food supplements europe

Comments on the notification 2024/0289/BE of 30 May 2024 by Belgium of a modification of three Royal Decrees relating to food supplements

We would like to comment on the notification 2024/0289/BE of 30 May 2024 by Belgium of a modification of three Royal Decrees:

- Royal Decree of 30 May 2021 on the placing on the market of nutrients and foodstuffs to which nutrients have been added
- Royal Decree of 29 August 2021 on the manufacture and marketing of food supplements containing substances other than nutrients and plants or plant preparations
- Royal Decree of 31 August 2021 on the manufacture and marketing of foods consisting of or containing plants or plant preparations

The notification explains that the aim of the modification of these decrees is to clarify their scope, to amend the definitions contained in those texts in accordance with the relevant European legislation and to update, in a harmonised manner, the notification procedure in the three Royal Decrees concerning nutrients, plants and other substances. The notification also indicates that the modifications do not add any additional administrative burden for economic operators.

Our analysis, however, identifies a number of provisions that significantly change the application of these legal texts and the legal certainty for economic operators and directly conflict with EU legislation and principles:

1. The new proposed definition of food supplement deviates significantly from the EU harmonised definition contained in Directive 2002/46/EC which results in a different scope as compared to the scope of the Directive.
2. The notification requirements go significantly beyond what Member States are allowed to do by Directive 2002/46/EC, by creating a pre-market authorisation system with associated administrative burden for economic operators.
3. The law also hinders the application of mutual recognition by preventing economic operators from using official documents to demonstrate in other Member States that the product has been duly notified to the Belgian authorities in compliance with the applicable legal provisions.

On the basis of these considerations, we ask the Commission to issue a detailed opinion against the adoption of these changes for non-compliance with EU law and principles.

The assessment in detail

1. The proposed definition deviates from the EU harmonised one

Although the proposal aims to implement 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, it significantly modifies the definition of food supplement that is laid down in Article 2(a) of the Directive.

We believe that a change of a harmonised definition that is specified in EU law goes beyond the discretion that Member States have for implementing a Directive at national level. In doing so, the proposed law creates a divergence with other Member States, in particular as to product classification and thus, legal uncertainty for economic operators in relation to the legal principles that the law intends to harmonise.

In addition, the proposed change is significant: The definition is worded differently from the respective language versions (Dutch and French) of the Directive[i] in that the concepts of 'concentrated sources' and 'dose form' are removed and the definition enables also to cover foods with added nutrients that do not fall under the EU harmonised definition but are subject to another harmonised legal framework (Regulation (EC) No 1925/2006)). No explanation is given for the reason underlying these deviations.

We ask the Commission not to accept this deviating definition and to ask Belgium to include the EU legal definition instead.

2. The proposed law imposes a pre-marketing authorisation procedure

While Article 10 of Directive 2002/46/EC allows Member States to set up a notification procedure for monitoring purposes, the procedure included in the Royal Decrees is equivalent to a pre-market authorisation procedure, which significantly exceeds the remit that Member States have under the Directive.

While the notification should consist of the 'model of the label used for the product', the information requested by the Royal decrees is significantly more demanding and includes all the information that is specified in Article 4, modifying Article 5 of the original Royal Decree of 30 May 2021, Article 8 modifying Article 3 of the Royal Decree of 29 August 2021 and Article 12, modifying Article 5 of the Royal Decree of 31 August 2021.

This information includes among other the product's recipe and analytical data relating to nutritional value, stability and toxicity. These requirements also apply to products lawfully marketed in other Member States, since the mutual recognition statement[ii] included in the original law allows the authorities to refuse mutual recognition, without specifying criteria and thus, in systematic ways for products not complying with the requirements of the Belgian law.

In addition, that the procedure is intended as a pre-market authorisation procedure is clear from the proposed procedural requirements:

- An acknowledgement letter of receipt is sent within 30 days following notification.
- Within 90 days of receipt, 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 is attributed to the product as the national reference number between the declarant, the Service and the Federal Agency for the Safety of the Food Chain.

  The proposed amendments now specify three conditions in which the Service is allowed to refuse attributing a notification number with the aim to prohibit the marketing of a food supplement. One of these is if the safety of products or ingredients is to be studied by advisory bodies. This gives the authorities a very broad power of decision, without accompanying criteria, that can be applied systematically to de facto prevent products lawfully marketed in other Member States from being placed on the market where they do not comply with Belgian law applicable to the composition of these products.

This aboven reflects current practice in Belgium, which the Chamber of Administrative Litigation of the Belgian Council of State[iii] has recently ruled as unlawful.

Since products not having received a notification number cannot be placed on the market before they have been subject to an opinion by one of the bodies specified by the law, this is clearly a pre-market authorisation process that is not allowed under the terms of Article 10 of Directive 2002/46/EC.

There is no doubt that the Belgian authorities have the right to investigate products and ask relevant information on products that have been placed on the market as part of their official controls obligations. This can however not take the form of a pre-market authorisation as is being proposed.

The consequence of the above procedure in practice is that companies will not place their products on the market before having received the authorities' comment after 90 days out of fear to be obliged to change composition or labelling. In addition, companies will not be able to market the product if no notification number is attributed before a decision is taken by the authorities based on advice of a relevant advisory body. These are clearly hindrances to the mutual recognition principle preventing the placing on the market of products lawfully marketed in other Member States.

We therefore ask the Commission not to accept these changes and also to investigate if the original law meets the correct implementation of Directive 2002/46/EC.

3. The proposed law prohibits the use of official document for mutual recognition purposes

The law proposes a prohibition for food business operators to use an official document issued by the Belgian authorities as part of the evidence to justify that a product is lawfully marketed in Belgium for the purpose of the procedures 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.

The proposed law literally states in each of the Royal Decrees:

> " *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.* "

We believe that a Member State does not have the legal right to prohibit economic operators the use of official documents as part of the documentation to support that a product is legally marketed in the Member State of origin.

In Belgium, food supplements can only be placed on the market after they have been notified to the competent authority in accordance with the law that is subject to this TRIS notification. It is practice that the letter of acknowledgement containing the notification number is used by food business operators to demonstrate in other Member States that the product has been duly notified in Belgium.

Prohibiting the use of this letter will prevent operators from providing such proof and may restrict the economic operator to apply for mutual recognition.

This proposed prohibition therefore constitutes an indirect hindrance of the application of mutual recognition. Such practice is not allowed by Regulation (EU) 2019/515 and goes contrary to the efforts of the Commission to ensure the correct application of mutual recognition by the Member States. It could even be considered in breach of the Treaty.

We therefore ask the Commission not to accept that Belgium adopts this provision in its law.

Food Supplements Europe, August 2024

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[i] It is noted that in the English version of the notified text, the translation of the original Dutch text is not correct and give a biased picture of the original wording. In fact, the correct translation of the proposed definition is as follows:

> " *food supplements: foodstuffs intended to supplement the normal diet and consisting of one or more nutrients, plants, plant preparations or other substances with a nutritional or physiological effect, alone or in combination, placed on the market in the form of nutrients or foodstuffs to which nutrients have been added or combined, placed on the market in administration form, namely presentation forms such as capsules, lozenges, tablets, pills and other similar forms, as well as sachets of powder, ampoules of liquid, dropper bottles and other similar forms of liquid or powder preparations intended to be taken in measured doses of small quantities.* "

The European definition from Directive 2002/46/EC however reads:

> " *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 proposed definition therefore includes three significant differences with the EU definition:

1. The proposed definition lacks the concept of 'concentrated sources'
2. The proposed definition lacks the concept of 'dose form'
3. The proposed definition includes foodstuffs to which nutrients have been added

[ii] E.g. Article 12 of the Royal Decree of 30 May 2021 states:

> " *Products lawfully marketed in another Member State of the European Union or in Turkey, or originating from a country that is a party to the EEA Agreement and lawfully marketed there, shall be deemed to be compatible with these provisions. The application of these provisions is subject to Regulation (EU) 2019/515 of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State.*
>
> *These products are subject to the following provisions:*
>
> *1° a notification file must be submitted in accordance with the provisions described in Article 5;*
>
> *2° in order to check whether mutual recognition can be applied, a declaration of mutual recognition must be submitted to the Service, referring to the notification file submitted****; if the Service determines that the application is inadmissible, the product must comply with all the provisions of this Decree****.* "

[iii] See: 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+&.

This ruling confirms that the current Royal Decree does not give the authorities the power to refuse the attribution of a notification number thereby prohibiting the placing on the market of such products. The aim of the proposed notified amendment is to give the authorities that mandate, which however exceeds the power given to the Member States by Article 10 of Directive 2002/46/EC.