WORKSHOP ON REGULATION (EC) NO 1924/2006

(NUTRIENT PROFILES AND HEALTH CLAIMS ON PLANTS AND THEIR PREPARATIONS, INCLUDING THE GENERAL REGULATORY FRAMEWORK FOR THEIR USE IN FOODS)

Centre Borschette, 21 June 2016

Summary points of the meeting

The Commission outlined the context of the study, which is the REFIT evaluation of the EU legislation on nutrition and health claims as announced in the Commission's Better Regulation Communication of 19 May 2015. In particular, the study focuses on two aspects of Regulation (EC) 1924/2006 where harmonisation has not yet taken place: a) nutrient profiles; and, b) health claims on plants and their preparations. On plants and their preparations, for completeness, the study extends beyond the issue of health claims to cover the adequacy of the overall current regulatory framework, including the safety of these products. The design of the study has taken into account the feedback already received to the Commission's Roadmap of 8 October 2015. The Commission also highlighted that the analysis of the impact of non-implementation poses particular methodological challenges in this study.

The contractor (Agra CEAS Consulting, Food Chain Evaluation Consortium - FCEC; in association with Areté) presented the study objectives and methodology. The study has just kicked off at the end of May. The present workshops with Member State Competent Authorities (MS CAs) and stakeholders aim to launch the consultation process; they have been purposely designed early in the process to raise awareness amongst all parties potentially affected by the issues under study so that they can prepare to collect the evidence and data required. This study affects a wide range of stakeholders. The contractors will therefore consult widely across the EU MS, product sectors, and the broader range of affected stakeholders, from consumers to SME companies, scientists and the wider public.

In view of the methodological challenges, a comprehensive data collection strategy has been developed, using multiple data collection tools, including two on-line surveys (of MS CAs and stakeholder organisations), specific consultation of SMEs, public consultation, case studies focusing on 9-10 MS, and targeted interviews at EU, MS and selected third country level. The purpose is to collect, verify and triangulate relevant data from multiple sources, so as to construct the evidence base required by the terms of reference (ToR) of the study[1].

In order for both MS CAs and stakeholders to start preparing their reflections on the issues raised by the study and their data collection, **certain key questions have been posed in the FCEC working document** distributed to participants ahead of the meeting[2].

The next key step of the consultation is the launch of surveys, which is planned in early autumn 2016. This will take place more or less in parallel to the other data collection tools. The full methodology will be finalised in early autumn, including the selection of MS for the case studies. The final report of the overall study is due to be completed by the contractor in late spring 2017.

[1] https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en

[2] These questions are not exhaustive and will be further detailed and amplified in the surveys and further consultation through the study course.

The presentation of the study was followed by discussion and feedback was provided by workshop participants, on the basis of the questions contained in the FCEC working document. The following summarise key points of the discussion, including any further clarifications.

Task 1: Nutrient profiles

- The focus of the study is on nutrient profiles developed **for the purpose of assessing whether products should be bearing claims**, in line with the objectives and provisions of the Regulation. In the context of the Regulation, nutrient profiles consist of maximum levels of nutrients (**saturated fat, salt and sugars**) above which nutrition claims are restricted and health claims are prohibited.
- Current situation: initiatives may have been developed in MS that are specific to the purpose of assessing claims, or to other purposes (e.g. nutrition labelling), or may be more generally related to nutrition and public health objectives. The aim of Q1 (FCEC working document) is to provide a mapping of the various initiatives developed in the EU-28 MS (as required by evaluation question 1 of the ToR), so as to establish the extent to which such national initiatives meet or fall short of the objectives of the Regulation, therefore the continuing relevance of setting nutrient profiles at EU level for this purpose. The basis of such schemes (in particular whether they are science based), and their impact, are also important elements for the study to consider.
- Early feedback indicates that, in many MS, the absence of specific legislation or initiatives in this area appears to be due to the provision in Article 4 of the Regulation that nutrient profiles would be set at EU level, hence MS expectations for harmonised EU action on this, rather than lack of interest or willingness to develop national initiatives.
- The **draft Commission proposal of 2009 is used by the study as a baseline** of what the overall approach (including e.g. potential exemptions for certain product categories) and nutrient thresholds (maximum levels of saturated fat, salt and sugars) might have been if EU nutrient profiles had been adopted. The purpose is to estimate the impact (costs and benefits) of having in place EU nutrient profiles in comparison to the impact of the current situation. **Annex I** to the FCEC working document provides a summary of the draft proposal. It is important, however, to reflect more broadly at the impact of EU nutrient profiles, beyond the detail of the draft proposal, and to justify with relevant data/evidence why the product categories and nutrient thresholds identified therein may, or may not, be appropriate for the different sectors. For example, consideration of costs due to nutrient profiles can be a range of monetary estimates depending on the product category coverage and on the thresholds potentially to be used. It is important for the contractors to identify the types of costs involved (e.g. re-formulation; re-labelling; loss of market value etc.), as well as the potential range of costs in monetary terms.
- The setting of nutrient profiles at EU level and its **potential impacts have already been analysed in previous work**. This includes e.g. the Commission's impact assessment in 2009, the EFSA Opinion of 2008, EU-funded research as the recently completed CLYMBOL project, as well as feedback provided by stakeholders (e.g. to the Roadmap). The contractors will be taking into account all relevant data/evidence that is already available. However, the situation is dynamic; the study covers the period to end 2015 and many developments have occurred in this area since 2009, both in terms of the national regulatory and non-regulatory environment, and in terms of the health and nutrition claims market. The contractors will need to provide **an updated analysis of the current situation**.

Task 2: Health claims on plants and their preparations

- The focus of the study in relation to **plants and their preparations used in foods** is on the **specific provisions of Regulation (EC) 1924/2006** on nutritional and health claims for the concerned products: the authorisation of health claims (assessment by EFSA through the procedure under Article 13(1) of the Regulation) is on hold since September 2010; however, health claims can be used under transitional measures (as foreseen under Article 28(5) of the Regulation) provided they comply with the applicable EU and national legislation.
- For an adequate assessment of the provisions of the Regulation, it is **necessary to consider the broader regulatory framework which applies to plants and their preparations** when used in food products, with a focus on safety, quality and non-misleading consumer information aspects. This implies that EU and national legislation on **food supplements** and on **traditional herbal medicinal products** (THMPs) are of particular relevance for the assessment, together with the application of the **mutual recognition principle**, governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU).
- Current situation: in the absence of harmonised EU legislation on plants and their preparations used in foods, significant differences exist among provisions applied at MS level. These differences are also linked to diverse national approaches to the classification of plant-based products. Mapping the current legislative framework applicable to plants and their preparations used in foods in each of the 28 MS falls within the scope of the study (as required by evaluation questions 15 and 16 of the ToR). It emerged from the workshops that a number of MS classifies plant-based products as food products or as medicines on a "case by case" basis. Certain MS developed positive and negative lists of plants and their preparations which can or cannot be used in foods. Groups of MS have also jointly developed these types of lists (e.g. BELFRIT), which can or cannot be legally binding. The sector of plant-based products is also affected by the presence/absence of notification (or authorisation) procedures at MS level, and by the different ways in which such procedures are applied by national CAs. Finally, also national specificities in the application of the mutual recognition principle can have an impact on intra-EU trade of plant-based products; the consequence is that the scope for the use of a certain plant or plant preparation as ingredient in food products can vary within the EU, and also manufacturing and marketing of plant-based products varies (such differences can emerge even within individual MS).
- A core part of the study is the assessment of the impacts of possible changes (or of the absence of changes) in the regulatory framework applicable to health claims on plants and their preparations used in foods. Two main scenarios (defined in the ToR for the study) were brought to the attention of participants to the workshops: from the resulting discussion, it emerged that **further refinement of such scenarios should be considered** during the inception phase of the study. In particular, the Commission clarified that **Scenario A** ("withdrawal of provisions on health claims made on plants and their preparations used in foods from the scope of Regulation (EC) 1924/2006") **does not imply leaving the sector unregulated**. It was also underlined that this study is not an impact assessment of any specific policy options for regulating health claims on plants and their preparations used in foods: it is an **assessment of the adequacy of the current legislative framework**. If the study concludes that the existing legislative framework is found inadequate, it could provide recommendations on potential future options for this sector. In the case of **Scenario B** ("full application of Regulation (EC) 1924/2006"), one such option would be to allow **consideration of traditional use** when assessing health claims for plants and their preparations used in foods, in line with the approach taken for the use of such substances in THMPs.

Agra CEAS Health Claims presentation -

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List of participating stakeholder organisation