

SYNADIET – Contribution to the roadmap

According to 2002/46/EC regulation:

“food supplements” means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities”

Food supplements are consumed by healthy people striving to maintain their optimum health status. Indeed, the absence of health claims for food supplements, particularly those containing plants will result in many of these products disappearing from the market and lead this healthy population to an unjustified consumption of risk unregulated products or medicine. Rapid Alerts system for Food supplements in 2014 reports only 49 cases from products originating in the EU and were mostly related to ingredients status that differs from one Member state to another.

Food supplements play a key role in the control of rising societal health care costs, as they help high-risk individuals to minimize the chance of having to deal with potentially costly health events and participate to consumers’ responsibility regarding their quality of life.

EC Regulation n°1924/2006 on nutrition and health claims (hereafter, “the Regulation”) aimed at ensuring reliable information to consumers, whilst facilitating free movement of goods and providing legal certainty. It should also ensure fair competition, promote and protect innovation in the area of foods including food supplements.

Nine years after the entry into force of the Regulation, one may discuss whether these objectives have been reached or not.

We welcome and fully support the commission initiative to submit this evaluation with the intention to check the fitness of the Regulation.

Questions raised in this roadmap fit with our own questions. Nevertheless we would like to address some additional comments on the point 2. Plants and their preparations used in foods and draw attention on issues related to Health claims regulation through more general considerations. Our comments are presented below.

1. Plants and their preparation used in foods

As a preamble, we would like to stress that food supplements containing one or several plant preparations represent a huge market in Europe and many micro-small and medium sized enterprises would disappear if the regulation or the lack of regulation result in an absence of claims for such products. This market is important in certain countries and these countries have

implemented regulatory systems which should provide the basis for harmonization at EU level, such as French Decree establishing the list of plants authorized in food supplements.

Of note, we feel that the statement “plants and their preparations in foods” needs to be clarified. Indeed, plants used in food supplements cannot be considered the same way than foods containing plant preparations. Actually, food supplements are delivered in doses so their consumption can be accurately monitored and restricted unlike other foods.

Moreover, health claims made on plants may not be analysed as health claims for other ingredients because, unlike chemically synthesized substances (such as vitamins and minerals), plants display a complex composition and most of the time, their properties cannot be ascribed to a single compound. Also, a same plant or even a same part of the plant can be used under different types of preparations.

Our suggestions in red in the text are listed below. They are mainly related to re-formulation proposals.

1. Effectiveness

- What progress has been made **on plants and their preparations used in foods** over time towards achieving the objectives of the legislative framework introduced by Regulation (EC) No 1924/2006. Is the progress in line with the initial expectations?
- **In case decisions would have been taken on the authorisation or rejection of health claims on plants and their preparations used in foods, would the objectives of the regulation be achieved?**
- To what extent the legislative framework applicable **to foods and to food supplements** has allowed achieving its objectives with respect to placing safe products based on plants and their preparations on the EU market and facilitating free movement of goods?

2. Efficiency

- What are the costs and benefits (monetary and non-monetary) associated with the absence of a final decision on the authorization of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006?
- What is the specific cost impact of authorisation procedures required for health claims on micro-small and medium sized enterprises?
- What are the alternatives, to the current provisions for regulating health claims on plants and their preparations used in foods **and food supplements**, which could achieve similar objectives **but with adapted regulatory framework compatible with plants specificities?**

- What are the costs **linked to the absence of a specific** legislative framework applicable to plants and their preparations used in foods?

3. Relevance

- **Given the distinctive characteristics of plants (totum of substances, complex matrix, diversity of preparations)** 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 food **supplements? Is a centralised procedure (i.e. EFSA scientific assessment and authorization by the commission) adapted to plants case? Are there any other objectives that should be considered?**
- To what extent is the legislative framework applicable **to foods** still relevant to deal with **the need of innovation for internal market evolution** with regard to plants and their preparation used in foods?

2. General considerations on Health Claims regulation

This evaluation of Health claims Regulation on nutrient profiles and plants and their preparations used in foods could also constitute an opportunity to address broader questions on the Health claims regulation itself.

Actually, since the introduction of European regulation 1924/2006, **130** health claim applications according to article 13.5 have been submitted to EFSA and only 18 (14 %) received a positive opinion.

One could consider that first applicants were not aware of the evaluation criteria applied by EFSA, and that the poor success rate was due to insufficient composition of the application dossier. However—since 2012, the percentage of positive opinions is similar: 13.2 %. During that time a conscientious scientific work have been carried out and a consistent amount of money invested by the applicants to meet EFSA requirements.

1. Effectiveness

- **Is the EFSA fulfilling the mandate given by the commission concerning the food supplement health claim evaluation regarding the definition of food supplements (foodstuffs having nutritional or physiological effect while claim evaluation is performed according to medicinal standards)?**
- **Is a success rate of 14 % (130 health claim applications submitted and only 18 (14 %) received a positive opinion) for health claim applications according to article 13.5. is normal situation?**

2. Efficiency

- Does the criteria settled in the scientific guidance published by EFSA give appropriate technical guidance and tools for stakeholders' innovation? How this situation fits with recital 33 of Regulation n°1924/2006¹

Finally, we hope these comments can be taken into consideration and as asStakeholders association, Synadiet we would be glad to be consulted by the contractor selected to perform the external study to be carried out and are looking forward to providing input to the stakeholder consultation in 2016.

¹: SMEs represent an important added value to the European food industry in terms of quality and preservation of different dietary habits. In order to facilitate the implementation of this Regulation, the European Food Safety Authority should make available appropriate technical guidance and tools, in due time, especially for SMEs.