ALLIANCE FOR NATURAL HEALTH EUROPE
SUBMISSION TO THE EUROPEAN COMMISSION
REGARDING TRIS NOTIFICATION 2024/0289/BE OF MAY 30TH, 2024,
CONCERNING THE AMENDMENT TO THE ROYAL DECREE ON THE
MARKETING OF NUTRIENTS AND FOODSTUFFS IN BELGIUM

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On May 30, 2024, the Belgium government notified the European Commission of its proposal to amend 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*"

The Alliance for Natural Health (ANH) Europe has a number of concerns over this draft amendment. We are a non-governmental association of companies, practitioners and citizens who market and sell, recommend or use natural products to help maintain or promote, human health. We represent organisations and individuals in all 27 EU member states and our European office is based in Amsterdam.

We have the two major concerns with specific provisions in the Belgian government's draft amendment, which are explained in further detail below, these being:

1. The notification procedure set out in the draft amendment goes far beyond the requirement stipulated in Article 10 of Directive 2002/46/EC.

2. The proposed "food supplement" definition does not align with the harmonized definition given under article 2a of the Directive 2002/46/EC

These provisions, if passed into Belgian law, would constitute a violation of Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU) and would contravene the principle of mutual recognition of goods lawfully marketed in another Member States under Regulation (EU) 2019/515.

Therefore, these amendments are contrary to EU law and should not be adopted.

CONCERN 1: NOTIFICATION PROCEDURE

The proposed notification procedure of the Belgian government goes far beyond the legal scope of Article 10 of Directive 2002/46, that 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*".

It is to be noted that this directive was adopted on the basis of Article 113 of the TFEU (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.

Article 5 of the Draft amendment entails far more cumbersome formalities than those permitted by the Directive stating:

"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). »

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 mere notification of the placing on the market of food supplements through communicating a copy of the labeling.

The "notification file" proposed by Belgian authorities 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."

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The draft amendment requires that these 7 items are mandatory given that it states that: "the notification **must** [*our emphasis*] contain each of the following items".

Items 4, 6 and 7 of the notification requirement are especially problematic as they are ambiguous and could be subject to highly variable interpretation, so contributing to substantial legal uncertainty complicating approaches to Belgian law taken both by stakeholders and regulators across different Member States.

The legal requirement to provide data relating to these 3 items also makes the notification procedure much more onerous than that required for notifications systems in other EU Member States that are in line with the Article 10 requirements of Directive 2002/46/EC, which indicates that they: "…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."

In short, only item 5 of the proposed amendment is consistent with Article 10 of Directive 2002/46/EC, all the other requirements (especially items 4, 6 and 7) providing additional obstacles for the natural products industry wishing to trade in Belgium, these obstacles acting as barriers to trade and contravening the mutual recognition principle.

In terms of further detail:

- Item 4 does not distinguish in which circumstances nutritional analysis would be applicable, or what nutrients or nutrient profiles should be subject to analysis or what methods might be appropriate for such analyses;
- Nutritional value, as specified in item 5, is not defined in Directive 2002/46/EC and can be subject to broad interpretation in both nutritional science and EU or national laws, and;
- Item 7, "the commitment to carry out frequent analyses at different times of the product and to make the results available to the Service" is particularly ambiguous and could be interpreted as going well beyond the burden of safety and quality that is already vested with food business operators, as set out in EU General Food Law (Regulation No. 178/2002).

These ambiguities and additional mandatory requirements for notification amount to an infringement of Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in one or more other EU Member States, as well as presenting a significant barrier to trade in the single market in violation of the TFEU.

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 authorisation process for the marketing of food supplements. These supplements can certainly be controlled once placed on the market and can be the object of different

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measures if the competent bodies find infractions to national legislation. They however cannot be controlled and refused **prior** to their placement on the market.

Moreover, 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 2002/46, that states:
'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.'

This Draft amendment will make it very easy for Belgium to refuse notification and fail to grant a notification number based on inadequate data, reinforcing a longstanding practice of the Belgian authorities that has recently been condemned by the Council of State[1]. According this practice, food supplements may not been placed on the Belgian market if the Belgian authorities refuse to give a notification number. In fact, the Council of State found that no legal provision provided the Belgian authorities the power to refuse to issue a notification number for notified food supplements by stating: 'the notification number is allocated solely on the basis of the administrative file and in no way constitutes recognition of the conformity of the product and/or its presentation with the regulations in force" and, on the other hand, "the allocation of a notification number in no way precludes the prosecution of proven infringements.'

The Belgian authorities now wish to justify their illegal actions by enacting a Royal Decree giving them the power to do so, consequently creating a barrier to trade that violates the principles of the single market and TFEU.

CONCERN 2: INCONSISTENT FOOD SUPPLEMENT DEFINITION

The proposed "food supplement" definition does not align with the harmonized definition given under article 2a of the 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;*".

The definition of a "food supplement" provided in the draft amendment omits the key term provided for in the "food supplement" definition given in Article 2(a) of Directive

[1] 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%5cffr%5c&HitCount=2&hits=16+17+&077182024916.

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2002/46/EC, being “concentrated sources of nutrients”. The term “concentration” in the definition bears with it critically important scientific and legal meaning.

Its omission in Belgian law could allow Belgian authorities to reject notifications on the basis of what might be considered excessive concentration of nutrients, increasing the risk of medicinal classification through the use of both the functional limb of the definition of medicinal products in Article 1(2)(b), Directive 2001/83/EC, as amended by Directive 2004/27/EC, and by Article 2(2) of the same Regulation (the ‘rule of doubt’).

The omission of the term “concentrated sources of nutrients…” in the draft amendment could therefore act as a barrier to trade, so violating articles 34 and 36 of the TFEU, and infringes the mutual recognition principle under Regulation (EU) 2019/515.

POTENTIAL IMPACT OF DRAFT AMENDMENT

There is a very real risk that, should the current version of the draft amendment be passed in Belgian law, it would impose a significant barrier to trade, so violating both the TFEU under Articles 34 and 36, as well as infringing the mutual recognition principle that allows products legally marketed in one member states to be marketed in another, assuming no overt safety concerns.

This means that a food supplement lawfully marketed in a Member State other than Belgium may be refused entry to the Belgian market based on doubt cast by Belgian regulators as to whether the product fulfills the status of “food supplement".

CONCLUSIONS AND RECOMMENDATIONS

The Alliance for Natural Health Europe requests that the Commission issues a detailed opinion of the nature and impact of the Draft amendment, on the grounds that it does not comply with EU law.

It is our considered view that the existing text of the draft amendment could be modified in a manner that ensured that Belgian food supplement law would neither pose a barrier to trade nor a violation of the TFEU and the EU law principle of mutual recognition.

For the reasons given above, this would require, at least, the removal of items 4, 6 and 7 of the newly proposed notification procedure in Article 5 of the draft amendment to the Royal Decree, as well as the addition of the phrase “concentrated sources of nutrients” in the definition provided in Article 2.

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