EVALUATION AND FITNESS CHECK (FC) ROADMAP			
TITLE OF THE EVALUATION/FC	Evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods		
LEAD DG – RESPONSIBLE UNIT	DG SANTE – UNIT E4	**DATE OF THIS ROADMAP**	10/ 2015
TYPE OF EVALUATION	Evaluation Ex-post Mixed	**PLANNED START DATE** **PLANNED COMPLETION DATE**	01 / 2016 06 / 2017
		PLANNING CALENDAR	http://ec.europa.eu/smart-regulation/evaluation/index_en.htm
This indicative roadmap is provided for information purposes only and is subject to change.			

A. Purpose

(A.1) Purpose

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods ("the Regulation") was adopted in 2006 to govern the use of these claims in the labelling, presentation and advertising of foods. It aimed in particular at enabling consumers to make healthier choices by protecting them from misleading information and ensuring a level playing field for food business operators within the internal market. Nutrition claims are statements like 'low fat', 'high fibre', while 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'.

The purpose of this evaluation is to assess whether two specific elements required for the implementation of the Regulation have proven to be "fit for purpose" and whether the Regulation, to date, with respect to these elements, has achieved, at minimum burden, its overall objectives on truthful information to consumers and the facilitation of the free movement of foods bearing claims.

The evaluation will examine whether nutrient profiles provided for in the Regulation, which have not yet been adopted, are warranted and adequate to ensure the objectives of the Regulation. These nutrient profiles are thresholds of nutrients such as fat, salt and sugars above which nutrition and health claims are restricted, thus preventing a positive health message on food high in these nutrients[1].

This evaluation will also examine whether the current rules concerning health claims on plants and their preparations used in foods are adequate, and how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations.

The results of this evaluation will be used to decide on the next steps regarding this policy area.

(A.2) Justification

In its Better Regulation Communication of 19 May 2015[2], the Commission announced to carry out an evaluation of the Regulation. This evaluation will focus on nutrient profiles and health claims on plants and their preparations added to foods. It 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.

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1 Nutrient profiles are not composition standards but only conditions for making nutrition and health claims. Nutrient profiles do not appear on labels and are not communicated to consumers.

2 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

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.

B. Content and subject of the evaluation

(B.1) Subject area

Before the adoption of the Regulation, nutrition and health claims were not harmonised. Member States took different orientations, ranging from the ban of health claims to an absence of any legislation, leading to internal market fragmentation. The aim is that the setting of lists of authorised nutrition and health claims at EU level would ensure the free movement of foods within the internal market.

While certain food business operators invested in research and development to substantiate the nutrition and health claims they made on their foods, others used nutrition and health claims as a marketing tool without ensuring that their claims were scientifically justified. This situation led to unfair competition and jeopardized the trust that consumers could have in scientifically justified claims.

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 the European Food Safety Authority (EFSA). The Regulation also provides for a list of permitted nutrition claims and for an authorisation procedure to establish the list of permitted health claims.

In addition, the Regulation obliges the Commission to set nutrient profiles, after consulting EFSA, which consist in maximum levels in foods of nutrients such as sugars, salt and fat, above which nutrition claims would be limited and health claims prohibited.

A. Nutrient Profiles

The European Food Safety Authority 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 in relation to scientific issues and potential economic impacts.

The currently applicable provisions of Regulation (EU) No 1169/2011 on food information to consumers maintained the previous rules already in place when the Regulation was adopted and requiring that nutrition or health claims can only be made if the food for which they are made is labelled with a factual indication ("nutrition declaration", often in table format) of the nutritional content of the food. This nutrition information relates to the energy value and the amounts of fat, saturates, carbohydrate, sugars, protein and salt. As of December 2016, such nutrition declaration will become mandatory for all foods. 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 provided with factual information on the nutritional value of the food in question.

B. Plants and their preparations used in foods

In the context of the implementation of the Regulation, more than 500 claims on plants and their preparations received an unfavourable assessment from EFSA in the context of their scientific assessments, and this raised many concerns among Member States and many stakeholders regarding health claims made on plants and their preparations used in food. To date, the remaining over 1500 submissions concerning such health claims have not yet undergone the scientific evaluation by EFSA.

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 considers human studies as essential for the substantiation of claims. 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. Under the legislation on medicinal products for human use, herbal medicinal products may undergo a simplified registration procedure 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'*[3]. According to the latter legislation, the long tradition of the medicinal product makes it possible to reduce the need for clinical trials, in so far as the efficacy of the medicinal product is plausible on the basis of long-standing use and experience. Pre-clinical tests are not considered necessary, where the medicinal product on the basis of the information on its traditional use proves not to be harmful under specified conditions of use. Nevertheless, these medicines remain subject to general provisions applying to all medicines such as pharmacovigilance, good manufacturing practices etc.

Under the current EU rules, it is possible for a Member State on a case-by-case basis to classify a product as food or as medicine depending on its presentation and claimed effect. Therefore it is possible that differences exist between Member States in the classification of products. 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.

Pending further action to regulate 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 periods foreseen in Article 28(5) of the Regulation which requires that health claims comply with the Regulation and with the existing national provisions applicable to them.

The Regulation 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 any safety considerations by EFSA on the use of the substance in foods when assessing the claim. This has given rise to increased concerns amongst the Member States on the authorisation of health claims on certain substances when no regard is given to the safety aspects of their use in foods. These concerns emerged strongly during the consultation of the Member States on the options for the way forward for those health claims on plants and their preparations that are "on hold"[4]. An Overview Report[5] which was finalised in 2015 based on a series of fact finding missions carried out by the Food and Veterinary Office (FVO) in Member States in 2013 and 2014 in order to gather information regarding the controls on food supplements highlights the problems that Member States face due to differing national rules for the use of plants and their preparations in foods. The report also highlights issues with enforcement of existing rules in view of the increase in internet sales of such products.

The Commission concluded in a report adopted in 2008 on the use of substances other than vitamins and minerals in food supplements[6] that substances "other than vitamins and minerals" (i.e. plants and plant preparations) have a very varied consumption pattern and that harmonisation in this area was currently not desirable. The report also stresses that the *"Community legal instruments described in this report already constitute a sufficient legislative framework for regulating this area and does not consider it opportune to lay down specific rules for substances other than vitamins and minerals for use in foodstuffs"*. However, in those conclusions, the Commission did not rule out the possibility, at a later stage, of carrying out a supplementary analysis in order to check whether they are still valid. Such supplementary analysis should examine the legislative framework applicable to the addition of substances other than vitamins and minerals as well as the evolution of the market of the products concerned.

(B.2) Original objectives of the intervention

1. Objectives for the EU measure on health and nutrition claims in general (see intervention logic in Annex 1):

- To ensure a high level of consumer protection and to facilitate healthier food choices;
- to improve the free movement of foods with nutrition and health claims within the internal market and to increase legal certainty for economic operators;
- to ensure fair competition when nutrition and health claims are being used and to promote and protect innovation in the area of foods.

2. Objectives of applicable rules covering plants and their preparations:

- To ensure that consumers are correctly informed on nutritional/health value of plants and their preparations

[3] 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

[4] "Discussion Paper on health claims on botanicals used in foods", July 2012

[5] Overview report on a series of fact finding missions carried out in Member States in 2013 AND 2014 in order to gather information regarding the controls on food supplements (DG(SANTE) 2015-7186 – MR): http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=80

[6] COM(2008)824, final (5.12.2008)

contained in food and to allow them to make an informed choice on a healthy diet;

- to ensure that foods containing plants and their preparations that are placed on the market are safe;
- to ensure the free movement of foods containing plants and their preparations within the internal market.

(B.3) How the objectives were to be achieved

Nutrient profiles (see intervention logic in Annex 1)

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 aims at avoiding a situation where nutrition or health claims could mislead consumers as to the overall nutritional quality of a food product when trying to make healthy choices in the context of a balanced diet.

Health claims on plants and their preparations (see intervention logic in Annex 1)

The Regulation should ensure reliable information to consumers, when trying to make healthier choices, by providing scientific justification of nutrition and health claims. This is aimed to be achieved by establishing an authorisation procedure, which requires a scientific assessment of the "the highest possible standard". As a result through creation of a level playing field it should lead to securing investment and promoting innovation.

Plants and their preparations used in foods

The legislative framework with regard to other substances[7], such as plants and their preparations, is such that there is no specific harmonised legislation at EU level.

Nevertheless, food products containing the substances in question are covered by various Union legislative texts of general 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 was adopted at the same time as Regulation (EC) No 1924/2006 in 2006, and was considered to be complementary to that Regulation. Article 8 of Regulation (EC) No 1925/2006 lays down a procedure whereby the use of other substances in foods may be prohibited, restricted or placed under Union scrutiny if a harmful effect on health has been identified. This provision allows the regulation at EU-level of substances already on the market and for which potential safety concerns have been raised. However, this provision only allows the banning and restriction of plants and plant preparations in food. It does not constitute a "positive list" of permitted plants and plant preparations in food. To date, this provision has been used for two plants and their preparations.

In the absence of applicable secondary EU law, the primary EU law on free movement of goods applies. This is governed by Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU).

C. Scope of the evaluation/FC

(C.1) Topics covered

This evaluation, covering the 28 EU Member States, aims at covering the following aspects of the Regulation: 1. Nutrient profiles and 2. Health claims on plants and their preparations. In this context, the evaluation will, where necessary, extend to other regulatory aspects, such as safety requirements for the use of plants and their preparations in food.

This evaluation excludes from its scope other aspects of the Regulation, besides the two mentioned above. The reason is that an evaluation of the Regulation in its entirety would be premature at this stage given that the list of authorised health claims only came into application in December 2012.

This evaluation aims at covering the situation on the EU market since the application of the Regulation in July 2007.

(C.2) Questions/issues to be examined

[7] Regulation (EC) No 1925/2006 defines "other substance" as a substance other than a vitamin or a mineral that has a nutritional or physiological effect.

1. Nutrient profiles

1. Effectiveness[8]

- Did the non-setting of nutrient profiles at EU level prevent the realisation of the objectives of the Regulation? If yes, to what extent and why? What are the objectives that are not met and to what extent?
- Which main factors have contributed to or stood in the way of achieving these objectives and to what extent?
- Beyond these objectives, has the non-setting of nutrient profiles at EU level entailed negative or positive impacts, especially on the use of national or private nutrient schemes, such as nutritional logos?

2. Efficiency[9]

- What are the costs and benefits associated with the absence of nutrient profiles in the context of the application of the Regulation?
- What are the alternatives to the setting of nutrient profiles at EU level that could achieve similar objectives but with a less burdensome measure?

3. Relevance[10]

- 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 following the adoption of the new EU Regulation on food information to consumers?

4. Coherence[11]

- To what extent can nutrition and health claims be considered as accurate and reliable given the non-setting of nutrient profiles at EU level?
- How and to what extend does the non-setting of nutrient profiles at EU level affect the trade of foods?
- 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?

5. EU added value

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

2. Plants and their preparations used in foods

1. Effectiveness

- What progress has been made over time towards achieving the objectives of the legislative framework introduced by Regulation (EC) No 1924/2006? Is this progress in line with the initial expectations?
- Did the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods prevent the realisation of the objectives of the Regulation, and if so how? What are the objectives that are not met and to what extent?
- To what extent the legislative framework applicable to plants and their preparations used in foods has allowed achieving its objectives with respect to placing of safe food on the EU market and facilitating free movement of goods?

2. Efficiency

- 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

[8] The degree to which something is successful in producing a desired result and the degree to which objectives are achieved and the extent to which targeted problems are solved.

[9] The ability to do something or produce something without wasting materials, time or energy: the quality or degree of being efficient.

[10] To know the relevance of something is to know why it matters or how it is important.

[11] Forming a unified whole.

context of the application of Regulation (EC) No 1924/2006?

- What is the specific cost impact of authorisation procedures required for health claims on micro- small and medium sized enterprises?
- 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?
- What are the costs and benefits of the legislative framework applicable to plants and their preparations used in foods?

3. Relevance

- To what extent is the legislative framework introduced by Regulation (EC) No 1924/2006 still relevant to address current needs and trends in relation to health claims made on plants and their preparations used in foods? Are there any other objectives that should be considered?
- To what extent is the 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?

4. Coherence

- To what extent are the requirements set out in Regulation (EC) No 1924/2006 coherent with EU legislation applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with traditional herbal medicinal products?
- How and to what extent does the regulatory framework for the use of nutrition and health claims affect the trade of foods bearing claims?
- How coherent is it to have a positive list at EU level of permitted health claims for plants and their preparations while the there is no positive list at EU level of permitted plants and plant preparations for use in food?

5. EU added value

- What are the merits and disadvantages in terms of the EU added value of the current governance of health claims on plants and their preparations used in foods?
- What would be the merits and disadvantages in terms of the EU added value of a positive list of plants and their preparations for use in foods?

D. Evidence base

(D.1) Evidence from monitoring

Minutes of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee): DG SANTE organises regular meetings (five - six meetings yearly) with Member States representatives in the form of a "Comitology Committee" to discuss practical problems of implementation of the relevant EU food legislation.

Outcome of discussions in various Working Group meetings with Member State experts, conferences and seminars with stakeholders.

(D.2) Previous evaluations and other reports

- 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[12].

[12] COM(2008)824, final (5.12.2008)

- 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

- 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.

(D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

(D.4) Consultation

Transparency and stakeholder involvement are vital for the success of the evaluation to be undertaken. The following consultations are planned in the context of this evaluation:

1) One open public consultation on the substance of the evaluation, based on a questionnaire with closed questions, which will run for a period of 12 weeks in the context of the preparation of the Commission's evaluation report. The intention is to launch this consultation towards the second half of 2016. Received comments in the context of this public consultation will be published on the website "Your voice in Europe", the Commission's portal to public consultations.

2) One stakeholders' consultation, which will run for a period of 8 weeks and which will be launched towards the second half of 2016. This consultation, which will be carried out in cooperation with DG GROW, will be based on a questionnaire of closed questions and it will specifically target SMEs.

Stakeholders to be consulted are provided in the table below:

Actors	**Forum**
Member States	Standing Committee on Plants, Animals, Food and Feed (PAFF) and Working Group on Nutrition and Health claims
Primary producers, food manufacturers, food retailers, advertisers, consumers, NGOs (consumer organisations, public heath organisations), etc.	Advisory Group for the Food chain, including the food industry representatives of various sectors and consumer and public health organisations

(D.5) Further evidence to be gathered

One external study, which will be carried out through the Framework Contract, will feed into this evaluation. The intention is to launch this study in the first half of 2016.

The contractor will be required to collect quantitative and qualitative data on the state of play in the field covered by the evaluation. The way evidence will be gathered will be discussed and agreed with the contractor depending on the available means.

E. Other relevant information/ remarks

Codex Guidelines on the use of nutrition and health claims.

The results of this evaluation will feed into the evaluation report required by Article 27 of the Regulation.

Annex 1: Intervention logic for health and nutrition claims