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Head of Unit, E.4
DG Health and Food Safety (DG SANTE)
[redacted]
Belgium

Brussels, 5 November 2015

Subject: FoodDrinkEurope input to the public consultation on the Roadmap for the evaluation of Regulation (EC) No 1924/2006

Dear [redacted],

FoodDrinkEurope would like to thank the European Commission for the opportunity to comment on the Roadmap for the evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods.

The envisaged evaluation is welcomed as it addresses two critical outstanding aspects of Regulation (EC) No 1924/2006. It is our hope that this exercise will in the end provide more legal certainty for operators and all parties involved. With a view to constructively contributing at this stage, we would like to make the following comments on the specifics of the proposed Roadmap as published for consultation. These comments can be found in **Annex 1**.

However, FoodDrinkEurope believes that the scope of the evaluation could usefully be broadened as there are other issues of concern with Regulation (EC) No 1924/2006 which, in our opinion, hamper the initial drivers for the establishment of this regulation and therefore deserve attention.

FoodDrinkEurope considers that a thorough evaluation should be carried out to assess whether the Regulation is indeed achieving its envisaged objectives (and is "fit for purpose"), including the objective of protecting and promoting research and innovation in the EU. This is particularly relevant in the context of the Better Regulation agenda of the European Commission and its focus on jobs and growth. As the Article 13 list of generally accepted health claims is the core element of the Regulation which was introduced to establish the list of claims that all operators would have access to, it is crucial to focus on the question whether the goal of establishing a list that covers all generally accepted claims has been achieved.

We do not share the view that it is premature to carry out a broader evaluation. It should in this regard be noted that, although the list of authorised claims was adopted in 2012, the Regulation applies since July 2007; since then, operators have started to implement the Regulation and have gained experience with the practical aspects of health claims in the EU. We also note that such an evaluation is anyway legally foreseen in Regulation (EC) No 1924/2006, as per Article 27.

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FoodDrinkEurope has undertaken a survey amongst its members to assess the main challenges with Regulation (EC) 1924/2006, the results of which can be found in **Annex 2**. We kindly request the European Commission to take these into consideration, regardless of whether they will be included in the envisaged evaluation exercise or not.

We trust that this receives your utmost attention, and are at your disposal in case you wish to discuss further, as necessary and appropriate.

Sincerely,



Deputy Director General
Director Consumer Information, Diet and Health

cc:



Annex 1: FoodDrinkEurope comments on the roadmap for the evaluation of Regulation (EC) No 1924/2006 with regard to nutrient profiles and health claims made on plants and their preparations.

Section “C. Scope of the evaluation/FC – 1. Nutrient profiles”

In general, we believe that the questions listed under Section “C. Scope of the evaluation/FC – 1. Nutrient profiles” are fairly complete and appropriate for the purposes of the proposed evaluation. However, we have comments on some of the specific questions and we would suggest the inclusion of some additional questions.

4. Coherence

- [...]
- *To what extent would the setting of nutrient profiles at EU level be considered coherent with other initiatives in the context of the EU Platform for Action on Diet, Physical Activity and Health?*

FoodDrinkEurope comments:

- **As nutrient profiles are foreseen for the purposes of nutrition and health claims, it is not clear what is referred to by “...‘other initiatives’ in the context of the EU Platform.”**

5. EU added value

- *Without nutrient profiles at EU level, how do Member States integrate the concept of nutrient profiles in the governance of nutrition and health claims on their market?*

FoodDrinkEurope comments:

- **We would suggest to re-phrase this question as follows: “Without nutrient profiles at EU level, have individual Member States integrated the concept of nutrient profiles in the governance of nutrition and health claims on their market? If so, how?”**

Section “C. Scope of the evaluation/FC – 2. Plants and their preparations used in foods

FoodDrinkEurope supports the questions raised with regard to the critical assessment of the difficulties in assessing the health benefits of and accordingly claims on plants and their preparations. We also support that the Commission broadens the scope evaluation to assess “to what extent the requirements set out in Regulation (EC) No 1924/2006 are 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”, to ensure consistency in the EU legal framework.

Section “D. Evidence based”, point “D4. Consultation”

The Roadmap foresees 1 open-public consultation of 12 weeks and one stakeholder consultation of 8 weeks, both based on questionnaires with closed questions. FoodDrinkEurope welcomes the Commission’s initiative to give the opportunity to the widest range of interested parties to share their views on this topic, which will bring more transparency and visibility to the process. We wonder whether a longer stakeholder consultation, as well a questionnaire which also includes open questions, would allow to receive more complete and in-depth contributions from interested parties.

Annex 2: Preliminary overview of the industry's main issues with Regulation (EC) No 1924/2006

FoodDrinkEurope acknowledges the advantages brought by Regulation (EC) 1924/2006 – in terms of, among others, increased legal certainty, harmonization, trade within the EU Single Market – as well as the significant improvements made to the claims authorisation process over the years. However, it should be acknowledged that the Claims Regulation has resulted in important challenges for European food business operators.

Regulation (EC) 1924/2006 sets a high standard for the authorisation of health claims. While the industry supports a high standard, as this promotes consumer trust, complying with it implies significant costs and burdens, particularly for SMEs. This in turn challenges the competitiveness of the EU market versus that of third countries, placing additional burdens on EU operators. Problems may also arise from the fact that third countries often look at the EU regime as a model when developing their own legislations.

Also in light of these existing challenges, we believe that it is important to address the many issues which have emerged in the course of the implementation of the Claims Regulation, with a view to improving the claims regime, in the interest of all parties involved. The main challenges with Regulation (EC) 1924/2006, as identified by our members, can be found below.

The majority of these issues relate to the risk management process; we trust that a review exercise would allow to improve this process and make it more fit for purpose in providing the consumer with the necessary information to make well-informed choices and to drive innovation. We also note in this context that the Commission's report on the application of Regulation (EC) 1924/2006, which was originally due by 19 December 2013, is still to be issued. Such a report would provide more clarity on the results achieved so far by the Regulation and on possible, future improvements to be brought.

Objectives of Regulation (EC) 1924/2006

Obstacles to research and innovation

A crucial element to be assessed is whether this legislation is actually achieving its objective to encourage and facilitate research and innovation. In this respect, we would like to note that **the rather long, complex and not entirely transparent claims authorisation process, as well as the other issues mentioned hereafter, *de facto* represent a burden for research and innovation.** Further to this, an adequate solution needs to be found to value emerging science with regard to functional foods whilst respecting a high level of scientific evidence for the substantiation of claims.

An important aspect to be addressed to support research and innovation is “**data protection**”. As European food and drink industry, we welcome the recognition of the principle of the protection of proprietary data by the Regulation. However, we note that, in order to get “data protection”, research data must not necessarily be unpublished at the time when the application is made provided the applicant has secured a proprietary status of the data or parts of it. Otherwise this would run against the Regulation's aim to support research and innovation. It would risk contributing to a culture of non-publication of research, diminishing public and academic scrutiny of new findings, delaying scientific progress and potentially diverting funding away from academic institutions dependent upon the publication of research. It also runs counter to regulatory regimes in other countries, for example the

United States where publication in peer-reviewed journals is a pre-requisite. It also represents an important costs for companies¹ which directly touches on their competitiveness². It is necessary to develop an understanding so that researchers can publish, and protection can still be given. **In FoodDrinkEurope's view, the wording of Art. 21 of Regulation 1924/2006 does not exclude an interpretation that would allow to consider data that is published prior to the submission of an application to be proprietary, provided that the ownership of the data still exists at the time the application for authorisation of a claim is made (e.g. by patent/utility model protection or other appropriate means).**

Consumer information and understanding of health claims

The Regulation requires consumer understanding of a claim and yet health claims wording is very technical and difficult to understand for consumers. **Due to the limited flexibility that is allowed in the wording of claims, often a rather scientific language has to be used which can make the understanding by consumers of specific benefits difficult to almost impossible.** In addition, from a marketing point of view, the language can often not do anything to support the appeal of a specific claim – which, of course, is rather counter-productive.

It should also be noted that **the interpretation of “understandable to consumers” and the degree of flexibility in claims wording to enable that understanding varies from country to country;** this is increasing the cost and complexity across the EU Internal Market, while serving no beneficial purpose to consumers.

Another issue is represented by the fact that there is rather **limited possibility to explain the underlying science and the context of the claim.** This situation discourages the industry from investing in R&D and affects consumer information and ability to select food/food ingredients which can be beneficial for their health, nullifying the positive impact that the Regulation could have on public health.

Interpretation and harmonization of the EU Single Market

Beyond any fitness check, the dimension of implementation and interpretation by Member States is key. Without common guidelines and common practices by Member States regarding implementation and interpretation, the idea “*to improve the free movement of foods with nutrition and health claims within the internal market and to increase legal certainty for economic operators*” is hampered.

It is noted that **the Commission's Guidance on Regulation (EC) 1924/2006** has never been revised/updated, although this dates back to 2007. A revision of this document would also allow to address the divergent interpretations which currently exist at national level.

Implementation of the Regulation

¹ To understand the costs that data protection implies for companies it must be considered that the development of a health claim dossier is a complex and costly exercise, which may take several years.

² For instance, an operator wishing to apply for the use of a claim also in the US would be disadvantaged, since in such a case studies would need to be public.

Besides nutrient profiles and Article 13(1) health claims on plants and plant preparations, there are other outstanding issues with regard to the implementation of Regulation (EC) No 1924/2006 which deserve further attention.

As the Article 13 list of generally accepted health claims is the core element of the Regulation that was introduced to establish the list of claims that all operators would have access to, it is crucial to focus on the question whether the goal of establishing a list that covers all generally accepted claims has been achieved.

In general, the implementation of Regulation (EC) 1924/2006 has thus far resulted in important challenges for operators. Among others, the different time frames set for its implementation have resulted – and are still resulting - in uncertainty and costs. **The long series of different time frames set in various articles of Regulation (EU) No 1924/2006 in connection to the time frames foreseen in Commission Regulation (EU) No 432/2012 had a significant impact on the industry both in terms of costs and dedicated employee time.** By way of example, a member denounced that two consecutive label changes in the course of one year in a range of 450 Articles for the EU Member States involved the intensive work of 15 employees as well as significant financial investment.

Furthermore, **Commission Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations) is giving rise to concerns** among food business operators and deserves attention under an evaluation of Regulation (EC) 1924/2006. In particular, the process and the criteria for applying for the use of a generic descriptor are rather complex and (too) demanding. For instance, the requirement to provide, upon request, supporting evidence related to consumer understanding might be difficult to meet (what evidence is actually there on consumers' understanding of a certain generic descriptor?). Furthermore, the fact that the application must be made for each Member State risks running against the Internal Market. In this respect, it could also be argued whether, by establishing a national scope for the derogations for generic descriptors, the Commission has exceeded the empowerment conferred on by Regulation (EC) 1924/2006. Additionally, there is no need to look at each language variant to determine if the denomination of each of the generic descriptors is in or out of scope of the Regulation (EC) No. 1924/2006; such an interpretation could entail consequences such as a lack of legal certainty and would not be in compliance with the principle of the free movement of goods which is necessary for the functioning of the Internal Market.

Another outstanding issue is also the fact that **the current list of nutrition claims and the criteria to define "significant amount", as referenced in Annex of Regulation (EC) 1924/2006, are set for the general healthy population and may not be consistent or not sufficient if applied to categories of population with particular nutritional needs.** For example, currently for claims on foods for infants and young children, the nutrient reference values (NRVs) for adults are used for setting the "significant amount" (as laid down in Annex XIII of Regulation (EU) 1169/2011 on Food Information to Consumers). These adult NRVs are not suitable for infants and young children. For this age group, separate labelling reference values exist in the legislation and should be used for any claims applying to foods for infants and young children.

Health claims authorisation process

EFSA scientific assessment

Although important improvements have been made in EFSA's scientific assessment of health claims applications, some issues remain which in our opinion would need to be addressed.

First of all, to further stimulate innovation, and increase chances for Return on Investment, FoodDrinkEurope maintains that the introduction of pre-submission consultations with EFSA is crucial. It would be advantageous if applicants could have some pre-submission access to the reviewers to get preliminary feedback which would help understanding EFSA's expectations for data needed to support the application/claim. **Pre-submission exchanges with EFSA would significantly strengthen the principles of transparency and visibility, while allowing both the applicant and EFSA to save time and resources.** In more general terms, the overall authorization process would benefit from an increased stakeholders' involvement and further dialogue with the applicant. In this respect, we would like to note that the comments made by applicants on EFSA's opinion, in accordance with Article 16(6), are not always taken into account.

Furthermore, while the guidance documents published by EFSA have provided a concrete help to operators, **further clarity on the requirements for an envisaged claim is needed.** For instance, more certainty on the selection of Clinical Trial Protocol parameters (e.g. endpoints, target groups) for an envisaged claim would result in a greater appetite to invest. Another issue is represented by the past, peer-reviewed publications which should be recognized and valued by EFSA in the scientific assessment process.

Risk management process

While deadlines are set for the scientific assessment process carried out by EFSA, no precise timing exists for the adoption of the final decision on the authorization of a health claim. A general concern is represented by the fact that this **process has proved to be very slow** (the overall authorization process takes at least 6 months, but it took even years for some claims being discussed in the Standing Committee). Such a long process, together with the fact that there is **no visibility of the timing** (i.e. it is not possible to know when a decision on the authorization of a claim will be taken), represents an actual cost for companies.

Furthermore, concerns arise from risk management decisions recently taken on specific claims. For instance, some health claims (e.g. Article 13(5) health claims related to glucose and energy-yielding metabolism and claims relating to the effect of fats on the normal absorption of fat soluble vitamins) have been rejected although positively assessed by EFSA. In other cases, conditions of use not in line with the EFSA opinion and arbitrarily setting *de facto* nutrient profiles have been established, as was for instance the case for the Article 13.1 health claim "carbohydrates contribute to the maintenance of normal brain function". While the Regulation clarifies that, in addition to EFSA's opinion, "*other legitimate factors*" shall be considered when taking a decision on the authorisation of a claim/on the conditions of use applying to this, we believe that, for the sake of legal certainty, impartiality and transparency, **any decision on the authorisation of claims should be primarily based on science** (i.e. on EFSA's opinion).

In more general terms, the overall authorisation process does not appear to be entirely clear and transparent. For instance, certain elements of the original application (e.g. the proposed claim wording, the ingredient definition, the application scope, etc.) can be modified in the course of the process, irrespective of the (costly) studies made by the applicant³.

Finally, another issue is represented by the fact that applicants can nowadays only use the procedures under Article 13(5) and 14, while it should be possible to also use the Article 13(4) procedure.

³ Members signalled a case where the scope of the original application was broadened during the process, ignoring the investment in R&D which was made for preparing a very specific dossier that included proprietary data. Similarly, it occurs that the CoU of a specific claim are changed to have a “better fit” into an existing broad legal framework.