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Head of Unit, E4
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5 November 2015

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

Dear [REDACTED],

UNESDA, representing the European soft drinks industry, would like to thank the European Commission for the possibility 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 result in more legal certainty for operators and other key stakeholders.

With a view to constructively contributing at this stage, we would like to make the following comments on the specifics of the roadmap which was published on the European Commission's website for consultation. These comments can be found in **Annex 1**.

However, **UNESDA strongly supports the FoodDrinkEurope view that the scope of the evaluation could usefully be broadened** as there are other issues of concern with Regulation (EC) No 1924/2006 which deserve attention.

UNESDA 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. Although the list of authorized 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.

UNESDA has assessed 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 eventually be included in the envisaged evaluation exercise.

Please do not hesitate to contact us should you wish to discuss further.

Yours sincerely

[REDACTED]
Regulatory Affairs Director

CC:

[REDACTED]

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Annex 1: UNESDA 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"

In general, we believe that the questions listed under section (C.2, – Nutrient profiles) are fairly complete and appropriate for the purposes of the proposed evaluation. However, we have the following comments on some of the specific questions and would suggest the inclusion of some additional questions.

*** Effectiveness:**

- *"Which main factors have contributed or stood in the way of achieving these objectives and to what extent?"*

UNESDA COMMENT: We consider there is a need to specify what "objectives" the Commission is referring to in this particular question. Are they the objectives with regard to Nutrient Profiles or with regard to the Regulation?

*** Relevance:**

- *"To what extent are nutrient profiles at EU level still relevant and needed, taking into account the evolution of the market and the evolution of the regulatory framework, especially following the adoption of the new EU Regulation on food information to consumers?"*

UNESDA COMMENT: We would suggest amending this question as follows: *Are nutrient profiles of less relevance to certain food categories, for example, for sports foods which are designed to meet the nutritional needs of people taking part in sport or exercise?*

*** 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 on Diet, Physical Activity and Health?"*

UNESDA COMMENTS:

a) 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".

b) We suggest the following additional question: *"To what extent is the non-setting of nutrient profiles at EU level coherent with the objective of enabling innovation?"*

*** 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?"*

UNESDA COMMENTS:

a) We would suggest re-phrasing 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?"*

b) We would suggest the following additional question: *"Did the non-setting of nutrient profiles at EU level lead to different assessment of the same claim on products sold in different member states?"*

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.

UNESDA welcomes the Commission's initiative to give the opportunity to the widest possible range of interested parties to share their views on this topic, which will bring more transparency and visibility to the process. We wonder, however, whether a longer stakeholder consultation, as well as a questionnaire which also includes open questions, would encourage more complete and in-depth contributions from interested parties?

Annex 2: Preliminary overview of some key issues in relation to Regulation (EC) No 1924/2006

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

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 result in improvements to 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 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.

Objectives of Regulation (EC) No 1924/2006

a) 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 above, 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.** We believe that it is necessary to develop an understanding that researchers can publish and protection can still be given. In this respect, again, UNESDA supports FoodDrinkEurope's view - i.e. that 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 authorization of a claim is made.

b) Aspects related to consumer information and understanding of health claims

The Regulation requires consumer understanding of a claim and yet the wording of health claims wording can be very technical and therefore challenging for consumers to understand. **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 highly challenging, if not impossible.** In addition, from a marketing point of view, the language often does not do anything to support the appeal of a specific claim which, of course, seems 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 increases 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 foods and drinks – and ingredients - which can be beneficial for their health, limiting the potential positive impact of the Regulation on public health.

c) Interpretation and harmonization of the EU Single Market

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

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.

Aspects related to the implementation of Regulation (EC) 1924/2006

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

In general, the implementation of Regulation (EC) 1924/2006 has resulted in important challenges for operators. Among others, the **different timeframes set for its implementation have resulted – and are still resulting - in uncertainty and costs¹**.

Furthermore, Commission Regulation (EU) No 907/2013 **setting the rules for applications concerning the use of generic descriptors (denominations) is also 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 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?). Additionally, the fact that the application must be made for each Member State risks running against the Internal Market. 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 appear to be in compliance with the principle of the free movement of goods.

¹ The long series of different time frames set in various articles of Regulation (EU) N. 1924/2006 in connection to the time frames foreseen in Regulation (EU) N. 432 / 2012 had a significant impact on the industry both in terms of costs and dedicated employees 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.

Health claims authorisation process

a) EFSA scientific assessment

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

First of all, to further stimulate innovation, and increase chances for return on investment, the introduction of **pre-submission consultations with the EFSA secretariat is crucial**. This would considerably 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.

b) "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 can take years for the most "controversial" 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 the "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) have been rejected although positively assessed by EFSA.

While the Regulation clarifies that, in addition to EFSA's opinion, "other legitimate factors" shall be considered when taking a decision on the authorization 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 authorization of claims should be primarily based on science (i.e. on EFSA's opinion)**.

Conditions of use that are not in line with the EFSA opinion and arbitrarily setting *de facto* nutrient profiles have been established - such as the Article 13.1 health claim "carbohydrates contribute to the maintenance of normal brain function" and the 'water' claims - '*Water contributes to the maintenance of normal physical and cognitive function*' and '*Water contributes to the maintenance of normal regulation of the body's temperature*'. The Scientific Opinion regarding both water claims ([EFSA Journal 2011;9\(4\):2075](#)) provided for the following conditions of use: "*In order to obtain the claimed effect, at least 2.0 L of water should be consumed per day. Such amounts can be easily consumed as part of a balanced diet. The target population is the general population*". After the discussions in the European Commission Claims Working Group and in the Standing Committee, the condition was introduced that the claims can be only be used on water complying with Directives 2009/54/EC and 98/83/EC, which is drinking water and natural mineral water. The conditions of use were introduced without any scientific justification and are clearly not in line with the EFSA scientific opinion.

In more general terms, the overall authorization 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 applicant².

² 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.