

UEAPME¹ position paper on the roadmap evaluation of Regulation N° 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations.

Introduction

UEAPME welcomes the review of specific elements of Regulation (EC) No 1924/2006 on nutrition and health claims. The first part of this paper will focus on the issues of nutrient profiles and botanicals that the Commission is planning to address in 2016. The second part will focus on general issues related to the health claims regulation.

1. Nutrient Profiles

This part of the legislation framework seeks to deal with claims made about a food either on the label or in advertisement. Claims can be about the nutrients in the food. These can be indications such as “low fat”, “sugar free”. Or claims can be about a link between the food constituent and health. Since its adoption in 2006, the implementation of the Claims Regulation remains incomplete since nutrient profiles, that the Commission was requested to set by January 2009, have not been established. According to UEAPME nutrient profiles are no appropriate means to assess the quality of a food product because they are not scientifically based. They are an attempt to classify foods according to their nutritional composition (salt, sugar and fat content). But in reality, there are no “good foods” or “bad foods”, but only “good diets” or “bad diets” on the basis of how foods are combined, according to the habits and traditions of the various countries. In 2008, EFSA recognized the “*scientific limits*” of nutrient profiles, stating that: “*they don’t take into account changes in nutrient content that occur during cooking or preparation, such as addition of fat, sugar or salt, nor does it take into account the habitual intake of the food or the pattern of consumption*”.

Moreover, nutrient profiles are now not necessary because consumers are sufficiently informed about the respective characteristics of a food product due to the mandatory nutrient labelling according to Regulation (EU) No 1169/2011 on the provision of food information to consumers which allows buyers to make responsible purchasing decisions, in full respect of the freedom of choice. This part of the Regulation comes into force in December 2016

Finally the limits set by nutrient profiles are very likely to generate rather negative consequences on the competitiveness of many important sectors of the European agri-food chain, (cheese, meat, sweets, baked goods and local products) because it would create a *de facto* “EU list of good and bad foods”, creating a powerful tool to justify additional taxes or other forms of restriction labelling (i.e. traffic light labelling) for all those foods that do not fall within the parameters established by the profiles, posing a potential threat potential to the detriment in particular of small and medium sized enterprises with a low bargaining power.²

The referral to nutrient profiles in the Claims Regulation should therefore be deleted, in order to avoid unjustified discrimination and help to significantly simplify Regulation (EC) No. 1924/2006, making it less burdensome, particularly for SMEs.

¹ UEAPME subscribes to the European Commission’s Register of Interest Representatives and to the related code of conduct as requested by the European Transparency Initiative. Our ID number is 55820581197-35

² Study by foodwatch (February -March 2016) https://www.foodwatch.org/fileadmin/Themen/Health_Claims/Dokumente/2016-03-31_foodwatch_study.pdf

2. Botanicals

UEAPME considers that the questions in relation to botanicals (listed in the roadmap) are the correct ones to be focusing on. The roadmap provides an excellent summary of the situation as it stands and the issues that need to be addressed. Some observations are:

- **Economic Study:** The roadmap makes reference to an external contractor that will be hired by the Commission to prepare a study on the botanicals issue. The economic importance of the sector, both in terms of level of sales but also jobs linked to the industry is extremely important. The majority of the companies operating in this sector are SMEs that cannot afford to invest in producing the clinical trial level data sought by EFSA for all other claims. Anything other than a more proportionate assessment process for botanical claims will inevitably lead to significant job loss. We consider that the Commission in framing an appropriate policy should have access to exact figures on the number of people dependent on the continued existence of the sector for employment. This study could focus on the key markets for botanicals in Europe. The study could also examine the significant legal costs for companies submitting health claims applications due to the lack of clarity on requirements. Access to key economic data when framing policy is a vital aspect of the 'better regulation' and the 'think small first' principle. UEAPME encourages the Commission to include a thorough economic study within the remit provided to the external contractor.
- **National Best Practice:** Many of the over 1500 botanical health claims currently on hold and which would be rejected under the standard EFSA evaluation process are widely accepted as valid in the scientific community and were previously accepted by multiple national authorities. The fact that many EU Member States have established practice in the field of botanical regulation should not be overlooked during the review to be carried out by the Commission. A proportionate system for assessing claims has to move away from the absolutist approach of EFSA. Foods are not drugs and should not be assessed as if they were. The Member States with the most to offer in terms of national expertise in this area are also the ones with the most to lose if harmonisation at EU level is not done properly. UEAPME therefore urges the Commission to look closely at the systems in place for the use of claims in the Member States with the most developed regulatory systems for botanicals and the largest markets.
- **Borderline Issue/ Mutual Recognition:** The Single Market strategy published by the Commission on 28 October 2015, highlighted market access issues posed by the lack of implementation of mutual recognition by Member States. Recent research by UEAPME showed that at best 50% of Member States apply the principle for food supplements. Particularly in the case of botanicals, many products which are accepted and have a long history of use as a food supplement in one Member State are considered as a medicine in another. UEAPME suggests that the Commission include the issue of mutual recognition in its consultation on botanicals in 2016.
- **Positive Lists Options:** UEAPME welcomes the inclusion of the positive list option in the roadmap and consider that the BELFRIT list defined by Belgium, France and Italy could provide the basis for a harmonised solution to the management of safety at EU level. This would require further work on the list to take into account botanicals used in other Member States. An evolution of the list as described in the previous sentence could secure the backing of enough Member States for its adoption in EU legislation to be realistic. Any positive list system would also clearly require a mechanism to allow for the list to be adjusted taking into account innovations in the food supplement sector.

3. General Observations on the Health Claims Regulation

- **Are the objectives of the regulation being met?** There are grounds for arguing that the objectives of the health claims regulation in terms of consumer protection are not being met. Companies manufacturing in Europe, are extremely restricted in the information they can provide to consumers. It is not good risk management practice to prohibit consumers from receiving at point of sale honest, accurate and meaningful information about the value of a product. At the same time, there has been a huge increase (10% in some Member States) of products sold over the internet from third countries many of which carry totally inappropriate claims and unsafe ingredients. Through examining rapid alerts for food supplements in 2014 for example, it is clear that the great majority of alerts (146) for food supplements derived from products imported from third countries. These included products with active substances not approved for use in food supplements and claims with no scientific basis. In comparison, the 49 alerts for food supplements originating in the EU were mostly related to different categories of the same product in different Member States. Lack of basic information previously available on labelling (often in the form of a

qualified claim) result in consumers searching products from websites in third countries that claim health benefits that in many cases are not valid. Aside from misleading the consumer, in many cases these products are also unsafe. Also claims like “With added vitamins” which imply a health benefit can legally be made on products that are so high in sugars or fats as to be unhealthy.

- **Why are there still no pre-submission meetings for applicants?** Only 18 of 130 applications for article 13.5 health claims received since Regulation (EC) No 1924/2006 came into force have been successful. This extremely high rejection rate shows that the current system is not working. Many companies have invested heavily in clinical trials and safety assessments only to find that these are not even considered by EFSA for reasons that could easily have been addressed had a pre-submission meeting been possible. Clinical trials can cost from €250,000 to €1 million but companies are prohibited the chance to discuss with EFSA to clearly define criteria before investing the money. The European Medicine’s Agency (EMA) holds pre-submission meetings with applicants, which is an example of best practice. EFSA’s assertion that such meetings could compromise the independent assessment subsequently carried out by its scientists does not stand up to scrutiny. If the Commission can make the resources available to EFSA to hold such meetings and instruct them to do so then investment in innovation will increase.
- **Is the standard applied to claims by EFSA appropriate?** Many of the health claims rejected by EFSA were approved by the national authorities in Member States when this area was regulated at national level. How can claims accepted as valid by multiple national authorities suddenly be considered invalid? How is it that many claims that are still widely used and accepted in other regions around the world continue to be rejected by EFSA? Much of the problems surrounding the implementation of the health claims regulation could be resolved through the NDA panel proposing conditional wordings for claims. Food may have a different positive physiological or nutritional effect with different subjects as is also the case with medicines. Even an approved medicine might work well for one subject but not for another. For substances such as glucosamine where there is clearly evidence to suggest a beneficial effect, the simple insertion of the “may” before “support joint flexibility” would provide a claim that is accurate, understandable to the average consumer and in no way misleading. For UEAPME, the major short-coming with the current implementation of the nutrition & health claims regulation is that it is limited to scientifically accepted statements of facts about the relationship between isolated food ingredients and specific beneficial effects on health; it does not facilitate evaluation of the complex effects of complex food ingredients on health; and it prohibits honest, accurate and meaningful communication about the historical use of foods and about the insights of emerging science. A science-based solution is needed that addresses these issues in the context of the fundamental principles identified in the nutrition and health Claims Regulation.

Conclusions

The conclusion that must be observed is that this area of legislation is rather complex and the implementation for small and micro food business is even more burdensome. Therefore, UEAPME is against nutrient profiling. Complex laws for small businesses do not work. Operating principles are more effective. This approach would be in the interests of small and micro food producers, caterers and health food shops who do not have the resources to commission an EFSA analysis and formal approval of what they say about their product. At the same time it would protect the public from spurious claims.

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Brussels, April 2016

EFSA opinion “The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006 - Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies” <http://www.efsa.europa.eu/it/efsajournal/pub/644.htm>