



Civic Association humanitarian & social activities monitoring, analysis domain of respect for basic human rights and duties Tel.: +420 723 925 746 Telefax: +420 234 639 628

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EUROPEAN COMMISSION
GROWTH DIRECTORATE-GENERAL
Single Market for goods
Prevention of Technical Barriers

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Our RF: 2408/2016-Všeob-HC, **handled by: Ing. Jiří Plicka**, bearer of international prize "In recognition of his courageous stand and personal engagement protecting democratic form of governance and his significant contribution to the Cause of Social Justice" Baden-Baden 2014; international exceptional prize "For outstanding educational leadership and dedication to Social Justice In Europe", Baden – Baden 2015; and international prize "Czlowiek Wolnosci i Nepodleglosci, za udzial i zaangazowanie w demokratyczne przemiany w Europie" Jastrzebie-Zdroj 2014. Tel: +420 773880075, e- mail: info@voxpopuli.sk, e-mail: sustrova.Jaroslava@seznam.cz

Case: MSG 002 IND 2016 0257 CZ EN 03-06-2016 CZ NOTIF

I. Comments on the draft Decree on food supplements and the composition of foodstuffs of Czech Ministry of Agriculture, 2016/257/CZ (hereinafter referred to as Decree)

Against the Decree, within given deadline, we are raising relevant objections and comments as follows:

- 1) All the provisions of § 5, par 1, par 2 of the Decree, as well as its Annex 1 and Annex 2, are in individual listed plants and plant parts capable of hindering the free movement of goods, because:
 - a) as an example from Annex 1 see following botanicals:
 - Dioscorea spp. (Jam family), dried tuber, Decree allows maximum permissible amount in daily allowance for this foodstuff only 100 mg (0.1 g), while Czech Pharmacopoeia, ISBN 978-80-247-5522-9, for medicinal use reserves daily dosage 15 30 g, i.e. having daily dosage for food food supplements proposed even up to the lower limit set by the Czech Pharmacopoeia, it still will not collide with daily dosage set by Czech Pharmacopoeia for medicinal use.

Further, we are informing that given tuber is used in Asia as a common side dish, similarly to potatoes, sweet potatoes, yuca, etc.

Schisandra chinensis, dried fruits, Decree allows maximum permissible amount in daily allowance for this foodstuff only 600 mg (0.6 g), while Czech Pharmacopoeia, ISBN 978-80-247-5522-9, for medicinal use reserves daily dosage 1.5 g, i.e. having daily dosage for food – food supplements proposed even up to the lower limit set by the Czech Pharmacopoeia, it still will not collide with daily dosage set by Czech Pharmacopoeia for medicinal use.





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Decree 2016/257/CZ is proposing so unreasonably low values of daily doses, that it puts retailers in the position of rainmakers, hence cheaters, without taking into account both requirements and experience from the market. Non-legitimate maximum daily dosage values further undermines consumer confidence in legislation, market and product credibility. Furthermore, the Decree is capable of hindering the free movement of goods – example: the very same foodstuff – food supplement will have different maximum daily dosage depending on the residence of the manufacturer/distributor.

b) while Annex 2 brings far more serious situation, because "List of other substances prohibited in food production – Plants prohibited in food production", lists botanicals, which are not prohibited identically in all EU member states, therefore it must be demonstrated, if a ban is going to be placed, on what precise findings such a ban is based. In case that such findings are not well backed-up (please note the lack of explanatory report), those respective botanicals must be omitted from the draft, since their inclusion on the list of banned substances will not be factually justified and therefore would discriminate producers, traders and consumers and will pose an obstacle to the free market.

Furthermore, the Czech Republic's Decree did not cope at all with both the very existence of the so-called BELFRIT list, i.e. list of botanical substances which was created after a complex joint assessment by three EU member states (Belgium, France, Italy), and also BELFRIT list position & relevance to those substances prohibited by present Czech Decree, which are simultaneously, hence contradictory, included in the positive (=permissive, allowed) list of BELFRIT.

As an example, we are referring to following botanicals prohibited in food production by the Decree:

- Asarum spp., haulm
- Clementis spp. (while Czech Pharmacopoeia sets medicinal use only if daily dosage above 3-6 g)
- Corydalis spp, tuber
- Pinellia ternata
- Rheum officinale, radix (while Czech Pharmacopoeia sets medicinal use only if daily dosage above 0.7-1.4 g)
- Rheum palmatum (while Czech Pharmacopoeia sets medicinal use only if daily dosage above 0.7-1.4 g)
- Lithospermum officinale
- Lobelia spp., haulm
- Tabebuia impetiginosa, dried bark
- Tussilago farfara, leaves, flower
- Vladímira souliei





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Conclusion:

The lack of the explanatory report or its public inaccessibility resulted, among other things, in breaching of the transparency principle of the European Union Law.

Proposed Decree stands apart of harmonization processes, as demonstrated above on the BELFRIT list, therefore the Government of the Czech Republic should explain and demonstrate alleged unwholesome effect on health of to-be-banned substances.

Contrary to 2002/178/ES, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Czech Republic continues to place discriminatory practices,

In particular:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.
- (2) A high level of protection of human life and health should be assured in the pursuit of Community policies.
- (3) The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.
- (8) The Community has chosen a high level of health protection as appropriate in the development of food law, which it applies in a non-discriminatory manner whether food or feed is traded on the internal market or internationally.
- (18) In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
- (19) It is recognized that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.
- (20) The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle.

Furthermore, the challenged Decree 2016/257/CZ is lacking realistic report of compatibility with existing and planned EU law framework.





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Also to be noted: within EU, there is a tool for banning ingredients from use in food – it is so-called "blacklist" of 2006/1925/ES, Annex III, Part A, Part B, Part C, updated by 2012/307/EC. Government of Czech Republic does not explain, why it is not using these blacklists, or more precisely why the Decree is proceeding far beyond 2006/1925/ES scope, i.e. why therefore is the Decree in direct contradiction with the principles of harmonization of EU legislation.

Proposed Decree in listed botanicals does not reflect requirements of customers – users/consumers who require those plants in question on the market.

- 2) In addition, in a timely manner within the deadline, we are raising against the Decree (more precisely its proposal) relevant objections and comments as follows:
 - a) Challenged Decree is getting into collisions with norms of higher legal force grounding and protecting basic human rights, notably European Convention on Human Rights and Freedoms, along with Charter of Fundamental Rights of the European Union (C 303/2009 EU), not mentioning violation of basic human rights and freedoms as enshrined in the basic documents of the UN.

The principle goes, that what is not forbidden by law, is allowed; thereinafter principle that all law and decrees must be interpreted and implemented in a manner conforming the spirit of basic human rights and freedoms. In our case, given Decree of Czech Ministry of Agriculture, 2016/257/CZ, disregards norms of higher legal force, which are defining and guaranteeing basic human rights and freedoms, notably the right to purchase any goods, which is not banned, in any EU member state; to use any substance, which is not banned, according to one's best conscience and thought; to educate oneself in sciences of alternative ways to the use of botanicals; to use herbs in rituals and ceremonies (the right of freedom of religion and free practice of religion within the limits permitted by basic human rights and freedoms and in the spirit of principle "my rights end where my neighbor rights begin", etc.)

Given human rights dimension is totally omitted from the Decree, therefore there is a danger of discrimination against persons using botanicals-containing-food as a part of their lifestyle, their belief and thought, and as a fulfillment of their freedom of expression.

Ing. Jiří Plicka
Authorized member of HC Executive Committee
Commissioner of HABEAS CORPUS (HC)