Assessment of health claims on Botanical Food Supplements in the EU

EHPM proposal | Briefing paper

Everything that is consumed has an immediate effect on body function with longer term implications for health. These effects are particularly apparent in foodstuffs obtained from plants and other vegetative organisms because such 'botanicals' contain not only a wide range of nutrients, but also many other biologically active substances that interact with the normal physiological processes of the body to benefit health and well-being. This multiple functionality also explains why there is such a rich culture of health benefits associated with botanical foodstuffs in Europe and all around the world.

In the EU the enactment of the Nutrition and Health Claims Regulation (EC 1924/2006) ('NHCR'), which sets out the rules for using health claims on foods, has been highly problematic for botanical foods and in particular for botanical food supplements. In 2010 some 2000 botanical health claims were placed 'on hold' because they could not be assessed through the initial approach adopted. In 2012 the EU Commission asked Member States if they wished to continue the initial approach – which would result in the majority of botanical health claims being prohibited – or, whether alternative measures, such as the traditional-use approach already applied to Traditional Herbal Medicinal Products, might be more appropriate.

To date, the challenge presented by botanical health claims remains unresolved. Pending a decision by the Commission, 'on hold' claims continue to be used, subject to certain provisos. However, the uncertainty created by this very lengthy 'temporary' arrangement is unsatisfactory for regulators, consumers and industry alike, leaving the future of botanical health claims for foods in general, and food supplements in particular, in the balance. If a legitimate way is not found to provide information on the health benefits associated with such food products, consumers will turn to uncontrolled, unregulated sources such as the Internet for both information and supply, thereby increasing the likelihood of being misled and seriously undermining the legitimate industry.

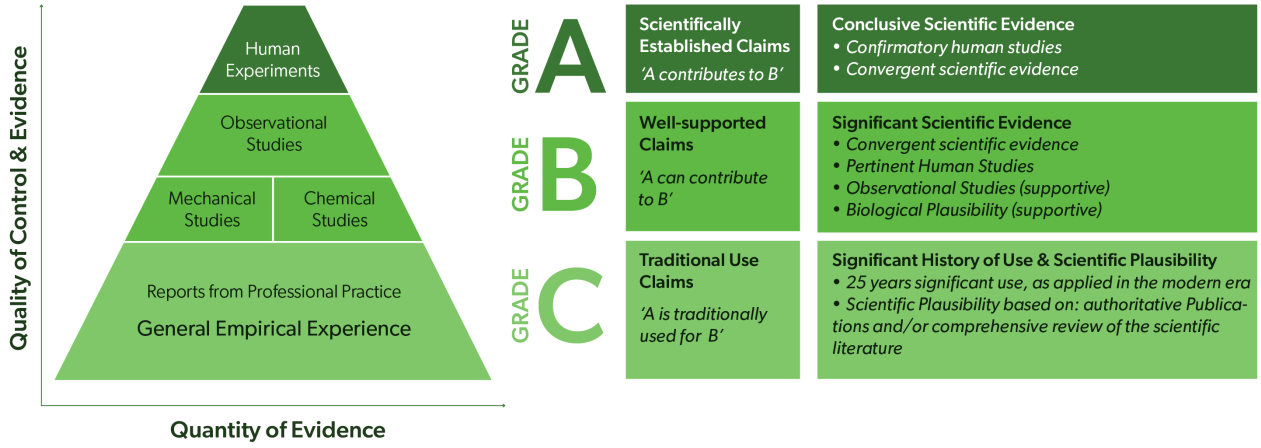
A root cause of the problem is that the NHCR prioritises the 'protection of the consumer from being misled' over 'the need to facilitate informed choice'. The body responsible for assessing health claims, the European Food Safety Authority (EFSA), implements the legislation through an authorisation process that requires scientific consensus of proof of a cause/effect relationship between isolated food constituents and health. Such an approach may be appropriate for nutrients, whose role in human physiology is already the subject of generally recognised science, but it is extremely problematic when applied to the more general health benefits associated with the multiple effects of the host of complex botanicals supplied under food regulations.

There are, however, other research approaches better suited to demonstrating the effects of complex foodstuffs on health. These typically look at the totality of evidence of the multiple effects of such foodstuffs as this evidence gradually evolves over an extended period of time. Research of

this nature also facilitates the use of different types of 'graded' claims, which themselves evolve over time to reflect the new evidence that is arising.

In this paper, the European Health Product Manufacturers Federation (EHPM) presents such a Graded Approach to health claims, as applicable to botanical foods in general and botanical food supplements in particular. The approach has been developed to be consistent with both the fundamental requirements of the NHCR and the systematic procedures already adopted by EFSA.

The Graded Approach to the Assessment of Botanical Health Claims



Three types of graded health claim are identified:

A. **Scientifically established health claims, similar to those already authorized by EFSA:** By qualifying the quality and scale of 'convincing' clinical studies to reflect what is practically achievable for complex botanicals, a modified approach is proposed for confirming a cause effect relationship between a botanical foodstuff and health. Claims validated in this way are expressed with a high degree of certainty; *e.g. 'Bacopa monnieri improves cognitive functions and memory'. Conditions of use of the claim should be defined e.g.: Minimum 120 mg Bacosides per day brought by Bacopa monnieri extract standardized in Bacosides (USP method).*

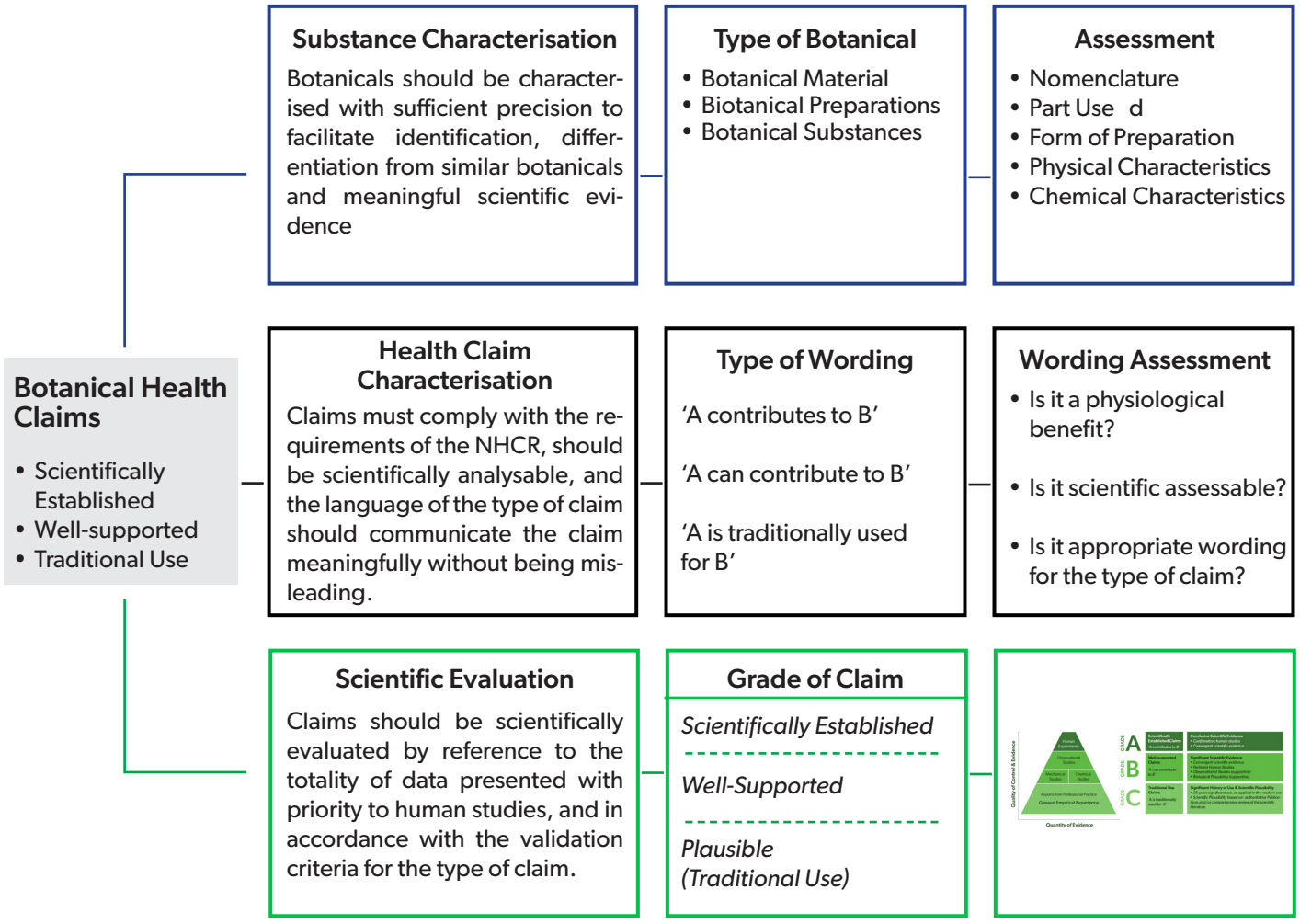
B. **Scientifically well supported health claims based on significant developments in modern science and experience.**
To be considered scientifically well-supported, botanical health claims must be based on a convergent body of evidence that includes detailed chemical profiling of the botanical, identification and study of active constituents in the laboratory, observation of the effects of the botanical in human beings, and well-conducted clinical trials which are of sufficient quality and scale to demonstrate an effect, but not enough to be considered conclusive; *e.g.: 'Isoflavones of red clover (trifolium pratense) can contribute to lowering LDL-cholesterol in postmenopausal women. Condition of use of the claim should be defined e.g.: a dose of 50 to 80 mg/day of red clover's isoflavones.*

C. Traditional use health claims that have been used for at least one generation and which are considered to be scientifically plausible.

Traditional use health claims are based on traditions of use substantiated by bibliographic evidence and/or industry data; the scientific plausibility of such claims must also be demonstrated by reference to recognised publications (e.g. Monographs), or by a critical appraisal of a comprehensive review of the scientific literature; *e.g. 'Thyme (thymus vulgaris) is traditionally used to support the health of the respiratory system'.*

Practical Assessment of Graded Health Claims for Botanicals

Any EU approach to health claims on foods must adhere to the requirements of the Nutrition and Health Claims regulation (NHCR) – consumers must be protected from being misled and a high-quality scientific assessment must be carried out. EHPM has therefore identified how the Graded Approach to health claims for botanical food stuffs, as particularly applied to food supplements, can be evaluated using the general approach already adopted by EFSA.



This common approach has three essential elements: Foodstuff Characterisation, Wording Assessment and Evaluation of the Cause/Effect Relationship:

- **Characterisation of the Botanical**

  The current system applied by EFSA to isolated substances, such as nutrients, requires a

level of characterisation that is not practical for complex botanicals. However, EFSA has also published appropriate additional guidance on how to characterise botanicals so as to take account of their complexity and variability in a way that allows for effective claims evaluation. Botanical characterisation is also described in more detail in Chapter 17 of the EHPM Quality Guide for Food Supplements, available on https://www.ehpm.org.

- **Wording Assessment**
  The wording of any health claim must conform to the basic requirements of the NHCR: it must be a genuine health claim (i.e. one of the types of claim specified in the legislation), and must not be misleading. In the case of graded claims, this means that the wording of each grade of claim must honestly, accurately and meaningfully communicate to the consumer the nature of the cause/effect relationship claimed and it must do so in a way that reflects the evidential basis for the claim. Thus, a claim may understate the level of scientific evidence, but may not over-state it. For example, the term 'traditional use' does not communicate to the consumer that the claim has been subjected to a stringent scientific assessment of plausibility – it merely asserts that a tradition exists.

- **Validating the Cause/Effect Relationship claimed**
  Although botanical health claims rarely achieve the same scientific consensus of proof as applied to isolated nutrients, the scientific analysis to which they are submitted ensures that the claim, as worded, does reflect current scientific understanding of the botanical and its effects on human health:
  A. Grade A claims require conclusive human studies, including at least 1 RCT;
  B. Grade B claims require a convergent body of evidence that includes at least one appropriately controlled trial on the specific botanical;
  C. The plausibility of Grade C claims is based on recognised Monographs and/or evaluation of a comprehensive review of the scientific literature.

Concluding Observations

The Nutrition and Health Claims Regulation, as currently implemented, is not an appropriate response to the challenges presented by the evolving understanding of the nature of food and its effects on human health. The protection of consumers from being misled has been prioritised over the rights, needs and aspirations of consumers for information. This has resulted in an excessively restrictive regulation that is inhibiting both authentic commercial activity and research and development; it is causing functional products to be placed on the market without any indication as to their safe and effective use and it is inducing consumers to seek information on their own initiative from uncontrolled sources. All these activities increase the risk of consumers being misled.

The EHPM proposals re-prioritise consumer choice and develop assessment methodologies, which reflect the long term, iterative nature of scientific inquiry. The approach shows that it is possible to grade botanical health claims from the certain to the plausible, to evaluate these claims by reference to specified levels of evidence and to use qualified language to communicate the

outcomes of these evaluations to consumers in a useful, honest, accurate and meaningful way. This approach logically involves dealing with uncertainty, but, the methodology proposed shows that this can be achieved without compromising the required stringency.

When considering how such an approach might be legislated for, the key issue is the interpretation of the term 'generally recognised science' as used in the NHCR:

- If this criterion is taken to allow only simple statements of fact based on scientific consensus of proof, then it is difficult to see how the ehpm proposals could be implement other than by new legislation;

- If, however, a more circumspect approach is adopted to the term and its implication, it would be possible to facilitate the ehpm proposals either by amending the NHCR together with new implementing regulations, or, simply by issuing new implementing regulations. These changes could either be enacted in the context of Food Law in general to cover all foods, or they could be implemented initially, in the context of food supplements, by an amendment to the Food Supplements directive.

The EHPM proposals are concerned solely with health claims in the context of the NHCR. Quality issues have only been addressed in so far as they are required for claims evaluation, and safety issues have not been addressed at all. In reality, however, quality, safety and claims substantiation should be managed in an integrated way as part of the development, production and supply of any products.

About EHPM

EHPM was created in 1975 and represents 1600 health-product manufacturers in 14 European countries. Through our member associations, EHPM aims to provide consumers with safe, science-based, high quality products as well as accurate and helpful information about their nutritional value and use, and to assure a fair European regulatory framework for the food supplement sector.

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