



European Federation of Associations of Health Food Products Manufacturers
EHPM

Position Paper on Botanicals

The European Federation of Associations of Health Product Manufacturers (EHPM) represents national food supplement associations in Belgium, Bulgaria, France, Germany, Greece, Hungary, Ireland, Italy, Poland, Portugal, Spain, the Netherlands, Turkey and the United Kingdom.

The outcome of the current reflection period that the European Commission has initiated through its “Discussion Paper on Health Claims on Botanicals used in Foods” is of the highest importance for the future of the Food Supplement sector and for the ability of consumers to continue to have the capacity to make informed choices. EHPM, through this position paper, outlines its common position on this issue of key importance.

1. Introduction

In the European Market several legal statuses for Botanicals coexist. This paper will address parallels in the treatment of¹:

- Botanicals as Traditional Herbal Medicinal Products (THMPs); and
- Botanicals as Foods/Food Supplements.

The justification for allowing THMPs on the market lies in the long Tradition of Use (ToU) of Botanicals for certain, scientifically plausible therapeutic effects. The distinction between the classification as food supplement or medicinal product depends on the specific conditions of use for each product and the effect (therapeutic or a physiological) to be delivered. Many factors are thus taken into account in the classification of a product (e.g. intended use, labelling, preparations and dosages). (See EU case law for the criteria)

Botanical products are marketed in several ways and European and National legislation confirm various realities, as only a partial level of harmonisation has been achieved to date at EU level e.g. through Regulation (EC) No 1924/2006) which regulates the use of health claims in advertising, presentation and labelling of Foods/Food Supplements. However, the peculiarities of traditional health claims on Botanicals are not adequately addressed in this legislation as:

- Botanicals are complex matrices, the qualitative and quantitative compositions of which vary during their ontogenetic cycle. (Regulation 1924/2006 does not concern “matrices,” or other qualitative or compositional aspects of foods. These aspects are regulated in Regulation 1925/2006/EC.)

The assessment and management process for nutrition and health claims on Botanicals under Regulation (EC) No. 1924/2006 that is currently on hold did not recognise the empirical evidence of the ToU as a key factor in Foods/Food Supplements as is the case in Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD). Under the THMPD, bibliographical or expert evidence regarding ToU of Botanicals is sufficient to support certain therapeutic indications and make medicinal claims.

All these considerations lead to the conclusion that there is a real need for a European legal framework which recognizes the peculiarities of Botanicals used as Food/Food Supplements with respect to quality, safety and the use of traditional health claims.

¹ The Registered Medicinal Product category incorporates two types of products that contain botanicals - Traditional Herbal Medicinal Products (THMPs) and Well established Use Products. The use of botanicals in cosmetics and as food additives is also subject to certain legal requirements.

2. Characterisation of Botanicals

The specificities of Botanicals must be recognised and a Botanical preparation should be characterised according to scientific standards. Specific attention should be focused on Safety and Quality Control of Botanicals in line with existing best practice.

In this regard, and first of all, a clear and unequivocal *legal* definition must be established for “botanicals.”

Although the use of Botanical Food Supplements has increased substantially during the last four decades, evidence for their efficacy and safety has not been well documented in all cases. Possible safety problems with Botanical Food Supplements include contamination with pesticides, herbicides and heavy metals, use of the incorrect part of the plants, and even misidentification of the plant species incorporated into the product². In some situations, the labelling of products does not allow the right identification of the Botanicals due to the absence of appropriate standards and terminology for doing so.

It is therefore necessary to address the following points:

- Exact determination of the plant (family, scientific name, eventually variety and chemotype)
- Part of plant used
- Nature of preparation (fresh, dried, extract, infusion, tincture, essential oil)
- Condition of use (quantity, frequency, duration)
- Characterization of the botanical or the botanical preparation

3. Recognition of the value of Tradition of Use (ToU) for Botanicals in Food Supplements

The "problem" of ToU has been examined from a scientific point of view since 2002³. Bibliographical or expert evidence concerning ToU is cited in Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD) as an acceptable threshold for market entry of traditional medicinal products. This threshold is not allowed in the Health Claims Regulation, although it is recognized by Botanical experts that ToU is applicable to food use of a Botanical even more than for its medicinal use. It would be illogical and discriminatory that evidence of ToU that is accepted in the consideration of THMP for approval is then not also accepted in the assessment of a health claim for a botanical food supplement.

EHPM considers that through using the following criteria to evaluate ToU of Botanicals, the scientific value of the data equivalent to the criteria laid down in the Medicinal Products Directive (bibliographical or expert evidence) can be assured:

- a. Documentation demonstrating a sufficiently long history of the observed effects.
- b. Documented use of the Botanical or the Botanical preparation in different regions, countries or continents, under the same or similar conditions of use.
- c. Documented information on the nature of the Botanical or the Botanical preparation and the modalities of use (traditional forms, frequency and level of use...).
- d. Observational evidence
- e. Availability of more recent compilations of traditional health effects in various monographs of Botanicals: World Health Organisation (WHO), European Scientific Cooperative on Phytotherapy (ESCOP), European

² R. B. van Breemen, et al. 2007. The Role of Quality Assurance and Standardization in the Safety of Botanical Dietary Supplements. *Chem Res Toxicol.* ; 20(4): 577–582

³ Aalt Bast et al., Botanical health products, positioning and requirements for effective and safe use. *Environmental Toxicology and Pharmacology* 12 (2002) 195-211

Medicines Agency Herbal Medicinal Product Committee (HMPC), Pharmacopoeias and recognised experts in this field.

- f. Support of the available documentation described above in relation to the ToU of the Botanicals or Botanicals preparations from various sources of scientific data (chemical, pharmacological, toxicological, clinical studies or other experimental data)⁴.

ToU represents knowledge that has been accumulated from the use of Botanicals or Botanical preparations. This ToU establishes that the health benefits associated with these botanicals are real and should be accepted in the absence of human intervention trials. ToU is also a crucial source of information to demonstrate the safety of many Botanicals⁵. In terms of regulating how to take into account ToU, Directive 2004/24/EC on herbal medicinal practice provides qualifying criteria that could be replicated – at least 30 years use which must include 15 years use in the EU.

On the basis of what has been described, we believe that it is important to establish a clear, open and accessible procedure that should lead to a harmonized European list of Botanicals (including conditions of use and warning statements where necessary) permitted for use in Food Supplements based on national expertise in the Botanical field.

4. Support for Option 2 Proposed by the European Commission

The "Discussion Paper on Health Claims on Botanicals used in Foods" proposed by the European Commission provides two options:

- Option 1: maintains the status quo.
- Option 2: recognises the peculiarity of the Botanicals case and addresses it through a review of the legislation.

Option 1: As the Food Supplement Industry is composed primarily of Small and Medium-sized Enterprises (SMEs), Option 1 would be devastating. The following is not exhaustive list of the problems associated with Option 1:

- The substantiation that would be required relies mainly on the availability of randomised controlled trials (RCTs) and does not consider ToU as evidence. This pharmaceutical approach applied to healthy subjects is not feasible.
- Conducting an RCT on many of these Botanicals is not appropriate in the majority of cases. Furthermore their cost ranges from €250,000 to €1 million, which is out of reach for the vast majority of SMEs.
- The Clinical trial models do not even exist and are definitely not adapted to the complex matrix of Botanicals.
- It is also important to stress that most of claims accepted for Vitamins and Minerals and published in the Regulation (EC) No 432/2012 have been accepted on the basis of their long history of use and biochemical functions and not just on the basis of clinical data evidence.

In the event that Option 1 is the approach taken:

- It is expected that most, if not all claims for Botanicals will receive negative opinions and therefore will be rejected for further use. This will result in many of these products disappearing from the market as sales will inevitably fall when labelling cannot indicate the purpose/benefit of using the products.

⁴ Robert Anton*, Mauro Serafini** and Luc Delmulle 2012. Traditional Knowledge for the Assessment of Health Effects for Botanicals – A Framework for Data Collection. EFFL 2|2012, 74-80

⁵ Robert Anton, Mauro Serafini and Luc Delmulle 2012

The role of Traditional Knowledge in the Safety Assessment of Botanical Food Supplements – Requirements for Manufacturers, EFFL. 5/2012. 241-250

- Only “stronger” therapeutic claims will continue to be accepted exclusively for Herbal Medicines based on their traditional use.
- If health claims are no longer possible, it is likely that manufacturers will look for alternative ways to continue to communicate the health effects of their products, by for instance adding systematically vitamins or minerals with accepted claims to their products.
- If legitimate products disappear, this will be to the benefit of products coming from other jurisdictions often advertised and sold via internet or other channels. Under option 1, for example, US products sold via distance sale would continue to carry claims that are legal in the US but banned in the EU. The end result would be the loss of revenue for the EU economy.
- In addition, under option 1, consumers would inevitably become more exposed to products carrying misleading claims originating from countries with less robust consumer protection regulatory structures.

Option 1 would create an unfair and disturbed competitive landscape between traditional health claims and traditional medicinal claims (between the Food Supplements and the Medicinal Products sectors) that cannot be justified on logical grounds and which could be legally challenged in the European Court of Justice on the basis of *inter alia* the principle of non-discrimination.

The food supplements sector is comprised of 2,000+ companies of which 85% are SMEs and conversion of production facilities to pharmaceutical status is prohibitively costly for these companies. Consumers will be less informed than was previously the case as companies will be prevented from informing consumers about the traditional health benefits associated with the consumption of specific products. This is not in line with the initial objective of Regulation (EC) No 1924/2006.

Option 2: could open the door to addressing the incoherency that has been created between Medicinal Products and Food Supplements by the non-acceptance of ToU under the health claims legislation. This option would enable also the Regulator to address the safety and quality aspects and to reflect on ways to improve the free movement of Botanical Food Supplements in the market. It would provide also legal certainty on the status of these products that are now often considered in different ways by national authorities. In addition to this, Option 2, recognizing the ToU, would allow stakeholders and in particular SMEs to have the necessary resources to invest in R&D and continue innovation in the field.

5. Conclusion

In conclusion, EHPM is in support of:

- i. Similar treatment of Botanicals in Food Supplements and those in THMP regarding the recognition of the ToU as an acceptable criterion for the substantiation of health claims on Botanicals.
- ii. Establishing a fair and accessible procedure leading to the harmonization of health claims, safety and quality aspects for Botanicals for Food Supplements use in the European Union (harmonized common list). This harmonized approach will ensure that a product accepted and marketed as food supplement in one EU Member State will be accepted as such in all other Member States of the European Union.
- iii. Easy and safe access for consumers to a wide variety of affordable and well regulated Food Supplements containing Botanicals in all Member States.
- iv. Optimization of positive economic impact on the Food Supplements sector in the European Union market.

The Small Business Act for Europe (SBA), adopted in June 2008 recognizes the central role of SMEs in the EU economy. The great majority of companies operating in the European Food Supplement Sector are SMEs. The contribution of Botanical Food Supplements sector to the European economy is estimated at €2.1 billion annually and accounts for more than 135 000 employees active as producers, suppliers of plants and extracts. If a proportionate approach is not taken to the regulation of botanical food supplements, this valuable

contribution to the European economy and the livelihood of those working in the sector will be placed in jeopardy.

For the reasons presented above, EHPM stresses the urgent need for taking steps on the road to a harmonized legal framework that offers a coherent approach and tailored solutions for Botanicals addressing health benefits, quality, and safety and demarcation issues under food legislation. EHPM is confident that this legal framework can be achieved through a process of constructive dialogue between all parties.

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