Comments on the draft Belgian 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 , ANNEX to the Royal Decree amending the Royal Decree on the manufacture of and trade in foods composed of or containing plants or plant preparations, List 3: Plants subject to notification if in pre-dosed form.

(TRIS notification number 2022/532/B)

ČASP (Česká a slovenská asociace pro speciální potraviny/Czech and Slovak Association for Special Foods) is an interest association of legal entities/FBO, founded in 2000. The Association represents the common interests of its members - manufacturers and distributors of food supplements - both nationally and internationally, and its main goal is to actively participate in the formation of an adequate and balanced legislative framework for health-promoting products.

We would like to bring the following comments to your attention, which we feel are not in line with EU legal principles and should be rectified.

With this letter we give our comments on this draft notification and urge the Belgian authorities to revise this draft since it would create important barriers to trade without a legitimate reason or justification based on a scientific proven risk for public health.

In order to be justified under article 36 of Treaty the measure that a Member state takes to protect public health it has to comply with the principle of proportionality. The measure in question has to be necessary in order to achieve the declared objective; the objective could not be achieved by less extensive prohibitions or restrictions, or by prohibitions or restrictions having less effect on intra-EU trade. In other words it would be better to consider the ‘less restrictive alternative’, like mandatory warnings of maximal levels of plant items in question.

It is to be noted that the original legislation was set in force in the August 1997 as Royal Decree of 29 August 1997 on the manufacture and trade of foods composed of or containing plants or plant preparations (**MINISTERE DES AFFAIRES SOCIALES, DE LA SANTE PUBLIQUE ET DE L’ENVIRONNEMENT,** F. 97 — 2706 [S − C − 97/22673] **29 AOUT 1997. — Arreˆte´ royal relatif à la fabrication et au commerce de denre´es alimentaires compose´es ou contenant des plantes ou preparations de plantes )**

and was effective in the same year as REGULATION (EC) No 258/97 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1). So it would be hard to suppose that Belgian Plant Commission of this time period would in August of the same year intentionally include Novel Food plants in national „Liste 3 : Plantes a` notifier si sous forme predosée“.

So during the years elapsed the FBO (Food Business Operators) were introducing in good faith the food supplements in national/EU market and were secured minimally up to validity of former rules under Regulation (EC) No 258/97 that were applicable until 31 December 2017 till the new rules fully applied from 1 January 2018 has set forth the obligation of FBO to check NF status of their ingrediens in case of doubt.

Recently the established position of most of botanicals currently used during the time larger than 25 years (required for traditional use of foods) without the disruption of the marketplace are being put into the area of insecurity by the unsubstantiated safety concerns, only on hardly traceable HoC a generation back .

The main non-transparency and not „transparency as possible that should be ensured as regards national initiatives for the establishment of technical regulations“ [DIRECTIVE (EU) 2015/1535 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification)] is the fact that the starting point of investigation into existing Belgian law in question was the idea of CAFAB WG NF members like „Competent Authority Food Assessment Body“ of NF to revise the given Belgian list **because national lists will also be included in the „NF catalogue**“. Due this reason, the process that led to the development of the BELFRIT list was re-evaluated and the argumentation depicted in Message 002 9. Brief Statement of Grounds „ other plants and plant parts were removed from the approved list due to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods“ came alive.

This is not proportional, since the Novel Food Catalogue is not legally anchored in REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL , nor in Comm. Implem. Reg. (EU) 2018/456 of 19 March 2018 on consultation process on NF status. It lists products of animal and plant origin and other substances subject to the Novel Food Regulation, and is based only from information provided by the EU Member States without any legal grounds. It is a non-exhaustive list and serves as orientation on whether a product will need an authorisation under the Novel Food Regulation.

It is also to be noted that it is difficult to obtain official proof demonstrating that a product has been lawfully placed on the market in Member States as HoC (History of Consumation) is not fully approachable because of the taxonomical development of working lists of known plant species that aimed to be comprehensive for all species of given whole Genera/spp. and the confidence level that have been peer reviewed is inferior.

This is another element that may deter a FBO company from entering the Belgian market and impose trade econonical burden to existing FBO products, especially SME.

So, in addition we want to emphasize that since long time the Belgian regulation has assured a proportionate and appropriate regulation of botanicals with a clear lists of forbidden and authorized plants, and with clear mandatory labeling and maximal levels when needed and we believe that the continuity will be achieved without similar disruptions to remove the established plant species just because of the direct communication of Belgian representatives of Ministry for Public Health with EC European Commission (DG Health and Food Safety ,Unit E2 "Food processing technologies and novel foods" ) within a.m. CAFAB without the appropriate participation of all EU MS experts.

Thus only when the use for specific population groups could entail potential risk or when a at a higher dose could lead to therapeutic effects the action is needed and not the borderline issues to liquidate the dual use of plants.

To a.m. argumentation, after the evaluation by experts on botanicals safety of the products and the finished preparations we are presenting to TRIS notification the ENCLOSURE table „ Plants and plant parts removed from BE DRAFT list 3 of novel of Royal Decree of 31 August 2021 because of their NFS status derived from not recorded HoC - comparison with CZ national positive list“ as the attachment.

We urge the European commission not to allow this decree to be set to further procedures without the recently legalized and used plant species.

On behalf of Czech and Slovak Association for Special Foods (CASP)

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ENCLOSURE TO COMMENTS OF CASP TO BE Notification Number: 2022/532/B

September, 12th 2022

**Plants and plant parts removed from BE DRAFT list 3 of novel of Royal Decree of 31 August 2021 because of their NFS status derived from not recorded HoC - comparison with CZ national positive list**

**Plant and their parts which were removed from the DRAFT\* of** “**Arrêté royal modifiant l’arrêté royal du 31 août 2021 relatif de denrées alimentaires composées ou contenant préparations de plantes” .**

***TRIS Notification Number: 2022/532/B (Belgium ), Date received: 29/07/2022, End of Standstill: 31/10/2022***

| **Plant name** | **Part of the plant/remarks** |
| --- | --- |
| **Betula alleghaniensis** Britton | bark, leaf  in precedent AR (Mon.21.XI.1997) it was listed Betula spp.- bark  Synonyms :  Betula alleghaniensis f. macrolepis (Fernald) Brayshaw  Betula alleghaniensis var. fallax (Fassett) Brayshaw  Betula alleghaniensis var. macrolepis (Fernald) Brayshaw  Betula lutea var. alleghaniensis (Britton) Rehder  Betula alleghaniensis/bark, leaf is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements*)* |
| **Eucalyptus dives** Schauer | leaf, twig  in precedent AR (Mon.21.XI.1997) it was listed Eucalyptus spp.  Eucalyptus dives/leaf,twig is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Eucalyptus radiata** Sieber ex DC. | leaf  in precedent AR (Mon.21.XI.1997) it was listed Eucalyptus spp.  Eucalyptus radiata essential oil is in BE NOT NFS list  Eucalyptus radiata/leaf is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Fragaria viridis** Weston | whole plant  in precedent AR (Mon.21.XI.1997) it was listed Fragaria spp.  Synonyms:  Fragaria vesca var. pratensis L  Fragaria vesca var. pratensis L. ex Weston  Fragaria vesca var. viridis (Duchesne) Fiori  Fragaria vesca subsp. viridis (Weston) Rivas Goday & Borja  Fragaria viridis Duchesne  Fragaria viridis subsp. viridis  N.B. Fragaria vesca L./leaf, fruit is in DRAFT\*  Fragaria viridis/whole plant is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Gelidium sesquipedale** (Clemente) Thuret  Synonym  Gelidium corneum (Hudson) J.V.Lamouroux  (agar-agar) | thallus  in precedent AR (Mon.21.XI.1997) it was listed Gelidium spp.  Gelidium corneum/thallus is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Laminaria palmata** Bory de St.Vincent | thallus  in precedent AR (Mon.21.XI.1997) it was listed Laminaria spp.  Laminaria palmata/thallus is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Larix occidentalis** Nutt. | whole plant  in precedent AR (Mon.21.XI.1997) it was listed Laminaria spp.  Larix occidentalis/whole plant is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Lavandula × intermedia Emeric ex Loisel. | aerial part other than flower, flowering tops is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Malus pumila Mill. | not only fruit, but also bud, flower, leaf is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Malus sylvestris (L.) Mill. | not only fruit, but also bud, flower, leaf is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements |
| **Mastocarpus stellatus** (Stackhouse) Guiry | thallus  Mastocarpus stellatus (Stackhouse) Guiry (syn. Gigartina stellata (Stackohouse) Batters) is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Melaleuca quinquenervia** (Cav.) S.T. Blake | leaf, twig  in precedent AR (Mon.21.XI.1997) it was listed Melaleuca spp.  Melaleuca quinquenervia is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Melaleuca viridiflora Sol. ex Gaertn. | twig ,  in precedent AR (Mon.21.XI.1997) it was listed Melaleuca spp.  leaf and twig is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Origanum compactum** Bentham | Only essential oil as the concentrated form of volatile components does no make sense  aerial part is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Pelargonium sidoides** DC. | whole plant  in precedent AR (Mon.21.XI.1997) it was listed Pelargonium spp.  Pelargonium sidoides is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Picea abies (L.) Karst. | needle  needles are in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Plantago orbignyana** Steinh. ex Decne | seed  in precedent AR (Mon.21.XI.1997) it was listed Plantago spp.  seed and testa Plantago orbignyana is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Polygala senega** L. | root, rhizome  in precedent AR (Mon.21.XI.1997) it was listed Polygala spp.  Roots and rhizomes of Polygala senega L. , Polygala amara L.,(whole plant) are in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Polygala sibirica** L. | root  in precedent AR (Mon.21.XI.1997) it was listed Polygala spp.  Polygala sibirica L., roots is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Polygala tenuifolia** Willd. | root  in precedent AR (Mon.21.XI.1997) it was listed Polygala spp.  Polygala tenuifolia Wild. roots is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Polygonatum odoratum** (Mill.) Druce | rhizome  Polygonatum odoratum rhizome  (Mill.) Druce is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Populus tremula** L. | bark, bud  in precedent AR (Mon.21.XI.1997) it was listed Populus spp.  Populus tremula L. and Populus tremuloides Michx. are in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Prunus africana** (Hook. f.) kalkman | bark  in precedent AR (Mon.21.XI.1997) it was listed Prunus spp.  Prunus africana (Hook.f.) Kalkman (syn. Pygeum africanum Hook.f.) is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Prunus avium (L.) L. | stalk  in precedent AR (Mon.21.XI.1997) it was listed Prunus spp.  Prunus avium (L.) L. fruit and stalk is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Quercus serrata subsp. Serrata | bark, fruit, nutgall, leaf  in precedent AR (Mon.21.XI.1997) it was listed Quercus spp.  Quercus serrata subsp.serrata Murray, all a.m.parts is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Rosa rubiginosa** L. | flower, fruit, leaf  in precedent AR (Mon.21.XI.1997) it was listed Rosa spp.  Rosa rubiginosa L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Rosa x damascena Mill. | fruit, leaf  in precedent AR (Mon.21.XI.1997) it was listed Rosa spp.  Rosa × damascena Herrm. fruit and leaf is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| Rubus rosa L.H. Bailey | fruit, leaf  in precedent AR (Mon.21.XI.1997) it was listed Rubus spp. |
| **Salix fragilis** L. | bark, leaf  in precedent AR (Mon.21.XI.1997) it was listed Salix spp.  Salix × fragilis L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Salix pentandra** L. | bark, leaf  in precedent AR (Mon.21.XI.1997) it was listed Salix spp.  Salix pentandra L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Thymus satureoides** Coss. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Thymus spp.  Thymus saturejoides Coss. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Trifolium arvense** L. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Trifolium spp./ Trigonella caerulea (L.) Ser. = Melilotus caerulea Des.\* [\* probably Trigonella melilotus-coerulea (L.) Asch. & Graebn has been superseded and should no longer be used.]  Trifolium arvense L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Trifolium campestre** Schreb. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Trifolium spp./ Trigonella caerulea (L.) Ser. = Melilotus caerulea Des.\* [\* probably Trigonella melilotus-coerulea (L.) Asch. & Graebn has been superseded and should no longer be used.]  Trifolium campestre Schreb. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Trifolium repens** L. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Trifolium spp./ Trigonella caerulea (L.) Ser. = Melilotus caerulea Des.\* [\* probably Trigonella melilotus-coerulea (L.) Asch. & Graebn has been superseded and should no longer be used.]  Trifolium repens L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Ulmus pumilla** L. | bark , leaf  in precedent AR (Mon.21.XI.1997) it was listed Ulmus spp.  Ulmus pumila L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Vaccinium myrtilloïdes** Michx. | fruit, leaf  in precedent AR (Mon.21.XI.1997) it was listed Vaccinium spp.  Vaccinium myrtilloides Michx. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Viola calcarata** L. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Viola spp.  Viola calcarata L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |
| **Viola palustris** L. | aerial part  in precedent AR (Mon.21.XI.1997) it was listed Viola spp.  Viola palustris L. is in Czech positive list of MoA , dated 12.7.2021 (The list of some plants for use in the production of food supplements) |