

The „BELFRIT“ initiative – Views from a Member State perspective

German views



Consumer perception on Plant food supplements

Plant food supplements are
natural and thus healthier and
safer than those containing
“synthetic chemical” substances.



“Looks like he died of natural causes.”

Request for EFSA to assess the safety of the botanicals

- Request of February 2013 of the Federal Public Service of Public Health of Belgium, National food Institute/ University of Denmark, anses France, BfR Germany, Ministry of Health of Luxembourg and AESAN Spain
- *“The safety of some of the plants used as food (juice, tea ...) marketed in Europe, and in particular food supplements, is a real matter of concern.”*
- *“A safety assessment of those "botanicals is now needed to ensure the highest protection of consumer's health”.*

Conclusions / Recommendations of the Heads of Agencies

- The EFSA scientific report of 2012 does not provide a sufficient basis for efficient risk assessments of individual products;
- Safety assessment should be undertaken at European level according to an harmonised approach;
- First step could be a compilation of the risk assessments already done in member states and a review of the available scientific data.

Regulation of food supplements in Germany

- Ordinance on Food Supplements (“Verordnung über Nahrungsergänzungsmittel”)
- Transposition of Directive 2002/46/EC
- Does not cover any “other substances” with nutritional or physiological effects such as plant, plant preparations and plant-extracts, amino acids, etc.

24.04.2013 | Folie 5

Regulation of “other substances” in Germany

- Treated in the same way as food additives (Section 2 (3) of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch, LFGB))
- Including, minerals and vitamin A and D (until upper limits including restrictions for the use of vitamins and minerals will be set by the European Commission);
- The use in all foods (food supplements, dietetic food, “normal” foods) is subject for authorisation.

24.04.2013 | Folie 6

Authorisation of “other substances” in Germany

- 1) By European Regulation(s);
- 2) By (national) ordinance(s);
- 3) By exemption permit under Section 68 of the Food and Feed Act (limited to the applicant; not generic);
- 4) By general decree under Section 54 of the Food and Feed Code (mutual recognition)..

Report of 2008 from the Commission on the use of “other substances” in food supplements

- Specific rules are not justified and not necessary;
- Feasibility is doubted;
- Recommendation to use of existing instruments such as:
 - Regulation (EC) No. 258/97 on novel foods and novel food ingredients;
 - Mutual recognition;
 - Article 8 of Regulation (EC) No. 1925/2006

Article 8 of Regulation 1925/2006

- Gives the possibility to put under scrutiny or to restrict the use of „other substances“;
- German Government has asked the Commission to include 10 botanicals in Annex III List A (September 2009);
- Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012

Pending procedures under Article 8

The Commission submitted the Scientific assessment of two plants the European Food Safety Authority (EFSA) for a safety assessment:

- Yohimbe (*Pausinystalia yohimbe*)
- Ephedra species (*Ephedra spp.*)

Current snapshot of Annex III of Regulation (EC) No. 1925/2006

L 404/38

EN

Official Journal of the European Union

30.12.2006

ANNEX III

SUBSTANCES WHOSE USE IN FOODS IS PROHIBITED, RESTRICTED OR UNDER COMMUNITY SCRUTINY

Part A — Prohibited substances

Part B — Restricted substances

Part C — Substances under Community scrutiny

24.04.2013 | Folie 11

Need of harmonisation

“Dear colleagues,

I would like to ask you for opinion about :

- Panax Ginseng.

What is acceptable daily intake Panax Ginseng (dried root and extract standardized for ginsenosides) in food and food supplements in your country?

Thank you very much in advance ...“

24.04.2013 | Folie 12

BELFRIT initiative

- Recognizes that specific regulation is necessary to achieve a high level of consumer's health protection;
- Pragmatic approach demonstrating the feasibility of better regulation of plant food supplements by a new instrument;
- Meaningful pooling of expert knowledge and experience;
- Meaningful bundling of existing (human) resources;
- Much important work was done by means of data collection and analysis.

BELFRIT initiative

- Prevents unnecessary duplication of work;
- Provides increased consumer's health protection;
- Relieves the competent authorities;
- Provides increased legal certainty for businesses;
- Reduces market distortions within the market of plant food supplements in the involved Member States

BELFRIT initiative

**Basis for further European
harmonisation ?**