**NPN contribution regarding TRIS notification 2024/0289/BE of May 30th, 2024**

*Amersfoort, 23-07-2024*

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 NPN, the Dutch trade association representing 104 companies in the food supplement sector, we wish to express our concern about this Draft amendment.

**Overall**

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.

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]](#footnote-1), articles 34 and 36 of the TFEU and Regulation (EU) 2019/515[[2]](#footnote-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.

**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.

Belgium has 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. It seems this information is used to be able to authorize products.

This Draft amendment is giving the possibility to refuse to send notification numbers. With that it 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[[3]](#footnote-3).

If the Draft amendment is adopted, the Belgian authorities will be able to refuse the placement on the market of food supplements and legal provisions are put in place to be able to authorize products. This 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. The reasons to prohibit and refuse the placement on the market of food supplements violate explicitly article 11.1 of the Directive as they are precisely the motives this article forbids using because they prohibit or restrict trade.

**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 for instance in the event of "doubt as to the status of the product as a food supplement".

Articles 34 and 36 of the TFEU prohibit 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.

**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;*”.

In the draft amendment, the essential wording “*concentrated sources*” is deleted from the definition of “food supplements” in articles 2, 6 and 10. This omission can have significant effects 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.

**Request**

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

1. Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. [↑](#footnote-ref-1)
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. [↑](#footnote-ref-2)
3. 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%5ffr%5c&HitCount=2&hits=16+17+&077182024916>. [↑](#footnote-ref-3)