

EHPM Contribution in the context of the TRIS notification: **2022/532/B**

On the Royal Decree amending the Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations

25/10/2022

The European Federation of Associations of Health Product Manufacturers, hereinafter EHPM, EU stakeholder registered on the EU Transparency Register (No. [65512466920-96](#)), would like to submit its contribution in the context of the TRIS notification number 2022/532/B on the Royal Decree amending the Royal Decree of 31 August 2021 on the production of and trade in foodstuffs composed of or containing plants or plant preparations (hereinafter “the decree”).

The decree foresees the removal of several plants and parts of plants from the list of authorised plants in foodstuffs in Belgium due to their alleged novel food status in accordance with the Novel Foods Regulation (EU) 2015/2283. Specifically, 39 plants and parts of plants with a long history of safe use based on tradition would be removed from the approved list in Belgium.

Novel Food status: matter subject to reinforced European harmonisation

EHPM would like to recall that the matter of the novel food status of ingredients used in food supplements is subject to reinforced European harmonisation since the adoption of Regulation (EU) 2015/2283¹ (known as the Novel Foods Regulation). *Recital 1* of the Regulation states that:

"Differences between national laws concerning the safety assessment and authorisation of novel foods may hinder the free movement of such food, thereby creating legal uncertainty and unfair conditions of competition".

To this end, the Novel Foods Regulation introduced a centralised European procedure for the assessment and authorisation of novel foods to replace previous national procedures.

¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 < <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02015R2283-20210327> >

Importantly, the Novel Foods Regulation contains several mechanisms for resolving questions about whether or not ingredients are novel foods, to which the Belgian approach is in evident contrast.

In fact, *Articles 4(2) and 5* of the Regulation provide, on the one hand, for a novel food consultation procedure and, on the other hand, for the possibility of adopting implementing acts in order to determine whether or not a particular ingredient falls under the novel food definition.

Belgium cannot therefore question the novel food status of plants and parts of plants already authorised through a national regulatory act without following the procedures provided for in Novel Foods Regulation. **Such an initiative would not only seriously undermine the harmonisation objective pursued by Regulation (EU) 2015/2283, but would also entail an additional risk of fragmentation of the novel food status of plants and parts of plants used in food supplements if Belgium was to be emulated by other Member States.**

Preserving legal certainty: what has been “not novel” cannot become “novel”

The fact that the Belgian Authorities intend now to consider as novel foods plants and parts of plants that the same Authorities authorised 25 years back consists a tremendous contradiction with wide detrimental consequences.

Belgium adopted its first Royal Decree on plants and parts of plants in August 1997 in accordance with the first Novel Foods Regulation (Reg. (EC) 258/97)² which was adopted in January 1997.

The list of plants authorised for use in foodstuffs was then established on the basis of history of safe use based on tradition. The message accompanying the TRIS notification makes this point very clear: *“For list 3, it should be noted that only the plants parts with a safe and traditional use are permitted in food.”*

The Belgian Authorities thus recognised the safe and traditional use of the concerned 39 plants and parts of plants in 1997. Now, more than 25 years later, the same Authorities are claiming that the same plants or parts of plants are in fact novel.

The impact of such unfathomable approach would have much more severe consequences that would go beyond the 39 plants and parts of plants in question. Indeed, reversing the presumption of “non-novel” food status of these plants and parts of plants would cause considerable legal uncertainty for operators and Authorities in all Member States, hindering the strength and harmonising purpose of the Novel Food regulatory framework.

² Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients < <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01997R0258-20090807> >. No longer in force since 31/12/2017. It was repealed by Regulation (EU) 2015/2283. See footnote 1.

Conclusion

The concerned plants and parts of plants have a long history of safe use in food supplements. They were authorised by the Belgian Authorities from 1997 onwards because of a history of safe use based on tradition. Belgium therefore recognised and gave detailed assurances to operators that these plants and parts of plants were not novel foods.

Revising the “*non-novel*” status of these plants and parts of plants 25 years after in such a way is in contrast with the EU Novel Foods regulatory framework and would have wide detrimental consequences on the strength and on the harmonising objective pursued by Regulation (EU) 2015/2283. This would result in profound European regulatory uncertainties and form an unacceptable barrier to trade in the internal market.

EHPM trust the EC to safeguard the principles laid down in Directive 2002/46 and those of the Novel Foods Regulation when evaluating this Belgian notification.

About EHPM

The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975 and since then EHPM is the voice of the food supplement sector in Europe. Through its 14 National Associations and 12 Member Companies, EHPM represents approximately 1600 health-product manufacturers and distributors in 17 European countries, the majority of which small- and medium-sized enterprises (SMEs).

EHPM proactively develops concrete proposals through its technical working groups and task forces to help improve the EU regulatory framework for food supplements and to establish and promote industry best practices for product quality, safety, and efficacy.