To: European Commission, Contact point Directive (EU) 2015/1535

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Subject: DRAFT of *Royal Decree amending the Royal Decrees of 30 May 2021 on the placing on the market of nutrients and foods to which nutrients have been added, and of 29 August 2021 on the manufacture and marketing of food supplements, TRIS Notification Number: 2024/0289/BE (Belgium), Date received:30/05/2024, End of Standstill: 02/09/2024*

Dear Sirs,

The Czech and Slovak Association for Special Foods (ČASP, www.casponline.cz) is an interest association of legal FBO entities, founded in 2000. The association represents the common interests of its members - manufacturers and distributors of food supplements - both at the national and international level, and its main goal is to actively participate in the formation of an adequate and balanced legislative framework for health-promoting products. At the same time, all members of the association undertake to comply with their own code of ethics for sales and marketing, which goes beyond the framework of valid legislation in the Czech Republic and Slovakia.

ČASP now represents 24 Czech and Slovak companies, which forms a substantial part of the food supplement market in 2 EU MS.

1. We agree with Dutch trade association NPN CONTRIBUTION REGARDING TRIS NOTIFICATION 2024/0289/BE OF MAY 30TH, 2024, done in Amersfoort, 23-07-2024, concerning the unilateral modification of the definition of “food supplement” by BE DRAFT, as well as APARD - Portuguese Food Supplement Association, done in Lisbon, 24/07/2024:

**Article 2.** Article 2(6) of the same Decree is replaced by the following:

‘6° food supplements: foodstuffs whose purpose is to supplement the normal

diet and **which consist of one or more nutrients, plants, plant preparations or**

**other substances with a nutritional or physiological effect**, alone or in

combination, marketed in measured doses, namely in forms of presentation

such as capsules, lozenges, tablets, pills and other similar forms, as well as

sachets of powder, ampoules of liquids, drop bottles and other similar forms of

liquid or powder preparations intended to be taken in small measured units;’.

*Original ENG of DIRECTIVE 2002/46/EC*

*Article 2*

For the purposes of this Directive:

(a) ‘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;

1. Also we are of the same opinion as presented in contribution of Belgian association Be-sup on 25.7.2024:

However, the central concept of 'concentrated sources' has been removed from the definition of 'food supplements' in Articles 2, 6 and 10 of the draft amendment. This omission is not insignificant, as it allows a larger quantity of foodstuffs to be brought within the scope of the draft amendment, thus allowing the restrictions on free movement described in the preceding paragraphs to be applied to a larger quantity of goods.

1. The Draft amendment also infringes Regulation (EU) 2019/515 on the mutual recognition of goods lawfully marketed in another Member States and constitutes a violation of the principle of proportionality and free movement of goods within Single Market.

DRAFT:

ARTICLE 4 , § 2.

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;

This notification number is not:

- a Belgian marketing authorisation;

- proof of conformity of the product;

- recognition of the status of the product.

**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.**

Regulation 2019/515 applies from 19 April 2020 and replaces Regulation (EC) No 764/2008. It defines the rights and obligations in relation to the mutual recognition principle for **competent authorities** and businesses when selling goods in another EU country. This Regulation should also ensure that existing rights and obligations deriving from the principle of mutual recognition are observed, by both economic operators and national authorities. Administrative decisions always need to be duly justified, to be legitimate, to be appropriate and to respect the principle of proportionality, and the competent authority has to make the least restrictive decision possible.

MRP Declaration in ANNEX of a.m. EU law requires also to „identify the Member State in which the goods or that type of goods are claimed to be lawfully marketed“ with the reference of the notification/authorisation decision which is only possible by granted **national number**.

*The sentence that „This notification number cannot be used in the context of Regulation (EU)*

*2019/515“ is unprecedent breach of EU Single Market legislation.*

We are strongly proposing to EC to refuse/not to adopt the new ammendments in question as argumented above.