the European Commission the incompatibilities of these aspects with EU law, with a view to having the related provisions amended.

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Executive summary

In the present opinion, we set forth that the Draft Royal Decree under TRIS notification 2024/0289/BE is incompatible with EU law on the following grounds:

- **Firstly**, the Draft Royal Decree establishes a notification scheme in which the obtention of a notification number is central to allow the business operator to place a food supplement on the Belgian market. By conferring the Federal Public Service (FPS) Health, Food Chain Safety and Environment (here after : "FPS Public Health") the possibility to refuse such notification number, a *de facto* pre-market authorisation system is put in place, which bypasses the purpose of notification envisioned by the EU legislator. Therefore, the Draft Royal Decree infringes Article 10 of Directive 2002/46/EC relating to food supplements, read in conjunction with Article 11.1 of that same Directive.

  In any case, even if the notification system authorised by Directive 2002/46 would not be regarded as being a standard of maximal harmonisation, the system established by the Draft Royal Decree hinders the placing on the Belgian market of food supplements legally produced and/or marketed in other Member States, without this hinderance being justified or justifiable by a public-interest objective in a proportionate manner. In this sense, the Draft Royal Decree infringes Articles 34-36 of the TFEU.

- **Secondly**, the Draft Royal Decree introduces a definition of 'food supplements' that fundamentally differs from the harmonised definition prescribed in Article 2(a) of Directive 2002/46/EC. By doing so, the Draft Royal Decree acts against the harmonisation set forth at EU level, since the term "food supplement" is legally defined by Directive 2002/46/EC and has to be regarded as a legal name under Regulation 1169/2011 on the provision of food information to consumers, pursuant to Article 6.1 of Directive 2002/46/EC.

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I. Legal context

(i) At European level

1. At European level, the frame Directive 2002/46/CE relating to food supplements[2] lays down common rules for the marketing of food supplements within the EU market and is aimed to remove the impediments on the internal market due to differing national rules.

On this point, the second recital of the *preamble* of the Directive states the following:

> « (2) *Those products [food supplements] are regulated in Member States by differing national rules that may impede their free movement, create unequal conditions of competition, and thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on those products marketed as foodstuffs.* »

2. This Directive constitutes a first stage towards full harmonisation of the several national regulations currently in place and lays down harmonised rules of vitamins and minerals that may be added for nutritional purposes in food supplements (Annex I to the Directive), authorised sources (vitamin and mineral substances) from which these vitamins and minerals may be manufactured (Annex II to the Directive), besides introducing labelling provisions specific for the marketing of food supplements within the European Union.

3. Furthermore, this Directive provides for the possibility for Member States to require from food business operators to notify the competent authorities of the placing on the market of food supplements by sending them a model of the label used for the product.

Article 10 of Directive 2002/46/EC states:

> « *To facilitate efficient monitoring of food supplements, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market by forwarding it a model of the label used for the product.* »

As clearly stipulated in Article 10 of Directive 2002/46/EC, the purpose of allowing Member States to introduce such notification obligation for the marketing of food supplements is to facilitate effective monitoring of these products.

[2] 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 (Text with EEA relevance) (OJ L 183, 12.7.2002, p. 51–57).

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4. Lastly, Directive 2002/46/EC lays down a harmonised definition of the concept of 'food supplements', which reads as follows:

> « *foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.* »

(ii) At Belgian level

5. At national level, the marketing of food supplements is regulated by three distinct Royal Decrees, depending on whether the food supplements contain nutrients, plants or other substances:

- Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added[3] ("RD Nutrients");
- 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[4] ("RD Other substances");
- Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations[5] ("RD Plants").

6. These Royal Decrees partially transpose the Directive 2002/46/EC and lay down among others the minimum and maximum amounts of vitamins and minerals per daily portion.

7. Furthermore, these Royal Decrees establish a national notification procedure required before the marketing of food supplements on the Belgian market, as is allowed under Article 10 of Directive 2002/46/EC.

[3] Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added, *BOJ*, 11 June 2021.
[4] 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, *BOJ*, 4 October 2021.
[5] Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations, *BOJ*, 4 October 2021.

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The notification procedure currently applicable, is set out as follows[6]:

> « *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*[7] *(www.santé.belgique.be).*
>
> *The notification file must include at least the following information:*
>
> *1° the nature of the food product;*
>
> *2° the complete list of ingredients (both qualitative and quantitative) for food products referred to in Article 3, and the list (qualitative and quantitative) of nutrients added per recommended daily intake portion of the food product indicated on the label, or per quantity of the food product equivalent to the average daily consumption of this product as specified in Annex 2 for the food products referred to in Article 4;*
>
> *3° the nutritional analysis;*
>
> *4° the label;*
>
> *5° the necessary data to assess the nutritional value;*
>
> *6° a commitment to regularly submit the product to composition control;*
>
> *7° proof of payment of a fee for each pre-dosed product notified, paid into the account of the Budgetary Fund for Raw Materials and Products in accordance with Article 10, § 1 of the Royal Decree of November 13, 2011, establishing the fees and contributions due to the Budgetary Fund for Raw Materials and Products.*
>
> *Within one month of receiving this file, the Service [FPS Public Health] sends an acknowledgment of receipt to the applicant. This acknowledgment includes a notification number.*
>
> *The Service may provide remarks and recommendations, among others, to adapt the labelling, notably by requiring the mention of warnings. Additionally, it may request the provision of data on the bioavailability of the nutrient(s).* »[8]

[6] Cf. Article 5 of RD Nutrients, Article 3 of the RD Other substances, and Article 5 of RD Plants.
[7] The FPS Public Health is the authority responsible for defining Belgium's food policy lines. See link for more information.
[8] Free translation from French: « *Un dossier de notification est introduit en un exemplaire, ou via l'application FOODSUP sur le site internet du SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement (www.sante.belgique.be).*
Le dossier de notification doit comporter au moins les données suivantes:
1° la nature de la denrée alimentaire;
2° la liste complète des ingrédients (qualitative et quantitative) pour les denrées alimentaires visées à l'article 3 et la liste (qualitative et quantitative) des nutriments ajoutés par portion recommandée de la denrée alimentaire

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II. The Draft Royal Decree under TRIS notification 2024/0289/BE[9]

8. The aim of the Draft Royal Decree notified to the European Commission on 30th of May 2024 is « *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* »[10].

9. These amendments to the national legal framework surrounding the marketing of food supplements follow a decision rendered by the Chamber of Administrative Litigation of the Belgian Council of State[11] (see Annex 3). In this decision, the Belgian Council of State ruled against the FPS Public Health and in favour of the food business operator to whose notified products was denied a notification number despite having submitted a complete notification file to the FPS Public Health. The Belgian Council of State decided:

> « *The submission of a notification file containing the data mentioned in paragraph 2 of Article 2 must give rise to the sending of an acknowledgement of receipt and a notification number, where appropriate subject to the formulation - by the authority - of comments and recommendations, in particular concerning labelling*.
>
> (…)
>
> *It follows from all these considerations that the regulatory provisions which the opposing party claims, in the words of the contested measure, to have applied did not confer on it*

à consommer chaque jour dans l'étiquetage ou par quantité de la denrée alimentaire égale à la consommation journalière moyenne de cette denrée prévue à l'annexe 2 pour les denrées alimentaires visées à l'article 4 ;
3° l'analyse nutritionnelle;
4° l'étiquetage;
5° les données nécessaires permettant d'apprécier la valeur nutritionnelle;
6° l'engagement de soumettre fréquemment le produit au contrôle de sa composition;
7° la preuve de paiement d'une rétribution par produit notifié sous forme prédosée au compte du Fonds budgétaire des matières premières et des produits conformément à l'article 10, § 1er, de l'arrêté royal du 13 novembre 2011 fixant les rétributions et cotisations dues au Fonds budgétaire des matières premières et des produits.
Dans le mois de la réception de ce dossier, le Service envoie un accusé de réception au requérant. L'accusé de réception comporte un numéro de notification.
Le Service peut faire des remarques et des recommandations, entre autres pour adapter l'étiquetage notamment en exigeant la mention d'avertissements. Il peut en outre demander de fournir des données sur la biodisponibilité du ou des nutriments. »

[9] See Annex 2 to this opinion.

[10] https://technical-regulation-information-system.ec.europa.eu/en/notification/25931 (last accessed on the 25th of June 2024, 14h27). See also Annex 1 to this opinion.

[11] Belgian Council of State (6th Chamber), 26 April 2023, n° 256.350, Société de droit français LES LABORATOIRES INELDEA. See Annex 3 to this opinion.

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the power to decide on the contested refusal. The opposing party does not identify any other provisions which would give it jurisdiction to adopt the contested measure. »[12]

10. The Draft Royal Decree therefore seeks to clarify the scope of the three Royal Decrees on nutrients, plants and other substances and to specify the conditions under which such notification number may be refused by the FPS Public Health, in order to prevent the recurrence of such similar disputes before the Council of State.

(i) Notification procedure for the marketing of food supplements

11. The main update of the Draft Royal Decree concerns the notification procedure laid down by the three Royal Decrees on nutrients, plants and other substances.

12. According to Articles 4§2, 8§2 and 12§3 of the Draft Royal Decree, the relevant Article 5 of RD Nutrients, Article 3 RD Other substances and Article 5 RD Plants, are divided into two distinct paragraphs.

The first paragraph obliges the food business operator wishing to market food supplements on the Belgian market to submit a notification file to the FPS Public Health before marketing these products. This obligation, along with the information the notification file must contain, was already foreseen in very similar, nearly identical terms in the text of the currently applicable Royal Decrees on nutrients, plants and other substances.

The next paragraph shifts its focus to the FPS Public Health and outlines the steps the Service must follow upon receiving a notification file from a food business operator. It details the timeline as well as the conditions under which such a notification number may be granted by the FPS Public Health. This paragraph, which has undergone the most significant revisions by the initiated TRIS notification, reads as follows:

[12] Free translation from French: *« L'introduction d'un dossier de notification comportant les données mentionnées à l'alinéa 2 de l'article 2 doit donner lieu à l'envoi d'un accusé de réception et d'un numéro de notification, le cas échéant moyennant formulation – par l'autorité – de remarques et recommandations, notamment à propos de l'étiquetage.*
(…)
Il suit de l'ensemble de ces considérations que les dispositions réglementaires dont la partie adverse déclare, selon les termes de l'acte attaqué, avoir fait application ne lui attribuaient pas la compétence de décider du refus contesté. La partie adverse n'identifie pas d'autres dispositions qui fonderaient sa compétence pour adopter l'acte attaqué. »

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« §2. Within 30 days of receipt of the notification file, the Service [FPS Public Health] 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 the Royal Decree and meets the requirements laid down in the 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 Royal 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:*

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

(ii) Introduction of a definition of 'food supplements'

13. In addition, the Draft Royal Decree introduces a definition of 'food supplements', « *in accordance with the relevant European legislation* »[13].

The proposed definition on 'food supplements' under the notified Royal Decree is as follows:

> « *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, pastilles, 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 unit* ».

III. Contradiction of the Draft Royal Decree with EU law

(i) As far as the pre-market notification is concerned

(a) The proposed notification procedure contradicts the principle laid down by Articles 10 and 11 of Directive 2002/46/EC

14. The proposed amendment to the notification procedure required for the marketing of food supplements on the Belgian market, exceeds the scope of the notification principle set in Article 10 of Directive 2002/46/EC. In this respect, Article 10 of Directive 2002/46/EC namely limits the notification principle to merely submitting a model of the label used for the food supplement marketed or presented as such.

15. It follows from the requirements imposed by the Draft Royal Decree that the notification procedure goes far beyond the mere "*act of giving information*"[14] and actually introduces a *de jure* and *de facto* pre-market authorisation procedure.

16. Indeed, although the Draft Royal Decree makes it clear that the notification number does not constitute a Belgian marketing authorisation, nor a proof of conformity of the product, nor a

[13] https://technical-regulation-information-system.ec.europa.eu/en/notification/25931 (last accessed on the 25th of June 2024, 14h27). See also Annex 1 to this opinion.
[14] notification noun - Definition, pictures, pronunciation and usage notes | Oxford Advanced Learner's Dictionary at OxfordLearnersDictionaries.com (last accessed on the 25th of June 2024, 16h44).

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recognition of the status of the product, it nevertheless identifies a series of circumstances where the FPS Public Health may refuse to grant a notification number, namely if:

- the FPS Public Health considers that the product does not fall within the definition of a food supplement,
- the product is intended for children under 3 years of age and the High Council for Health has not issued a positive opinion, and
- the FPS Public Health considers that there are food safety concerns about the product which must primarily be examined by the Advisory Committee on Plant Preparations, the High Council for Health or by the FPS Public Health itself.

17. However, it happens that the obtention of a notification number is crucial for a business operator to be able to market food supplements in Belgium.

Indeed:

a) According to Articles 4§2, 8§2 and 12§3 of the Draft Royal Decree, the notification number *"serves as the national **reference number** between the declarant, the Service and the Federal Agency for the Safety of the Food Chain"*. The notification number hence constitutes an essential element to identify a food supplement on the Belgian market.

b) On the field, the obtention of a notification number is a prerequisite for a food supplement to appear in a **public database** held by the FPS Public Health and to which the FPS Public Health, the FASFC (*Federal Agency for the Safety of the Food Chain)* and the Belgian Poison Control Center systematically refer to (see link to the database here)[15].

In this respect, the FASFC has dedicated a specific web page providing guidance to consumers on how to recognize reliable food businesses selling food supplements (see link to the webpage here, Annex 4)[16].

The very first piece of advice given on this webpage by the FASFC is titled "1. *A reliable company only provides products authorized in Belgium*" and is detailed as follows:

> « *It has never been easier to have products delivered to your home from the other side of the world. However, be cautious with foreign websites.*

[15] https://apps.health.belgium.be/foodsupPublicApp/pages/public/publicSearch.xhtml;jsessionid=QDm5vQ92UiACk9cWpCpTg2vKlLnKdHRz_I6nFs8S.node2?dswid=8313 (last access on the 25th of June 2024, 17h19).
[16] https://favv-afsca.be/fr/publication/vous-arrive-t-il-dacheter-des-aliments-ou-des-complements-alimentaires-en-ligne-ces-conseils-de (last accessed on the 25th of June 2024, 17h23).

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Some products that are legally sold abroad may not be authorized in Europe or Belgium. Therefore, ensure that a product contains only substances permitted in Belgium. Your package might be held at the European border and seized. Food supplements available on the Belgian market must be known to the Belgian authorities. As a consumer, you can access the list of food supplements that have received a notification number in Belgium through this page of the FPS Public Health. »[17]

Another web page of the FASFC (see link to the webpage here, Annex 5)[18] recalls the rules concerning the marketing of food supplements in Belgium with reference to the importance of obtaining a notification number:

« *Counterfeit or unauthorized foods or food supplements pose a risk to consumers. There are no guarantees regarding their safety and efficacy. Before placing food supplements on the market, companies are required to submit a notification for market placement to the FPS Public Health, Food Chain Safety and Environment.*

A food supplement notified on the Belgian market is systematically accompanied by a notification number granted by the FPS Public Health. As a consumer, you have access to the list of food supplements that have obtained a notification number in Belgium by consulting the "FOODSUPP" application of the FPS Public Health.

FOODSUPP Application:
https://apps.health.belgium.be/foodsupPublicApp/pages/publicSearch.xhtml?dswid=-8542

We advise against consuming food supplements for which no notification number has been assigned. »[19]

[17] Free translation from French : « *Il n'avait encore jamais été aussi facile de se faire livrer, à la maison, des produits provenant de l'autre bout du monde. Mais méfiez-vous des sites web étrangers. Certains produits dont la vente est autorisée à l'étranger ne sont pas toujours autorisés en Europe ou en Belgique. Informez-vous donc pour savoir si un produit contient bien uniquement des substances autorisées en Belgique. Il est possible que votre colis soit retenu à la frontière européenne et saisi. Les compléments alimentaires qu'il est possible de se procurer sur le marché belge doivent être connus des autorités belges. En tant que consommateur, vous pouvez accéder à la liste des compléments alimentaires ayant reçu un numéro de notification en Belgique via cette page du SPF Santé publique.* »

[18] https://favv-afsca.be/fr/produits/complements-alimentaires-ou-contre-le-coronavirus-covid-19 (last accessed on the 25th of June 2024, 17h26).

[19] Free translation from French: « *Les aliments ou compléments alimentaires contrefaits ou non autorisés présentent un risque pour les consommateurs. Il n'y a aucune de garanties quant à leur sécurité et leur efficacité. Avant de mettre sur le marché des compléments alimentaires, les entreprises sont tenues d'introduire une*

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To this, we add that the Belgian Poison Control Center indicates in very similar terms that (see link to web page here, Annex 6)[20]:

> « *In Belgium, food supplements must be declared to FPS Public Health and must receive a notification number before they can be marketed. FPS Public Health verifies that the product's composition complies with the legal restrictions set for plants, vitamins and minerals (maximum limits), and other substances. To learn more about the regulatory aspects and check if a food supplement has been notified, visit the FPS Public Health website.* »[21]

18. Consequently, for food business operators wishing to market their food supplements in Belgium, the obtention of a notification number is of huge importance, affecting and hindering its professional marketing activities in Belgium if such notification number would not be granted by the FPS Public Health. This constitutes evidently a hinderance to the placing of food supplements on the Belgian market, contravening Article 11.1 of Directive 2002/46/EC, which states that:

> «*1. Without prejudice to Article 4(7)[22], Member States shall not, for reasons related to their composition, manufacturing specifications, presentation or labelling, prohibit or restrict trade in products referred to in Article 1 which comply with this Directive and, where appropriate, with Community acts adopted in implementation of this Directive.* »

It follows from the wording of the draft Royal Decree, as well as the role that the administrative practice has given to the issuance of a notification number that the notification system proposed

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notification pour la mise sur le marché auprès du SPF Santé publique, Sécurité de la Chaine alimentaire et Environnement.

Un complément alimentaire notifié sur le marché belge est systématiquement accompagné d'un numéro de notification accordé par le SPF Santé publique.
En tant que consommateur, vous avez accès à la liste des compléments alimentaires qui ont obtenu un numéro de notification en Belgique en consultant l'application « FOODSUPP » du SPF Santé publique.

Application FOODSUPP
: https://apps.health.belgium.be/foodsupPublicApp/pages/publicSearch.xhtml?dswid=-8542
Nous vous déconseillons de consommer des compléments alimentaires pour lesquels aucun numéro de notification n'a été attribué. »

[20] https://www.centreantipoisons.be/m-dicaments/compl-ments-alimentaires (last accessed on the 25th of June 2024, 17h31).

[21] Free translation from French : « *En Belgique, les compléments alimentaires doivent être déclarés auprès du SPF Santé et doivent recevoir un numéro de notification avant de pouvoir être commercialisés. Le SPF Santé vérifie que la composition du produit est conforme aux restrictions légales fixées pour les plantes, pour les vitamines et minéraux (limites maximales) et pour d'autres substances. Pour en savoir plus sur les aspects réglementaires et vérifier si un complément alimentaire a été notifié, rendez-vous sur le site web du SPF Santé.* »

[22] Article 4.7 of Directive 2002/46/EC relates to the existing national restrictions or bans on trade in food supplements containing vitamins and minerals not included in the list in Annex I or in the forms not listed in Annex II of Directive 2002/46/EC, which may continue to be applied by the Member States.

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by the draft Royal Decree goes far beyond the purpose of mere facilitating effective monitoring and contradicts the purpose and limits set forth by Article 10 of Directive 2002/46/EC.

For the sake of completeness, it is worth noting that, in Belgium, enforcement of food law falls within the scope of competence of the FASFC, not of the FPS Public Health (see Art. 5 of Belgian Act 4 February 2000 relating to the creation of the Federal Agency for the Security in the Food Chain).

19. **From the above developments, it follows that the notification scheme introduced by Articles 4§2, 8§2 and 12§3 of the Draft Royal Decree contradicts Article 10 of Directive 2002/46/EC, read in conjunction with Article 11.1 of that same Directive. This is because it establishes a notification procedure in which the obtention of a notification number is essential for the product to appear in a public database of notified products, in addition to conferring important leeway to the FPS Public Health to refuse such notification number. It therefore installs a *de facto* authorisation process which undermines the purpose of notification envisioned by the EU legislator.**

(b) In the alternative, notification procedure infringes the provisions of TFEU regarding the free movement of goods

20. In the alternative, if it ought to be considered that the national notification scheme deriving from Article 10 of Directive 2002/46/EC, cannot be considered a standard of maximal harmonisation, it has to be pointed out that the notification procedure under the Draft Royal Decree infringes upon the provisions of the TFEU on the free movement of goods.

21. Article 34 of the TFUE prohibits quantitative restrictions on imports and all measures having equivalent effect between Member States. This prohibition covers « *all commercial rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade* »[23].

22. It is settled case law that national rules forming obstacles to the free movement of goods, even if those rules apply without distinction to all products, constitutes measures of equivalent effect.[24] Except where these can be justified on ground of a public-interest objective taking precedence over the free movement of goods in accordance with Article 36 of the TFEU, such rules are prohibited.

In line with article 36 TFUE, which highlights the necessity to apply the principle of proportionality, measures that restrict the free movement of goods must be limited to what is necessary to achieve the protection objectives legitimately pursued. Thus, where the competent national authorities restrict the free movement of goods in order to protect human health, they

[23] Point 74, CJEU, 28 January 2010, *Commission v. French Republic*, case C- 333/08, ECLI:EU:C:2010:44.
[24] CJEU, 20 February 1979, *Cassis de Dijon*, case C-120/78, ECLI:EU:C:1979:42 ; CJEU, 24 November 1993, *Keck and Mithouard*, cases C-267/91 and C-268/91, ECLI:EU:C:1993:905

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must demonstrate, in each case, that their regulation is necessary to effectively protect public health.

In the case C-333/08 "*Commission v. France*"[25], the Court of Justice of the European Union recalled this principle as follows:

> « *Since Article 30 EC [currently Article 36 of TFEU] contains an exception, which must be narrowly interpreted, to the rule of the free movement of goods within the Community, it is for the national authorities which invoke it to demonstrate in each case, taking account of the results of international scientific research, that their legislation is necessary in order effectively to protect the interests referred to in that provision, and, in particular, that the marketing of the products in question poses a genuine threat to public health (see, to that effect, Commission v Denmark, paragraph 46, and Case C-24/00 Commission v France, paragraph 53 and case-law cited).* » (point 87).

In addition, the Court of Justice of the European Union has already stated that the objective of facilitating controls of products is not recognised public-interest objectives, capable of taking precedence over the free movement of goods. In case C-104/75 "*De Peijper*"[26], the Court has explicitly stated:

> « *§18. In particular article 36 cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required.* »

23. In the case at hand, the entry on the Belgian market of food supplements is *de facto* conditional on the obtention of a notification number, although, as a matter of fact, food supplements may be marketed in the EU without having to a obtain a pre-market authorisation.

24. As previously explained (see section (a) above), a notification number is granted by the FPS Public Health only if the product for which a notification file was submitted 'passes' the control of the FPS Public Health. When no notification number is granted, the product will not appear in the public database of the FPS Public Health, even if the product was duly notified to the competent authority.

The notification scheme laid down by the Draft Royal Decree may therefore impede the introduction and marketing of food supplements in Belgium which are legally produced and/or marketed in other Member States.

[25] CJEU, 28 January 2010, *European Commission v. French Republic*, case C-333/08, ECLI:EU:C:2010:44.
[26] CJEU, 20 May 1976, *De Peijper*, case C- 104/75, ECLI:EU:C:1976:67.

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This obstacle to the free movement of goods is not and cannot be justified in accordance with Article 36 TFUE.

25. **Firstly**, in its TRIS notification of the Draft Royal Decree, the Belgian State did not specify any public-interest requirement which is pursued by foreseeing such notification scheme which hinders intra-Community trade.

26. **Secondly**, *as such,* it is apparent from the text of the Draft Royal Decree that the grounds allowing the FPS Public Health not to grant a business operator with a notification number cannot be justified by any public-interest objective, such as the protection of public health.

As we recall, the Draft Royal Decree provides for the following exceptions where no notification number is granted by the FPS Public Health.

Specifically:

(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.

Criticism: this provision concretely prevents the placement on the market of products marketed as 'food supplements' in case of a mere doubt from the FPS Public Health regarding the status of the product. This may not reasonably constitute a sufficient reason to prevent the placement on the market of a product legally produced and/or marketed in another Member State.

In addition, in Belgium, only the Minister of Health has the authority to take a decision on the status of a product in those circumstances, upon opinion of the Joint Commission. In according with Royal Decree of 28 October 2008, the marketing of a product is not suspended by the seizure of the Joint Commission and pending the decision of the Minister of Health. Consequently, refusing to issue a notification number to an operator pending the issuance of an opinion of the administration / agency cited in the Draft Royal Decree impedes the free movement of goods in a way that is incompatible with EU law.

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

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Criticism: this provision starts from the general assumption that food supplements for children under the age of 3 must *a priori* not be placed on the Belgian market.

This barrier to the free movement of goods is disproportionate as it is not based on the existence of a genuine threat to public health, as demonstrated by international scientific research.

(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.

Criticism: The circumstances under which those 'advisory bodies' are required to provide an opinion and are apparently left at the discretion of the FPS Public Health (with the exception of the opinion of the Advisory Committee on Plant Preparations) are not set forth neither by law, nor by the three Royal Decrees on plants, nutrient and other substances.

Hence, this provision paves the way for a general possibility not to grant a notification number in all cases where the FPS Public Health deems it appropriate – namely, at its own discretion. This barrier to the free movement of goods is disproportionate as it is not based on the existence of a genuine threat to public health, as demonstrated by international scientific research. It is therefore incompatible with EU law.

27. **As a result, even if the pre-market notification procedure authorised by Article 10 of Directive 2002/46/EC ought to be considered as not being a harmonised provision, it remains that Articles 4§2, 8§2 and 12§3 of the Draft Royal Decree infringes Articles 34-36 of the TFEU by establishing a notification scheme which hinders the placing on the Belgian market of food supplements legally produced and/or marketed in other Member States, without this hinderance being justified or justifiable by a public-interest objective in a proportionate manner.**

(ii) The definition of 'food supplements' in the Draft Royal Decree deviates from the harmonised definition laid down by Directive 2002/46/EC

28. Articles 2, 6 and 10 of the Draft Royal Decree introduce a definition of 'food supplements', which fundamentally deviates from the harmonised definition laid down by Article 2(a) of Directive 2002/46/EC.

29. Following this harmonised definition of food supplements, four conditions are required to be met in order to meet this definition, that is:

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- The purpose of supplementing the normal diet;
- A source of nutrients, and/ or other substances with a nutritional or physiological effect;
- A concentrated source;
- Marketed in doses or intended to be taken in small measured units.

According to Article 6(1) of Directive 2002/46/EC, the term "food supplement" is a legal name under article 51) of Directive 2000/13/EC, now being embedded in Article 17(1) of Regulation (EU) 1169/2011 on the provision of food information to consumers[27].

Pursuant to Article 2.2(n) of Regulation (EU) 1169/2011:

> « *'legal name' means the name of a food prescribed in the Union provisions applicable to it or, in the absence of such Union provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers;* »

From this definition, it follows that a hierarchy is established: where a legal name is provided for Union law, this name has precedence over any name and connected meaning given by national laws, regulations or administrative provisions.

Directive 2002/46/EC explicitly requires that products meeting the definition of 'food supplements' as enacted in Article 2(a) of Directive 2002/46/EC must be marketed under this legal name. Since, the name for the products falling under 'food supplements' is clearly prescribed by Union law, it is therefore only this name and its associated definition, that may – and must - apply.

30. **Hence, by proposing a definition of 'food supplements' which fundamentally deviates from the harmonised definition set forth in Article 2(a) of Directive 2002/46/EC, Articles 2, 6 and 10 of the Draft Royal Decree contradict the superior standard, being Directive 2002/46/EC.**

IV. Conclusion

31. In conclusion, we respectfully ask the Commission to take our comments into consideration and to communicate observations to the Belgian State in the context of the TRIS notification number 2024/0289/BE, drawing its attention to the fact that:

[27] 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 Text with EEA relevance (OJ L 304, 22.11.2011, p. 18–63).

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- Articles 4§2, 8§2 and 12§3 of the Draft Royal Decree contradict the possibility given to Member States under Article 10 of Directive 2002/46/EC to require the communication of a model of the label in view of facilitating monitoring. At least, and in the alternative, these provisions infringe the principle of free movement of goods laid down in Article 34 of the TFEU. Consequently, they should be withdrawn from the notified text; and

- Articles 2, 6 and 10 of the Draft Royal Decree infringe the harmonised definition of food supplement set forth in Article 2(a) of Directive 2002/46/EC and has to be amended accordingly.

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List of Annexes

Annex 1 – Notification details of TRIS Notification 2024/0289/BE ;

Annex 2 – Draft Royal Decree amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foods to which nutrients have been added, and of 29 August 2021 on the manufacture and marketing of food supplements

Annex 3 - Belgian Council of State (6th Chamber), 26 April 2023, n° 256.350, Société de droit français LES LABORATOIRES INELDEA ;

Annex 4 – Web page of the FASFC : « *Vous arrive-t-il d'acheter des aliments ou des compléments alimentaires en ligne* » ;

Annex 5 – Web page of the FASFC : « *compléments alimentaires ou thé contre le coronavirus Covid-19* » ;

Annex 6 – Web page of the Poison Control Center: "*Compléments alimentaires*".

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