B A C H I

Hoeilaart, 3 december 2016

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

CONCERNING: Comments on the draft Implementing Decree on food supplements and the composition of foodstuffs (TRIS notification number 2016/0257/CZ)

The draft decree on food supplements and the composition of foodstuffs, with notification number 2016/257/CZ, which includes a list of maximum limits for plants and substances and, more importantly, a list of plants and other substances that would be forbidden in food supplements.

With this letter we would like to give our comments on this draft notification and urge the Czech 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.

The prohibitions or restrictions in this draft decree constitute a means of arbitrary discrimination and are unjustified restrictions on trade between Member States. We encourage the Czech authorities to publish the scientific justification for the prohibition of the use of certain plants in food supplements and for the maximal levels that would restrict this use.

In order to be justified under article 36 of Treaty[1] the measure that a Member state takes to protect public health 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 each Member State has the obligation to opt for the 'less restrictive alternative', like mandatory warnings of maximal levels.

The fact that the Commission, Denmark, Spain and stakeholders issued comments and even Poland issued a detailed opinion shows that this decree cannot be published in the current state. It simple goes against the basic principles of the European union. Decisions taken based on this decree could be challenged.

Let us enumerate some of the most important flaws in this draft decree.

First of all we remark that the plant names do not allow to clearly identify to which precise plant species the disposition actually would apply. The Latin names in the first list of Annex 1 are not the complete, nor always the accepted Latin binominal names of the species. For the plants in the first list of Annex 2 no Latin name is mentioned. The English names are often used for several different species and thus

[1] Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union - Consolidated version of the Treaty on the Functioning of the European Union - Protocols - Annexes - Declarations annexed to the Final Act of the Intergovernmental Conference which adopted the Treaty of Lisbon, Official Journal C 326 , 26/10/2012 P. 0001 - 0390

they are not specific enough to discern between toxic or non-toxic species within one genus. This will most definitely lead to confusion and legal uncertainty. A correct identification is of utmost importance to assure the safe use of plants.
We strongly advice to completely revise the list, and to use the correct and complete binominal Latin name, with mention of the author, in order to identify the plants correctly. The peer-reviewed website www.theplantlist.org is currently the most accurate source for this purpose.

Besides this we also noticed that the second list of Annex 2 with the title "Other plants prohibited in food production" actually lists substances. Thus the title, or its translation, seems to be incorrect.

The first list of Annex 1 mentions maximal levels for some plants. For some of these plants specific standardized extracts are mentioned (e.g. "Rhodiola rosea"). It is unclear if the maximal levels apply to these specific extracts only. If so, it is unclear if this means that for other extracts no maximal level is applicable. If this would mean that only these specific extracts are allowed to be used in food supplements, the disposition could be considered a violation of the general European principle of non-discrimination. This would be a legal and scientific unjustifiable barriers to trade.

More importantly, the maximum permissible amounts in the above mentioned list range from ultra conservative to utterly derisory. How can one limit the dried Schizandra fruits to 600 mg per day, when they are worldwide used as breakfast cereal. Furthermore it beggars belief that the whole genus of Dioscorea is associated with one toxic species whereas the majority of species are harmless and even basic human in distinct regions (e.g. *Dioscorea alata* L.).

Apart from the obvious toxic plants (species containing pyrrolizidine alkaloids, aristolochic acid, tropane alkaloids, etc…); the first list of Annex 2 also mentions indiscriminately the genera "Senna", "Clematis", Rhubarb species, "Crow-dipper", "Schisandra chinensis", and the tops and flowers of Borago.
These plants, several species of the genera or at least the plant parts mentioned have traditionally been used in food and are perfectly regulated in terms of daily dosage, safety, quality under food regulation in many other member states, for example in Belgium[2], France[3] and Italy[4].

Quite a few plants like Neem, Clematis, Corydalis lose their intrinsic toxicity immediately upon exsiccation, decoction or other treatments. The dried form, as described in Materiae medicae worlwide and being the only historical form in which the plant is consumed, displays no toxicity at all. In this line of reasoning all beans and many basic foods (e.g maniok) would have to be forbidden as well.

<u>However we want to aspire to submit a constructive comment on the decree.</u>

So, in addition we want to emphasize that since more than a decade 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*. Thus only when the use for

[2] Arrêté Royal du 29 aout 1997 relatif à la fabrication et au commerce de denrées alimentaires composées ou contenant des plantes ou préparations de plantes, Moniteur Belge 21.11.1997
[3] Arrêté du 24 juin 2014 établissant la liste des plantes, autres que les champignons, autorisées dans les compléments alimentaires et les conditions de leur emploi, JORF n°0163 du 17 juillet 2014 page 11922, texte n°26
[4] Decreto 9 luglio 2012 disciplina dell'impiego negli integratori alimentari di sostanze e preparati vegetali, Gazzetta Ufficiale 21-7-2012, serie generale n. 169

specific population groups could entail potential risk or when a at a higher dose could lead to therapeutic effects.
The authorities in Belgium require the food business operators to notify the food supplements or enriched food products with an electronic notification system and they have a scientific advisory commission with experts on botanicals to evaluate the safety of the products, the plants and the preparations.

In addition, we would like to draw the attention to the fact that Belgium recently notified a new draft Royal Decree amending the Royal Decree of 29 August 1997 on the manufacture and trade of foods composed of or containing plants or plant preparations (TRIS nr° 2015/162/B).
The lists in this decree are based on intensive consultation between the authorities of Belgium, France and Italy in the BELFRIT project. The BELFRIT list was drafted together with renown experts on botany and pharmacognosy, submitted to the European commission *and all member states*. It contains the accepted complete Latin names, detailed and valuable information on botanicals and it takes their traditional use into account. It's a simple practical tool to assure their safe use in food supplements and should not be ignored.

In France and Italy a very similar approach is followed.

The above mentioned Belgian list imposes clear mandatory warnings and science based maximal levels in order to assure a proportionate regulation of the use of these preparations in food supplements.

Let us enumerate some examples of this proportionate, pragmatic and science based approach:

- The use of several anthranoid containing plant species of the genus Cassia, Rheum and Rhamnus; as well as Aloe and Frangula is allowed under conditions, already for a long time in Belgium.
- Although the plant *Pinellia ternata* (Thunb.) Makino ('Crow-dipper' in English) is mentioned on the list of forbidden plants in Belgium, a preparation of the dried root can be allowed, because the toxic substances of the fresh plant are eliminated during the heat treatment.
- Preparations of the flower and the seed (e.g. the oil) of *Borago officinalis* L. are already authorized for many years. The new decree specifies that the levels of toxic pyrrolizidine alkaloids in the preparation must be lower than 4 µg/kg.
- The decoct of branch, the boiled young leaves and the fruit of *Schisandra chinensis* (Turcz.) Baill. are currently allowed in food supplements. The future decree will impose an additional mandatory warning to ensure the safe use in case of concomitant use of anticoagulants.
- The use in food supplements of preparations of several species of the genus Clematis is allowed in Belgium as long as analysis demonstrates that the preparation does not contain detectable amounts of aristolochic acid and a botanical certificate must be submitted to proof a correct identification.
- This **pragmatic and science based approach, which takes the traditional use into account,** has been proven to be efficient and kept the Belgian market free of any adverse effects during the last decade !

This Belgian decree and the decrees in France and Italy should serve as an example for appropriate legal dispositions and a proportionate science based approach.

The Czech draft decree does not take the legal practices and applicable legal texts in other member states into account. The fact that plants are not clearly defined and that certain commonly used plants would be forbidden, and the fact that low maximal levels are imposed shows that recent and well-established scientific proof about the safe use of these plants and substances was not taken into account.

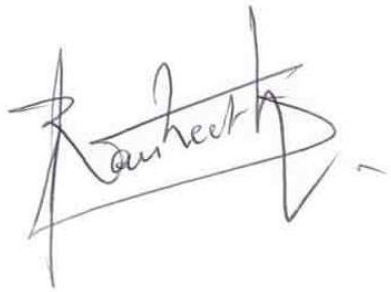
In conclusion of the above, we consider it highly advisable that the Czech authorities, assisted by ad hoc experts, revise the lists in this draft decree and provide scientific justification if the use of certain plant preparations in food supplements would need to be restricted, in accordance with the principles of the European union, and science based policies.

It would good if the Czech autorities would consider to engage in active consultation with its fellow member states in the European union. We would advise to do this with assistance of experienced ad hoc experts on botany with expertise in pharmacognosy and traditional knowledge of plants.
It would be even better if the Czech republic would align their lists of authorized and forbidden plants as much as possible with the abovementioned newly notified Belgian decree. The work has been done already, let us build further upon this.

We urge the European commission not to allow this decree to be published. In fact, at this point of evaluation within the REFIT program, maybe the European commission could consider it as part of its role to set up a more structural approach to facilitate such consultations concerning food supplements, especially those with botanicals.

Yours faithfully,

René Van Reeth
Director



BELGIAN ASSOCIATION OF THE CONSUMER HEALTHCARE INDUSTRY