HUDSA
Hungarian Dietary Supplement Association

**HUDSA (HUNGARIAN DIETARY SUPPLEMENT ASSOCIATION) CONTRIBUTION REGARDING TRIS NOTIFICATION 2024/0289/BE OF MAY 30TH, 2024**

Belgium notified to the European Commission on May 30, 2024 its draft amendment to 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 referred to as the "Draft amendment").

As a trade association representing Hungarian companies in the food supplement sector, we wish to express our concern about this Draft amendment.

Currently, these three Royal Decrees partially transpose the Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. They regulate the marketing of food supplements, depending on whether the food supplements contain nutrients, plants or other substances.

Belgium claims that the aim of the Draft amendment is to "clarify" the scope of application of the Royal Decrees by:

- modifying the definitions contained within them in conformity with the applicable EU law; and
- updating in a harmonious manner the notification procedure of food supplements.

However, the modifications contained in the Draft amendment create in reality a premarket authorization requirement in order to place food supplements on the Belgian market in violation of Directive 2002/46/CE[1], articles 34 and 36 of the TFEU and Regulation (EU) 2019/515[2]. They also adopt a national definition of "food supplement" which differs from the uniform EU definition provided for in Directive 2002/46/CE.

These amendments are contrary to EU law and should not be adopted.

1. **A notification procedure equivalent to a premarket authorization requirement in violation of articles 10 and 11.1 of Directive 2002/46/EC**

With regard to the marketing of food supplements on the territory of Member States, Article 10 of Directive 2002/46/EC allows Member States to set up a procedure which requires operators to inform the national authorities of the Member States. This article 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*

[1] Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.
[2] Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

*competent authority of that placing on the market by forwarding it a model of the label used for the product*".

It is to be noted that this directive was adopted on the basis of Article 113 of the Treaty on the Functioning of the European Union (formerly Article 95 of the EC Treaty) and aims at full harmonization on the points covered by the directive, with the only exception being the possibility for Member States to adopt divergent measures in particular to ensure the protection of public health, provided that their justification is proven.

Belgium states having made use of the possibility to require to be notified of the placing on the market of food supplements, in conformity with Directive 2002/46/EC.

However, the notification requirement in the Draft amendment entails far more cumbersome formalities than those permitted by the Directive. Instead of forwarding a model of the label used for the products, all of the following information and engagements are required:

"*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*[3]*;*
*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*" (article 4 ; article 8 and 12 of the Draft amendment are drafted almost identically).

Also, the Draft amendment provides that once the food supplement is notified, the Belgian authorities will send a notification number to the operator – except:

"*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;*

[3] Point 3° differs in articles 8 and 12 which require instead: "*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*" (article 8) and "*3° the list of qualitative and quantitative data on known significant active substances or markers, per unit and per daily portion, toxicity and stability*" (article 12).

*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"* (articles 4, 8 and 12 of the Draft amendment).

The Draft amendment provides that "*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*" (same articles). Yet, it is much more than a simple reference number.

All of the cited articles begin by stating that it is prohibited to place on the market food supplements that have not been notified in accordance with the "following provisions". Those following provisions include in fact the receipt of a notification number.

The circumstance that food supplements cannot be marketed if they do not receive a notification number is confirmed by the practice of the Belgian authorities. On official websites, Belgian authorities indicate that "*a reliable company only provides products authorized in Belgium*"[4] and "*in Belgium, food supplements must be declared to [the authorities] and must receive a notification number before the can be marketed*"[5].

This Draft amendment giving the possibility to refuse to send notification numbers reinforces a longstanding practice of the Belgian authorities that has recently been condemned by the Council of State. In fact, the Council of State found that no legal provision provided the power to the authorities to refuse to send a notification number to notified food supplements[6]. Belgian authorities now wish to justify their illegal actions by enacting a Royal Decree giving them the power to do so.

If the Draft amendment is adopted, the Belgian authorities will be able to refuse the placement on the market of food supplements. This refusal would interfere with article 10 of the Directive 2002/46/CE which only allows a notification system and not an authorization process for the marketing of food supplements. These goods can certainly be controlled once placed on the market and can be the object of different measures if the competent bodies find infractions to national legislation. They however cannot be controlled and refused prior to their placement on the market.

The reasons for the refusal of a notification number mentioned above only accentuate the violation of the Directive 2002/46/EC as article 11.1 explicitly indicates that:

---

[4] Free translation of "*Une entreprise fiable ne fournit que des produits autorisés en Belgique*", see: Federal Agency for the Safety of the Food Chain, article "*Vous arrive-t-il d'acheter des aliments ou des compléments alimentaires en ligne ? Ces conseils de l'AFSCA vous aideront à acheter en toute sécurité !*", available on: https://favv-afsca.be/fr/publication/vous-arrive-t-il-dacheter-des-aliments-ou-des-complements-alimentaires-en-ligne-ces-conseils-de.

[5] Free translation of "*En Belgique, les compléments alimentaires doivent être déclarés auprès du SPF Santé et doivent recevoir un numéro de notification avant de pouvoir être commercialisés*", see: Poison control center, article "*Compléments alimentaires*", available on: https://www.centreantipoisons.be/m-dicaments/compl-ments-alimentaires.

[6] Council of State, April 26, 2023, decision number 256.350, available on: http://www.raadvst-consetat.be/Arrets/256000/300/256350.PDF#xml=http://www.raadvst-consetat.be/apps/dtsearch/getpdf.asp?DocId=42297&Index=c%3a%5csoftware%5cdtsearch%5cindex%5carrets%5cfr%5c&HitCount=2&hits=16+17+&077182024916.

"*Without prejudice to article 4(7), 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*".

In fact, if this Draft amendment is adopted, the Belgian authorities will be able to refuse to provide a notification number to operators for the exact motives that are prohibited by article 11.1 of the Directive, namely reasons related to:

- their composition ("in case of doubt regarding the status of the product as a food supplement" (1°), "if the safety of products or ingredients is to be studied" (3°));
- as well as presentation and labelling ("*if the product contains claims that attribute to the product preventive, treating or curing properties for a disease or indicate similar properties*" (1°) and "*to products intended for children under three years of age in the absence of an opinion from the High Council for Health*" (2°)).

It follows from the elements examined that article 10 of the Directive 2002/46/EC is violated by the Draft amendment as the system Belgium plans on adopting goes far beyond a notification of the placing on the market of food supplements through communicating a copy of the labeling. It rather equates with a premarket authorization through the communication of numerous information and engagements and gives the authorities the possibility to refuse the placing on the market of food supplements. The reasons that will be used for this refusal violate explicitly article 11.1 of the Directive as they are precisely the motives this article forbids using because they prohibit or restrict trade.

**2. Violation of the principle of mutual recognition and free movement of goods**

The Draft amendment also infringes Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member States.

In fact, a food supplement lawfully marketed in another Member State may be refused entry to the Belgian market on the grounds set out above, in particular in the event of "doubt as to the status of the product as a food supplement".

These constraints also therefore constitute barriers to the free movement of goods within the EU in violation of articles 34 and 36 of the TFEU as they are likely to have an impact on manufacturers from other Member States already lawfully marketing their food supplements in other member states and wishing to market them in Belgium.

Articles 34 and 36 of the TFEU prohibit indeed quantitative restrictions on imports and all measures having equivalent effects except if justified on grounds such as the protection of public health. However, Belgium does not justify the restriction on import on these grounds.

**3. Unilateral modification of the definition of "food supplement"**

Finally, the Draft amendment modifies the definition of "food supplement" which is yet a harmonized term within the EU through article 2 a) of Directive 2002/46/EC:

"*'food supplements' means 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;*".

However, the central notion "*concentrated sources*" is deleted from the definition of "food supplements" in articles 2, 6 and 10 of the Draft amendment. This omission is not insignificant in that it allows a greater quantity of foodstuffs to be included within the scope of the Draft amendment which allows to apply the restrictions on free movement described in the previous points to a larger quantity of goods.

* * *

To conclude, HUDSA asks the Commission to issue a detailed opinion against the Draft amendment on the grounds that it does not comply with EU law.

Budapest, 5th August 2024

Tamás Horányi
President
Hungarian Dietary Suppliment Association