

**European Commission**

DG SANTE — Directorate-General for Health and Food Safety

[www.eucope.org](http://www.eucope.org)

Telephone: [REDACTED]

Telefax: [REDACTED]

E-Mail: [REDACTED]

25 April 2016

**Roadmap to review the Nutrition and Health Claims legislation – expression of interest to contribute to the upcoming external study**

Dear [REDACTED],

As you know, EUCOPE has a keen interest in the topic of nutrition and health claims made on food. I have attached our Discussion Paper on Health Claims on Botanicals used in Foods for your information. I would also like to mention that we are regularly participating in similar Commission studies: only recently we were interviewed for DG SANTE's study on off-label use by the Netherlands Institute for Health Services Research (NIVEL) and also took part in the respective brainstorming meeting in Amsterdam.

As you have already outlined the questions/issues to be examined during the evaluation phase on the Commission's dedicated [website](#) we would like to provide you already at this stage with a few comments:

***C. Scope of the evaluation/FC******2. Plants and their preparations used in foods******1. Effectiveness***

**What progress has been made over time towards achieving the objectives of the legislative framework introduced by Regulation (EC) No 1924/2006? Is this progress in line with the initial expectations?**

According to Article 13(2) of Regulation (EC) No. 1924/2006 (Health Claims Regulation - HCR) the Member States were to submit to the European Commission lists of health claims on substances in food by 31 January 2008. These claims were to be evaluated by EFSA and based on this evaluation the Commission had to draft a Community List of admissible health claims and adopt this list in accordance with the procedures of Article 5a of Council Decision 1999/468/EC until 31 January 2010. However, the assessment of claims referring to botanical substances has been suspended by the EFSA at the European Commission's request. In the end, 2095 out of submitted 4600 health claims still have to be assessed. Thus, the timelines provided for in Article 13 HCR for the adoption of the list were not met.

Therefore, EUCOPE does not consider that the initial expectations have been met. EUCOPE is concerned that currently health benefits are claimed that are not based on scientific evidence. Yet, consumers are still confronted with these non-assessed health claims.

**Did the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods prevent the realisation of the objectives of the Regulation, and if so how? What are the objectives that are not met and to what extent?**

The objectives of Regulation No 1924/2006 encompass to ensure a high level of protection for consumers. Health claims should only be used after a scientific assessment of the highest possible standard. As explained above, consumers are still confronted with health claims that have not been subject to such an assessment. This objective has clearly not been met.

**To what extent the legislative framework applicable to plants and their preparations used in foods has allowed achieving its objectives with respect to placing of safe food on the EU market and facilitating free movement of goods?**

Both objectives of the Health Claims Regulation - to safeguard consumer protection and to facilitate the free movement of goods - have not yet been achieved due to the lack of comprehensive decisions on the authorisation or rejection of health claims on botanicals. The European Commission's decision not to pursue with the assessment of health claims for botanicals has a significant impact on the trade in both food supplements and OTC medicinal products as it favours manufacturers of food supplements with botanical ingredients over those with chemical ingredients (as these products have been assessed on the basis of the criteria provided).

## **2. Efficiency**

**What are the costs and benefits (monetary and non-monetary) associated with the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006?**

EUCOPE does not see any benefit of the current situation of legal uncertainty regarding health claims for botanicals. By contrast, for companies in both sectors - food supplements and medicinal products - a clear and predictable legal framework for their products is crucial to make coherent and sustainable business decisions.

**What is the specific cost impact of authorisation procedures required for health claims on micro, small and medium sized enterprises?**

For small and mid-sized pharmaceutical companies the lack of legal certainty in relation to health claims constitutes a severe concern. Given the different regulatory regimes for medicinal products and food supplements and in particular the fact that the development of a medicinal product requires considerable higher financial resources, the lack of a complete assessment of submitted health claims leads to a situation where companies might refrain from developing respective medicinal products since they cannot exclude competition from manufacturers of food supplements.

**What are the alternatives, to the current provisions for regulating health claims on plants and their preparations used in foods, which could achieve similar objectives to the objectives of the Regulation, but with less burdensome requirements?**

EUCOPE advocated for the perpetuation of the regime providing for an assessment of health claims by EFSA. Thus, we do not see any alternative that could be equally effective other than continuing the assessment of health claims by EFSA. Besides, the current requirements are not "burdensome" as the pragmatic assessment of vitamins and minerals by EFSA has shown. The evaluation of health claims on botanical substances is possible under the criteria applied by EFSA. There is no scientific

rationale why these criteria cannot be applied to claims on botanicals. This is especially not contradicted by the allegation that it is more difficult in the case of botanicals to submit sufficient data to substantiate health claims as can be shown by fully authorised medicinal products containing botanical substances. On the contrary, if it is not possible to substantiate a specific claim in a scientifically founded way, this claim is clearly not eligible to be used towards the consumer.

**What are the costs and benefits of the legislative framework applicable to plants and their preparations used in foods?**

The European Commission and EFSA have shown in their case-by-case assessments for health claims concerning chemical compounds that the current legislative framework of the Health Claims Regulation is appropriate to conduct a scientifically based assessment of health claims. Even if accepting an exceptional position of botanicals, this principle would not change.

### **3. Relevance**

**To what extent is the legislative framework introduced by Regulation (EC) No 1924/2006 still relevant to address current needs and trends in relation to health claims made on plants and their preparations used in foods? Are there any other objectives that should be considered?**

The principal aim of the Health Claims Regulation as expressed in its Recital 1 is to ensure a high level of protection for consumers and to facilitate their choice. This aim is without doubt as relevant as it was when the Regulation was adopted. In addition and referring to Recital 10 of the Regulation it can be concluded that the Regulation also seeks to enable consumers to rely on the accuracy of all health or nutrition claims made on food. Again, the relevance of this aim persists and urgently needs to be achieved.

**To what extent is the legislative framework applicable to plants and their preparations used in foods still relevant to deal with issues related to the evolution of the market with regard to plants and their preparations used in foods?**

EUCOPE does not see any structural evolutions of the market which would trigger the need to change the existing EU legislation other than the distortions resulting from the uncertainty introduced by the current *status quo* which can be dissolved by mandating EFSA to resume to its assessment. Especially it is not needed to consider the creation of a new product category of so-called 'herbal health products' by way of EU law since the existing regime for medicines (Directive 2001/83/EC) and foods (Health Claims Regulation) already allows for a clear allocation of a product to the different product categories (medicines or foods).

### **4. Coherence**

**To what extent are the requirements set out in Regulation (EC) No 1924/2006 coherent with EU legislation applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with traditional herbal medicinal products?**

In the discussion on the evaluation of claims on botanical substances references have been made to the concept of traditional use in the field of medicinal products as established in Chapter 2a of Directive 2001/83/EC. These references are misleading and do not alter the clear legal framework for the evaluation of claims on botanicals as laid down by the Health Claims Regulation. The concept of traditional use of Directive 2001/83/EC refers explicitly and exclusively to medicinal products. Medicinal products have specific functions and definitions and are subject to strict limitations with regard to their application, indication and target population. In particular, unlike food, they require prior authorisation and are subject to strict vigilance standards.

This is a substantial difference in comparison to foods. For these reasons, food and medicinal products are neither factually nor legally comparable and a simple transfer of the concept of traditional use from one regime to the other is not appropriate.

### **How and to what extent does the regulatory framework for the use of nutrition and health claims affect the trade of foods bearing claims?**

According to Recital 9 one objective of the Health Claim Regulation is to create equal conditions of competition for the food industry. Not pursuing the assessment of Health Claims for Botanicals has a significant impact on the trade in both food supplements and OTC medicinal products:

- Within the field of food supplements the competition is distorted because legal certainty only exists for chemical substances but not for botanical substances while the Health Claims Regulation does not foresee a different approach for the evaluation of botanical and chemical substances. On the contrary, claims on botanical substances are not even mentioned as a separate category of claims that would require special considerations. In this regard it is important to underline that the European legislator was clearly aware of different types of claims and provided for distinctive rules for some of them (such as claims on the reduction of a health risk, Art. 14). The fact that no special provisions have been enacted for claims on botanicals shows that a distinctive approach for these was not intended.
- Similarly, products for which unassessed claims are used gain an undesirable competitive advantage over medicinal products. As indicated before, there are many cases, where substances used in medicinal products may - in lower doses and under varied conditions - be also used in food supplements.

### **How coherent is it to have a positive list at EU level of permitted health claims for plants and their preparations while there is no positive list at EU level of permitted plants and plant preparations for use in food?**

EUCOPE does not see the need for legislative changes in the field of food law regarding botanical substances. The European Commission concluded in a report adopted in 2008 on the use of substances other than vitamins and minerals in food supplements - COM(2008)824, final (5.12.2008) - that substances "other than vitamins and minerals" (i.e. plants and plant preparations) have a very varied consumption pattern and that harmonisation in this area is not desirable. This conclusion is still valid from our point of view as it cannot be concluded that this indeed different consumption pattern has changed over the last 8 years. The tradition concerning botanicals and herbal medicine differs significantly from Member State to Member State and therefore national competency and the principle of subsidiarity should be stressed in this respect. This is especially true because no barriers to trade have been identified by the Commission neither in this Commission report nor in the new Roadmap document. Furthermore, sufficient instruments exist to deal with potential barriers to trade such as the **mutual recognition principle and Article 8 of Regulation (EC) Nr. 1925/2006 which allows the Commission to set up a negative list** on certain ingredients used in food and food supplements, a procedure never used until now.

## **5. EU added value**

### **What are the merits and disadvantages in terms of the EU added value of the current governance of health claims on plants and their preparations used in foods?**

EUCOPE is concerned that the average consumer will generally not be aware of the fact that some claims currently in use have been assessed by EFSA while others have not. This gives manufacturers of food containing botanical substances the opportunity to widely use claims that are not based on scientific evidence. It does compromise the ability of the consumer to make a well based compar-

page 5

ison between different products that accidentally may contain botanical or chemical compounds or a selection of both categories.

**What would be the merits and disadvantages in terms of the EU added value of a positive list of plants and their preparations for use in foods?**

Please see our reply to question 12.

We look forward to receiving further information on the intended study in order to mention our interest on the matter and to offer our contribution to the selected consultant. If you have any questions on the above, please let me know.

Yours sincerely

\_\_\_\_\_  
\_\_\_\_\_