



EHPM response to EFSA consultation on the safety assessment of Botanicals

February 2008

The European Federation of Associations of Health Product Manufacturers (EHPM), represents the interests of specialist health products manufacturers, in particular food supplements, in Europe. The EHPM brings together 26 associations from 22 European countries and represents more than 2000 health product manufacturers including large pan-European companies and many SMEs. The European food supplements industry contains a very high proportion of SMEs, about 85% of companies in trade association membership. We welcome the opportunity to present comments on the EFSA consultation document on the safety assessment of botanicals.

We however have serious concerns about the content of these documents, which in our opinion covers many regulatory aspects that are outside the scope of EFSA self-imposed mandate.

We support the detailed comments that have been submitted by the European Botanical Forum and in addition we would like to submit the following comments:

EFSA COMPETENCE

EFSA mandate indicates that it should prepare guidance ‘to assess the safety of botanicals & botanical preparations to be used in food supplements’, which is in line with its competence as risk assessor and advisor to the EU institutions conferred by its statutes.

We are however concerned that many aspects of the consultation document address issues that are regulatory by nature and therefore fall outside the competence of EFSA and also outside of its specific mandate. This is in particular the case of proposed regulatory procedures to assess the safety of end products, or its use of information concerning the regulatory status of botanicals as food supplements or medicines.

The issue of borderline between food and medicine should not be addressed by EFSA, but is a regulatory matter resolved in accordance with applicable EU legislation and European Court of Justice case law. In particular we are very concerned with the number of references to medicinal use of botanicals, which has no bearing on the safety assessment of such plants. This classification is the result of the different national regulatory approaches on the status of botanicals and is therefore irrelevant to the assessment of safety.



We therefore submit that EFSA should stay within its competence and mandate and address only safety issues and not regulatory ones, in particular those relating to the status of botanicals ingredients used as food or medicines, which are the exclusive competence of the EU institutions or national governments. In addition we believe that all references to medicinal use should be removed from the guidance document.

COMPENDIA

We note that the compendia are not necessary for the application of the EFSA guidance note as they are of a regulatory nature.

We are concerned that they would add confusion, despite the disclaimer, and could be wrongly used as regulatory tools despite their shortcomings. In particular, we note that the criteria used are not clear and the decision tree has not correctly been applied to many inclusions.

We believe that some plants are missing or not sufficiently characterised in Compendium 1 and others are indicated as used as food supplements, whereas it is not the case. It also ignores the use of quality assurance measures to avoid /remove toxicological risks.

We therefore submit it would be a waste of the already stretched resources of EFSA to work of those botanicals assessment, whereas at the same time EFSA has the obligation to advise on important issues for our sector such the evaluation of vitamin and minerals sources and the evaluation of health claims.

We also believe that Compendium 2 is purely based on the regulatory classification, and therefore is not safety related and has no relation to EFSA mandate.

We therefore submit that Compendium 2 should be removed from the document.

SAFETY & QUALITY

We note that EFSA guidance notes mixes safety related aspects and quality related ones as some parts of the documents relate to the safety of botanicals and other to end product quality. In particular, the submission of an application relating to end product quality parameters, similar to those used in medicinal product licensing, appears to be totally ignoring current food law requirements and is not relevant to the safety of botanicals as such as it applies to end products.



We would like to point out that the quality of food supplements containing botanicals is already regulated under the provision of food laws, in particular the EU General Food Law Requirements and the relevant EU Hygiene and Contaminants rules. Manufacturers put in place quality assurance schemes to comply with their legal obligations. EHPM has notably published a quality guide for the manufacture of food supplements covering the various rules and best practices applicable.

We therefore submit that the safety assessment should focus on botanicals only, not on end products, and that section 3.1 which relates to quality should be removed.

PROPORTIONALITY

EHPM membership is largely composed of SMES who are very concerned about the proportionality of measures proposed and we would like to remind EFSA that due consideration should be given to the impact that any requirements proposed may have on SMEs and how these can be achieved in practice.

For example, we believe that the use of mandatory genotoxicity testing for all level B substances is at odds with the rather more pragmatic approach applicable to botanicals when used in traditional herbal medicinal products, where such data is only required when there is a known or reported risk.

We look forward to the response of EFSA to comments received on this consultation.