Position Paper on Botanicals

AFEPADI, AFIM, APARD, FEDERSALUS, NAREDI and SYNADIET (hereinafter referred to as the Associations) represent Food Supplements manufacturers in Spain, Greece, Portugal, Italy, Belgium and France.

The outcome of 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. The Associations, through this position paper, outline their common position on this issue of key importance.

1. Introduction

In the European Market two legal statuses for Botanicals coexist:

   i. Botanicals as Traditional Herbal Medicinal Products
   ii. Botanicals as Foods/Food Supplements.

The justification for the existing situation lies in the long Tradition of Use (ToU) of Botanicals for health-related 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).

Botanicals products are marketed in several ways and European and National legislation confirm both realities, as only a partial level of harmonisation has been achieved to date at EU level. Regulation (EC) No 1924/2006 regulates the use of health claims in advertising, presentation and labelling of Foods/Food Supplements. However, the peculiarities of 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.

The assessment process for 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 THPMD, ToU of Botanicals is sufficient to support therapeutic indications.

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 health claims.
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.

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. Possible 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 product\(^1\). In some situations, the labelling of products does not allow the right identification of the Botanicals due to the absence of appropriate standards 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)

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 2002\(^2\). ToU is cited in Directive 2004/24/EC on Traditional Herbal Medicinal Products (THMPD) as a plausible factor that can be taken into consideration in assessing pharmacological effects or efficacy for THMP. This is not allowed for evaluation of Botanicals in Foods/Food Supplements whereas 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 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.

The Associations consider that through using the following criteria to evaluate ToU or of Botanicals, the scientific value of the data can be assured:

a. Availability of an important body of 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 preparation and the modalities of use (traditional forms, frequency and level of use…).

d. Evidence coming from experience gathered from observational studies

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


\(^2\) Aalt Bast et al., Botanical health products, positioning and requirements for effective and safe use. Environmental Toxicology and Pharmacology 12 (2002) 195-211
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). ToU represents knowledge that has been accumulated over decades from the use of Botanicals, which 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 Botanicals.

On the basis of what has been described, we believe that it is important to establish a harmonized European list of Botanicals (including conditions of use and warning statements where necessary) permitted for use in Food Supplements and 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.
- The cost of conducting an RCT on the scale that required under Option 1 ranges from €250,000 to €1 million. This cost perspective is not financially feasible for 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.
- 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.

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4 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
• If legal products disappear, this will be to the benefit of illegal products, often advertised and sold via internet or other channels that are not under the control of the National Authorities.

Option 1 would create an unfair and disturbed competitive landscape between Food Supplements and pharmaceutical sectors that cannot be justified on logical grounds and which could be legally challenged in the European Court of Justice.

The food supplements sector is comprised of 2,000 companies of which 85% are SMEs and conversion of production facilities to pharmaceutical status is not achievable for these companies. Consumers will be less protected than was previously the case which is not in line with the initial objective of Regulation (EC) No 1924/2006.

**Option 2:** could address 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 AFEPADI, AFIM, APARD, FEDERSALUS, NAREDI and SYNADIE are in support of:

i. Similar treatment between Botanicals in Food Supplements and in THMP regarding the recognition of the ToU for the substantiation of health claims on Botanicals.

ii. Harmonization on safety and quality aspects for Botanicals for Food Supplements use in the European Union (harmonized common list).

iii. Limitation of divergent classifications of products as Food Supplements or THMP between the Member States and improvements of the free circulation of Food Supplements.

iv. Easy and safe access for consumers to a wide variety of affordable and well regulated Food Supplements containing Botanicals in all Member States.

v. Limitation of significant 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 this reason, the Associations stress the urgent need for 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. The Associations are confident that this harmonisation can be achieved through a process of constructive dialogue between all parties.

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