

## SANTE FRAMEWORK CONTRACT ON EVALUATION, IMPACT ASSESSMENT AND RELATED SERVICES

### **1. Title of the assignment**

Study supporting the evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food ('the Regulation') 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.

### **2. Context of the assignment**

Following the Better Regulation Communication of 19 May 2015<sup>1</sup> the Commission announced to carry out an evaluation of the Regulation with regard to nutrient profiles and health claims made on plants and their preparations. This evaluation will also consider the more general regulatory framework for the use of such substances in foods since it is closely related to the use of health claims.

This assignment makes part of this evaluation and it aims at providing rigorous evidence base to inform the Commission in its decision-making and enable the Commission to draft a report on the effectiveness, the efficiency, the relevance, the coherence and the usefulness of the Regulation's provisions with respect to nutrient profiles and to health claims on plants and their preparations added to foods. This assignment will also examine how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations.

#### **2.1. Description of the Policy Area to be evaluated**

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition<sup>2</sup> and health<sup>3</sup> claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. The Regulation aims in particular at enabling consumers to make healthier choices by protecting them from misleading information and at ensuring a level playing field for food business operators within the internal market.

This Regulation applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer.

The Regulation provides for the definitions of nutrition claims and health claims as well as for the general principles and conditions for their use. It also provides for specific authorisation procedures for establishing the lists of permitted nutrition and health claims.

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<sup>1</sup> COM(2015) 215 final. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS. Better regulation for better results - An EU agenda. [http://ec.europa.eu/smart-regulation/better\\_regulation/documents/com\\_2015\\_215\\_en.pdf](http://ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf)

<sup>2</sup> Nutrition claims are statements like 'low fat', 'high fibre'.

<sup>3</sup> Health claims make the link between a food constituent and health, like 'Vitamin D is needed for the normal growth and development of bone in children'.

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More specifically, the Regulation stipulates that nutrition and health claims made on food must be based on and substantiated by generally accepted scientific evidence and that health claims should only be authorised for use in the Union after a thorough scientific assessment by an independent scientific body, the European Food Safety Authority (EFSA).

In addition, the Regulation obliges the Commission to set nutrient profiles<sup>4</sup>, after consulting EFSA, which are thresholds of nutrients such as fat, salt and sugars in foods, above which nutrition claims would be limited and health claims prohibited, thus preventing a positive health message on foods high in these nutrients.

### 2.2. Specific and operational objectives of the activity/action

The main objectives of the Regulation are the following:

- *To achieve a high level of consumer protection by providing further voluntary information, beyond the mandatory information foreseen by EU legislation, and more particularly to ensure that nutrition and health claims are not misleading for consumers;*

The objective of high level of consumer protection is established by the principle that health claims may only be used under strict conditions, following an independent scientific assessment of the *'highest possible standard'* and subsequent Union authorisation through a well-defined authorisation procedure. This ensures that only reliable information is passed on to consumers by guaranteeing the scientific justification of nutrition and health claims.

Furthermore, foods promoted with nutrition or health claims might be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products without claims. The application of nutrient profiles foreseen in the Regulation aims at avoiding a situation where nutrition or health claims mask the overall nutritional status of a food product, that could have a high content of fat, salt or sugar, which could mislead consumers as to the overall nutritional quality of a food when trying to make healthy choices in the context of a balanced diet.

- *To improve the free movement of foods bearing such claims within the internal market;*
- *To increase legal security for economic operators;*

In view of the proliferation of the number and type of claims appearing on the labels of foods and in the absence of specific provisions at European level before the adoption of Regulation (EC) No 1924/2006, some Member States adopted legislation and other measures to regulate their use. This resulted in different approaches and in numerous discrepancies both regarding the definition of the terms used and the conditions warranting the use of claims. These discrepancies did not result in a consistently high level of consumer and public health protection across the EU, and they constituted obstacles to the free movement of foods and the proper functioning of the internal market. For these reasons, harmonisation of rules on claims at Union level, the establishment of EU lists of permitted nutrition and health claims

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<sup>4</sup> Nutrient profiles do not appear on labels and are not communicated to consumers.

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and a centralised authorisation procedure for claims was advocated with the adoption of the Regulation.

- *To ensure fair competition in the area of foods;*
- *To promote and protect innovation in the area of foods;*

While certain food business operators invested in research and development to substantiate the nutrition and health claims they made on their foods, others simply used nutrition and health claims as a marketing tool without ensuring that their claims were scientifically true. This situation led to unfair competition and jeopardized the trust that consumers could have in scientifically justified claims. The Regulation, ensuring that only scientifically justified claims may be made, creates a level playing field and thus promotes innovation and secures investment.

The objectives concerning the use of plants and their preparations in foods according to the general regulatory framework are the following:

- *To ensure that food containing plants and their preparations that is placed on the market is safe;*

Regulation (EC) No 178/2002 provides for the safety of food placed on the EU market by establishing a general safety obligation and a general requirement of verification of compliance with this safety obligation (for all actors in the food chain), and furthermore, specific requirements providing for the withdrawal and recall of unsafe food and restricting the export of unsafe food.

In addition, Regulation (EC) No 1925/2006 establishes a procedure to be used in case of potential risks to human health from the addition of a substance other than a vitamin or mineral to foods or food supplements, e.g. plants and their preparations. Following an assessment by EFSA of the available information on the substance, the use of the substance in foods may be prohibited, restricted or placed under Union scrutiny. This procedure allows the regulation at EU level of substances already on the EU market and for which potential safety concerns have been raised.

- *To ensure the free movement of foods containing plants and their preparations within the internal market.*

The free movement of such goods is governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU) and can thus be subject to national restrictions within the limits laid down by Article 36.

### **2.3. Legal basis and duration of the activity/action**

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods was adopted on 20 December 2006. The Regulation progressively harmonises the governance of nutrition and health claims since its entry into application from 1 July 2007.

The list of permitted nutrition claims came into application from 19 July 2010, at the end of the transitional period for nutrition claims while health claims on the role of a nutrient or other substance in growth, development and the functions of the body, on psychological and behavioural functions, or on slimming, on weight-control, on the reduction in the sense of

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hunger, on the increase in the sense of satiety or on the reduction of the available energy from the diet, could be used in the EU market up to the date of application of the measure establishing the list of permitted claims.

A first list of permitted health claims started to apply in December 2012<sup>5</sup> and since the list of authorised health claims has been constantly updated. However, a long list of claims concerning plants and their preparations in foods remains unregulated since December 2012.

In addition, the Regulation foresees the adoption by the Commission of nutrient profiles by January 2009; however such nutrient profiles are still not established.

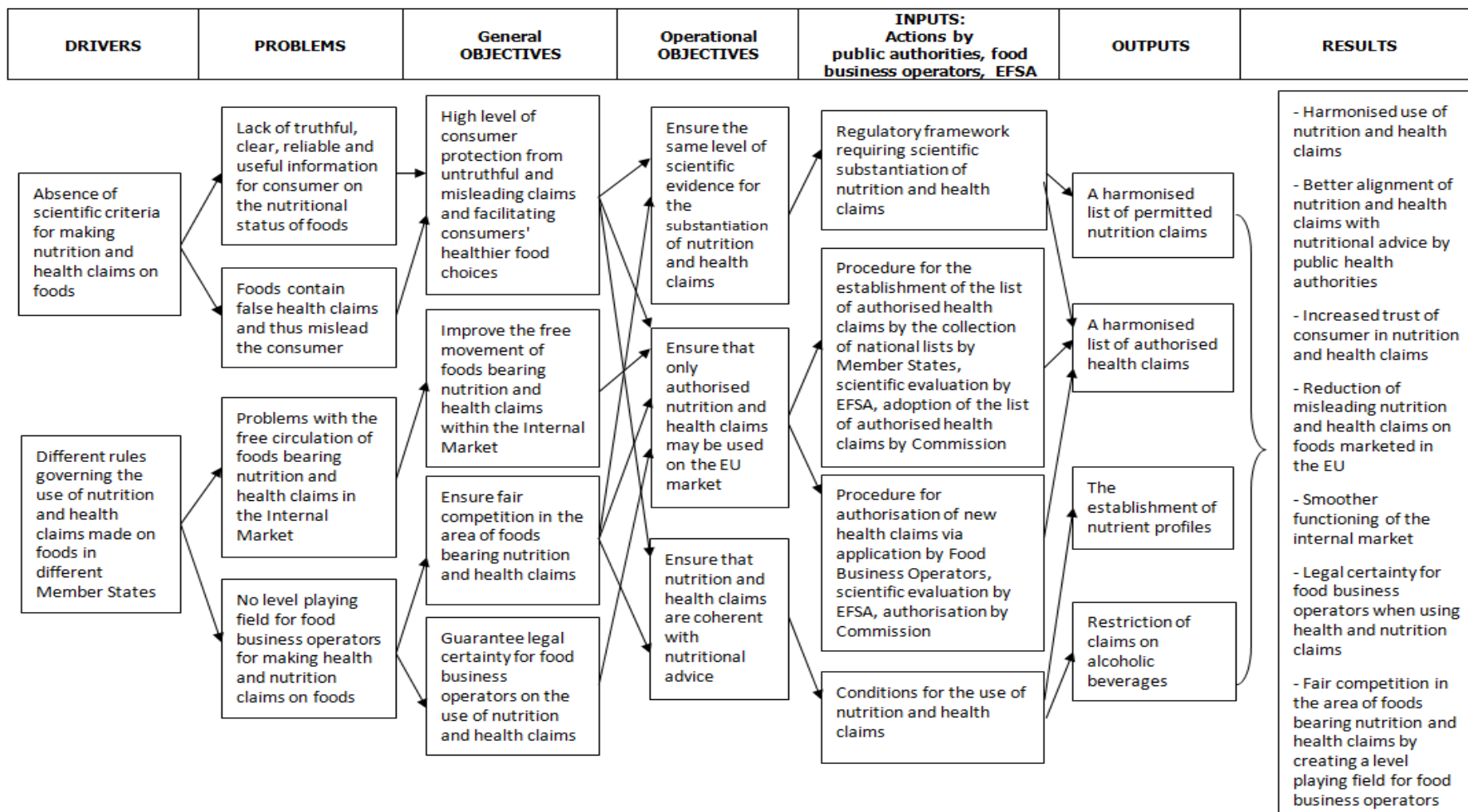
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<sup>5</sup> Commission Regulation (EU) No 432/2012 of 16 May establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

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2.4. Intervention Logic

*Intervention logic for health and nutrition claims*



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**2.5. Background on the activity/action to be evaluated***Nutrient Profiles*

In the context of the Regulation, nutrient profiles consist in maximum levels of nutrients such as saturated fat, salt and sugars above which nutrition claims are restricted and health claims are prohibited.

The setting of nutrient profiles pursues public health considerations and should promote manufacturing and labelling practices that are supportive of public health. Therefore they have to be based on generally acceptable scientific data relative to the relationship between diet and health. They should also, following the Regulation, take into account other considerations such as the need to allow for product innovation, the variability of dietary habits and culinary traditions.

The Regulation foresees that nutrient profiles will be established for food or certain categories of foods by the Commission after seeking the advice of EFSA and after having consulted with interested stakeholders, in particular food business operators and consumers.

EFSA adopted a scientific opinion on the setting of nutrient profiles in 2008, and the Commission started to consult the Member States and the stakeholders on a draft Commission Regulation establishing a nutrient profiles system.

The setting of nutrient profiles has been postponed, due to the complexity of the subsequent discussions, where certain sectors of the food industry pointed to alleged economic losses and lower competitiveness which they expected from an implementation of the proposed system.

Since nutrient profiles have not been set, all foods can bear nutrition or health claims when substantiated by EFSA, independently of their levels in nutrients such as fat, saturates, sugars or salt. The level of consumers understanding, empowerment and willingness to engage into healthy dietary habits is paramount in setting priority for action.

*The use of health claims on plants and their preparations*

In the context of the implementation of the Regulation, more than 500 claims on plants and their preparations<sup>6</sup> received an unfavourable assessment from EFSA during its scientific assessment. This raised many concerns among Member States and many stakeholders regarding health claims made on plants and their preparations used in food. To date, over 2000 submissions concerning such health claims still remain to be treated.

The Regulation provides that all health claims, including those on plants and their preparations used in food, should be assessed on the basis of scientific evidence at '*the highest possible standard*'. In this context, EFSA reviews the totality of the scientific data provided,

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<sup>6</sup> In the absence of a definition of plants and their preparations in EU food legislation, the Commission had to apply a pragmatic case-by-case approach to decide which claims in the consolidated list, i.e. the list of claims submitted by the Member States on the basis of Article 13(2) of Regulation (EC) No 1924/2006, corresponded to claims on plants and their preparations. As a first step, the Commission took into account Member States' classification when they submitted claims to the Commission, but also the definition of herbal substances and herbal preparations in the Traditional Herbal Medicinal Products legislation. From these claims, the Commission excluded those claims for which the subject of the claim would normally be expected to be consumed in significant quantities in a balanced and varied diet. An exception was made for those substances that are subject to evaluation by the European Medicines Agency's Committee on Herbal Medicinal Products.

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including handbooks and monographs, to see if they contain data from which conclusions can be drawn (pertinent data) for the scientific substantiation of claims. However, EFSA considers human studies as essential for the substantiation of claims, given that such studies allow the drawing of scientific conclusions at the highest possible standard. Hence, EFSA considered that evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations (*'traditional use'*) alone cannot be considered sufficient to allow for the scientific substantiation of a health claim made on foods.

*'Traditional use'* is a very important source of evidence for plants and their preparations. Because of the consideration given by EFSA to the evidence related to 'traditional use', no claim on plants and their preparations based on this kind of evidence alone has obtained a positive assessment so far. On the other hand, evidence of traditional use is given a different consideration in the case of therapeutic indications on herbal substances used in Traditional Herbal Medicinal Products (THMPs)<sup>7</sup>.

Under the legislation on medicinal products for human use, certain herbal medicinal products may undergo a *'simplified registration procedure'* upon applications by operators, instead of an authorisation procedure, on the basis of criteria specified in the legislation on medicinal products for human use, such as evidence on medicinal use throughout a period of at least 30 years *'traditional use'*<sup>8</sup>. According to the latter legislation, the long tradition of the medicinal product makes it possible to reduce the need for clinical trials, to the degree that the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Nevertheless, these medicines remain subject to general provisions applying to all medicines such as, the need for pre-market registration, need for a licence to manufacture, pharmacovigilance, good manufacturing practices etc. In addition, Registered THMPs bear indication of their therapeutic effect in a specific way: "*Traditional Herbal Medicinal Product used...*". Also, they must bear the following sentence in the labelling and package leaflet: "*The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use*".

*Borderline substances/classification as medicinal product or food*

Certain plants and their preparations are used in both food supplements and for manufacturing medicinal products, in particular THMPs.

Under the current EU rules, Member States may decide on the classification, on a case-by-case basis, of a product as food or as medicine, taking into account all the characteristics of the final product, including its function and presentation, not only of the ingredients contained therein. This is done on a case-by-case basis and it is possible, as stated on several occasions by the Court of Justice of the EU<sup>9</sup>, that differences exist between Member States in the classification of a same product as a food or as a medicine. In other words, as EU law stands, it is possible that the same product is classified as a foodstuff in one Member State and as a medicinal product in another, if the national authority considers, taking account of all the

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<sup>7</sup> Legislation on medicinal products for human use

<sup>8</sup> Defined as medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the Union

<sup>9</sup> E.g. Judgment of the Court of 9 June 2005 In Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03, HLH Warenvertriebs GmbH (C-211/03), Orthica BV (C-299/03 and C-316/03 to C-318/03).

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characteristics of the product, that this complies with the definition of foodstuff or of medicinal product.

It further complicates the matter when the same plants are sometimes used in both foods and medicines and consumers may sometimes struggle to perceive the difference between certain claims/therapeutic indications of their physiological effect (e.g. "*relief of minor articular pain*" vs. "*maintenance of normal joints*". "*Treatment of common cold* vs. "*supports immune system*").

According to settled case law, the definition of a medicinal product by presentation is subject to broad interpretation, so as to avoid consumers being misled by improper presentation. Certain food supplements containing plants and their preparations are liable to fall within the definition of a medicinal product by virtue of their presentation.

The divergent views and practices have been documented in an Overview Report resulting from a survey carried out by the audit service of DG SANTE, the Food and Veterinary Office (FVO) that gathered information regarding the controls on food supplements. This report demonstrated the problems that Member States face due to differing national rules for the use of plants and their preparations in foods. In particular, the control of internet sales of food supplements containing plants and their preparations is a challenge for the competent authorities.

Pending further action to regulate the use of health claims on plants and their preparations, health claims made on such substances and which were submitted in the context of the establishment of the list of permitted health claims, may still be used pursuant to the transitional measures foreseen in Article 28(5) of the Regulation which requires in particular that the use of such claims complies with the general principles and conditions of the Regulation and with the existing national provisions applicable to them.

Regulation (EC) No 1924/2006 provides for the substantiation of health claims made on plants and their preparations used in foods by demonstrating the causal link between consumption of such foods and the claimed beneficial effect. This precludes in general any safety considerations by EFSA on the use of the substance in foods when assessing the claim.

*The applicable legal framework on plants and their preparations used in foods*

The use of plants and their preparations in foods, including food supplements<sup>10</sup>, is not harmonised by means of specific legislation at EU level. Such food products are covered by various Union legislative texts of general/horizontal application such as Regulation (EC) No 178/2002 on the general principles of food law, and other legal acts applicable to certain categories of foods, such as Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

Regulation (EC) No 1925/2006 (Regulation on 'fortified foods') which was adopted at the same time as Regulation (EC) No 1924/2006 was considered to be complementary to the Regulation on nutrition and health claims. This is because foods to which vitamins and minerals or other substances are added are usually accompanied by a nutrition or health claim for these nutrients and substances. Article 8 of the Regulation on 'fortified foods' provides for a procedure to be used when a potential risk to human health has been associated with the

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<sup>10</sup> Food supplements are considered to be a 'food' as defined by Article 2 of Regulation (EC) No 178/2002.

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addition of a substance other than a vitamin or mineral to foods, including food supplements. Following an assessment by EFSA of the available information on the substance, the use of the substance in foods may be prohibited, restricted or placed under Union scrutiny. This procedure allows the regulation at EU level of substances already on the EU market and for which potential safety concerns have been raised. To date this procedure has been used for two plants and their preparations. It must be noted that certain conditions must be fulfilled in order for the procedure to be used and these have been laid down in Commission Implementing Regulation (EU) No 307/2012.

*Mutual recognition principle*

To the extent that Union law does not include specific provisions on the use of plants and their preparations in foods, the free movement of such goods is governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU) and can thus be subject to national restrictions or bans within the limits laid down by Article 36.

*Current situation*

In 2008, the Commission submitted a report to the European Parliament and to the Council on the use of ‘other substances’, such as plants and their preparations, in foods which concluded that it was not opportune at the time to harmonise their use in foods. However, it did not rule out the possibility, at a later stage, of carrying out a supplementary analysis to the report, examining the conditions for the addition of these substances to foodstuffs in general.

*National rules*

In the absence of specific harmonised rules for the use of plants and their preparations in foods, certain Member States (such as Belgium, France and Italy) have adopted national rules to regulate the use of such substances in foods, including positive and negative lists and conditions of use in some cases. Other Member States have indicated their intention to notify similar national rules. The adoption of national rules that may differ in terms of permitted plants and their conditions of use, has led to a situation whereby food business operators and Member States’ competent authorities are faced with inconsistencies between the practices in the different Member States. As a result food business operators complain about unfair competition and Member States’ competent authorities fear safety concerns regarding the placing on the market of certain products.

*On-going trends*

Belgium, France and Italy have taken the initiative to develop a common approach for the safety evaluation of plants and their preparations in foods in a project called BELFRIT. The rationale for this project is to guarantee the safety, quality and legal security of food products containing plants in the light of the current situation whereby different approaches exist in the Member States. These three Member States would like the other Member States to follow in their footsteps and to adopt a similar approach on a national level.

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### **3. Description of the assignment**

#### **3.1. Purpose and objective of the study**

The purpose of this study is to feed the evaluation in question assessing whether two specific elements required for the implementation of the Regulation can be considered “*fit for purpose*” and whether the Regulation, to date, in view of these elements, has achieved, at minimum burden, its overall objectives.

##### *Nutrient profiles*

The evaluation will examine whether nutrient profiles provided for in the Regulation, which have not yet been adopted, are still necessary to ensure the overall objective of the Regulation and more specifically to avoid a situation where nutrition or health claims mask the overall nutritional quality of a food.

The evaluation will also examine if alternative and less burdensome solutions can be envisaged to reach these objectives. In that respect the legislation in third countries could be considered. For example, in the USA, the issue of nutrition and health claims on foods high in nutrients such as fat, saturates, salt and sugars is not managed by a horizontal regulatory tool like the nutrient profiles but by punctual disqualifying nutritional criteria, which are part of the conditions of use of certain health claims. For example, a health claim on fibre and heart health is only possible for foods that do not contain more than 3% fat and more than 1.5% saturated fat<sup>11</sup>.

It should be noted that the currently applicable provisions of Regulation (EU) No 1169/2011 on food information to consumers maintain the previous rules requiring that nutrition or health claims can only be made if the food for which they are made is labelled with a factual indication of the nutritional content of the food. This nutrition declaration is often in a table format presented on the back of pack. This nutrition information relates to the energy value and the amounts of fat, saturates, carbohydrate, sugars, protein, fibre and salt. As of December 2016, such nutrition declaration will become mandatory for all foods. The only difference is that the fibre content will not be required anymore. Thus, while there is currently no legal link between certain levels of fat, sugars and salt and the possibility to make health and nutrition claims, the consumer is in any case provided with factual information on the nutritional value of the food in question.

It should also be noted that simplified nutrition labelling schemes are more and more used on the front of pack in order to facilitate the understanding of the nutritional information. From a regulatory point of view, they are sometimes considered as alternative means of expression of the nutrition declaration. Such systems are regulated under Regulation (EU) No 1169/2011. Sometimes, such systems identify healthier nutritional options with a logo, which can be considered as nutrition claim like the Swedish keyhole<sup>12</sup>. Such systems are based on nutrient

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<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064919.htm>

<sup>12</sup> [http://www.livsmedelverket.se/en/food-and-content/labelling/nyckelhalet/?\\_t\\_id=1B2M2Y8AsgTpgAmY7PhCfg%3d%3d&\\_t\\_q=keyhole&\\_t\\_tags=language%3aen%2csiteid%3a67f9c486-281d-4765-ba72-ba3914739e3b&\\_t\\_ip=158.169.40.9&\\_t\\_hit.id=Livs\\_Common\\_Model\\_PageTypes\\_ArticlePage/\\_e8c7a1ac-ef79-49fd-b297-187937cf1a97\\_en&\\_t\\_hit.pos=1](http://www.livsmedelverket.se/en/food-and-content/labelling/nyckelhalet/?_t_id=1B2M2Y8AsgTpgAmY7PhCfg%3d%3d&_t_q=keyhole&_t_tags=language%3aen%2csiteid%3a67f9c486-281d-4765-ba72-ba3914739e3b&_t_ip=158.169.40.9&_t_hit.id=Livs_Common_Model_PageTypes_ArticlePage/_e8c7a1ac-ef79-49fd-b297-187937cf1a97_en&_t_hit.pos=1)

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profiles, above which the use of the logo is allowed. These nutrient profiles are not harmonised but should be in line with the EU nutrient profiles, if set.

The evaluation should therefore include all these above mentioned aspects when assessing the issues linked to the non-setting of nutrient profiles. Its results will be used to decide whether there is a need to review the implementation of the Regulation with respect to the setting of nutrient profiles.

*Health claims on plants and their preparations and the more general regulatory framework for their use*

The evaluation will also examine whether the rules foreseen in the Regulation concerning the use of health claims relating to plants and their preparations used in foods, which remain unimplemented, are adequate and necessary to ensure the objectives of the Regulation. In that context, this evaluation should also look into whether adapting the rules foreseen in the Regulation concerning the use of health claims relating to plants and their preparations used in foods, to recognise "*traditional use*" for the scientific substantiation of such claims, would ensure the objectives of the Regulation in the spirit of the co-legislators.

Currently, pending harmonisation of the use of health claims on plants and their preparations, such health claims are currently used in accordance with the transitional measures, under the responsibility of food business operators, and subject to the national legislation applicable to the use of a given plant and its preparations.

The results of this evaluation will be used to decide whether there is a need to review the rules and/or the implementation of the Regulation with respect to health claims on plants and their preparations and whether harmonisation in this area is indeed necessary, while the use of those substances in foods is governed by national rules.

This evaluation should further examine how the use of such health claims interacts with the current applicable food regulatory framework on plants and their preparations. It will extend further to other regulatory aspects on the use of products containing plants and their preparations, such as their safety requirements.

The evaluation exercise should provide a supplementary analysis to the Commission report of 2008<sup>13</sup> on the use of other substances in foods, and in particular it should assess how the use of health claims on plants and their preparations interacts with the current applicable food safety regulatory framework on plants and their preparations.

More specifically, the evaluation exercise should assess whether the current legislative framework applicable to these substances is sufficient in terms of i) the safety of use of plants and their preparations in foods, ii) the smooth functioning of the internal market for these substances. The evaluation exercise should take into account recent market data regarding food products containing plants and their preparations, as well as information regarding the free circulation of such products. The evaluation exercise should gather evidence on the safety problems related to the use of these products, including by means of internet sales that are encountered by the Member States competent authorities, and should take into account the notifications done by the Member States via the Rapid Alert System for Food and Feed (RASFF) ([http://ec.europa.eu/food/safety/rasff/portal/index\\_en.htm](http://ec.europa.eu/food/safety/rasff/portal/index_en.htm))

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<sup>13</sup> COM(2008)824, final (5.12.2008)

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The objective of the evaluation is to increase the understanding of the impact of the current legislative framework applicable to food products containing plants and their preparations on the safety of such products and on the controls carried out by Member States' competent authorities.

The results of this evaluation will be used to decide whether there is a need to review the current legislative framework applicable to food products containing plants and their preparations used in foods with respect to the above-mentioned aspects.

### 3.2. Evaluation issues to be addressed

Since its adoption in 2006, the implementation of the Regulation remains incomplete since nutrient profiles, that the Commission was requested to set by January 2009, have not been established and due to the fact that health claims on plants and their preparations used in foods are still unregulated. In addition, the situation with regard to the unregulated health claims on plants and their preparations has led to a broader reflection regarding the use of plants and their preparations used in foods.

#### *Nutrient Profiles*

Current situation: An assessment of how the situation has evolved since the adoption of the regulation, of what has happened/ is happening to different stakeholders. While nutrient profiles have not been developed for the governance of claim in general, as this is harmonised, it should be pointed out that the concept of nutrient profiles is now widely used. Although the different systems are not compatible, effects should nevertheless converge and be in line with nutritional recommendations. Some are interfering with the legislation, when they define conditions for the use of nutritional logo considered as nutrition claims (only the one subject to national legislation).

Effectiveness: Extent to which the Regulation, in the non-setting of nutrient profiles at EU level, has achieved its objectives.

Efficiency: Costs and benefits of the non-setting of nutrient profiles at EU level, and the extent to which costs have been proportionate to the benefits. Evaluation of possible alternatives to the setting of nutrient profiles at EU level that could achieve similar objectives but with a less burdensome measure.

Relevance: Extent to which the nutrient profiles are still relevant, including scientific developments on nutrition and consumer empowerment, in the current market and with the current regulatory framework to meet the objectives of the Regulation.

Coherence: Extent to which the current state of implementation of the Regulation with the non-setting of nutrients profiles at EU level provides a coherent governance of nutrition and health claims, including front of pack nutritional logos. Coherence of the nutrient profiles as a tool to govern the use of nutrition and health claims with the other initiatives (regulatory and non-regulatory, EU and Member States' level, and private initiatives) aiming at healthier diets in the area of public health. These initiatives are, for example, the promotion of healthy diet, the promotion of food reformulation, regulatory measures to limit food advertising to children, regulatory measure on financial incentives promoting healthier diets.

EU added value: The additional value resulting from the setting of nutrient profiles at EU level compared to what could be achieved by Member States at national level and the extent

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to which an action is required at EU level. What would be the likely consequences of withdrawing the existing EU provision on the setting of nutrient profiles?

*Health claims on plants and their preparations and their use in foods*

Current situation: An assessment of how the situation as regards the use of plants and their preparations in foods, including the use of health claims on such substances, has evolved since the adoption of Regulation (EC) No 1924/2006, of what has happened/ is happening to different stakeholders.

Effectiveness: Extent to which the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods has prevented the realisation of the objectives of the Regulation, and which main factors (e.g. implementation by Member States, actions by stakeholders) have contributed to or stood in the way of achieving these objectives. Extent to which the current legislative framework applicable to plants and their preparations used in foods has achieved the objectives of ensuring safe food products containing such substances on the market and of ensuring a functioning internal market for such products. Extent to which the expectations of food business operators and Member States' competent authorities have been met. If they were not met, what factors have hindered their achievement at EU level (e.g. mutual recognition principles) and at Member States' level (e.g. impact on controls).

Efficiency: Costs and benefits associated with the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006, and the extent to which costs have been justified given the effects achieved. What alternatives, to the current provisions for regulating health claims on plants and their preparations used in foods, could have achieved similar objectives to the objectives of the Regulation, but with less burdensome requirements. Costs and benefits of the existing legislative framework applicable to the use of plants and their preparations in foods, and the extent to which costs have been justified given the effects achieved. Actions to reduce regulatory burden, and potential alternative policy instruments or mechanisms that could improve cost-effectiveness should be assessed.

Relevance: Extent to which the legislative framework introduced by Regulation (EC) No 1924/2006 and the current legislative framework applicable to plants and their preparations used in foods still corresponds to the current needs within the EU taking into account marketing trends and forecasts, and scientific advances in the sector of plants and their preparations.

Coherence: Extent to which the requirements set out in Regulation (EC) No 1924/2006 are coherent with the current EU legislative framework applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with traditional herbal medicinal products.

EU added value: Merits and disadvantages in terms of the EU added value of regulating health claims on plants and their preparations used in foods at EU level. Merits and disadvantages in terms of the EU added value of governance at EU level of the use of plants and their preparations in foods.

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### 3.3. Scope of the evaluation (operational, temporal, geographical...)

#### Operational scope:

- A. The implementation of Regulation (EC) No 1924/2006 with regard to:
- Nutrient profiles (Article 4);
  - Health claims on plants and their preparations (submitted pursuant to Article 13);
- B. The interaction of the use of health claims on plants and their preparations with the current applicable food safety regulatory framework on plants and their preparations.

#### Geographical scope:

The evaluation must cover the 28 EU Member States.

#### Temporal scope:

This evaluation will cover the period 2005 until the end of 2015. The years 2005-2006 are included as a baseline in order to enable a comparison of the situation without the Regulation to the one following its implementation, paying special attention to the way the EU market evolved after the application of the Regulation in July 2007, and after December 2012, when implementing Commission Regulation (EU) No 432/2012 establishing the list of permitted health claims came into application, marking the end of the transitional period for non-authorised claims.

### 3.4. Evaluation questions (indicative list, more questions can be suggested)

#### *Nutrient profiles*

##### **Current situation**

1. To what extent has the non-setting of nutrient profiles has affected the different stakeholders?
2. How has the use of nutrition and health claims, national (e.g. Swedish keyhole) or private nutrient schemes (e.g. EU Pledge) evolved since the adoption of the Regulation with respect to the non-setting of EU profiles? Please provide a country mapping of the various initiatives in the 28 EU Member States. In addition, please examine the current tools used in third countries, such as US, to address the issue of foods high in nutrients such as salt, fat and sugars bearing health claims.

##### **Effectiveness**

3. To what extent has the non-setting of nutrient profiles at EU level prevented the realisation of the objectives of the Regulation of:
  - a. ensuring accurate and reliable information to consumers regarding nutrition and health claims and in particular limiting claims on products high in fat, sugar and salt;
  - b. free circulation of foods bearing these claims;
  - c. legal certainty and fair competition for food business operators;
  - d. promotion and protection of food innovation?

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4. Which main factors (e.g. actions by Member States, actions by stakeholders) have contributed to or stood in the way of achieving these objectives in relation to nutrient profiles and to what extent?
5. To what extent have the alternatives identified in Q2 been effective in achieving the objectives of the Regulation? Have they been equally effective as the establishment of nutrient profiles would have been?
6. To what extent may the alternatives identified in Q2 be a consequence to the non-setting of nutrient profiles at EU level?

### Efficiency

7. What are the costs and benefits and their proportionality, associated with the non-setting of nutrient profiles at EU level in the context of the application of the Regulation for consumers, food business operators and in terms of public health?
8. To what extent have the alternatives identified in Q2 been more or less cost effective in comparison to the potential setting of nutrient profiles at EU level in achieving similar objectives?

### Relevance

9. To what extent nutrient profiles at EU level are still relevant and needed taking into account the evolution of the market and the evolution of the regulatory framework, especially given the development of the nutritional information on the front (logos, simplified nutrition declaration) and on the back (nutrition declaration) of pack?

### Coherence

10. To what extent can nutrition and health claims be considered as accurate and reliable given the non-setting of nutrient profiles at EU level?
11. 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 (e.g. EU Pledge)?

### EU added value

12. What would be the additional value resulting from the setting of nutrient profiles at EU level compared to what is already achieved by Member States at national level, with the alternatives identified in Q2? To what extent is an action required at EU level?
13. What would be the most likely consequences of withdrawing the existing EU provision on the setting of nutrient profiles?

### *The use of plants and their preparations used in foods*

#### Current situation

14. To what extent has the current legislative framework applicable to plants and their preparations used in foods, including Regulation (EC) No 1924/2006, affected the different stakeholders, including the pharmaceutical industry on herbal medicinal products?

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15. What progress has been made over time in the context of the legislative framework introduced by Regulation (EC) No 1924/2006? Please provide a country mapping of the current applicable legislative framework as regards health claims made on plants and their preparations used in foods in the 28 EU Member States.
16. How does the current legislative framework as regards plants and their preparations used in foods apply in each of the 28 EU Member States? Please provide a country mapping of the current applicable legislative framework for plants and their preparations used in foods in the 28 EU Member States, taking also into account e.g. safety assessment procedures for plants and their preparations and their classification criteria as food or medicinal product.
17. What is the legislative framework as regards plants and their preparations used in foods applicable in third countries, in relation to health claims, safety and classification as food or medicinal product?

**Effectiveness:**

18. To what extent has the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods prevented the realisation of the objectives of Regulation (EC) No 1924/2006 with respect to:
  - a. the smooth functioning of the internal market
  - b. ensuring a high level of consumer protection
  - c. ensure fair practices in the trade of such products
19. Which main factors (e.g. implementation by Member States, national rules) have contributed to or stood in the way of achieving these objectives?
20. To what extent has the general regulatory framework concerning the use of plants and their preparations in foods, including Regulation (EC) No 1924/2006, achieved its objectives with respect to:
  - a. the smooth functioning of the internal market (e.g. mutual recognition principle and its exemptions)
  - b. ensuring a high level of consumer protection
  - c. ensure fair practices in the trade of such products
  - d. placing safe food on the EU market
  - e. ensuring an effective approach to the Member States competent authorities controlling activities
21. Which main factors (e.g. national rules, application of mutual recognition principle) have contributed to or stood in the way of achieving these objectives?
22. To what extent has the procedure under Article 8 of Regulation (EC) No 1925/2006 been instrumental and successful in prohibiting, restricting or placing under Union scrutiny, those plants and their preparations for which safety concerns were identified?

**Efficiency**

23. What are the costs and benefits (monetary and non-monetary) associated with the absence of a final decision on the authorisation of health claims on plants and their preparations used in foods in the context of the application of Regulation (EC) No 1924/2006 for consumers, food and pharmaceutical industry, public health? To what extent have these costs been proportionate to the benefits?

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24. What are the costs and benefits (monetary and non-monetary) associated with the more general regulatory framework (both at European and national level) on the use of plants and their preparations in foods? To what extent have these costs been proportionate to the benefits?
25. What are the alternatives, to the current provisions for regulating health claims on plants and their preparations used in foods, which could achieve similar objectives to the objectives of the Regulation, but with less burdensome requirements?
26. What is the specific cost impact of authorisation procedures required for health claims, in particular on micro- small and medium sized enterprises?

### Relevance

27. To what extent is the legislative framework introduced by Regulation (EC) No 1924/2006 still relevant taking into account the evolution of the market and the current regulatory framework concerning the use of plants and their preparations in foods?
28. To what extent do the original objectives of Regulation (EC) No 1924/2006 still correspond to the current needs and trends within the EU, in relation to health claims made on plants and their preparations used in foods? Are there any other objectives that should be considered?
29. To what extent is the current legislative framework applicable to plants and their preparations used in foods still relevant to deal with issues related to the evolution of the market with regard to plants and their preparations used in foods?

### Coherence

30. To what extent are the requirements set out in Regulation (EC) No 1924/2006 coherent with the current legislative framework applicable to plants and their preparations used in foods, including the part on legislation on medicines for human use dealing with traditional herbal medicinal products?
31. How and to what extent does the current legislative framework for the use of nutrition and health claims affect the trade of herbal medicinal products bearing therapeutic indications?
32. To what extent is it coherent to have EU harmonised rules on the use of health claims on plants and their preparations used in foods while their use in foods (e.g. safety) may be governed by national rules, in the absence of harmonisation at EU level of the use of plants and plant preparations in food?
33. To what extent are rules on the use of health claims on plants and their preparations used in foods coherent with other international initiatives (e.g. CODEX Alimentarius)?

### EU added value:

34. What would be the additional value that would result from a decision on the authorisation or rejection of health claims on plants and their preparations used in foods at EU level compared to what is/could be achieved by Member States at national level? To what extent is an action required at EU level?

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35. What would be the most likely consequences of withdrawing health claims made on plants and their preparations used in foods from the scope of the existing EU provision?
36. What would be the merits and disadvantages in terms of the EU added value of harmonising at EU level the use of plants and their preparations in foods?

### 3.5 Expertise required from the evaluation team

The contractor is responsible for proposing the adequate team of evaluators to be involved, describe their skills and qualifications, quantify the input of each member of the team in terms of days and explain the distribution of tasks between the different evaluators. Considering the scope of the evaluation, it is required that the team will have expertise in the fields of law (e.g. regulatory measures), health and economics in relation to the questions presented. The team must have the capacity to work in the different fields and languages needed. In particular, among the members of the team, the following should be clearly identified:

- At least 5 years expertise in evaluation methods, including in carrying out public policy evaluations.
- At least 5 years expertise in food legislation, in particular in legislation in the area of nutrition and health claims, food supplements, fortified foods, horizontal legislation applicable to foods, the regulatory framework applicable to the use of plants and their preparations in foods, and legislation on human medicines, in particular THMPs, both at national and EU level.
- At least 2 years expertise in economics of small businesses.

All staff-related issues will be clarified during the kick-off meeting.

### 3.6. Methodology

The methodology of this evaluation should be drawn up by the contractor. The contractor will have a free choice as to the methods used to gather and analyse information and for making the assessment, but must take into account that the evaluation must be based on recognised evaluation techniques and triangulation methods are required.

The contractor should provide, as part of the offer submitted, the choice and a detailed description of the methodology and multidisciplinary approach he considers using to successfully address his assignment.

The contractor should suggest benchmarks, define suitable indicators and judgement criteria, taking into account the objectives and the scope outlined above. The contractor should list in particular the tools and methods that intends using for each task. Advantages, limitations and risks involved in using the proposed tools and techniques should be explained. There should be a clear link between the evaluation questions addressed and the corresponding methodology proposed. The evaluation questions can be further elaborated, e.g. by providing operational sub-questions under each question.

A mix of different tools for data collection and analysis may be proposed by the contractors as he sees fit, including where relevant, but not limited to the following methodologies, to establish a baseline for the intervention key indicators:

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- Thorough literature research/ desk research (including for example, but not limited to, consultations of the Directorate for health and food audits and analysis of DG SANTE Member States and Commission documents, stakeholder positions);
- surveys with Member States and stakeholders;
- survey with SMEs;
- interviews,
- workshops with Member States and stakeholders to be organised by the contractor with at least one held at the beginning of the evaluation (inception report stage) and one towards the end of the evaluation (draft final report). The European Commission will provide the premises, but it is for the contractor to prepare the background documents, give the presentation, collect and analyse the contributions and prepare the workshop reports. Costs incurred by stakeholder participation can be charged as reimbursable to the contract.
- A number of relevant case studies should also be identified to address the substance of the evaluation questions but also to allow for solid considerations on cost/benefit relationships, including costs of compliance versus generated value added. The case studies should be proposed by the contractor, taking into account stakeholder's inputs, and agreed with the Commission. For the purpose of the evaluation, case studies based on purposive sampling should also be considered (in particular in Member States with key markets on botanicals, such as Belgium, France, Italy, Germany, Romania and Hungary).

An open public consultation of 12 weeks should be held by the Commission via its website "Your voice in Europe" in the course of the evaluation. In addition, a consultation specifically targeting small and medium enterprises should also be held. To this aim, the contractor will be responsible for conducting the consultation work, elaborate on the methodology, prepare the consultation document(s) to be published by the Commission, analyse the replies received and include conclusions to the final report.

Considerable emphasis should be placed on the analysis phase of the evaluation. In addressing the evaluation questions, quantitative indicators should be sought and used as far as possible. The contractor must support findings and recommendations by explaining the degree to which these are based on opinion, analysis and objectively verifiable evidence. Where opinion is the main source, the degree of consensus and the steps taken to test the opinion should be given.

Submissions should explain possible limitations. They should keep in mind the importance of objective data versus opinions. Therefore a first attempt to break down the evaluation questions into judgement criteria, indicators and data sources is expected in the offers.

The approach proposed by the contractor must be clearly set out in the bid. It should clearly identify: a) data to be collected, b) consultation strategy, c) the analysis to be conducted.

Actors of particular importance for this study are the primary producers, food industry, including SMEs, (manufacturing/retail/distribution), advertisers, consumers, Non-Governmental Organisations, in particular those dealing with consumer protection and rights and public health, should be consulted both at national and European level. Of particular importance are also the national competent authorities and must be thus consulted in the context of this assignment. An indicative list of relevant stakeholders to consider is provided in Annex I.

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### 3.7. Reporting and deliverables

#### A. GENERAL REPORTING REQUIREMENTS

The present assignment includes the submission of a series of deliverables: reports and presentations.

The contractor will deliver the following reports at key stages of the evaluation process: kick-off meeting report, inception report, interim progress report, draft final report and final report with executive summary. Each report should be written in English, professionally edited, and critically assessed as it provides the basis for tracking the quality of the work done by the evaluator.

These reports will be submitted to the Commission (evaluation manager) who will transmit it to the established Inter Service Steering Group (ISSG), which may ask for complementary information or propose adjustments in order to redirect the work as necessary. Reports must be approved by the Commission.

It is essential that all the reports be clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested (for example, this could be done via colour-coding parts of the report developed at the offer, inception, interim and draft final stage). An indicative size of each report to be provided is (excluding annexes):

- Inception report: up to 40 pages
- Interim report: up to 80 pages
- Final report: up to 130 pages
- Executive summary: 5/6 pages in EN, FR and DE

The reports should be provided to the Commission in both MS-Word and Adobe Acrobat (PDF) format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference and agreed with the ISSG.

Furthermore, the following reports and presentations shall be delivered:

#### *Kick-off meeting report*

After signature of the contract, the contractor will participate in a kick-off meeting, which will be held in Brussels. The overall objective of a kick-off meeting is to arrive at a clear shared understanding of what is required by the contracting authority. In particular, the meeting should therefore accomplish the following:

- Introduction to contracting authority of contractors' team members and verification of the composition and eligibility of the contractor's team.
- Review of the project scope and objectives and ensure the contractor's general understanding of the Terms of Reference.
- Review of the overall planning/timelines and milestones.
- Review of the project responsibilities and deliverables (including their structure).

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- Verification of the proposed general approach to the work methodology.
- Validation of the proposed workflow.
- Identification of main challenges.
- Confirming next steps.

Following the meeting, a clear set of minutes detailing agreements and conclusions should be drawn up by the contractor and approved by both parties.

### B. KEY DELIVERABLES

Each report (except the final version of the Final Report) should have an introductory page providing an overview and orientation of the report. It should describe what parts of the document, on the one hand, have been carried over from previous reports or been recycled from other documents, and on the other hand, represent progress of the evaluation work with reference to the work plan.

All reports must be drafted in English and submitted according to the timetable below to the responsible body. Electronic files must be provided in Microsoft® Word for Windows format. Additionally, besides Word, the Final Report must be delivered in Adobe® Acrobat pdf format and in five hard copies.

#### *Inception report – within one month following the kick-off meeting*

The report should describe how the methodology proposed by the Contractor is going to be implemented in detail, after e.g. having further examined the sources of secondary and primary data that will be used for the evaluation. It shall not exceed 40 pages, annexes excluded.

The inception report, that shows the understanding of the task by the contractor, completes the structuring phase of the evaluation. It aims at describing the organisation of the work, adapting and substantiating the overall approach, the methodology required for each evaluation question and/or specific task requested as well as the work plan outlined in the proposal.

It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each evaluation question to be answered via establishment of judgement criteria and within these, of evaluation indicators. In addition, the table should have a further column indicating the evaluation tools chosen. The inception report should include enough detail that allows the ISSG to gain a good understanding of the evaluation tools and related methodological steps proposed.

The report may complete and/or suggest additional evaluation questions the contractors consider suitable (see above paragraph). As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications and questions.

The known sources of information, use of tracers (case studies), contact persons in Member States, as well as the way the contractor will interact with Member States representatives will be fully clarified at this stage.

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On the basis of discussion of the ISSG, including the contractor, changes and improvements may be requested. Final version of evaluation tasks/questions suggested by the contractor and evaluation indicators to be used will be validated by the ISSG and the Commission at this stage. The contractor will submit a final version within two weeks.

### *Interim report –four months after signature of the contract*

The report is to be produced after the desk and field research has been completed, and should, to the extent possible, include some preliminary conclusions.

The report must as a minimum provide:

- An overview of the status of the evaluation project;
- A description of problems encountered and solutions found;
- A summary of initial findings and results of the data gathering;
- An assessment of the data, whether it meets expectations and will provide a sound basis for responding to the evaluation questions;
- A conclusion whether any changes are required to the work plan, or any other solutions should be sought in order to ensure that the required results of the evaluation are achieved. If any such issues are to be identified, they must be discussed in the meeting with the Steering Group dedicated to this report;
- A proposal for the final structure of the Final Report, as well as a structure of the Executive Summary.

It shall not exceed 80 pages, annexes excluded.

The report will provide the Commission and the ISSG with an opportunity to check whether the evaluation is on track and whether it has focused on the specified information needs.

The contractor will submit a revised interim report with the necessary updates of the report after discussion with the ISSG.

### *Draft final report – nine months after signature of the contract*

This document should deliver the results of all tasks covered by these Terms of Reference, and must be clear enough for any potential reader to understand.

The structure of the report should follow a broad classification into the following parts:

- **Main report:** The main report must be limited to 130 pages and present, in full, the results of the analyses, conclusions and recommendations arising from the evaluation. It must also contain a description of the subject evaluated, the context of the evaluation, and the methodology used (including an analysis of its strengths and weaknesses).
- **Annexes:** These must collate the technical details of the evaluation, and must include questionnaire templates, interview guides, any additional tables or graphics, and references and sources.

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*Final report – to be submitted within 11 months of the signature of the contract or within 1 month after reception of comments made by the Commission on the draft final report (whatever date occurs first)*

The Final Report follows the same format as the draft Final Report. The document must take into account the feedback from the Steering Group on the draft Final Report, insofar as these do not interfere with the autonomy of the Contractor in respect of the conclusions they have reached and the recommendations made.

The final report must be structured along the lines of common standards, formatted as requested by Publication Office, respecting the Commission's visual identity and containing all identifiers and disclaimers, and should include:

- the **main report** (reflecting on the content of the assignment and presenting the results of the analysis in full and the contractor's conclusions – structure of main report to be confirmed by Commission Services),
- by an **Executive Summary** of no more than **6** pages.<sup>14</sup> The Executive Summary summarises the evaluation's main conclusions, the main evidence supporting them (factual data and synthesis of analysis) and the recommendations arising from them. After being agreed with the Commission Services, it should be translated into English/French and German by a professional translation agency.
- **an abstract** of no more than 200 words in English/French and German, preceding the Executive Summary, should be provided. The purpose of the abstract is to act as a reference tool helping the reader to quickly ascertain the evaluation's subject.
- **technical annexes** (one of which will be the Task Specifications and a compilation of all requested country-based information), and

The contracting authority will publish the Final Report, the Executive Summary, the Abstract, the annexes and the Quality Assessment Grid (as *annexed to the Terms of Reference – Annex II*) providing assessment of the evaluation final report on the Commission's central website.

In view of its publication, the final report by the contractors must be of high editorial quality. In cases where the contractor does not manage to produce a final report of high editorial quality within the timeframe defined by the contract, the contracting authority can decide to have the final report professionally edited at the expense of the contractor (e.g. deduction of these costs from the final payment)."

The Commission holds the rights to the report once the final payment is executed.

The executive summary (including the Key Messages section preceding it) should be provided too as a separate document of maximum 5 pages, both in at least EN, FR and DE. It should provide synthesis of analyses, conclusions and recommendations.

The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of the Commission, the contractor

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<sup>14</sup> 1 page = 1500 characters

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should provide presentations to interested stakeholder groups, as it may be needed. The copyright of the reports remains with the Commission.

Suggested minimum annexes are:

- Annex 1: Procedural information concerning the process to prepare the evaluation
- Annex 2: Stakeholder consultation
- Annex 3: Methods and Analytical models used in preparing the evaluation

### C. PROGRESS REPORTS

The Contractor will deliver Progress Reports on monthly basis summarising on one page progress of the evaluation work (i.e. state of execution of the tasks) made with reference to the work plan. The Contractor will report particularly on difficulties re-encountered and mitigation measures taken or suggestions to changes required to the work plan to ensure that the required results of the evaluation are achieved. The Steering Group might call for a meeting if the Progress Report raises concerns about progress of the works.

#### 3.8. Quality assessment

It is reminded that the final report must be published together with an executive summary, a Quality Assessment (*Annex II*) and a Commission disclaimer if appropriate.

In order to ensure the necessary level of quality for the independent study, contractors should always bear in mind that:

- a) The study must respond to the information needs, in particular as expressed in the Task Specifications/questions and following discussions with the Commission;
- b) The methodology and design must be appropriate for obtaining the results needed to address the tasks and answer the evaluation questions;
- c) The collected data must be appropriate for their intended use and their reliability must be ascertained;
- d) Data must be analysed systematically to address the tasks and answer the evaluation questions and to cover all the information needs in a valid manner;
- e) Findings must follow logically from and be justified by the data/information analysis and interpretations based on the pre-established criteria and rationale;
- f) To be valid, conclusions must be non-biased and fully based on findings;
- g) Particular attention will be given to the conclusions. All areas which need improvements must be identified in conformity with the conclusions.

The study must comply with the quality criteria and the state of the art in the field, and assessments should be well argued on the basis of rigorous qualitative and quantitative analysis. The reasoning followed in the analysis, indicating among other things, the underlying hypotheses of the reasoning, and the limitations of the analysis, must be clearly described. Any judgements provided should be clear and explicit. The study should also be conducted in such a way that the results can be used to improve policy decision-making and thus improve action taken in future.

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While it is possible that detailed data cannot be obtained for all EU Member States, the study should be based on data from as many Member States as possible in order to ensure representativeness of the EU28. Extrapolations should be carried out only if they can be adequately justified. They should be strongly evidence-based and the methodology and assumptions used should be clearly described. Data should be aggregated for presentational purposes but raw data shall also be provided to the Commission. Data shall be presented in a consistent format, to allow for comparisons.

Submissions should explain possible limitations due to insufficient data or number of events.

### 3.9. Organisational framework, timetable and budget

#### *Organisation*

The contract will be managed by Unit E1 – Food information and composition, food waste of the European Commission Directorate-General for Health and Food Safety.

A Steering Group will be involved in the management of the evaluation. The responsibilities of the Steering Group will include:

- establishment of the Evaluation Mandate;
- establishment of the Terms of Reference;
- providing the external evaluator with access to information;
- supporting and monitoring the work of the external evaluator;
- assessing the quality of the reports submitted by the external evaluator, while ensuring that the Contractor's independence is not compromised.

#### *Meetings*

It is expected that the contractor participates in 4 to 6 meetings in Brussels with the evaluation Steering Group. For these meetings, minutes should be drafted by the contractor, to be agreed among the participants.

#### *Timetable*

The indicative starting date is May 2016. The contract will start after both parties have signed it. The period of execution of the contract is 11 months.

### 3.10. Budget

The estimated budget for the evaluation of the action, covering all the results to be achieved by the contractor as listed above, is within the range of **EUR 200.000 up to a maximum of EUR 250.000**.

### 3.11. Special requirements

The contractor should consider whether the involvement of any member of the team in any test could present potential problems of conflict of interest with the mission in the context of this assignment, which could jeopardise the independence of the findings of this evaluation,

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and deal with them in transparency. In addition, the Staff Regulation cooling off period needs also to be respected in case the project works with former EC staff.

### **4. References**

#### **4.1. Annexes to the Task Specification**

Annex I: Indicative list of relevant stakeholders

Annex II: Checklist - Quality Assessment for (Draft) Final Evaluation Reports

#### **4.2. Other existing documentation/data and how to access it**

- Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies - The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006 - Adopted on 31 January 2008 - The EFSA Journal (2008) 644, 1-44 <http://www.efsa.europa.eu/en/scdocs/doc/644.pdf>
- Report by Commission to EP and Council on advisability of establishing specific rules for the use of substances with a nutritional or physiological effect other than vitamins and minerals. COM(2008)824, final (5.12.2008).  
[http://ec.europa.eu/food/safety/docs/labelling\\_nutrition-supplements-comm\\_2008\\_0824\\_en.pdf](http://ec.europa.eu/food/safety/docs/labelling_nutrition-supplements-comm_2008_0824_en.pdf)
- Scientific Opinions of the Panel on Dietetic Products, Nutrition and Allergies – on health claims on plants and their preparations.  
<http://www.efsa.europa.eu/en/publications.htm?entity=nda&scdtype=opinionop&subpanel=nda9>
- Food and Veterinary Office (FVO) Overview Report on the series of fact finding missions in 2013 and 2014 in order to gather information regarding the controls on food supplements, 2015.  
[http://ec.europa.eu/food/fvo/overview\\_reports/details.cfm?rep\\_id=80](http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=80)
- Notified measures on national lists of plants and their preparations used in foods permitted to be used in foods or prohibited for use in foods.

#### **4.3. Useful web-links**

[http://ec.europa.eu/food/safety/labelling\\_nutrition/claims/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/claims/index_en.htm)

[http://ec.europa.eu/food/safety/labelling\\_nutrition/supplements/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/supplements/index_en.htm)

[http://ec.europa.eu/food/safety/labelling\\_nutrition/vitamins\\_minerals/index\\_en.htm](http://ec.europa.eu/food/safety/labelling_nutrition/vitamins_minerals/index_en.htm)

[http://ec.europa.eu/food/safety/general\\_food\\_law/index\\_en.htm](http://ec.europa.eu/food/safety/general_food_law/index_en.htm)

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Annex I

Indicative list of relevant stakeholders

Acronym	Full Name	Contact
AESGP	Association of the European Self- Medication Industry	<a href="http://www.aesgp.eu/">http://www.aesgp.eu/</a>
BEUC	The European Consumer Organisation	<a href="http://www.beuc.eu">http://www.beuc.eu</a>
EHPM	European Federation of Associations of Health Product Manufacturers	<a href="http://www.ehpm.org/">http://www.ehpm.org/</a>
EuroCommerce	Retail, Wholesale and International Trade Representation to the EU	<a href="http://www.eurocommerce.be/">http://www.eurocommerce.be/</a>
FoodDrinkEurope	Confederation of the food and drink industries of the EU	<a href="http://www.fooddrinkeurope.eu">www.fooddrinkeurope.eu</a>
Food Supplements Europe	European Food Supplement Industry	<a href="http://www.foodsupplementseurope.org/">http://www.foodsupplementseurope.org/</a>
EASL	The European Association on the Study of the Liver	<a href="http://www.easl.eu/">http://www.easl.eu/</a>
EBF	European Botanical Forum	<a href="http://www.botanicalforum.eu">http://www.botanicalforum.eu</a>
EFSA	European Food Safety Authority	<a href="http://www.efsa.europa.eu/">http://www.efsa.europa.eu/</a>
EDA	European Dairy Association	<a href="http://eda.euromilk.org/home.html">http://eda.euromilk.org/home.html</a>
EHN	European Heart Network	<a href="http://www.ehnheart.org/">http://www.ehnheart.org/</a>
ELC	Federation of European Speciality Food Ingredients Industry	<a href="http://www.elc-eu.org/">http://www.elc-eu.org/</a>
EPHA	European Public Health Alliance	<a href="http://www.ephpa.org/">http://www.ephpa.org/</a>
HFMA	The health Food Manufacturers' Association	<a href="http://www.hfma.co.uk/">http://www.hfma.co.uk/</a>
	Bleu Blanc Coeur	<a href="http://www.bleu-blanc-coeur.org/#!">http://www.bleu-blanc-coeur.org/#!</a>
AIBI	European branch association of plant bakeries (includes German Bakers Confederation as member)	<a href="http://www.aibi.eu/">http://www.aibi.eu/</a>

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	German Bakers Confederation	<a href="http://www.baeckerhandwerk.de/">http://www.baeckerhandwerk.de/</a>
AIJN	European Fruit juice Association	<a href="http://www.aijn.org/">http://www.aijn.org/</a>
AIPCE-CEP	EU Fish Processors Association - EU Federation of National Organisations of Importers and Exporters of Fish	<a href="http://www.aipce-cep.org/">http://www.aipce-cep.org/</a>
CAOBISCO	Association of the Chocolate, Biscuit and Confectionery Industries of Europe	<a href="http://caobisco.eu/">http://caobisco.eu/</a>
CEEREAL	European Breakfast Cereal Association	<a href="http://www.ceereal.eu/asp2/welcome.asp">http://www.ceereal.eu/asp2/welcome.asp</a>
CEFS	Comité Européen des Fabricants de Sucre	<a href="http://www.comitesucre.org/site/">http://www.comitesucre.org/site/</a>
CLITRAVI	Liaison Center for the Meat Processing Industry in the European Union	<a href="http://www.clitravi.eu/">http://www.clitravi.eu/</a>
COPA-COGECA	European farmers – European Agri-cooperatives	<a href="http://www.copa-cogeca.be/Menu.aspx">http://www.copa-cogeca.be/Menu.aspx</a>
ECFF	European Chilled Food Federation	<a href="http://www.ecff.net/">http://www.ecff.net/</a>
EDA	European Dairy Association	<a href="http://eda.euromilk.org/home.html">http://eda.euromilk.org/home.html</a>
EEPA	European Egg Processors Association	<a href="http://www.eepa.info/">http://www.eepa.info/</a>
ENSA	European Natural Soyfoods Manufacturers Association	<a href="http://www.ensa-eu.org/">http://www.ensa-eu.org/</a>
ESA	European Snack Association	<a href="http://www.esasnacks.eu/">http://www.esasnacks.eu/</a>
EUROGLACES	European Ice Cream Association	<a href="http://www.euroglaces.eu/en/">http://www.euroglaces.eu/en/</a>
EU salt	European Salt Producers 's Association	<a href="http://eusalt.com/">http://eusalt.com/</a>
FAIBP	Federation of the Stocks and Soups Industry Associations in the EU	<a href="http://www.culinaria-europe.eu/">http://www.culinaria-europe.eu/</a>
FEDIOL	EU Oil and Proteinmeal Industry (seed and bean crushers, meals producers, vegetable oils and fats producers/processors)	<a href="http://www.fediol.be/">http://www.fediol.be/</a>

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FIC	Federation of the Condiment Sauce Industries, Mustard and Fruit and Vegetables Prepared in Oil and Vinegar of the European Union	<a href="http://www.culinaria-europe.eu/">http://www.culinaria-europe.eu/</a>
IMACE	International Margarine Association of the Countries of Europe	<a href="http://imace.org/en/homepage/">http://imace.org/en/homepage/</a>
OEITFL	European Association of Fruit and Vegetable Processing Industries	<a href="http://www.profel-europe.eu/">http://www.profel-europe.eu/</a>
UNESDA	Union of the European Beverages Associations	<a href="http://www.unesda.eu/">http://www.unesda.eu/</a>

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## Annex II

**Quality Assessment for (Draft)<sup>15</sup> Final Evaluation Reports**

According to the Commission **Better Regulation Guidelines and toolbox** the Quality Assessment (QA) by the Inter Service Group judges the external contractor's report and its overall process. It is the final "sign off" by the ISG of the contractor's work and includes a judgement on whether key aspects of the work conducted meet the required standards and provides any related comments.

If the evaluation is selected for review by the Regulatory Scrutiny Board, this QA and minutes of the last ISG meeting will form part of the package<sup>16</sup> submitted to the RSB.

In compliance with the above, this documents provides a **Quality Assessment checklist** to be completed **for all interim and ex-post evaluations**, in order to:

- give a structured feedback to the Evaluator on the draft report, and
- support and justify the approval of the final version of the report.
- Provide stakeholders and citizens with an overview of the strengths and weaknesses of the evaluation.

The assessment criteria included should be applied also with reference to the specific Terms of Reference for the evaluation to be assessed and specific agreements made between the evaluation Steering Group and the Evaluator during the execution of the contract.

The checklist can be quickly filled out by ticking boxes, but becomes most useful when also including comments in the open fields.

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<sup>15</sup> If the QA is carried out on the draft final report (as opposed to the final report), it will need to be updated once the final report is being reviewed.

<sup>16</sup> The package is composed of the draft final SWD; the draft final report produced by the consultants; roadmap and minutes of the last SG meeting.

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<b>Quality Assessment for Evaluation XXXXXXXX [Draft] Final Report</b>	
<b>DG/Unit</b>	[DG/Unit]
Official(s) managing the evaluation:	[Name(s)]
<b>Evaluator:</b>	[Company/name]
<b>Assessment carried out by<sup>(*)</sup>:</b>	
Steering group	<input type="checkbox"/>
Evaluation Function	<input type="checkbox"/>
Other (please specify)	<input type="checkbox"/>
(*) Multiple crosses possible	
<b>Date of assessment</b>	[DD/MM/YYYY]

<b>Objective of the assessment</b>	<b>Aspects to be assessed</b>	<b>Fulfilled? Y, N, N/A</b>	<b>Comments</b>
1. Scope of evaluation	Confirm with the Terms of Reference and the work plan that the contractor :		
	a. Has addressed the evaluation issues and specific questions	<input type="checkbox"/>	
	b. Has undertaken the tasks described in the work plan	<input type="checkbox"/>	
	c. Has covered the requested scope for time period, geographical areas, target groups, aspects of the intervention, etc.	<input type="checkbox"/>	

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2. Overall contents of report	Check that the report includes:	
	a. Executive Summary according to an agreed format, in the three languages	[ ]
	b. Main report with required components	[ ]
	<ul style="list-style-type: none"> <li>▪ Title and Content Page</li> <li>▪ A description of the policy being evaluated, its context, the purpose of the evaluation, contextual limitations, methodology, etc.</li> <li>▪ Findings, conclusions, and judgments for all evaluation issues and specific questions</li> <li>▪ The required outputs and deliverables</li> <li>▪ Recommendations as appropriate</li> </ul>	
	c. All required annexes	[ ]
3. Data collection	Check that data is accurate and complete	
	a. Data is accurate	[ ]
	<ul style="list-style-type: none"> <li>▪ Data is free from factual and logical errors</li> <li>▪ The report is consistent, i.e. no contradictions</li> <li>▪ Calculations are correct</li> </ul>	
	b. Data is complete	[ ]
	<ul style="list-style-type: none"> <li>▪ Relevant literature and previous studies have been sufficiently reviewed</li> <li>▪ Existing monitoring data has been appropriately used</li> <li>▪ Limitations to the data retrieved are pointed out and explained.</li> <li>▪ Correcting measures have been taken to address any problems encountered in the process of data gathering</li> </ul>	
4. Analysis and judgments	Check that analysis is sound and relevant	
	a. Analytical framework is sound	[ ]
	<ul style="list-style-type: none"> <li>▪ The methodology used for each area of analysis is clearly explained, and has been applied consistently and as planned</li> <li>▪ Judgements are based on transparent criteria</li> <li>▪ The analysis relies on two or more independent lines of evidence</li> <li>▪ Inputs from different stakeholders are used in a balanced way</li> <li>▪ Findings are reliable enough to be replicable</li> </ul>	
	b. Conclusions are sound	[ ]

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	<ul style="list-style-type: none"> <li>▪ Conclusions are properly addressing the evaluation questions and are coherently and logically substantiated</li> <li>▪ There are no relevant conclusions missing according to the evidence presented</li> <li>▪ Findings corroborate existing knowledge; differences or contradictions with existing knowledge are explained</li> <li>▪ Critical issues are presented in a fair and balanced manner</li> <li>▪ Limitations on validity of the conclusions are pointed out</li> </ul>	
5. Usefulness of recommendations	a. Recommendations are useful	[ ]
	<ul style="list-style-type: none"> <li>▪ Recommendations flow logically from the conclusions, are practical, realistic, and addressed to the relevant Commission Service(s) or other stakeholders</li> </ul>	
	b. Recommendations are complete	[ ]
	<ul style="list-style-type: none"> <li>▪ Recommendations cover all relevant main conclusions</li> </ul>	
6. Clarity of the report	a. Report is easy to read	[ ]
	<ul style="list-style-type: none"> <li>▪ Written style and presentation is adapted for the various relevant target readers</li> <li>▪ The quality of language is sufficient for publishing</li> <li>▪ Specific terminology is clearly defined</li> <li>▪ Tables, graphs, and similar presentation tools are used to facilitate understanding; they are well commented with narrative text</li> </ul>	
	b. Report is logical and focused	[ ]
	<ul style="list-style-type: none"> <li>▪ The structure of the report is logical and consistent, information is not unjustifiably duplicated, and it is easy to get an overview of the report and its key results.</li> <li>▪ The report provides a proper focus on main issues and key messages are summarised and highlighted</li> <li>▪ The length of the report (excluded appendices) is proportionate (good balance of descriptive and analytical information)</li> <li>▪ Detailed information and technical analysis are left for the appendix; thus information overload is avoided in the main report</li> </ul>	
<b>Overall conclusion</b>		
The report could be approved in its current state, as it overall complies with the contractual conditions and relevant professional evaluation standards		[ ]