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COMMISSION STAFF WORKING DOCUMENT

EVALUATION

of the

Regulation (EC) No 1924/2006 on nutrition and health claims made on foods with regard to nutrient profiles and health claims made on plants and their preparations and of the general regulatory framework for their use in foods

{SWD(2020) 96 final}

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This evaluation covers the 27 EU Member States and the United Kingdom, since during the period covered by the evaluation (2005-2018) the United Kingdom was still a Member of the European Union[1]. It should be noted that when the Staff Working Document refers to the EU Member States in the presentation of the results, these results also include the United Kingdom.

[1] The United Kingdom withdrew from the European Union and became a third country as of 1 February 2020.

APPENDIX 1: LEGISLATIVE FRAMEWORK AND STATE OF PLAY: THE REGULATION AND OTHER RELEVANT EU LEGISLATION *(A)*

Table 1: List of the legislative framework and state of play

Policy area/ legal act	Description of legislative framework / revisions	Applicability of the legislation
Nutrition and health claims	EU rules on nutrition and health claims have been established by Regulation (EC) 1924/2006. This provides a legal framework to be used by food business operators when they want to highlight the particular beneficial effects of their products on its label or advertising. The rules apply to nutrition claims (such as "low fat", "high fibre") and to health claims (such as "Vitamin D is needed for the normal growth and development of bone in children"). The objective is to ensure that any claim made on a food's label, presentation or advertising in the EU is clear, accurate and based on scientific evidence. The Commission has provided guidance on the implementation of the Regulation.	Applicable since July 2007
Food information to consumers (FIC)	The EU 'FIC' Regulation (Regulation (EU) 1169/2011 on the provision of food information to consumers) considerably changed previous legislation on food labelling including nutrition information on processed foods, origin labelling of fresh meat from pigs, sheep, goats and poultry, highlighting allergens e.g. peanuts or milk in the list of ingredients etc. The new rules build upon the previous legislative framework, i.e. Directive 2000/13/EC (labelling, presentation and advertising of foodstuffs) and Directive 90/496/EEC (nutrition labelling for foodstuffs).	The new rules applied from 13 December 2014, except the rules on nutritional labelling which fully applied from 13 December 2016
General food law	Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety entered into force on 21 February. It aims to ensure a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment, and applying this in a non-discriminatory manner.	Full application (Framework regulation applicable since 2005)
Official controls along food chain	Regulation (EU) 882/2004 on official controls provides a general framework for official controls performed by Member States' competent authorities to verify compliance with feed and food law, animal health and animal welfare. It includes rules on the financing of official controls, administrative assistance and cooperation, enforcement and rules on controls on imported products. This legislation was recently reviewed and will after a transition period be replaced by Regulation (EU) 2017/625 on Official Controls. The aim of revision was to simplify and clarify the legal framework, and consolidate the integrated approach to official controls in all areas related to the feed and food chain.	Rules applicable since 2005 to be replaced by revised rules after end of transitional period
Food improvement agents	EU rules on food additives, enzymes and flavourings, also known as "Food improvement agents", provide a common EU authorisation procedure for these agents. This is laid down in a legislative package which includes four regulations: Regulation (EC) 1331/2008 establishing a common authorisation procedure; Regulation (EC) 1332/2008 on food enzymes; Regulation (EC) 1333/2008 on food additives; and Regulation (EC) 1334/2008 on flavourings. A practical guidance for applicants on the submission of applications on these agents has been provided by the Commission.	Applicable since January 2011 *(b)*

Food supplements (vitamins and minerals)	The objective of the EU harmonised rules on those products (which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, intended as an addition to a normal diet) is to protect consumers against potential health risks from those products, and to ensure that consumers are not provided with misleading information. The main EU legislation is Directive 2002/46/EC related to food supplements containing vitamins and minerals. The Directive lays down a harmonised list of vitamins and minerals that may be added for nutritional purposes in food supplements (Annex I), and a list of permitted sources from which those vitamins and minerals may be manufactured (Annex II); these lists were subsequently amended to include additional substances. Two related guidance documents for authorities (related to submissions for safety evaluation of substances, and to control of compliance with the legislation) have been provided by the Commission. The Commission has also issued since 2006 a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs; although having consulted extensively with MS and interested stakeholders on the issue, no proposal has been presented yet on this issue due to its complex nature and the divergent views that were expressed. A report has also been prepared by the Commission (COM(2008) 824) on the use of substances other than vitamins and minerals in food supplements.	Applicable since June 2002 *(c)*
Foods for specific groups (Dietetic foods)	Regulation (EU) 609/2013 (new Regulation on Food for Specific Groups) replaced previous Directives on foodstuffs intended for particular nutritional uses (including Directive 2009/39/EC on Dietetic foods). The new Regulation aims to protect specific vulnerable groups of consumers, by regulating the content and marketing of products intended for them (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control), as well as to increase legal clarity for business and to facilitate correct application of the rules. The new rules applied from 20 July 2016.	New rules applied from July 2016
Novel Food Regulation	Regulation (EC) No 258/97 harmonises the authorisation and use of novel foods and food ingredients in the EU since 1997, when the Regulation was adopted. Novel food is food not consumed to a significant degree in the EU prior to 15 May 1997 (cut-off date of the Regulation) and which falls under one of the categories listed in the Regulation (e.g. food consisting of or isolated from micro-organisms, fungi or algae). Novel foods need to be pre-approved and must undergo a scientific assessment prior to authorisation to ensure safety. A New Regulation was formally adopted in 2015 and new rules apply since December 2017.	New Rules applied from December 2017

(a) This table includes other relevant secondary legislation covered by this Report and does not intend to provide an exhaustive list of all provisions in EU food law that are relevant for this evaluation. The level of detail provided here includes relevant information to enable a better understanding of the issues that are raised by this Report for each piece of legislation, and does not aim to provide a consistent full description of the aims and requirements of the existing legislation.

(b) Regulation (EC) 1331/2008 entered into force in 2009; sectoral legislation (Regulations (EC) 1332/2008, 1333/2008 and 1334/2008) entered into force January 2011 latest, with precise dates of entry into force varying between the regulations.

(c) Directive 2002/46/EC: MS implementation by 31 July 2003; trade in products complying with this Directive permitted from 1 August 2003; trade in non-complying products prohibited, from 1 August 2005.

***Source**: External contractor's report, Part One, p. 2.*

APPENDIX 2: SPECIFIC NUTRIENT PROFILES AND CONDITIONS OF USE, WHICH FOOD OR CERTAIN CATEGORIES OF FOOD MUST COMPLY WITH IN ORDER TO BEAR NUTRITION OR HEALTH CLAIMS

Table 2: Commission's draft legal act of 2009 concerning the nutrient profiles

Food category		Specific conditions*	Thresholds		
			Sodium (mg/100g or 100ml)	**Saturates (g/100g or 100ml except when specified otherwise)**	**Sugars (g/100g or 100ml)**
Vegetable oils and spreadable fats as defined in Council Regulation (EC) No 2991/94		-	500	30 kcal /100g	-
Fruits, vegetables, seeds, and their products, except oils	Fruits, vegetables, and their products, except oils**	Minimum 50g of fruit and/or vegetable per 100g of finished products	400	5	15
	Seeds*** and their products, except oils	Minimum 50g of nuts per 100g of finished products	400	10	15
Meat or meat based products		Minimum 50g of meat per 100g of finished products	700	5	-
Fish, fishery products, crustaceans, and molluscs		Minimum 50g of fish per 100g of finished products	700	10	-
Dairy based products	Dairy based products, except cheeses	Minimum 50g of dairy constituents per 100g of finished products	300	2,5	15
	Cheeses	Minimum 50g of dairy constituents per 100g of finished products	600	10	15
Cereal and cereal products	Breads containing at least 3 g of fibre per 100 g or at least 1,5 g of fibre per 100 kcal.	Minimum 50g of cereals per 100g of finished products	700 until [date of adoption + 6 years] 400 from [date of adoption + 6 years]	5	15
	Cereal and cereal products except breakfast cereals	Minimum 50g of cereals per 100g of finished products	400	5	15
	Breakfast cereals	Minimum 50g of cereals per 100g of finished products	500	5	25

Food category	Specific conditions*	Thresholds		
		Sodium (mg/100g or 100ml)	**Saturates (g/100g or 100ml except when specified otherwise)**	**Sugars (g/100g or 100ml)**
Ready meals, soups and sandwiches	Minimum 200g per serving size Minimum 2 of the following for ready meals and sandwiches: - 30g fruits, vegetables and/or nuts, 30g cereals, 30g meat, 30g fish and/or 30g milk	400	5	10
Non-alcoholic beverages	Liquid foods, insofar as they do not qualify for one of the above mentioned food categories	-	-	8
Other foods	Solid foods, insofar as they do not qualify for one of the above mentioned food categories	300	2	10

* the minimum quantity required should be calculated on the basis of the ingredients entering into the recipe.

** vegetables include potatoes, beans, and pulses.

*** seeds include seeds, kernels, nuts. Nuts include peanuts and tree nuts.

APPENDIX 3: AN OVERVIEW OF IDENTIFIED NATIONAL (REGULATORY) SCHEMES/INITIATIVES

Table 3: Examples of national schemes/initiatives implemented/proposed/announced

Name of the scheme/initiative	MS	Food categories covered	Elements covered [a]	Approach for classification	Main objectives/drivers
FOP nutrition labelling, including pictorial nutrition claims					
Healthy Choices	(NL[b])	Nearly all categories of general food products	SO, SAFA, TFA, AS, FI, EN	Threshold for each nutrient by product category	• Encourage food improvement; • Promote healthier food choices amongst consumers
Nordic Keyhole [c]	DK, SE, LT	33 Specific food products sectors	F, SAFA, SU, SO, FI, WG	Threshold for each nutrient by product category	• Promote healthier food choices amongst consumers
Traffic Light	UK	All categories of food products	F, SAFA, SU, SO, EN	General threshold for each nutrient	• Improve consumers' information and promote healthier food choices
Nutriscore	FR, BE DE, ES, LU and NL	All categories of food products	SAFA, SU, SO, EN, PR, FI	General algorithm[d]	• Encourage food improvement
Other schemes/initiatives					
Akkoord Verbetering Productsamenstelling (reformulation all food)	NL	Specific food product sectors	F, SAFA, SU, SO, EN	Threshold for each nutrient by product category	• Encourage food improvement • Promote healthier food choices amongst consumers
Salt in bread (reformulation)	EL	Craft bread	SO	Threshold for each nutrient by product category	• Salt intake reduction
Salt in bread (reformulation)	PT	Bread	SO	Maximum salt level in bread	• Salt intake reduction
Public Health Product Tax	HU	Specific food product sectors	SO, SU and others	Thresholds for pre-packed foods	• Promote healthier food choices amongst consumers; • Increase revenues for public health programmes.
Soft drinks tax	PT	Specific food product sectors	SU	N/A	• Sugar intake reduction
Soft drinks tax	FR	Specific food product	SU	The tax applies regardless of the amount of added	• Sugar intake reduction

		sectors		sugar/sweeteners in foods	
Broadcasting Code (advertising to children)	IE	All categories of food products	F, SAFA, SU, SO, EN, FI, PR	Threshold levels of nutrients to assign scores to a food	• Restrict advertising and promotion of foods high in FSS content to children
OFCOM model (advertising to children)	UK	All categories of food products	All nutrients	Threshold for each nutrient by product category	• Restrict advertising and promotion of foods high in FSS content to children
Advertising to children and school canteens	CZ	Foods for specific groups	F, SAFA, SU, SO	Threshold for each nutrient by product category	• Prevent chronic nutrition-related diseases • Restricting the promotion, offer and sale of foods high in FSS content
School canteens	EL	Foods for specific groups	F, SAFA, SU, SO, SFA	Threshold for some nutrients per category of foods permitted to be sold in school canteens.	• Encourage children's improvement of dietary habits
School canteens	PT	Foods for specific groups	F, SAFA, SU, SO	Mixed approach	• Protect children's health
Voedingsapp (mobile phone application)	NL, planned	All categories of food products	F, SAFA, SU, SO, CA, FI	N/A	• Improve consumers information and promote healthier food choices

*(a) **AS**: added sugars; **CA**: calories; **EN**: energy; **F**: fat; **FI**: fibre; **PR**: protein; **SO**: sodium; **SAFA**: saturated fats; **SU**: sugars; **TFA**: trans fatty acids; **WG**: wholegrain.*

(b) Choices logo introduced as private scheme in the NL in 2006 and formally as national scheme in 2011 (included in Dutch Commodities Act (warenwet) in 2013), but withdrawn in October 2017.

(c) Nordic Keyhole established in SE in 1989, extended to other EU countries (DK and LT) in resp. 2009 and 2013. Also adopted by non-EU countries (NO, IS).

(d) Minor modifications to the general algorithm for cheese, added fats, and beverages to improve consistency between Nutri-Score classification and nutritional recommendations.

***Source**: External contractor's report, Part Two, p. 21.*

APPENDIX 4: OVERVIEW OF IDENTIFIED PRIVATE SCHEMES/INITIATIVES

Table 4: Examples of private schemes/initiatives

Name of the scheme/initiative	Country /ies	Food categories covered	Elements covered[(a)]	Approach for classification	Main objectives/drivers
1. FOP nutrition labelling, including pictorial nutrition claims					
Healthy Choices	CZ, PL	All categories of food products	SO, EN, SAFA, TFA, FI, AS	Threshold for each nutrient by product category	• Encourage food improvement ; • Promote healthier food choices amongst consumers
Heart Symbol	FI	9 food product sectors	F, SAFA, TFA, SO, FI, SU (in some categories)	Threshold for each nutrient by product category	• Improve consumers' information, promote healthier food choices
Eroski (retailer logo)/ traffic light	ES	Foods under the EROSKI trade mark	EN, SU, F, SAFA, SO, FI	Threshold for each nutrient by product category	• Simplify consumers' food choices
Traffic light (retailer)	PT	All categories of food products	EN, F, SAFA, SU, SO	Threshold for each nutrient by product category	• Improve consumers' information
SENS	PL	All categories of food products	EN	Threshold for each nutrient by product category	• Improve consumers' information
Soft drinks FOP label	NL	soft drinks	SO	Threshold for each nutrient by product category	• Improve consumers' information
2. Other schemes/initiatives					
Kidsmarketing: adv. code for food	NL	Specific food product sectors	SO, SU, SAFA, CA	N/A	• Children health protection
Advertising to Children	PL	Foods for specific groups	SO, FA, SU, FI, VI, MI	Threshold for each nutrient by product category	• Encourage food improvement ; • Restrict advertising of foods high in FSS content to children
Advertising to Children	SI	All categories of food products	SU	Threshold for each nutrient by product category	• Improve children's health
EU Pledge Nutrition Criteria (advertising to children)	FR	9 food product sectors	SO, F, EN, SU	Threshold for each nutrient by product category	• Improve children's health

Name of the scheme/initiative	Country /ies	Food categories covered	Elements covered[(a)]	Approach for classification	Main objectives/drivers
Belgian Pledge (advertising to children)	BE	Specific food products	SO, F, SAFA, TFA, SU	Threshold for each nutrient by product category	• Improve children's health
SALZminusBROT (reformulation)	DE	Bread	SO	Threshold for salt	• Encourage food improvement
Food Innovation	SI	All categories of food products	Various nutrients	Nutrient profiling using a scoring system.	• Encourage food improvement

(a) ***AS****: added sugars;* ***CA****: calories;* ***EN****: energy;* ***F****: fat;* ***FI****: fibre;* ***PR****: protein;* ***SO****: sodium;* ***SAFA****: saturated fats;* ***SU****: sugars;* ***TFA****: trans fatty acids;* ***WG****: wholegrain.*

Source*: External contractor's report, Part Two, p. 29.*

APPENDIX 5: POSITIVE AND/OR NEGATIVE LISTS OF PLANTS ALLOWED IN FOOD SUPPLEMENTS

Positive and/or negative lists of plants allowed in food supplements available			
Member State	**Positive list**	**Negative list**	**Status**
	y/n	**y/n**	**legally binding / official guideline / industry guideline / …**
AUSTRIA	Y	Y	Official guideline
BELGIUM	Y	Y	legally binding
BULGARIA	N	Y	Legally binding
CROATIA	Y	Y	legally binding
CZECHIA	Y	Y	Legally binding
DENMARK	N	Y	Official guideline
ESTONIA	N	Y	Official guideline
FINLAND	N	Y	Official guideline
FRANCE	Y	N	Legally binding (BELFRIT list is applied for mutual recognition)
GERMANY	Y	Y	Official guideline
GREECE	N	N	-
HUNGARY	N	Y	Official guideline
IRELAND	N	Y	Official guideline
ITALY	Y	N	Legally binding
LATVIA	N	N	-
LITHUANIA	N	Y	Legally binding
NETHERLANDS	N	Y	Legally binding
POLAND	Y	N	Unofficial internal guideline
PORTUGAL	N	N	-
ROMANIA	Y	Y	Negative list - legally binding Positive list - unofficial guideline
SLOVAKIA	N	N	-
SLOVENIA	Y	Y	Official guideline
SPAIN	N	N	-
SWEDEN	N	Y	Official guideline
UK	N	N	-

Source: Information provided by Food Supplements Europe

APPENDIX 6: PROCEDURAL INFORMATION CONCERNING THE PROCESS TO PREPARE THE EVALUATION

Identification of lead Directorate General (DG)

The Directorate General for Health and Food Safety (DG SANTE) was the lead DG for the Evaluation on the Claims Regulation.

On 19 May 2015[2], in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Better Regulation for better results – an EU Agenda, the Commission committed under the REFIT programme[3] to review and evaluate and *"prepare the ground for possible future action across a wide range of policies and legislation, for instance […] food nutrition and health claims"*.

The Regulation on nutrition and health claims was adopted in December 2006 and entered into force on 19 January 2007. It was not accompanied by an impact assessment and it has never undergone a comprehensive evaluation since its adoption.

This evaluation considers nutrient profiles and health claims made on plants and their preparations, as well as the more general regulatory framework for the use of such substances in foods since it has been closely linked to the use of health claims.

This evaluation covers the 27 EU Member States and the United Kingdom, since during the period covered by the evaluation (2005-2018) the United Kingdom was still a Member of the European Union[4]. It should be noted that when the Staff Working Document refers to the EU Member States in the presentation of the results, these results also include the United Kingdom.

Organisation and timing

Roadmap

A roadmap[5] was published on 8 October 2015. The roadmap was the first step in the evaluation process and outlined the purpose, content and scope of the evaluation. It set out the evaluation questions based on the main evaluation criteria to be addressed in this evaluation exercise, namely on:

- Effectiveness (have the objectives been met?);
- Efficiency (What are the costs and benefits involved?);

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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. To be found at: http://ec.europa.eu/smart-regulation/better_regulation/documents/com_2015_215_en.pdf (last accessed 13 June 2018).

3 The Regulatory Fitness and Performance Programme (REFIT) is the Commission's programme for ensuring that EU legislation remains fit for purpose and delivers the results intended by EU law makers. REFIT is not about deregulation but rather about regulating better. It aims to unlock the benefits of EU law for citizens, businesses and society as a whole in the most efficient and effective way, while removing red tape and lowering costs without compromising policy objectives. REFIT is not a one-off review: it is a lasting commitment to keeping the body of EU law lean and healthy.

4 The United Kingdom withdrew from the European Union and became a third country as of 1 February 2020.

5 http://ec.europa.eu/smart-regulation/roadmaps/docs/2015_sante_595_evaluation_health_claims_en.pdf

- Coherence (Does the policy complement other actions or are there contradictions?);
- Relevance (Is EU action still relevant?);
- EU added value (Can or could similar changes have been achieved at national level, or does EU action provide a clear added value?).

Stakeholders submitted feedback on the roadmap via a dedicated webpage[6]. Feedback received during the first four weeks after publication of the roadmap was considered in the design of the evaluation. The Commission received feedback from 20 stakeholders (for more details see the synopsis report, Appendix 9).

External Study

In order to allow for a systematic (both qualitative and quantitative) data gathering, an external study was carried out in order to feed into this evaluation. The external study, supporting the evaluation, was carried out by the Food Chain Evaluation Consortium (FCEC), from May 2016 to June 2018 on 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[7] ('the external study').

The assignment of the external study aimed 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, health claims on plants and their preparations added to foods and the general regulatory framework with respect to plants and their preparations used in foods.

Inter-service Steering group

To ensure the quality assessment of the external study and of the overall process of the evaluation, an inter-service steering group was established, comprising of ten services of the Commission. These included: Secretariat-General ('SG'), Legal Service ('SJ'), DG for Agriculture and Rural Development ('AGRI'), DG for Internal Market, Industry and Entrepreneurship and SMEs ('GROW'), DG for Maritime Affairs and Fisheries ('MARE'), DG for Justice and Consumers ('JUST'), DG for Research and Innovation ('RTD'), DG for Trade ('TRADE), Directorate General Joint Research Centre ('JRC') and Directorate General For Health and Food Safety – Units A1 – Better regulation, B4 – Medical products: quality, safety, innovation, C4 – Health determinants and international relations, D1 – Food chain science and stakeholder relations ('SANTE').

6 https://ec.europa.eu/food/consultations-and-feedback_en#fbk (last accessed 7 February 2020)

7 Food Chain Evaluation Consortium, 2018, Evaluation of Regulation (EC) No 1924/2006. Link to be found at: https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en.

The inter-service steering group held 8 meetings as outlined in

Table 5 below.

Table 5: ISG meetings on the Evaluation of the Claims Regulation

6 July 2015	Agreement in principle on the **roadmap** and discussion on the scope of the evaluation.
27 May 2016	**Kick-off meeting** with the presence of the external contractor to clarify the scope of the external study, the evaluation questions, the required consultations (workshops, case studies, online public consultation) and the study timetable.
10 November 2016	Discussion on the **inception report** of the external study with the contractor – final endorsement through email consultation on 28 April 2017.
20 June 2017	Discussion on the **interim report** of the external study – final endorsement through email consultation on 25 September 2017.
8 November 2017	Internal discussion with the inter-service steering group on the **draft final report** in order to collect all comments, exchange on them and discuss on the next steps.
22 November 2017	Discussion on the **draft final report** of the external study with the contractor.
29 May 2018	Final discussion of the interservice steering group on the **draft final report** of the external study. Decision of the inter-service steering group to partially accept the draft final report and to reduce the final payment of the external contractor, as the quality of the final deliverable was not considered up to the contractual standards.
22 March 2019	Discussion on the draft **staff working document** on the Evaluation of the Claims Regulation.

APPENDIX 7: METHODOLOGY

The evaluation was supported by an external study, as explained in Appendix 5. The methodology followed by the external study is presented in the external contractor's report, Part One. An overview of the elements assessed in this evaluation is presented below.

1. Data collection strategy

The purpose of this external study was to feed the evaluation in question assessing whether two specific elements (nutrient profiles and the health claims made on plant substances) required for the implementation of the Claims Regulation can be considered "*fit for purpose*" and whether the Claims Regulation, to date, in view of these elements, has achieved, at minimum burden, its overall objectives.

The data collection strategy for the external study was based on the use of a suite of complementary tools. The aim of using multiple tools was to collect a broad evidence base which could be triangulated to reduce bias and increase robustness. The central pillar of the data collection was an extensive consultation process, ensuring that all views and available evidence was taken into consideration.

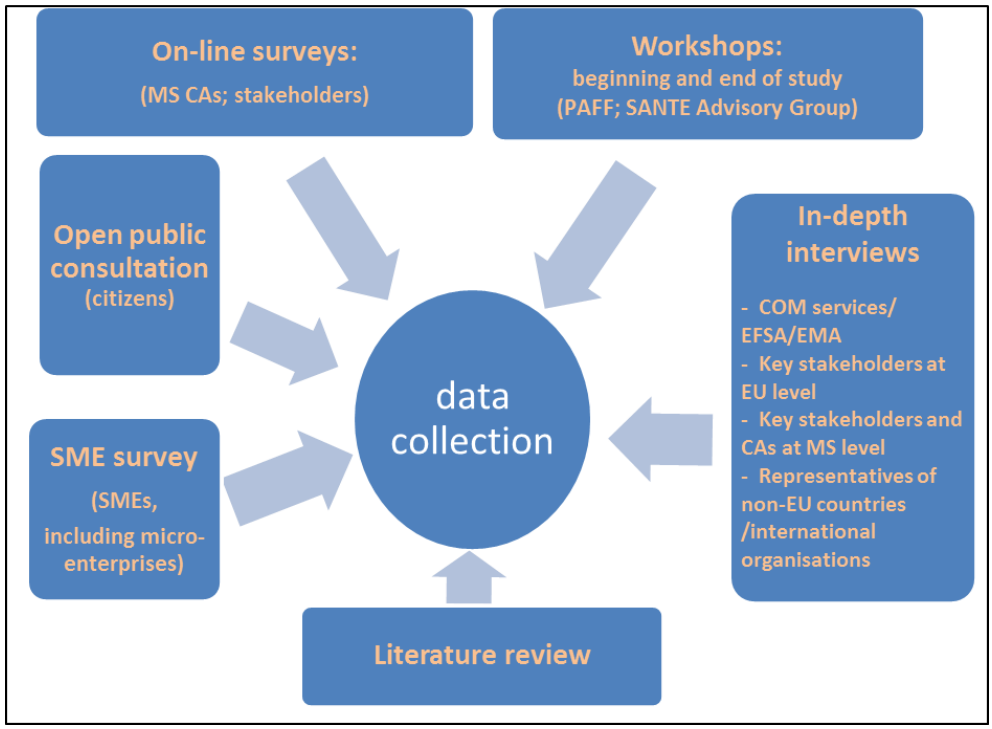
The external study was based on 36 evaluation questions ('EQs'), focusing on the following evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value, in line with the Better Regulation guidelines[8]. The judgment criteria and indicators that were used to address these 36 EQs were set out in a detailed evaluation matrix[9].

An overview of the data collection strategy for the external study is summarised in Figure 1 below.

[8] Terms of Reference of "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", dated 14.03.2016. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-claims_terms-of-references.pdf.

[9] *See* external contractor's report, Annexes, Annex 3.

Figure 1: Data collection strategy



Source: External contractor's report, Part One, p. 8

The data collection in the external study involved a two-step process:

- **First step**: Workshops and targeted on-line surveys were the first step of the evidence gathering process, before proceeding to examine in-depth issues at a later step. The working documents supporting the workshops and the surveys were designed to collect an essential set of perceptions and other qualitative, as well as quantitative, data from the highest possible number of participants
- **Second step**: Interviews and case-studies were aimed at deepening the evidence base and focusing on (qualitative/quantitative) data collection in specific areas that merited further investigation/analysis.

Each of the data collection tools played a distinct role: the survey of stakeholders was addressed to associations representing the agri-food chain, consumers and NGOs, while individual companies, including micro-enterprises, were targeted by the SME Panel. The targeted survey of Member States was addressed to the EU 28. The interviews and case studies provided more in-depth investigation into focus areas of the external study.

1.1. Primary data collection

1.1.1. Stakeholders' and Member States' workshops

Two sets of one-day workshops, with stakeholders and Member States were held at the beginning and at the end of the consultation process. These meetings took place in the context of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health (stakeholders) and the

Working Group on nutrition and health claims (Member States). Both workshops opened with a general presentation of the evaluation study context and methodology performed by the contractor. This was followed by a discussion focusing on the two issues under assessment by the external study.

- First workshop (21 June 2016): the purpose was to get an exploratory feedback on the main issues under study and inform participants of the scope and process of the evaluation, in particular of the data collection needs and what was expected of them during the main phase, so as to generate interest in further participation and to allow from an early stage to prepare and coordinate data collection at their end. The discussion was based on a specific working document disseminated to workshop participants one week before the workshop. This document provided a first set of key questions under study in order to guide participants on the type of qualitative and quantitative data that would be required of them in the course of the evaluation. To that end, the workshop provided the opportunity to participants to raise questions regarding the data and outline any challenges for the data collection.
- The benefits of this set of workshops were two-fold. Firstly, the workshops informed participants of the evaluation process, and provided further clarifications and explanations to allow them to develop better targeted, quality inputs in the context of the data collection tools used (*e.g.* targeted surveys, case studies, interviews) for the study. This was important as, typically, EU-level stakeholders need to hold internal discussions with their members, and Member States internally within their services and/or with other authorities involved, in order to perform their evidence gathering and data collection. Secondly, early involvement in the process enabled stakeholders to feel ownership of the evaluation process thus improving the validity of the results ultimately obtained. The approach has been to consider stakeholders as partners in the evaluation process, while always being mindful that their job is to protect the interests of their members, hence a wider stakeholder involvement and triangulation of evidence provided has been an important element our methodology. Conducting the workshops has facilitated working relations, while it has improved the transparency/visibility of the evaluation with the different actors consulted, and provided for a balanced exchange of information and analysis on the issues covered by the evaluation.
- Second workshop (26/27 October 2017): Towards the completion of the data collection phase, the second set of workshops, with both stakeholders and Member States, took place. The purpose of these workshops was to present the findings of the analysis of the external study, in particular the aggregate results of the targeted surveys, and to stimulate further discussions/exchange on these, as well as to validate these findings. In addition, this second set of workshops allowed for updating the Member States and stakeholders on the progress of the evaluation, timeline and next steps.

These workshops contributed to the Commission's commitment to transparency during the process of the evaluation.

1.1.2. Targeted on-line surveys

Two targeted (internet based) surveys of stakeholders and Member States took place (simultaneously) in the period December 2016 - February 2017 (8 weeks). One survey was directed

at the 28 EU Member States and the EFTA countries[10]; the other targeted stakeholders, i.e. associations representing the interests of various business operators along the food and feed supply chains, NGOs (e.g. public health NGOs) and consumer associations (as identified in

[10] Iceland, Liechtenstein, Norway, Switzerland.

Table 8).

These on-line surveys aimed at collecting essential information and data from the highest possible number of participants. Both surveys investigated the same issues to understand points of agreement and areas where competent authorities and stakeholders take different positions. The reasons for this, and evidence to support these positions, was sought in the context of the surveys and were further investigated in more depth in the context of the case studies. The surveys were used to gather initial perceptions and available (qualitative and quantitative) evidence/data using a series of questions covering the mandatory evaluation criteria (effectiveness, efficiency, relevance, coherence and EU added value).

1.1.3. SME Panel

Small and medium enterprises (SMEs) dominate the food and drink manufacturing sector in the EU. It was therefore considered essential to consider the impact of the issues subject to the evaluation on SMEs, particularly on micro- and small-enterprises, as these food business operators are likely to have a different capacity to interact with legislation. SMEs, including micro-enterprises, were consulted through the Europe Enterprise Network SME Panel by means of a survey. This consultation aimed at allowing, in the context of this evaluation, to consider how easy it has been for SMEs to comply with the legislation and whether they incurred disproportionate costs in comparison with their limited staff and turnover. This consultation took place in the period April-June 2017 (10 weeks).

1.1.4. Online pubic consultation (OPC)

In line with the requirements of the Better Regulation guidelines, an online public consultation was held by the Commission via its "Your voice in Europe" website. Consultation was open to anyone wishing to respond and was made available for a 12-week period. The online public consultation was mainly addressed to citizens in their function as consumers of products bearing claims, taking into account that other stakeholders, such as consumer groups, civic society groups, companies and their associations, public (competent) authorities and others were expected to provide detailed feedback through other targeted consultation tools, as outlined above. The results of the online public consultation are, however, not statistically significant as the underlying sample is not representative of the EU population due to over-representation of one Member State and is not adequately sized given the number of contributions received.

1.1.5. In-depth interviews

Extensive interviews (on the basis of interview guides developed for the specificity of the evaluation), with the purpose to further investigate, clarify and analyse elements that came up in the context of the online surveys, were conducted. These involved key stakeholders both at Member States' level and at EU level (e.g. EU associations of food business operators in the different sectors and stages of the food supply chain, associations of food business operators in the pharmaceutical sector, and EU consumer associations), officials from the Commission, EFSA, and EMA, MS stakeholders in the context of the case studies (e.g. representatives of national food industry associations), officials of The Member States' competent authorities in the selected Member States

covered by the case studies and three selected non-EU countries (i.e. US, Canada and Australia). The main phase of the interview programme took place in the period January to September 2017 (some interviews were also conducted on an exploratory basis during June to November 2016).

1.2. Secondary data collection

1.2.1. Case studies

Case studies were designed to provide more in-depth analysis of certain issues under study that merit further investigation, focussing on the advantages/disadvantages and costs/benefits of the current situation. To this end, six thematic case studies were carried out, three for each of the two elements (nutrient profiles and health claims on plants) of the evaluation, involving a total of nine Member States. This helped to identify where national initiatives and implementation are important in determining the observed impacts. An overview of the themes of the case studies together with the selected Member states is summarised in Table 6 below.

Table 6: Case studies themes

Theme	Focus/MS	Objectives/Criteria for selection
<u>Nutrient Profiles</u>		
Theme 1: FoP nutrition claims	DK, SE (NORDIC KEYHOLE) NL (other approaches) *Legal base: Claims Regulation*	*Objective: investigate the implementation of a NP developed in the context of an FoP nutrition claim* • wide application within the MS that have Nordic keyhole; • based on an NP developed on the basis of scientific criteria; • adopted under the Claims Regulation; • NL: previous scheme (Choices) removed – new approaches under development • *explicitly quoted in EQ2*
Theme 2: Advertising to children – EU Pledge & national approaches	DK, IE (EU Pledge/ national) UK (national: OFCOM - ASA) *Context: EU Platform on Diet, Physical Activity and Health*	*Objective: investigate the implementation of a NP developed in the context of advertising to children (EU Pledge; national)* • EU-wide application; • based on an NP developed on the basis of scientific criteria and WHO recommendations; • food for children identified as a distinct category in literature; • although voluntary, linked to restrictions in some MS • specific initiative adopted in context of the EU Platform on Diet, Physical Activity and Health (EQ11); • *explicitly quoted in EQ2 and EQ11*
Theme 3: FoP (nutrition) labelling	UK (Traffic lights) FR (Nutri-score) *Legal base: FIC Regulation*	*Objective: investigate the implementation of a NP developed in the context of a FoP labelling (a)* • wide application within the MS that have it; • several MS currently planning/introducing; • private initiatives planned • based on an NP developed on the basis of scientific criteria; • scheme adopted in the context of the FIC Regulation

Theme	Focus/MS	Objectives/Criteria for selection
<u>Plants and their preparations used in foods</u>		
Theme 1: **Hydroxy-anthracene derivatives: EFSA assessment of health claim and procedure under Article 8 of Regulation (EC) No 1925/2006**	DE FR	*Objective: identify the main issues behind the presentations of a claim for plants and their preparations and investigate the implementation of the procedure under Article 8 of Regulation (EC) No. 1925/2006* • the first favourable EFSA outcome for a health claim on substance derived from plants; • potential data on costs and benefits; • relevant for safety issues; • *Article 8 explicitly quoted in EQ 22.*
Theme 2: **Traditional use for substantiation of health claims on plants and their preparations**	DE FR IT SE	*<u>Objective</u>: investigate the costs and benefits of the inclusion of traditional use for the scientific substantiation of a health claim made on foods vis-à-vis with the current situation* • relevant topic for all stakeholders; • would feed the study with quantitative data on costs; • some MSs already use traditional use for assessing claims under the transitional measures; • definition of traditional use available.
Theme 3: **BELFRIT project and other lists of substances**	DE IT LT	*<u>Objective</u>: investigate in depth the implementation of the positive and negative lists of plants, including the most developed project of multi-MS list (BELFRIT project)* • wide application within the MSs of positive and negative lists of substances; • development at MS and inter-MS level of positive and negative lists seen as a way to overcome the absence of harmonisation at EU level of provisions on plants and their preparations used in foods; • wide demand for harmonised lists at EU level (survey results).

1.2.1. Desk research and literature review

Desk research was an important aspect of the evaluation as it allowed to collect useful information to fine-tune the proposed methodology and tools, to identify the quantitative and qualitative data sources that would be considered in the context of data collection, as well as the related data gaps to be addressed; and, lastly, to inform the definition of judgement criteria and indicators used for the analysis of the two elements of the evaluation (i.e. nutrient profiles and health claims on plants). The literature review drew on a wide range of relevant documentation, specific reports and other material produced within and for Commission Services, Member State Competent Authorities as well as the body of academic literature and stakeholder position papers.

This evidence base was further complemented by literature and other external studies, including reports from the health and food audit and analysis service of DG SANTE, formerly known as the 'Food and Veterinary Office' ('FVO'), relevant studies in the literature and case-law of the Court of Justice of the European Union.

1.2.2. MINTEL's Global New Products Database

The research conducted by the external contractor highlighted that publicly available data on the prevalence of nutrition and health claims on foods and on their nutrition composition are not available. However, the Commission services made use, through EFSA, of a private database: MINTEL's Global New Products Database (GNPD)[11], which captures and compiles data of new products (including foods and drinks) accessing the market every day. This allowed the Commission services to identify and compare market trends of foods bearing claims within different food categories across the Member States.

Methodology for analysis of Mintel Global New Product Database data

Nutrient Profiles

Data on new food products were downloaded from MINTEL GNPD for the period from January 2005 to December 2017, for a selection of EU countries (Italy, UK, France, Sweden, Poland) representing a mix of North, South, West and East Member States and for selected food categories. The food categories selected for the analysis correspond to the ones that stakeholders identified as potentially misleading for consumers due to their overall poor nutritional content despite bearing claims (see section 5.1.1 in staff working document). These categories are:

- Breakfast Cereal (cold and hot)
- Carbonated Soft Drinks
- Bakery:
    - Bread & Bread Products
    - Cakes, Pastries & Sweet Goods
    - Savoury Biscuits/Crackers
    - Sweet Biscuits/Cookies
- Dairy:
    - Drinking Yogurts/Liquid Cultured Milk
    - Fresh Cheese & Cream Cheese

[11] To be found at: https://www.mintel.com/about-mintel (last accessed 7 June 2018).

    - Margarine & Other Blends
    - Soft Cheese & Semi-soft Cheese
    - Soft Cheese Desserts
    - Spoonable Yogurt
- Juice Drinks:
    - Fruit/Flavoured Still Drinks
    - Juice
    - Nectars
- Sports & Energy Drinks
    - Energy Drinks
    - Sports Drinks

Overall, the data downloaded from MINTEL GNPD included 6469 products with claims for France, 4970 for Italy, 2557 for Poland, 1525 for Sweden and 8355 for the UK. The data were stored and analysed with Microsoft Excel.

For each food category, e.g. breakfast cereals, an **analysis of the data on nutritional content** (quantities of saturated fat, sodium and sugar) was carried out based on the nutrient profiles proposed by the European Commission in 2009 (Annex 1C). This analysis was possible only for products that had nutritional information on the content of saturated fat, sodium and sugar. Therefore, products, for which nutritional information on these three nutrients was not available, were excluded from the analysis. The number of products with claims included in the analysis amounted to 4 918 for France (out of 6 469 products with claims), 3 338 for Italy (out of 4 970 products with claims), 1 952 for Poland (out of 2 557 products with claims), 1 073 for Sweden (out of 1 525 products with claims) and 6 576 for the UK (out of 8 355 products with claims). The lack of nutritional information was mainly noted for new products entering the market between 2005 and 2013. This could be explained by the requirement of the FIC Regulation to include the nutritional declaration on all foods as of December 2016 and possible prior adaptation by the food industry.

In cases where the nutritional information indicated the amount of salt (g), but not the amount of sodium (mg), the amount of sodium was calculated using the following formula:

Sodium content in mg = (salt content in g*1000)/2.5[12].

In cases where the nutritional information indicated the amount of carbohydrates but not the amount of sugar for the product category of drinks[13], the amount of sugar was approximated to be equal to the amount of carbohydrates[14]. The difference between the two nutrients for drinks is usually minimal and can be explained by the presence of pectin in drinks containing fruits. Indeed, where nutritional information for drink products was complete, the amount of carbohydrates corresponded mostly to the amount of sugar.

Once the database was cleared from products without nutritional information, for each product category, formulas in Microsoft Excel were used to count for every year the number of products with claims that have a content of sodium and sugar and saturates below or equal to the thresholds

[12] This formula is in line with Annex I of the FIC Regulation, and with the online salt sodium converter of the Australian Heart Foundation. To be found at: https://www.heartfoundation.org.au/healthy-eating/food-and-nutrition/salt/sodium-and-salt-converter (last accessed on 21 February 2019).

[13] Carbonated soft drinks, juice drinks, and sport and energy drinks.

[14] An exception was made for sport and energy drinks in powder form or containing maltodextrin.

included in the 2009 Commission's draft legal act[15]. This number indicates the number of products that do not exceed any of the three thresholds. By subtracting this number from the total number of products, we calculated the number of products exceeding one or more of the thresholds for saturated fat, sodium and sugar. The corresponding percentages were also calculated and are presented in Table 3 and Table 4 of the SWD.

Based on the definitions included in the MINTEL GNPD and in the Claims Regulation, the following claims from MINTEL GNPD were considered relevant for the purpose of this evaluation: added calcium, antioxidant, functional – bone health, functional – brain & nervous system, functional – cardiovascular, functional – digestive, functional – energy, functional – eye health, functional – immune system, functional – other, functional – skin, nails & hair, functional – slimming, functional – weight & muscle gain, high/added fibre, high/added protein, low/no/reduced calorie, low/no/reduced fat, low/no/reduced saturated fat, low/no/reduced sodium, low/no/reduced sugar, vitamin/mineral fortified, wholegrain.

In addition, the MINTEL GNDP was used for counting the number of new foods and drinks accessing the market on a yearly basis with and without claims and for analysing the prevalence of such new products bearing at least one claim. In particular, this analysis looked into:

- the 20 EU countries, that were included in the MINTEL GNDP (namely, Slovakia, Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, UK, Ireland, Romania, Italy, Netherlands, Poland, Portugal, Spain, Croatia, Sweden),
- the entire foods and drinks market, and
- the time period between 2000 and 2017. This time period was selected to allow for a comparison between the time period prior to 2007 (which marks the adoption of Regulation (EC) No 1924/2006) and after.
- the claims matching one or more of the following options: Diet/Light, Added Calcium, Low/Reduced Sugar, No Added Sugar, Vitamin/Mineral Fortified, Low/No/Reduced Cholesterol, Low/No/Reduced Fat, Low/No/Reduced Carb, Sugar Free, High/Added Protein, Low/No/Reduced Calorie, Functional, Low/No/Reduced Saturated Fat, High/Added Fiber, Low/No/Reduced Sodium, Low/No/Reduced Transfat, Low/No/Reduced Glycemic.

The analysis described above presents two main limitations. First, the MINTEL GNPD covers only new products that enter the market every year. Therefore, these products are not a representative sample of the overall market and do not represent the entire market. Nevertheless, they give an indication of the trends among new products available on the market. Second, nutritional information was not available for all products. Products for which the field 'nutritional information' was blank or marked as 'not indicated on pack' and products for which there was no information on the amount of saturated fat, sugar or salt/ sodium were excluded from the analysis. This has reduced the number of new products in the database for which the nutritional composition was analysed.

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[15] The Excel 'COUNTIFS' function, which returns the count of cells that meet one or more criteria, was used for the analysis. The following formula was used to count the number of products above the thresholds proposed in 2009 for each year and product category:
=COUNTIFS(*range of cells containing data on year of entry to the market*; "*=year of interest*"; *range of cells containing data on saturated fat*; "*<=threshold set by Commission's draft legal actl*"; *range of cells containing data on sodium*; "*<=threshold set by Commission's draft legal act*"; *range of cells containing data on sugar*; "*<=threshold set by Commission's draft legal act*").

1.3. Limitations and robustness of findings

This evaluation faces a number of challenges, some of which relate to the fact that this is an assessment of the effects of non-implementation. The key challenges, approaches and mitigating measures that have been taken by the external contractor are outlined below.

Challenges and mitigating measures

What would have happened had Regulation (EC) No 1924/2006 been implemented fully?

Challenge: Evaluating the effects of non-implementation of parts of the Regulation is a key challenge. The analysis of the effects on non-implementation, therefore incomplete harmonisation, was complicated by two factors. On the one hand, the exact way in which nutrient profiles might have been set is not certain. On the other hand, the full implementation of the Regulation on plants and their preparations and the harmonisation of their general regulatory framework related to foods remain hypothetical.

Mitigating measure: How the situation has evolved in the absence of full implementation of a harmonised EU approach was investigated in the external study, to assess whether/what problems are being encountered in practice, the extent of these problems, and – ultimately – the extent to which the original objectives are being met. A review (in the context of case studies) of the current situation in selected Member States that have implemented national measures, explored the effects of these measures, to the extent relevant, and whether/how they interacted with the objectives of the Regulation.

The likely impacts of having set nutrient profiles and having harmonised the use of plants and their preparations in foods and having implemented the Regulation in this area are drawn from the problems identified from not having done this to date. Some issues that stakeholders consider a result of the current situation may be resolved from implementation/ harmonisation. The approach has been to consult the wider range of stakeholders potentially affected by these issues and to apply triangulation, in order to eliminate any potential bias in the opinions put forward by stakeholders with varied interests. In addition, a comparison of the current situation in selected Member States was carried out.

Availability of quantitative data

Challenge: The quantification of impacts was difficult to achieve in some cases, due to both the lack of objective, verifiable data and the hypothetical comparisons set out above (i.e. '*what if*' the Regulation had been implemented fully). For example, there was scarcity of data and difficulties to measure in quantitative terms the extent to which the non-setting of nutrient profiles has affected the use of claims and associated costs, or the monetary benefits associated with the absence of a final decision on the authorisation of health claims on plants and their preparations used in food.

Mitigating measure: The external study has sought to collect quantitative data for the quantification of impacts by consulting stakeholders. In particular, stakeholders were asked about the (actual) costs and benefits arising from the current situation versus the (hypothetical) costs and benefits that would have arisen from full implementation.

Where the external contractor was not able to monetise costs and benefits (e.g. the hypothetical implementation of provisions that are not known in the level of detail required for quantification; or, where data are missing/incomplete to allow quantification), alternative more qualitative approaches were followed. These include, for example, the identification of the categories of costs and benefits

involved (monetary and non-monetary) and their relative importance. This is done by exploring the extent to which food business operators (including SMEs, and in particular micro-enterprises, to which the dedicated SME Panel was addressed) and competent authorities raise any specific concerns on costs (whether experienced currently or likely to be experienced under full implementation) and which cost categories are the most burdensome. Where costs were reported to occur, evidence to support any assertion of costs has been requested and, where applicable, triangulation of the evidence gathered in order to arrive at reasoned judgements.

In addition, the Commission services accessed, through EFSA, market data on foods bearing claims from a private database. This allowed expanding the quantitative evidence basis for the evaluation.

Stakeholder bias; the number of stakeholders

Challenge: The views on nutrient profiles as well as on plants and their preparations are rather polarised across different stakeholder groups. To add to this, the issue of nutrient profiles has raised interest amongst a large number and range of stakeholders. Furthermore, the range of stakeholder interests provides a potential bias in the collected evidence and increased the requirement to perform triangulation.

Mitigating measures:

- requests were made to consulted stakeholders[16] for concrete examples and verifiable data, particularly in terms of costs and benefits, in order to minimise bias;
- in-depth consultation was carried out with all parties involved (including Member State competent authorities, EFSA, EMA, WHO, academic community etc.);
- workshops were held to both enable the consultation of multiple stakeholders at once, and to encourage the discussion/triangulation of any evidence brought forward by the consulted parties; and,
- to the extent possible, triangulation of the information collected taking into account the differing viewpoints of the stakeholders and other relevant consulted parties.

Considering the challenges and mitigating measures highlighted, the main limitation of this evaluation is that the analysis of impacts is largely based on stakeholders' views.

[16] In depth consultations were carried out mainly with representatives of stakeholder organisations, rather than individual companies, to avoid the overloading from one particular interest group. Nonetheless, for the collection of specific data (e.g. costs of reformulation in specific product cases – nutrient profiles; costs of applications for authorisation – health claims on plants and their preparations), the collection of data from individual companies has been necessary.

APPENDIX 8: STAKEHOLDERS' MAPPING

2. Relevant stakeholders

This study was relevant to a wide and varied range of stakeholders[17] as illustrated below.

Table 7: Stakeholder groups and reasons for consultation

Stakeholder group	Reason for consultation
1. Citizens	Consumers are explicitly identified as an important group by the objectives of the NHC Regulation: "*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*." It is important to understand to what extent the implementation of the regulatory framework, with regards to the provisions under study and the situation as it has evolved in the absence of harmonisation in certain areas, has achieved the objectives.
2. Consumer organisations and public health interest groups (European and national level), including participants to the EU Platform for action on diet, physical activity and health	
3. Organisations/associations representing businesses, at European and national/regional level, in the specific product sectors affected (i.e. food supplements, food and drinks and their individual product sectors, traditional herbal medicinal products, etc.), as well as those representing retail trade and e-commerce	The remaining three objectives of the NHC Regulation; "*to improve the free movement of foods bearing such claims within the internal market*"; "*to increase legal security for economic operators*" and "*to ensure fair competition in the area of foods*" relate directly to businesses, including SMEs. This evaluation falls under the Commission's Better Regulation initiative, hence the need to understand the effects of the NHC Regulation on businesses and whether there is need and/or potential for simplification and reduction of regulatory burden.
4. SMEs (in particular the smaller and micro-enterprises, given their relative importance in this sector)	The Commission remains committed to encourage the growth of SMEs and assess the effects of regulation on SMEs including micro-enterprises. Furthermore, SMEs have a relatively high presence in the food and herbal medicines sector.
5. Member States' competent authorities (MS CAs) (the relevant ministries, enforcement authorities and sector-specific national regulatory bodies, both for food and herbal medicines)	Competent Authorities hold positions on the issues being examined under the two study tasks. Not only do they have experience of the evolution of the current situation, but in some cases they have influenced it too. They will be impacted by any future changes.

[17] The list includes **external stakeholders only**. In addition, consultation has taken place with the Commission services, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).

Stakeholder group	Reason for consultation
6. European networks/organisations of research and specialist scientists in this field (e.g. nutrition experts), including those participating in relevant EU and nationally funded research projects[18]	Considerable research and academic work in the field of nutrient profiles and plant preparations has been carried out. The consultation of this stakeholder group will allow an examination of the specific issues under study, beyond any relevant content which has been published.
7. NGOs and other associations representing other interests, other than those listed above	The associations listed above may not cover the whole range of stakeholders with an interest in the issue of health claims; most notably, health claims may be of secondary interest for certain associations/NGOs in the context of their primary interests. Such stakeholders are captured by this group.
8. International dimension: selected third country authorities and relevant international organisations (e.g. Codex Alimentarius, WHO)[19]	The consultation of this stakeholder group is of particular importance for the understanding of the regulatory approaches and systems developed in non-EU countries (which is a requirement for both tasks).

3. List of consulted stakeholders

A detailed mapping of the EU-level stakeholders including consumer groups and NGOs that were identified as being most relevant to consult for this evaluation (except MS CAs, non-EU and international organisations) is set out below.

[18] The following EU-funded research projects were identified as most relevant:
- CLYMBOL project (includes analysis of consumer attitudes to claims) (relevant for nutrient profiles);
- FLABEL project (includes consumer attitudes to nutritional labelling) (relevant for nutrient profiles);
- PlantLIBRA (relevant for the issue health claims made on plants and plants used in foods);

Other projects of relevance include: BACCHUS project (claims related to the reduction of cardiovascular diseases); and REDICLAIM project (covers disease reduction claims).

[19] In particular:
- For nutrient profiles, the following approaches to nutrient profiles were identified to merit further investigation: US FDA; Australian model; WHO model for restrictions on advertising to children.

For the issue of health claims made on plants/ plants used in foods, the following international/third countries models were identified to merit further investigation: US, Canada.

Table 8: List of relevant stakeholders, including consumer groups and relevant NGOs targeted by the consultations in the context of the external study (except Member States, non-EU and international organisations)

	Acronym	Organisation	ToR	Commented on roadmap	Member Advisory Group WG on NHCs	Member of EU Platform Nutrition	Type	Nutrient profiles	Plants and their preparations used in foods
1	ACT	Association of Commercial Television in Europe				x	business	x	
2	AESGP	Association of the European Self-Medication Industry	x	x	x		business		x
3	AIBI	European branch association of plant bakeries (includes German Bakers Confederation as member)	x				business	x	
4	AIJN	European Fruit juice	x				business	x	
5	AIPCE-CEP	EU Fish Processors Association - EU Federation of National Organisations of Importers and Exporters of Fish	x				business	x	
6	AMFEP	The Association of Manufacturers and Formulators of Enzyme Products					business		
7	AREFHL	Fruit Vegetable and Horticultural European Regions				x	business	x	
8	AVEC	Association of Poultry Processors and Poultry Trade in the EU			x		business	x	
9	BEUC	The European Consumer Organisation	x	x	x	x	NGO	x	x
10	Brewers of Europe	The Brewers of Europe					business		
11	CAOBISCO	Association of the Chocolate, Biscuit and Confectionery Industries of Europe	x				business	x	
12	CEEREAL	European Breakfast Cereal Association	x				business	x	
13	CEEVS	Comité Européen des Entreprises Vins					business		
14	CEFS	Comité Européen des Fabricants de Sucre	x	x			business	x	
15	CELCAA	Comité Européen de Liaison des Commerces AgroAlimentaires			x		business	x	
16	CES/ETUC	Confédération Européenne des Syndicats/European Trade Union					business	x	
17	CESS	European Confederation Sport and Health				x	NGO	x	
18	CLITRAVI	Liaison Centre for the Meat Processing Industry in the European Union	x				business	x	
19	COCERAL	Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'Union Européenne					business	x	
20	COFACE	Family Associations				x	NGO	x	
21	COPA-COGECA	European farmers –European Agri-cooperatives	x		x	x	business	x	
22	CPME	Standing Committee of European Doctors				x	NGO	x	
23	EACA	European Association of Communications Agencies				x	business	x	

	Acronym	Organisation	ToR	Commented on roadmap	Member Advisory Group WG on NHCs	Member of EU Platform Nutrition	Type	Nutrient profiles	Plants and their preparations used in foods
24	EASL	The European Association of the Study of the Liver	x	x			NGO	x	
25	EASO	European Association for the Study of Obesity				x	NGO	x	
26	EBF	European Botanical Forum	x				business		x
27	ECA	European Cacao Association					business	x	
28	ECF coffee	European Coffee Federation					business	x	
29	ECF Cyclists	European Cyclists' Federation				x	NGO	x	
30	ECFF	European Chilled Food Federation	x				business	x	
31	ECL	Association of European Cancer Leagues				x	NGO	x	
32	EDA	European Dairy Association	x		x		business	x	x
33	EDE	Energy Drinks Europe					business		x
34	EEPA	European Egg Processors Association	x				business	x	
35	EFAD	European Federation of the Associations of Dieticians				x	NGO	x	
36	EFBW	European Federation of Bottled Waters					business		
37	EFFA	European Flavour Association					business		x
38	EFFAT	European Federation of Food, Agriculture and Tourism Trade Unions					business	x	
39	EFLA	European Food Law Association					other	x	x
40	EFM	European Flour Millers					business	x	
41	EFPRA	European Fat Processors and Renderers Association					business	x	
42	EHIA	European Herbal Infusions Association and European Tea Committee					business		x
43	EHN	European Heart Network	x	x		x	NGO	x	
44	EHPM	European Federation of Associations of Health Product Manufacturers	x	x	x		business		x
45	ELC	Federation of European Speciality Food Ingredients Industry	x	x			business		x
46	EMRA	European Modern Restaurant Association					business	x	
47	ENGSO	European Non-Governmental Sports Organisation				x	NGO	x	
48	ENSA	European Natural Soyfoods Manufacturers Association	x				business	x	x
49	EPEGA	European Poultry Egg and Game Association					business	x	
50	EPHA	European Public Health Alliance	x	x		x	NGO	x	
51	ERRT	European Retail Round Table					business	x	
52	ER-WCPT	European Region of the World Confederation for Physical Therapy				x	NGO	x	
53	ESA (snacks)	European Snack Association	x				business	x	
54	ESA spices	European Spice Association					business		x
55	ESA seeds	European Seed Association					business		

	Acronym	Organisation	ToR	Commented on roadmap	Member Advisory Group WG on NHCs	Member of EU Platform Nutrition	Type	Nutrient profiles	Plants and their preparations used in foods
56	ESPGHAN	European Society of Paediatric Gastroenterology, Hepatology and Nutrition				x	NGO	x	
57	ESPREVMED	European Society of Preventive Medicine				x	NGO	x	
58	ESSNA	The European Specialist Sports Nutrition Alliance					business		x
59	EUFIC	European Food Information Council				x	other	x	
60	EUPPA	European Potato Processors					business	x	
61	EUCOFEL	European Fruit and Vegetables Trade Association					business	x	
62	EUCOLAIT	European Association of Dairy Trade					business	x	
63	EUCOPE	The European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	x	x			business		x
64	EUROCHAMBRES	Association of European Chambers of Commerce and Industry					business	x	x
65	EuroCommerce	Retail, Wholesale and International Trade Representation to the EU	x		x	x	business	x	x
66	EUROCOOP	European Community of Consumer Cooperatives			x	x	business	x	
67	EUROGLACES	European Ice Cream Association	x				business	x	
68	EuroHealthNet	EuroHealthNet				x	NGO	x	
69	Europa Bio	European Association of Bioindustries					business	x	
70	EuropeActive	EuropeActive (formerly: EHFA)				x	other	x	x
71	EUROPREV	European Network for prevention and Health Promotion in general practice/family medicine				x	NGO	x	
72	EU SALT	European Salt Producers 's Association	x			x	business	x	
73	EVA	European Vending Association				x	business	x	
74	EUVEPRO	European Vegetable Protein Federation					business	x	
75	EVU	European Vegetarians Union					NGO	x	
76	EUWEP	European Union of Wholesale with Eggs, Egg Products and Poultry and Game					business	x	
77	FAIBP	Federation of the Stocks and Soups Industry Associations in the EU	x				business	x	
78	FACENetwork	Farmhouse and Artisan Cheese and dairy producers' European network					business	x	
79	FEAP	Federation of European Aquaculture Producers					business	x	
80	FEDIMA	Federation of EU manufacturers and suppliers of ingredients to Bakery, Confectionary and Patisserie industries					business	x	
81	FEDIOL	EU Oil and Proteinmeal Industry	x	x			business	x	
82	FEEDM	European Federation of Honey Packers & Distributors					business	x	

	Acronym	Organisation	ToR	Commented on roadmap	Member Advisory Group WG on NHCs	Member of EU Platform Nutrition	Type	Nutrient profiles	Plants and their preparations used in foods
83	FERM	Federation of European Rice Millers					business	x	
84	FIC	Federation of the Condiment Sauce Industries, Mustard and Fruit and Vegetables Prepared in Oil and Vinegar of the EU	x				business	x	
85	FoodDrink Europe	Confederation of the food and drink industries of the EU	x	x	x	x	business	x	x
86	Food Service Europe	European Federation of Contract Catering Organizations			x	x	business	x	
87	FSE	Food Supplements Europe	x	x			business		x
88	FRESHFEL	Forum for the European fresh fruits and vegetables chain			x	x	business	x	
89	FRUCOM	European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs					business	x	
90	HFMA	The health Food Manufacturers' Association	x	x			business		x
91	IADSA	Int'l Alliance of Dietary Supplements Associations					business		x
92	IBFAN	International Baby Food Action Network				x	NGO	x	
93	IDF Europe	International Diabetes Federation – European Region				x	NGO	x	
94	IMACE	International Margarine Association of the Countries of Europe	x				business	x	
95	INDEPENDENT RETAIL EUROPE	EU representation of groups of independent retailers to EU and international institutions		x			business	x	x
96	IPA Europe	International Probiotics Association					business	x	
97	ISCA	International Sport and Culture Association				x	NGO	x	
98	OEIT	European Organisation of Tomato Industries					business	x	
99	PGEU	Pharmaceutical Group of the European Union					business		x
100	PFP + members	Primary Food processors (FEDIOL; CEFS; European Flour Millers; etc.)					business	x	
101	PROFEL	European Association of Fruit and Vegetable Processors					business	x	
102	SAFE	SAFE food advocacy group					NGO	x	x
103	SpiritsEUROPE	European Spirits sector					business		
104	SEMOULIERS	Union des Associations des Semouliers de l'UE					business	x	
105	Serving Europe	Branded Food and Beverage Service Chains Association (formerly EMRA)			x	x	business	x	x
106	SNE	Specialised Nutrition Europe (formerly IDACE)					business		x
107	OEITFL	European Association of Fruit and Vegetable Processing Industries	x				business	x	

	Acronym	Organisation	ToR	Commented on roadmap	Member Advisory Group WG on NHCs	Member of EU Platform Nutrition	Type	Nutrient profiles	Plants and their preparations used in foods
108	UEAPME	European Association of Craft, Small and Medium-sized Enterprises		x	x		business	x	x
109	UECBV	Union européenne du commerce du bétail et de la viande			x		business	x	
110	UNESDA	Union of the European Beverages Associations	x	x			business	x	x
111	WFA	World Federation of Advertisers				x	business	x	
112	WOF	World Obesity Federation (formerly: IOTF)				x	NGO	x	

APPENDIX 9: SYNOPSIS REPORT OF THE STAKEHOLDERS' CONSULTATIONS

A wide range of stakeholders was consulted as part of this evaluation, based on the mapping presented in Appendix 8, through online surveys, workshops, interviews and case studies. Stakeholders were consulted as part of the external study and the results of the consultations were analysed by the external contractor.

The results of the stakeholder consultation activities are presented below.

1. Feedback on the evaluation roadmap

The Commission received feedback on the evaluation roadmap from 20 stakeholders[20]. These stakeholders were representatives of the industry, consumers and health NGOs. In general, the comments received welcomed the possibility for stakeholders to submit comments on the roadmap and in the context of the evaluation. Some stakeholders representing the food industry questioned the limited scope of this evaluation especially, in the context of the report that is legally required in Article 27 of the Claims Regulation which will evaluate the impact of that Regulation on the market.

Some stakeholders representing health NGOs questioned the appropriateness to evaluate the need of establishing nutrient profiles arguing that nutrient profiles should just be set, rather than be questioned, especially given that overconsumption of foods with relatively unhealthy nutrient profile is a problem in the EU. On the other hand, stakeholders representing the industry welcomed the Commission's initiative to evaluate the need of nutrient profiles given the new provisions of the Regulation on food information to consumers which recently came into application.

Stakeholders representing the industry with an interest in plants and plant substances used in foods welcomed this evaluation, especially the intention to evaluate the plants used in foods in a holistic way.

Member States did not submit comments on the roadmap, however in the Standing Committee meeting of 4 November 2015[21] they expressed their positions. There was consensus that nutrient profiles should be set as soon as possible and that such evaluation would delay even more their setting, if not put their fate in question. As regards plants and plant substances, Member States were satisfied with the Commission's approach to study them in such comprehensive manner.

2. Targeted stakeholder consultation

Two targeted surveys of stakeholders and Member States took place (simultaneously) during the period December 2016 - February 2017 (8 weeks). The results of the two targeted surveys were analysed in a consolidated manner bringing together per theme the results of stakeholders and Member States, but presented separately per topic (i.e. nutrient profiles/plants used in foods). In addition to the targeted surveys, the Commission received an ad-hoc contribution from the Association of the European Self-Care Industry (AESGP) on the requirements applicable to the

[20] Stakeholders' feedback is publicly available on the website: https://ec.europa.eu/food/consultations-and-feedback_en#fbk

[21] https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_gfl_20151104_sum.pdf

registration/authorisation of herbal medicinal products (four different categories) in the EU and Food Supplements Europe (FSE) on the number of new products containing plant substances launched on the market in Member States.

2.1. Summary of the consultation process

The survey of Member States was addressed to the national competent authorities of the EU 28 (including the UK). A total of 26 out of targeted 28 Member States replied to the targeted survey (Bulgaria and Malta did not reply to the survey). In addition, a reply was received from Norway.

Another survey targeted stakeholder organisations representing business operators in the various segments of the supply chain (i.e. food business operators) and organisations representing consumers and NGOs active on the issues under study. Concerning the part on plants used in foods, the survey also targeted the pharmaceutical sector). Individual companies were indirectly consulted through their umbrella organisations/associations representing their sector (e.g. some of the larger companies are direct members of such organisations at Member States' level and/or at EU level; SMEs are broadly represented by the association UEAPME, as well as by sectoral organisations for the various product sectors).

The stakeholder survey results are based on 113 complete responses (of 119 total replies); of these, 101 were received from associations representing business interests (i.e. food business operators for nutrient profiles and for the part on plants; as well as the pharmaceutical sector for the part on plants), and 12 were received from consumers, citizens, public health and wider public interest groups/NGOs. Amongst the 113 respondents, 60 replied to questions relating to nutrient profiles, 35 to questions relating to plants used in foods and 18 to both; thus, the complete set of replies per subject was as follows:

- 78 respondents replied to the part of the survey addressing nutrient profiles (N=78); of these, 70 organisations represented business and 8 non-business interests. The business organisations that have responded to this part of the survey were for the most part (N=54) active in a combination of food and drinks sectors; 14 organisations were active in food, drinks as well as food supplements and sports nutrition. The various main categories of food and drink products were all relatively well represented, ranging from 22 organisations active in the breakfast cereals and fish/ fish products sectors, 23 active in the various (non-alcoholic) beverage sectors, 26 active in the vegetable oils and spreadable fats sector, 29 and 30 - respectively - active in fruit and vegetable product sectors, 33 active in dairy (other than cheese) and meat/meat products sectors, to 34 organisations active in the cheese sector.
- 53 respondents replied to the part of the survey addressing health claims on plants and the general framework on plants used in foods (N=53); of these, 47 organisations represented business and 6 non-business interests. The business organisations that have responded to this part of the survey were for the most part active in the food sector (N=37), while 6 were active in the pharmaceuticals sector, and 4 were active in both sectors.

For some of the questions, in particular those relating to costs, the overall findings were limited only to replies received from operators, *i.e.* excluding consumers and NGOs (nutrient profiles N=70; plants and plant preparations in food: N=47).

2.2. Consultation results

A summary of the consultation results per main subject-matter is provided in the paragraphs below.

A. Nutrient profiles

Current situation

Mapping of the various schemes/initiatives developed in the 28 EU Member States since the adoption of the Regulation[22]

There is overall consensus amongst all consulted parties (Member States, food business operators, consumer organisations and NGOs) that:

- there is an apparent proliferation of schemes/initiatives having nutritional objectives that have been developed at national and/or private level;
- these schemes are designed to serve various other purposes and objectives, and are not directly related to the needs and objectives of nutrient profiles as set out in the Claims Regulation;
- they would have been developed in any case, irrespectively to the non-setting of nutrient profiles at EU level (EU-NPs).

Some type of national regulatory schemes/initiatives was reported to be implemented in 15 out of the 26 Member States that responded to the consultation. Out of the 11 Member States where no such schemes were reported, 8 Member States indicated that this was due to waiting for harmonised regulatory action (e.g. nutrient profiles to be established at EU level).

Impact of the nutrition declaration and the identified schemes/initiatives, in the absence of EU-NPs

- **Extent to which the nutrition declaration contributes to the objectives of nutrient profiles as set out in the Claims Regulation**

There was ***limited consensus*** amongst consulted parties on the contribution of the nutrition declaration in terms of the various direct and indirect objectives pursued by EU-NPs, with focus on meeting consumer objectives:

- A majority of respondents among the *Member States* and *stakeholders* believe that the nutrition declaration is not fulfilling the primary direct objective of EU-NPs to limit the use of claims on foods high in fats, sugar or salt (FSS). However, the 40% level of "do not know" responses from business stakeholders should be noted.
- *Industry stakeholders* tend to consider consumer-related objectives more fulfilled than the *consumer organisations and public health NGOs* tend to consider.

[22] The focus has been on national (regulatory) and private initiatives/schemes, developed on a voluntary basis in each MS as well as across the EU, concerning the nutritional status of food products, with potentially relevant objectives to the theme of the study, i.e. aiming to: 1) Some form of nutrition labelling - referred to, generally, as 'voluntary (nutrition) labelling schemes' - whether this applies to foods bearing claims or food more generally; 2) Some form of conditions of use/restrictions for foods high in certain nutrients, whether these are used for the purpose of bearing claims (i.e. similarity in purpose as intended by the EU NPs) or more generally (e.g. in the context of protecting specific vulnerable groups/children, nutrition and diet improvement strategies, obesity control strategies/plans, taxation (e.g. sugar/fat taxes) etc.). Furthermore, the focus has been on initiatives/schemes covering nutrients that were targeted by the EU-NPs as envisaged in the Claims Regulation (salt/sodium, fat/saturated fat and sugars).

A majority of all groups of consulted parties (*Member States, food business operators, consumer organisations and NGOs*) consider that the compulsory application of the nutrition declaration on all foods ensures that accurate and reliable information is provided to consumers regarding nutritional composition; facilitates consumers' healthier food choices, in terms of choosing between products with claims and products without claims; and, drives reformulation. However, despite an overall positive feedback, *consumer organisations and NGOs* consider these (consumer) objectives to have been more (partially) fulfilled than *industry stakeholders*. In particular, *consumer organisations* (as well as several Member States) pointed out that there is evidence[23] that the back of pack nutrition declaration is less read and less well understood/interpreted by consumers when compared to front of pack (nutrition) labelling, and that nutrition and health claims create a health 'halo' effect that distorts consumer perception of the healthiness of foods / makes them overlook the information provided in the nutrition declaration.

- **Extent to which schemes/initiatives contribute to EU-NP objectives**

Stakeholders and Member States were consulted on the extent to which the identified schemes/initiatives set limits to the FSS content in foods bearing claims and the extent to which they drive reformulation of the FSS content in foods bearing claims. Overall, there were differences between consulted parties:

- The only cases in which all consulted parties (*Member States, food business operators, consumer organisations and NGOs*) agreed that conditions for the use of claims in relation to the FSS content currently exist, is the case of schemes that constitute a FoP nutrition claim themselves[24]. For these schemes, the nutrient criteria to apply the nutrition claim (i.e. the logo/label conferred by the scheme) are not used in any way (positive or negative) to determine whether foods should bear other nutrition or health claims.
- *Industry stakeholders* indicated some other private initiatives that have an impact: e.g. guidance on nutrition and health claims (private initiative of the SE food industry); and, some private company based nutrient-profile schemes applied across the company's product range to determine which products should bear claims.
- Other categories of identified schemes/initiatives[25] were, on balance, not considered to have an impact relevant to the EU-NPs objectives:
  - From the perspective of *Member States*, neither the national (regulatory) nor the private schemes/initiatives already in place meet the objectives of EU-NPs[26]. National (regulatory) schemes/initiatives are largely expected to be continued if EU-NPs were to be set, since the rationale for their introduction is not related to the absence of EU-NPs.
  - The view that the identified schemes/initiatives do not meet the objectives was also expressed by *consumer organisations* and *public health NGOs*.

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23 *E.g.* by referring to the CLYMBOL project.

24 Under Article 23 of the Claims Regulation. E.g. The Nordic Keyhole logo (SE, DK; also, NO and IS); and, the Choices logo (NL, but *withdrawn in October 2017*; similar schemes in CZ and PL)

25 Such as FoP (nutrition) labelling, restrictions to advertising to children, reformulation etc.

26 Over two-thirds of Member States (16 to 19 out of 26 Member states) replied 'do not know' to the various aspects of potential contribution of the schemes, as explored in the survey, pointing to the lack of evidence on the actual impact more generally of the schemes; in case study interviews, consulted *Member States* indicated that, for most schemes, their contribution to meeting EU-NP objectives is expected to be relatively limited, given the voluntary character and partial relevance in the scope of the schemes.

- The *industry* was rather divided: for just under a third of organisations representing food business operators, the identified schemes/initiatives impact the placing on the market of products bearing claims in terms of the FSS content contained in these products; while one third of organisations did not identify any impacts and a third did not know.

- The difficulties in comparing the EU-NPs with other schemes/initiatives to identify advantages and disadvantages for meeting the objectives of the EU-NP were highlighted extensively throughout the consultation by all consulted parties[27]. Bearing this caveat in mind, *Member States* identified the key disadvantages of relying on schemes/initiatives rather than EU-NPs: their voluntary application; partial (or no) relevance in terms of EU-NP objectives; and lack of verifiable research on their impact. This view was partly shared by some *industry stakeholders*. On the other hand, voluntary application was also the main advantage identified by most *industry stakeholders*; coupled with the observation that schemes/initiatives are often developed in consultation with, or even by, the industry; therefore, they are more likely to take into account the industry's needs and constraints and do not create barriers to trade or additional costs and burdens for operators.

Problems identified from the absence of EU-NPs

Member States and stakeholders were asked about any problems experienced in the absence of EU-NPs, despite the contribution of the nutrition declaration and the identified schemes/initiatives. Generally, there were differences between consulted parties: *consumer organisations, NGOs* and *Member States* tend to identify considerably more problems, particularly in terms of meeting consumer objectives, than *industry stakeholders*:

- 18 out of 26 *Member States* identified problems, in particular:
  - 13 of the 18 Member States identifying problems have already implemented national regulatory schemes/initiatives having nutritional objectives and five also reported private schemes/ initiatives in place in their country;
  - Problems are particularly identified in the following product categories: fortified products (addition of minerals and vitamins in foods, irrespective of their macro-nutrient content; e.g. foods with added sugar), composite foods (constituted of/combining a nutritious and a non-nutritious food component), and non-essential foods (typically, products rich in FSS nutrients);
  - According to two thirds of Member States, the current situation brings considerable legal uncertainty and is at variance with national guidelines and priorities. The existing legal provisions are not considered sufficient to ensure enforcement, when authorities have been faced with claims on foods they consider as high-FSS content based on their national dietary guidelines. Authorities indicated that it is almost impossible to enforce the general principles of the claims when the claim is authorised[28]; while it is also difficult to reject the use of health claims on foods with a high FSS content on the basis of

[27] This explains the large number of '*do not know'* responses in the survey. E.g. 10 to 14 (out of 26) Member States did not know whether relying on schemes/initiatives rather than EU-NPs has advantages/benefits, and 10 to 13 Member States whether it has disadvantages/shortcomings. Similarly, about one quarter of stakeholders did not know whether it has advantages/benefits, and about one third whether it has disadvantages/shortcomings.

[28] *See* Article 3 of the Claims Regulation: "…the use of nutrition and health claims shall not (a) be false, ambiguous or misleading"

the Regulation on Food Information to Consumers[29], as a lengthy legal dispute is probable in these cases.

- Nearly all *consumer organisations* and *NGOs* indicated problems. *Consumer organisations* highlighted examples of commonly used nutrition claims that could be considered misleading as to the overall nutrient status of the food, including the claims '*light'*, *'low-fat'*, *'no added sugar'*, and *'fat-free'*[30]. They also noted that a product bearing these claims can also be heavy on calories or in another nutrient (e.g. low-fat foods and drinks can have high content in added sugar and can be high in calories). Fortified foods and foods marketed to children are two product sectors in which the presence of foods high in FSS nutrients was commonly highlighted by consumer organisations.
- According to two thirds of *industry stakeholders*, there are no problems stemming from the non-setting of EU-NPs:
  - While the absence of EU-NPs did not hinder the achievement of most business objectives, it was not considered to ensure legal certainty, did not encourage reformulation, and did not support the development of new business opportunities with new/reformulated products and new/innovative claims. However, other factors were identified as also impeding the achievement of these objectives[31].
  - While the potential 'discrepancy' between the message conveyed by the claim (as understood by consumers) and the overall nutritional status of the product was acknowledged for certain sectors, this was attributed to the nature of the products and the positive contribution of these products to a balanced diet was also highlighted (e.g. role of fat in dairy products).
  - Despite the overall positive feedback, nearly one fifth of *industry* stakeholders indicated some problems for consumers; most of these respondents identified private schemes/initiatives having nutritional objectives in place in their country.

Relevance, coherence and added value of setting EU-NPs

There were differences between consulted parties on whether the setting of EU-NPs continues to be relevant, necessary and feasible, with the views being broadly correlated to the extent to which problems were identified by each stakeholder group. *Consumer organisations, NGOs* and *Member States* tend to consider the setting of EU-NPs more relevant and necessary, particularly in terms of meeting consumer-related objectives of the Claims Regulation, compared to *industry stakeholders*.

- 22 out of 26 Member States indicated that EU-NPs are relevant and necessary; according to 13 of these 22 Member States considered that they are feasible as well, while the remaining 9 Member States did not know.
- For two thirds of *consumer organisations/NGOs* EU-NPs are relevant and necessary.

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[29] *See Article 7.1. of Regulation on Food Information to Consumers,* stipulating that '*Food information shall not be misleading'*).

[30] Light: food must contain 30% less fat or calories than the standard version. Low fat: food must contain less than 3g of fat per 100g for food or 1.5g of fat per 100ml for drinks. No added sugar: must have no sugar or sweetener added. Fat free: must contain less than 0.5g fat per 100g.

[31] E.g. for the ability to reformulate, the existence of regulatory and/or technical constraints; for innovation, broader challenges surrounding the development of health claims.

- On the other hand, almost three quarters of *industry stakeholders* did not consider EU-NPs to be relevant or necessary. However, at the level of *individual operators*, the industry is divided on this:
    - Most food industry stakeholders[32] argue that the EU-NPs are no longer necessary or relevant, given the evolution of the market and regulatory developments. Their main arguments are that: foods bearing health claims do not constitute a large market segment and are not used widely by consumers; considerable efforts have been made in some sectors or by some operators to reformulate, driven by market trends, food labelling and other initiatives; the regulatory framework has changed since the adoption of the Claims Regulation, particularly with the complete entry into force of the nutrition declaration; and, the regulatory scrutiny provided by the conditions of use that are specifically tailored to certain nutrition and health claims.
    - For certain operators within the industry – largely irrespective of product sector or size of business - the setting of EU-NPs continues to be relevant and necessary. These operators have experienced the gaps and adverse impacts for business, as outlined above, i.e.: the lack of incentive to reformulate or, for those that have reformulated, lack of a level-playing field with competing operators/products that have not reformulated; and/or, legal uncertainty to innovate.

The consulted stakeholders have ***different opinions*** on the impact of setting EU-NPs, in terms of coherence with the initiatives of the EU Platform on Diet, Physical Activity and Health and with the broader regulatory framework, as well as in terms of EU added value:

- According to *Member States* and *consumer organisations/NGOs*, the setting of EU-NPs would improve coherence and bring the advantages of a harmonised approach; for them, the setting of EU-NPs constitutes a key underlying principle to ensure the correct and consistent application of the Claims Regulation and to encourage product reformulation.
- *Industry stakeholders* are divided and uncertain on this[33]. They have indicated that ultimately the impacts of EU-NPs will depend on their actual design, i.e. the nutrients/product categories covered and the thresholds chosen. It is noted that in some cases, opposition from part of the industry/in some sectors to setting EU-NPs does not reflect concerns over the actual/potential impact of their use for the purposes of the Claims Regulation[34], but perceived potential ripple effects if they are used in other contexts and/or to 'stigmatise' certain foods. This concern was quite widespread amongst the consulted industry sectors, even where the use of claims is relatively limited, e.g., for traditional products and specialities.

B. Health claims made on plants and their preparations

Current situation

Implementation of Claims Regulation on plants and their preparations used in foods

There is a ***general consensus among all consulted Member States*** that there are no significant limitations in the use of health claims included in the on-hold list originating from national

[32] Mostly meat, dairy and cheese sectors.

[33] It should be noted that half of the responding stakeholders did not know whether the establishment of EU-NPs would improve or deteriorate coherence with other EU initiatives.

[34] Notably Article 4 of the Claims Regulation.

provisions. All respondents to the Member States' survey indicated that health claims made on plants and their preparations which were submitted in the context of the establishment of the list of permitted health claims[35], can still be used under the transitional measures foreseen in the Claims Regulation[36]. At the same time, it was reported that to a certain extent there is a non-homogenous application of these transitional measures; though findings indicated that such different application at national level is not aimed at limiting the use of health claims on foods containing plant substances.

Before the introduction of the Claims Regulation, the majority of Member States had no specific national legislation on health claims made on plants and their preparations used in foods in place (80.8%, i.e. 21 MS)[37].

Impact of the absence of a final decision at EU level on health claims on plants and their preparations

The impacts of the current situation on the use of health claims on plants and their preparations was explored in terms of deviation from the original objectives of the Claims Regulation for each main group of stakeholders. Consequently, there are ***differences between consulted parties*** both in terms of the issues examined/identified and in terms of views.

- *Impacts on consumers and public health*

The majority of consulted parties indicated that in the absence of full application of the Claims Regulation regarding plant substances used in foods, and with the current use of the on-hold list of permitted claims, the Claims Regulation only partly achieved its objective of ensuring a high level of consumer protection. A large majority (83.3%[38]) of *consumer organisations/NGOs* pointed out that the current use of the on-hold list of health claims is rather unsatisfactory from the standpoint of consumer protection. In their views, consumers who purchase these products are generally unaware that the claimed effects have not been scientifically assessed and that the health claims have not been risk-managed. The large majority of consulted parties indicated that in the current situation, which allows the continued use of unsubstantiated health claims, consumers cannot make their choices in a fully informed manner. The majority of *Member States* also deemed that there are disadvantages for consumers caused by the current absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods and by the use of the on-hold list of permitted claims. A minority of Member States indicated that the effectiveness of controlling activities is hampered by the non-implementation of the Claims Regulation, and that this can affect consumers and public health.

- *Impacts on food business operators*

The majority of *food business operators* deemed that the establishment of the on-hold list of claims avoided serious negative implications for the competitiveness of food business operators; the on-hold list was generally judged favourably in comparison with the full implementation. By contrast, the vast majority (5 out of 6) of the *pharmaceutical sector consultees* indicated that the implementation of the on-hold list of health claims had a strong negative impact on their sector. Respondents in the

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35 Precisely, Article 13(2) of the Claims Regulation.

36 Namely, Article 28(5) of the Claims Regulation.

37 Five Member States (Austria, Croatia, Germany, Greece and Italy) had a national legislation in place that limited to some extent the use of health claims on food products also before the implementation of the Claims Regulation.

38 2 out of 6 (33.3%) respondents indicated "*partially unsatisfactory*" and 3 out of 6 (50%) indicated "*unsatisfactory*".

pharmaceutical sector identified as "negative" the impacts of the absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods on competitiveness, innovation, investments and costs for the operators of their sector ("*fair trading practices*").

There is an overall industry consensus that the lack of a final decision creates legal uncertainty; the uncertainty on the future of the on-hold list is generally seen as a threat to the competitiveness of operators. Limits to the innovation of products caused by the current situation in the implementation of the Claims Regulation have also been reported by the majority of the industry consultees, and the lack of future legal certainty is deemed to hinder investments.

The extent to which companies producing foods containing plant substances currently use health claims on their products varies according to the type of products. Nevertheless there is an overall consensus that food supplements containing plants and plant preparations are marketed with claims in most cases.

- *Impact on Member States*

The majority of Member States indicated that the absence of a final decision at EU level on the authorisation of health claims on plants and their preparations used in foods has negatively affected their activities. In particular, several Member States raised concerns about: difficulties in the enforcement of legislation and in control activities of products placed on the market; increased administrative burden caused by control activities on the use of claims included in the on-hold list; and difficulties in dealing with the numerous questions received from FBOs on issues concerning the use of health claims on food products containing plants and their preparations.

Relevance, coherence and added value at EU level

Relevance, coherence and added value of the legislative framework introduced by the Claims Regulation and of its current situation for plants and their preparations used in foods (on-hold list of claims)

There is a general consensus among both *stakeholders* and *Member States* regarding the relevance of the three original needs addressed by the Regulation[39]. However, a diverging position between *business operators in the food* and *pharmaceutical sectors* emerged on the existence of new needs that the Claims Regulation currently does not address. According to the majority of *food sector stakeholders*, new needs have actually emerged while *pharmaceutical sector stakeholders* believed that no new needs have emerged.

As for the coherence of the Claims Regulation with the legislative framework applicable to the use of plants and plant preparations in foods, there is a general consensus that the overall coherence would improve by harmonising some provisions in the general legislative framework. However, the extent of such improvements would largely depend on the width of the scope of harmonised provisions, as well as on the modalities of harmonisation. Member States identified some inconsistencies between the Claims Regulation and other EU provisions defining the overall regulatory framework for the use

[39] E.g. "ensuring a high level of consumer protection" was considered "fully relevant" by 83.0% of respondents to the stakeholder survey. "Giving the consumer the necessary information to make choices in full knowledge of the facts" was considered "fully relevant" by 88.7% of respondents; and "creating equal conditions of competition for the food industry" was deemed "fully relevant" by 88.7% of respondents.

of plant substances in foods, such as the Novel Food Regulation and the Food Supplements Directive.

In terms of coherence of the current legislative framework applicable to plants and their preparations used in foods with the legislation on medicines for human use dealing with traditional herbal medicinal products (THMPs), diverging positions emerged from the consultation:

- Several consulted parties, mainly representing *food sector interests*, but also including *some Member States*, identified a number of inconsistencies between the legislation on medicines for human use dealing with traditional herbal medicinal products (THMPs) and the Claims Regulation. The key conflicting aspect was identified in the consideration of tradition of use for medicinal products which should treat or prevent a disease, whereas the same tradition of use cannot be used for products (e.g. food supplements) with beneficial properties in relation to a normal health status.
- By contrast, *pharmaceutical sector stakeholders* and a *number of Member States* did not identify any inconsistencies between the THMPs Directive and the Claims Regulation. The concept of traditional use of Directive 2001/83/EC refers explicitly and exclusively to medicinal products and cannot be used in the food sector.

As for the added value of a decision at EU level on the authorisation or rejection of health claims on plants and their preparations used in foods, there was a general consensus among the consulted parties that dealing with health claims at EU level resulted in an added value versus a Member States' level approach, in particular in terms of avoided additional costs for establishing national systems to govern the use of claims.

Full application of Regulation (EC) No 1924/2006 (costs and impacts)

Consulted parties - in particular those representing the food sector and the pharmaceutical sector - showed quite diverging views on the potential impacts of a full implementation of the Claims Regulation for plants and their preparations used in foods. The full implementation of Claims Regulation was explored in terms of effects on various stakeholders: consumers; food operators and pharmaceutical operators.

- Consumers. According to *Member States* and *consumer organisations/NGOs*, the full implementation of the Claims Regulation would mainly have a positive impact in terms of consumers' protection, availability of adequate information on products and of safety of products placed on the market. The majority of the *Member States* and *consumer organisations/NGOs* also deemed that public health would be positively impacted by the full implementation of the Claims Regulation. On the other hand, *food business operators* indicated some negative consequences stemming from the presence on the market of products without claims.
- Business operators. According to *food business operators*, in case of full implementation of Claims Regulation the impacts on the main activities of companies would mostly be negative. In particular, the impacts on the overall marketing practices would be strongly negative, as would be the impacts on the competitive position on the market.
- By contrast, pharmaceutical sector consultees mainly expected positive impacts on their activities. In particular, the competitive position on the market would experience a strong positive impact; also the innovation – launching of new products would experience a strong positive impact, and export opportunities may increase. In general, *Member States* agreed that

the full implementation of the Claims Regulation would mainly have negative impacts on food operators and positive impacts on pharmaceutical operators.

As for the costs for the application, most food *supplements sector consultees* estimated the costs for preparing and submitting a dossier for a new health claim on plants and their preparations in the case of full implementation of the Claims Regulation as falling in a range between €1 and €1.3 million: their estimates include the cost of 2 or 3 clinical trials (each one costing around €0.5 million). The costs of clinical trials emerged as the main cost item for preparing a dossier.

Inclusion of traditional use as evidence for the scientific substantiation of health claims made on foods (costs and impacts)

Consulted parties expressed ***conflicting and rather polarised opinions*** about the impacts on their main activities stemming from the inclusion of traditional use as evidence for the scientific substantiation of health claims. The inclusion of traditional use was also explored in terms of effects on various stakeholders: consumers; food operators and pharmaceutical operators.

- Consumers. Diverse positions emerged with respect to the issues of (1) the safety of products on the market and (2) provision of adequate information to consumers. Regarding the first aspect, according to several *food business operators* the safety of food products on the EU market would not be modified by the inclusion of traditional use, as all food products need to be safe in order to be lawfully marketed in the EU and given that the Claims Regulation only covers information-related aspects of consumer protection. The positions of *Member States* on the impacts on consumers of inclusion of traditional use as evidence for substantiating health claims were found to be quite varied[40]. As for the *stakeholders representing non-business interests* (in particular *consumer organisations*) several stakeholders indicated that the inclusion of traditional use in the assessment of health claims would potentially be misleading for consumers.
- Business operators. *FBO stakeholders* were mainly in favour of the inclusion of traditional use for assessing health claims on plants and plant preparations. According to *food sector stakeholders* the inclusion of traditional use would mainly have (strong or moderate) positive impacts[41] on their main activities of the inclusion of traditional use as evidence for substantiating health claims.
- By contrast, pharmaceutical sector *stakeholders* expressed a different, and rather the opposite position: according to the sector's views, all the relevant aspects of their activities would be more or less negatively affected, with strong negative impacts occurring in most of the cases.

As for the costs of preparing and submitting a scientific dossier for a new health claim with the possibility to include traditional use as evidence for the application, *several food sector stakeholders* estimated these costs as falling within a range from €30,000 to €60,000[42]. *Food sector stakeholders* agreed on the fact that clinical trials, which emerged as the most relevant cost item in case of full

[40] According to the Member States' survey results, consumers would be positively impacted for 42.3% of respondents and negatively impacted for 46.1% of respondents.

[41] E.g. 63.9% of survey respondents deemed that the competitive position on the market would experience a strong positive impact. Marketing practices would experience a strong positive impact for 61.1% of respondents and marketing costs would benefit from a strong positive impact for 58.3% of respondents.

[42] In no cases were costs higher than €100,000 indicated.

implementation of the Claims Regulation, would be no longer needed with the inclusion of traditional use as evidence, thus considerably reducing the overall cost of submitting a dossier.

C. The general regulatory framework for the use of plants and their preparations in foods

Current situation

Mapping of national (Member States') legislation on the use of plants and their preparations in foods

The ***majority of the 26 Member States*** which took part in the survey indicated that some form of national legislation on the use of plants and their preparations in foods has been adopted in their countries (19 Member States). Most of these Member States (15 of the 19) implemented a procedure of notification for the marketing of food products containing plant substances. The notification procedure can be differently implemented, but it is generally applied to the broader category of food supplements. Nine Member States have developed positive lists of plant substances[43]. 11 Member States have developed negative lists of plant substances[44].

According to *Member States*, classification issues are generally dealt with on a case-by-case basis (i.e. for each product placed on the market) by Member States. The most frequent case of controversy is the classification of products as "medicines" or as "food supplements". In partial contrast with the above, *consultees more broadly* indicated that such classification is often performed in the context of varying national traditions and practices (rather than on a case-by-case basis), which result in different national interpretation of the harmonised definitions of "food" and "medicine" provided by EU legislation.

The absence of action at EU level was found to result in different outcomes: some Member States preferred to react by developing national legislation, while other Member States preferred to wait for decisions to be taken at EU level. 63.2% of surveyed *Member States* indicated that the absence of an EU harmonised legislation on the use of plants and their preparations has been relevant for developing a national legislation. The non-implementation of the Claims Regulation was indicated only by two Member States as a reason behind the development of national legislation. Finally, the majority of surveyed Member States (15 out of 26) saw no need to further expand the scope of national legislation on the use of plants and their preparations in foods.

Impacts of the general regulatory framework

The impacts of the current absence of a harmonised framework for the use of plants and their preparations in foods were explored for each main group of stakeholders.

- *Impacts on consumers*

Consulted parties expressed different views with regard to the effects of the general regulatory framework in ensuring the presence of safe products on the market. Several stakeholders

[43] For six Member States these positive lists are legally binding and five of these lists have been notified to the European Commission. Both tradition of use and scientific evidence are largely used as elements for compiling positive lists of substances.

[44] Ten of these lists are based on scientific evidence. The notion of traditional use was taken into account for developing four of these lists. Eight negative lists are notified by *Member States* to the European Commission.

representing the interests of the *food sector* indicated that there are currently no serious concerns related to the safety of products on the EU market. These stakeholders were generally satisfied or partially satisfied with the current situation and believe that the protection of consumers is generally ensured with the intrinsic safety of products ensured under current EU and national legislation. At the same time, business operators in the *pharmaceutical sector* deemed that the objective of ensuring a high level of consumer protection is not achieved in the current situation[45]. Half of Member States also deemed that the achievement of the objective of ensuring a high level of consumer protection is unsatisfactory in the current general regulatory framework; and half of survey respondents representing *consumers', citizens' and public health groups* believed that the objective of ensuring consumer protection is not achieved under the current framework. According to these various stakeholders, different practices among Member States in drawing the border between food supplements and medicines (together with different interpretation and management of health claims) have resulted in an unsatisfactory level of consumer protection.

With regards to the online sales of food products containing plants and their preparations, there was a consensus among consulted parties that online sales of these products are rapidly increasing, sharing concerns as regards the lack of an effective monitoring system in place to prevent EU consumers from purchasing illegal and potentially unsafe products through this marketing channel.

- *Impacts on food business operators*

There was general consensus among *food business operators* that the absence of a harmonised regulation on the use of plants and their preparations in foods at EU level has mainly negative impacts on their activities[46]. In particular, food business operators expressed dissatisfaction about the achievement of the objectives of ensuring the smooth functioning of the internal market and of ensuring fair trading practices in trade of products containing plants in the current situation. The presence of different national rules and different interpretation of EU provisions at Member State level was considered to negatively impact the smooth functioning of the single market. Food business operators indicated that access to specific national markets is often denied, and that operators face difficulties related to the practical application of the Mutual Recognition principle. Consulted parties were basically aligned in their understanding of the provisions which have a negative impact on their sectors: "criteria for classification of products as foods or as medicines" were considered as having moderate or strong negative impacts for business operators in a significant number of cases.

There was also ***broad consensus*** among consulted parties that legal certainty and fair competition among operators of different Member States are not ensured in the current general regulatory framework. Industry stakeholders also deemed that innovation is negatively affected by the current general regulatory framework. Companies are reluctant to invest in innovation when it is not possible to market the same product in multiple Member States simultaneously.

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[45] 66.7% of survey respondents in the pharma sector deemed the situation "unsatisfactory" in terms of meeting the objective of placing safe food on the market.

[46] The impacts of the absence of a harmonised framework on business operators were investigated with respect to the following key aspects: i) the smooth functioning of the internal market (including the mutual recognition principle and its exemptions); ii) legal certainty and fair competition and; iii) the promotion and protection of innovation.

Finally, a majority of industry stakeholders reported increased costs caused by the lack of a harmonised framework[47].

- *Impact on Member State Competent Authorities*

There was general consensus among *Member States that* they are mainly negatively affected by the current general regulatory framework on the use of plants and their preparations in foods. In particular, it emerged that Member States are experiencing an increased workload for the enforcement of provisions in the current lack of legal certainty. The case-by-case decision on the classification of products was also found to determine a greater administrative burden and increased costs, and to make the enforcement of legislation difficult.

Relevance, coherence and added value at EU level

Relevance of the current legislative framework

The relevance of the current legislative framework is a key topic addressed by the European Commission in the 2008 Report on the use of substances other than vitamins and minerals in food supplements. In 2008 the EC concluded that there was no need to develop specific rules for substances other than vitamins or minerals for use in foodstuffs (including plants and their preparations used in foods).

There was consensus among the majority of the consulted parties (*Member States, consumers' organisations and food business operators*), other than the pharmaceutical sector, that the conclusions of the European Commission's Report of 2008 are not valid anymore, implying that there is the need to lay down specific rules for the use of plants and their preparations in foods at EU level[48]. By contrast, an ample majority of *pharmaceutical sector stakeholders* (83.3% of those surveyed) deemed that the conclusions of the 2008 European Commission's Report still correspond to the current needs and trends.

Food sector stakeholders indicated that the main reason behind the need for specific harmonised rules at EU level are the barriers to free circulation of goods that currently exist in the single market. *Member States are* almost all in favour of developing specific rules at EU level linked the need to lay down specific rules for the use of plants and their preparations in foods with i) the need to improve the free circulation of foods containing plants and their preparations, ii) the need to find a solution to the current differences in the classification of products, and iii) the need to enhance the efficacy of controlling activities. *Consumers' organisations* indicated that a harmonised legal framework at EU level could homogenise the different approaches applied at Member State level, increasing the degree of protection and the quality of the information granted to consumers of food products containing plants and their preparations.

Need for action at EU level

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47 FBOs were unable to provide systematic cost data: however, companies reported to bear (1) the costs of legal consultancy services, needed for understanding the legal requirements for selling a product in a certain Member State; and (2) the cost of compliance with different requirements, which mainly consists in the development of multiple products with different labels and recipes, each one in compliance with the legislation in force in a certain national market.

48 E.g. 23 out of 26 surveyed *Member States* and 28 out of 37 respondents representing food business operators (75.7%) expressed criticism about the current validity of the conclusions of the 2008 EC Report.

- **Preferences in terms of provisions on the use of plants and plant preparations in foods to be harmonised.**

Consulted parties were generally in favour of increasing the harmonisation at EU level of the key provisions on foods containing plants and their preparations.

- A majority of *Member States* indicated that the following provisions should be somehow harmonised at EU level: "safety requirements for production and marketing of products", "provisions on information to consumers" (22 of the 26 Member States which responded in both cases) and "procedures for assessing the classification of products as foods or as medicines" (20 of 26 Member States). 19 of the 26 Member States indicated that there is also a need for regulating "positive and negative lists" at EU level. As the sole exception, a majority of Member States indicated that "authorisation procedures" do not need to be regulated at EU level".
- A majority of *food sector stakeholders* showed a strong preference for the development of EU-level positive lists of plant substances (61.1%) and for the development of negative lists of these substances (55.6%). The procedure for assessing the classification of products as foods or as medicines should be regulated at EU level for the vast majority of food sector stakeholders; and the same applies to safety requirements and information to consumers.
- *Pharmaceutical sector stakeholders* were unified in opposition to the development of positive lists of substances at EU level. In contrast, they were also unanimously in favour of the development of negative lists of substances at EU level. With respect to the classification of products, stakeholders considered the current provisions at EU level to be sufficient, but deemed that they should be completely applied.

- **Merits and disadvantages in terms of EU added value of harmonising at EU level the use of plants and their preparations in foods.**

The merits and disadvantages associated with the harmonisation of the general regulatory framework were investigated for the three main categories of involved stakeholders: consumers, business operators (in the food sector and in the pharmaceutical sector) and competent authorities.

- Consumers and public health. *Consumer associations* indicated that a harmonised framework would offer strong advantages in terms of consumer protection and information to consumers. As for potential disadvantages of harmonisation from a consumers' perspective, they indicated that consumers might face different possible limitations of their choices or, on the opposite, access to a wider range of products, depending on the type of harmonised provisions and on the related implementation modalities.
- Food business operators. *FBOs* emerged as being generally favourable to the development of EU harmonised provisions on plants and their preparations used in foods because this would offer advantages in terms of promotion of innovation, fair competition, smoother functioning of the internal market, reduced costs, and trade with third countries. Although the majority of the consulted parties in the food sector emerged as being in favour of a certain degree of harmonisation, some potential disadvantages stemming from harmonisation were also identified. Such disadvantages would be linked with the type of harmonisation which would be achieved. In particular, the consulted parties indicated that harmonised provisions should be respectful of national specificities in order to avoid disadvantages.

- Competent authorities. Most *Member States* agreed that harmonised provisions aimed at promoting more homogeneous practices at EU level in the use of plant substances in food products would contribute to improving the effectiveness of the activities aimed at combating online sales of non-compliant products manufactured in third countries. In addition, harmonisation would reduce administrative burden and obstacles to an effective enforcement of legislation by Member States in the food sector.

3. SMEs consultation

Background

Through the Enterprise Europe Network[49] the Commission reached out to SMEs and received a very good response rate to a survey dealing with such a specialist subject. SMEs constitute the backbone of the EU food and drinks sector, as well as being very important in the plant-based medicines sector. The replies gathered through the consultation helped to understand the experience of SMEs with the legal obligations of the Claims Regulation and the compliance burden that these entail. The replies gathered in this consultation also informed about the SMEs' views on the difficulties faced in the context of the current implementation of the Regulation.

Results of the SME Panel are presented below for each of the two focus themes of this evaluation, as respondents were different for each theme.

A. Nutrient profiles

A.1 Respondents

Of the 400 replies received to this theme, a quarter do not make any claims on their products. The survey was addressed only to those that make claims (301 enterprises). Of these, nearly 90% manufacture and/or trade in food products that make nutrition claims in text, while 31% and 45% respectively manufacture and/or trade in products that make nutrition claims in pictures/images and in products that make health claims.

Responding enterprises represent a good balance of the range of identified food sectors, with most of them involved in more than one product sector.

This consultation received responses from enterprises established in 18 Member States. Most enterprises that responded to the consultation are established in Romania and Poland (14.6% and 14.0% respectively), followed by France (10.3%), Denmark and Italy (10.0% each), and Greece (6.3%). Respondents from other Member States (Spain, Bulgaria, Sweden, Germany, Finland, Lithuania, UK, Portugal, Belgium, Hungary, Czech Republic and Slovenia) accounted for less than 5% in each case.

Nearly one third (30.2%) of respondents are micro-enterprises (1-9 employees) [1], followed by medium-size (29.6%), small (24.6%) and larger enterprises (11.6%). Most enterprises trade both in the domestic (national) and the EU/EEA market: almost all respondents (96.7%) trade in the national market, about half (50.8%) trade in the EU/EEA market, and only a third (32.9%) in markets outside the EU/EEA.

[49] Defined in terms of the number of employees only: http://een.ec.europa.eu/.

A.2 Current situation

Food products that make nutrition/health claims account for three quarters of their business, in terms of total sales value, for just over a third of responding enterprises (35.3%). On the other hand, for just over a quarter of respondents (25.7%), food products with nutrition/health claims account for less than 10% of their total sales value.

The majority of respondents indicated that they do not currently sell any food products that make nutrition/health claims and could potentially be considered high in fat, saturated fat, sugar or salt ('FSS' nutrients): enterprises mostly indicated that their products bearing nutritional/health claims are not high in saturated fat (68.4% of respondents), salt (65.4%), fat or sugar (60.8% each). A relatively low percentage of enterprises indicated that their products bearing nutritional/health claims are potentially high in fat (25.2%), sugar (24.3%), salt (19.6%) and saturated fat (15.6%); nonetheless, these products represent less than 10% of the sales value of all products with claims for nearly half (45%) of respondents (and over 50% of the sales value for 18% of respondents).

In terms of reformulation efforts since 2007, less than a third of respondents have reduced nutrient content in food products making nutrition/health claims, with most (34.2% of respondents) focused on reducing sugar, and least (26.6%) on reducing saturated fat, while just under 30% of respondents have reduced fat and salt.

For over two thirds (68.9%) of those that have changed the FSS nutrient content in their food products making nutrition/health claims, the main driver has been market trends, including consumer demand for 'healthier' products and competitors' offer of 'healthier' products. The second most commonly cited driver (just over half of respondents) was the mandatory nutrition declaration on the back of the product's pack.

A.3 Need for action

When placing their food products making nutrition/health claims on the national market, nearly three quarters (73.8%) of enterprises do not currently face any problems due to rules developed by national authorities or by industry initiatives on the level of FSS nutrients in these products; only about 10% of respondents indicate some problems while the rest do not know. Only 6% of respondents indicate some problems when placing their products on other markets in the EU. As noted above, almost all enterprises trade in the national market and nearly half in the EU/EEA market, while a relatively low percentage of respondents indicate that their products bearing nutritional/health claims are high in FSS nutrients.

Nonetheless, most respondents think that some limits in FSS nutrient content need to be set for food products making nutrition/health claims across the EU (62.8%) and for specific product categories (52.2%), although a large number of respondents do not know (16.9% and 29.2% respectively). This view tends to be shared mostly amongst enterprises that, since 2007, have reformulated i.e. reduced FSS nutrient content in their products making claims.

Therefore, a relatively high percentage of enterprises indicate that they would probably not need to take any action to comply with potential limits on FSS nutrient content in food products bearing nutrition/health claims. Furthermore, according to most respondents, EU-level limits on FSS nutrient content in foods making nutrition/health claims would rather improve or have no impact on their business. A small percentage of enterprises expect they would need to take some action, and that various aspects of their business would worsen. However, a large number of respondents do not know what the impacts would be.

B. Plants and their preparations used in food

B.1 Respondents

The survey on this theme was addressed only to enterprises that operate in the food and/or medicinal sector containing plants and their preparations (269 of the 286 that responded to this theme). Three quarters of these are manufacturers and/or traders of food products containing plant substances, while the remaining quarter are manufacturers and/or traders either of both foods and medicines containing plant substances (20%) or only of medicinal products containing plant substances (5%).

Several respondents are involved in more than one product sector: in particular, 60% of respondents operate in the product sector of food supplements; 40% in general foods and drinks; 19% in sport nutrition; and, 19% in pharmaceutical products.

Enterprises from 22 Member States contributed to this consultation. Most enterprises are established in France (21.2%), followed by and Denmark (12.6%), Romania (7.4%), Finland (7.1%), Italy and the Netherlands (6.7% each). Respondents from other Member States (Poland, UK, Germany, Bulgaria, Spain, Czech Rep. Belgium, Lithuania, Sweden, Portugal, Hungary, Austria, Ireland, Luxemburg, Greece and Slovakia) accounted for less than 6% in each case.

More than one third of respondents are micro (1-9 employees) and small enterprises (10-49 employees) (31.6% and 37.9%, respectively); 20.4% are medium size (50-249 employees) and 5.9% are large enterprises (>250 employees) [1].

Nearly all (97%) of the respondents trade their products on the national market, three quarters (70.6%) on the EU/EEA markets and nearly half (46.1%) outside the EU/EEA markets.

B.2 General regulatory framework

A majority of respondents (68.4%) is affected by the absence of specific harmonised rules at EU level on the use of plant substances in foods. Negative consequences were reported by these respondents to be: the increase in production costs (50.0% of respondents); the increase in marketing costs (74.1%); and, negative impacts on innovation potential (47.0%), on trading opportunities (41.6%), on overall competitive position on the market (41.1%), and on sales potential (43.8%).

Nearly three quarters (72.9%) of respondents face difficulties in trading their products containing plant substances with other EU countries. Of these, nearly half face difficulties due to: classification issues of products as food or as medicine (45.4%); the absence of specific EU rules such as positive lists of permitted plant substances (45.7%); and, existing national rules for placing a given substance on the market (49.1%).

Regarding the need for harmonisation of the general regulatory framework, enterprises tend to favour the harmonisation of specific provisions. In particular, over two thirds of respondents believe that a positive (70.6%) as well as a negative (71.7%) list of plant substances used in foods should be harmonised at EU level; and, nearly two thirds (63.6%) believe that specific additional information provided to consumers should be harmonised. Just over half (51.7%) of respondents believe that classification of products containing plants and their preparations as “foods” or “medicines” should be harmonised; while, nearly half (45.0%) believe that authorisation procedure before marketing food products containing plants and their preparations should be harmonised.

B.3 Health claims

For over a quarter (28.5%) of respondents from the food sector, the value of the sales of food products containing plant substances that make health claims is higher than 75% of their enterprises' total sales value. On the other hand, for a similar share of respondents (26.2%) the value of the sales of food products containing plant substances that make health claims is lower than 10% of their enterprises' total sales value.

Main reasons for marketing food products containing plant substances without claims are the following: regulatory obligations are not clear enough (47.8%); regulatory obligations are too complicated to comply with (40.3%) or it is too expensive to comply with them (35.8%); or health claims do not influence their consumers' purchasing habits (11.9%). It is noted that the majority of respondents (72.3%) have never submitted, or considered submitting, an application for the authorisation of a new health claim on food products. On the other hand, only 5.9% submitted an application.

Regarding the costs for including a new health claim on a plant substance in a food product, the main types of costs identified are the following: familiarising with the regulatory obligations, including training (58.2% of respondents); production of new data and/or processing of existing data (including clinical trials) (57.8%); other administrative tasks (55.1%); and, buying equipment and other supplies, including for modifying labels (39.1%).

In terms of the benefits of obtaining the authorisation for a new health claim on plant substances contained in food, most of respondents identified the attraction of new costumers and the possibility to present new products on the market as the main benefits (60.5% and 58.6%, respectively, of respondents).

In conclusion, costs of presenting a dossier for a new health claim are higher than benefits for one third of respondents (35.5%). On the other hand, only 16.0% of respondents consider that benefits of obtaining a claim are higher than costs of presenting a dossier, while 39.1% of respondents indicated they do not know.

If consideration of traditional use was included in the assessment of health claims, the majority (53.2%) of respondents would consider submitting an application; of the rest, 17.8% would not submit an application, while 29.0% do not know if they would. In this case, the overall costs for an enterprise applying for a new health claim on a plant substance in a food product would be lower than currently, according to a third of respondents, although a quarter of respondents do not know what the costs might be. Beyond the impact on costs, for the majority of respondents, key benefits of including traditional use in the assessment of health claims would be: the increase the innovation potential (according to 66.9% of respondents); the increase in export opportunities and improvement in their competitive position on the market (51.3% and 60.2% of respondents, respectively).

4. Online public consultation

The online public consultation (OPC) took place from 2 March 2017 to 1 June 2017 and was conducted using the EU Survey website. The questionnaire was available in 23 languages to allow all citizens across the European Union (EU) to contribute to this consultation, published here: http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20170302_nutrition-health-claims_en.htm.

The purpose of the consultation was to allow citizens to provide views and opinions on the evaluation of the Claims Regulation and how plant substances used in foods are regulated in the EU. In particular, it focussed on the following topics:

- how citizens, as potential consumers of foods marketed with nutrition or health claims, understand these claims and other nutrition information provided on the label of a food product;
- how they perceive the healthiness and benefits of foods making such claims; and,
- what specific elements drive their food choices.

A total of 2001 replies to the consultation were received from citizens in all Member States as well as from citizens from outside the Union. Just over 85% of respondents accepted to share their replies publicly, but around 55% preferred to do so anonymously.

Most respondents were 30 to 49 years old (61%), female (71%) and without children under the age of 18 (70%). Furthermore, 81% of respondents hold a university degree and 84% are currently employed (of which: full/part time employed: 65%; self-employed 19%).

By far the highest number of respondents came from Romania, accounting for 59% of the total sample. As illustrated below, beyond Romania, the highest response came from Germany (7%), the UK (7%) and Sweden (6%). Around 1% of responses were from outside the Union. The high response rate from Romania, significantly affected the replies to certain questions and, therefore, the results were processed depending on the magnitude of the difference in replies for the three groups (total responses; total responses excluding Romania; and Romania only) to allow for identifying any differences in the pattern of the findings.

The high response rate from Romanian citizens may reflect familiarity with nutrition/health claims, as well as with food products containing plant substances and could also contribute to explain the generally more positive attitudes of Romanian citizens toward such food products. In terms of familiarity with nutrition/health claims made on foods, almost all respondents are aware of the use of nutrition and health claims made on foods or food advertising. In particular, most of them indicated that they occasionally or frequently (67% of non-Romanian and 89% of Romanian citizens) purchase food products because they bear a nutrition/health claim on their label or in advertising. On the contrary, 30% of non-Romanian and only 10% of Romanian citizens indicated that they never/almost never purchase such food products. Similarly, Romanian respondents indicated they purchase food products containing plant substances more frequently than was the case amongst non-Romanian respondents.

A. Nutrient profiles

The key findings of the OPC in relation to the nutritional information currently available on food products are summarised as follows:

- ***Respondents tend to believe that nutrition and health claims provide reliable information, and, to a certain extent, facilitate consumers' healthier choices.***

Results indicate that most respondents, 52% of non-Romanian and 73% of Romanian citizens, tend to believe that the message of a nutrition/health claim on the food label provides reliable information about the nutrient/ingredient on which the claim is made. However, 41% of the non-Romanian and 21% of Romanian respondents indicated that they do not tend to believe so.

The majority of the respondents consider that foods with a nutrition/health claim facilitate healthy choices, compared to foods without a claim. This majority is higher amongst Romanian respondents (34% to a certain extent, 43% very much) than amongst non-Romanian respondents (42% to a certain extent, 16% very much).

Amongst non-Romanian respondents it is believed that, in general, foods with a nutrition/health claim are healthier in terms of their content in fat, sugars or salt than foods without a claim, either very much (8%) or to a certain extent (33%) while 31% considered those foods not very much healthier and one quarter (26%) believe that they are not healthier at all. On the contrary, amongst Romanian citizens the majority considers that they are very much healthier (32%) or to a certain extent healthier (38%).

Results indicate that 73% of non-Romanian and 48% of Romanian respondents are very familiar with the nutrition declaration.

Similarly, 50% of non-Romanian and 36% Romanian respondents are very familiar with additional forms of expression and presentation of the nutrition declaration in the front of a product's pack.

Respondents are relatively less familiar with logos or symbols indicating that a product is a healthier choice, with relatively small differences between non-Romanian and Romanian citizens. Amongst all respondents, 26% are quite and 25% are very familiar with the above-mentioned logos or symbols, while 20% are slightly familiar and 22% are not or have never seen it in their countries (the latter is higher (32%) amongst non-Romanian citizens).

- ***When there is a nutrition or health claim, respondents tend to look for any other nutritional information provided on the food label, particularly the nutrition declaration***

Results indicate that, when there is a nutrition/health claim, almost all respondents look for any other nutritional information provided on the food label (43% do so sometimes, 51% always). This comprises the nutrition declaration (three quarters of respondents look for this information, while 39% of respondents only look at the nutrition declaration), and 36% of respondents also look at other information as well as the nutrition declaration. A relatively low percentage of respondents (8% in total) looks exclusively for other information beyond the food product's label.

When it comes to the importance that respondents give to information on the label when purchasing a food product, around half of non-Romanian and 35% Romanian respondents "do not know". Amongst those that provided an answer, 28% of non-Romanian and 40% of Romanian respondents indicated that they find most important the nutrition declaration, while 17% of non-Romanian and 12% of Romanian citizens find most important the nutrition and health claims. 7% of non-Romanian and 9% of Romanian respondents indicated that they find most important logos & symbols, while 7% of both respondents find most important the FoP labelling.

Finally, over three quarters of all respondents indicated that they have been discouraged from purchasing a food because of the high content in fat, sugars and salt indicated on the nutrition

declaration, thus confirming the importance of the nutrition information in directing respondents' purchasing decisions.

- ***Respondents tend to consider unacceptable that a food product with a high content of fat, sugars or salt can make a nutrition or health claim***

Results indicate that around half of respondents consider unacceptable that a food product which has a high content of fat, sugars or salt can make a nutrition or a health claim. At the same time, 35% of respondents consider this to be acceptable.

B. Plants and their preparations used in food

The key findings of the OPC in relation to food products containing plant substances are summarised as follows:

- ***Respondents in general tend to purchase food products containing plants and their preparations.***

Results indicate that 81% of non-Romanian respondents purchase food products containing plants substances, with 33% of respondents to purchase these products frequently, 27% occasionally and 21% rarely. The share of respondents which have never/almost never purchased these products rises to 18%.

In Romania, 97% of Romanian respondents purchase food products containing plants substances, with 86% of respondents to purchase these products frequently, 11% occasionally and 2% rarely. In fact, less than 1% of respondents of such Member States have never/almost never purchased food products containing plants substances.

- ***Respondents tend to purchase food products containing plants and their preparations because they are already familiar with the substances contained in these products or because they trust the advice from professionals or people close to them.***

Results indicate that the main reason why respondents purchase food products containing plant substances is the previous knowledge of the substances contained in the product (36% of total respondents indicated this option). Advice from a health professional or nutritionist is relevant for purchasing these products for 24% of total respondents. For 15% of total respondents only, health claims on the labels are among the main reasons to purchase these products only.

- ***Respondents tend to believe that health claims on food products containing plant substances provide reliable information.***

In general, the level of confidence on the benefits claimed on the label is high among respondents that purchase food products containing plant substances. In particular, trust in health claims on the labels is very high (option "very confident") for 15% of non-Romanian and 63% of Romanian respondents. In addition, 58 of non-Romanian and 35% of Romanian respondents are slightly or quite confident that consumption of the food products bearing health claims on the label will actually result in the claimed benefit(s). On the other hand, 23% of non-Romanian and 1% of Romanian respondents are not confident at all about the benefits claimed on the label. The findings above indicate that respondents of Romania are much more confident with the health claims on food products containing plant substances than the non-Romanian respondents.

- ***Respondents do not have a prevailing opinion about the scientific evidence of benefits claimed on the labels of food products containing a plant substance.***

Amongst non-Romanian respondents, 30% deem that health claims on the label of a food product containing a plant substance *is* supported by scientific evidence and 26% deem that the health claim *is not* supported by scientific evidence. Respondents were uncertain and opted for "maybe" (38%) or "do not know/no opinion" (5%). In Romania, the share of respondents which deem that the health claim on the label *is not* supported by scientific evidence is higher (41%).

- ***Respondents tend to consider important the use of the traditional use and of the scientific evidence in order to assess health claims on food products containing plant substances.***

A high number of respondents replied "do not know/no opinion" to this question. Nevertheless, almost one quarter of respondents (23%) attached maximum importance to the condition that health claims should be all based on traditional use within EU. On the other side, 21% of respondents attached maximum importance to the fact that health claims should be assessed on the basis of scientific evidence before marketing the product. Nonetheless, a high number of respondents gave a "do not know/no opinion" reply to the question concerning this issue.

Results are quite different when looking at the figures without the inclusion of Romania, whose respondents are strongly in favour of traditional use for assessing health claims. Looking at total results excluding Romania, 43% of respondents considered as highly important the condition that health claims should be assessed on the basis of scientific evidence before marketing the products. On the other side, 18% of respondents considers less relevant recourse to traditional use within the EU for assessing claims, and only 5% ranked this condition as the most important.

- ***Respondents tend to consider acceptable to purchase food product containing a plant substance bearing a health claim based on traditional use and not backed by science.***

Around half of non-Romanian respondents (49%) would purchase a food product with a health claim based on traditional use not backed by science, 26% of respondents are uncertain, and might purchase them, while 22% of respondents would not purchase these products. In Romania, the majority of respondents (92%) would purchase a food product containing a plant substance bearing a health claim based on traditional use not backed by science, while only 2 % of respondents would *not* purchase products with such a claim. These results indicate that Romanian respondents are strongly in favour of traditional use

- ***Respondents do not have a prevailing position about the difficulties in purchasing a food product containing a given plant substance that they normally buy as a food supplement in one EU country but not in another because it is considered a medicine or it is not sold.***

Results indicate that 38% of total respondents faced difficulties in purchasing a food product containing plants because it is considered a medicine or it is not sold. On the other hand, the same share of total respondents (38%) never faced such difficulties. It should be noted that a significant share of total respondents (24%) replied "do not know/no opinion" to this question.

- ***Respondents tend to have purchased at least once a food product containing a plant substance on the internet.***

Results show that amongst non-Romanian respondents, 40% purchased such products on the internet while 60% they do not. Consistently, in Romania a greater share of respondents (77%) purchased at least a food product containing plant substances on-line while 22% they do not.

- ***Respondents tend to purchase food products containing plants and their preparations on the internet because of non-availability of such products in their country, convenience and low price.***

Looking at the reasons behind on-line shopping of food products containing a plant substance, 15% of non-Romanian and 28% of Romanian respondents indicated that they purchase on-line because products are not available in their countries. 18% of non-Romanian and 23% of Romanian respondents indicated that they purchase on-line because, more in general, it is considered as an easy way of purchasing products (not only food products containing plant substances). Another reason often indicated for purchasing products on-line is the lower price of products sold on the internet (20% of all respondents). Only 3% of all respondents indicated the need of medical prescription in their country as a reason to purchase food products containing plant substances on-line.

- ***Respondents tend to believe that food products containing plant substances do not have any possible adverse health effects.***

Non-Romanian respondents indicated that are very confident (23%) and slightly/quite confident (51%) that food products containing plant substances do not have any possible adverse health effects while 20 % indicated that they are *not* confident at all.

A quite higher level of confidence was selected by respondents in Romania, where respondents indicated that are very confident (70%) or slightly/quite confident (27%) in the absence of any possible adverse health effects of food products containing plant substances. Only 2% of Romanian respondents indicated that they are *not* confident at all.

Replies from Romania show that Romanian citizens are more favourable and confident toward food products containing plants and their preparations compared with non-Romanian citizens. This may reflect the higher familiarity of Romanian respondents to these products. This could also explain, in more general terms, the high participation to this consultation of Romanian citizens.

APPENDIX 10: KEY DIFFERENCES BETWEEN SCHEMES/INITIATIVES AND EU-NPS

	Schemes/initiatives	**EU-NPs**
Application:	• (mostly) **voluntary** Currently existing schemes/initiatives, whether national regulatory or private, generally apply on a voluntary basis. Few compulsory schemes exist (advertising to children, UK and IE codes; taxes).	• **compulsory**
Objectives:	• variable **FoP labelling**: to provide factual, easy to read/comprehend, information on nutrient content, helping consumers to make informed choices according to their dietary needs. **Other**: variable	• to restrict claims on high FSS foods To govern the binary decision to make claims on foods (i.e. either to allow the claims, or not to allow them) on the basis of criteria which are not *per se* communicated to the consumer
Scope (product categories):	• variable • not specific on foods bearing claims	• harmonised (with category specific approach) – *to be defined when set* • only applicable to foods bearing claims
Scope (nutrient criteria):	• variable • not specific on FSS nutrients	• harmonised (with category specific approach) – *to be defined when set* • FSS; other nutrients – *to be defined when set*
Geographical scope:	• variable (**exist only in some MS**)	• harmonised (EU-wide)
Approach:	• variable: designed to serve the specific scheme's needs/objectives. E.g. some promote healthier foods (positive FoP claims and labels), some restrict 'unhealthy' foods (negative FoP labels; advertising restrictions). • some schemes/initiatives are based on comprehensive and harmonised nutrient profile models (purpose-built for the scheme)	• harmonised (EU-wide)

***Source**: External contractor's report, Part Two, p. 36.*

APPENDIX 11: OVERVIEW OF PROBLEMS/GAPS IDENTIFIED FOR BUSINESS OPERATORS IN THE CURRENT SITUATION

Source	Main problems/gaps identified
CLYMBOL[(a)]	• *Generally, claims are <u>not</u> made on foods higher in FSS content than comparable foods without any claims – identified gaps are specific.* • **Prevalence of claims is important in some sensitive product categories** (fortified foods in various sectors; non-essential foods): nutrition claims: ≤25-30% of foods; health claims: ≤13-17% of foods. • **30% of foods with health claims and 39% of foods with nutrition claims, did not pass the FSANZ NPSC model[(b)]**, although differences were in most cases **relatively '*modest*'**.
Member States[(c)]	• Three categories of products on which claims are extensively used, but there may be issues with their overall nutritional status: **fortified foods; non-essential foods; composite foods**. • **More generally**, high-FSS processed foods bearing claims can convey their healthiness to consumers unlike foods not able to make claims that feature highly in national/international dietary guidelines for healthy eating, such as fresh fruit and vegetables or fibre–rich carbohydrates, or compared to foods with other quality attributes such as traditional products. The **potential 'distortions'** when consumers compare the nutritional value of these foods could have been minimised if EU-NPs were in place.
Consumers[(d)]	• **Commonly used nutrition claims, fortified foods and foods marketed to children** (often fortified, e.g. breakfast cereals) were the categories on which problems were most frequently identified.
Industry	• Although not identified high-FSS foods as such, in certain specific product sectors there is **potential '*discrepancy*'** between the message conveyed by the claim and the overall nutritional status of the product due to the nature of the products: **dairy and meat products; natural fruit juices; primary ingredients;** and, **sports nutrition sector.**

(a) This is the most systematic evidence, despite its caveats). The findings of the SME panel appear to corroborate the available evidence from CLYMBOL.
(b) This model is used in Australia and New Zealand to restrict the use of health claims in foods.
(c) MS enforcement authorities could not provide any data to substantiate these observations.
(d) Consumer organisations could not provide any data to substantiate these observations; BEUC has recently started a new action to systematically identify specific product cases in the different product categories.

***Source**: External contractor's report, Part Two, p. 50.*

APPENDIX 12: OVERVIEW OF COSTS – BENEFITS IDENTIFIED IN THE EVALUATION

I. Overview of costs – benefits identified in the evaluation							
		Citizens/ Consumers		**Businesses**		**Administrations**	
		Qualitative	**Quantitative / monetary**	**Qualitative**	**Quantitative / monetary**	**Qualitative**	**Quantitative / monetary**
Absence of EU-level nutrient profiles							
Public health costs	Recurring direct health costs	Consumers are exposed to foods bearing claims that have high sugar/fat/salt content. This can mislead consumers' food choices and could lead to high intake of sugar/fat/salt that is correlated to non-communicable diseases.	Quantitative estimates not available due to lack of data on consumption of foods bearing claims and difficulties in establishing causality.	Not applicable	Not applicable	In many EU countries, healthcare is largely (if not fully) financed by the government budget. Increasing non-communicable diseases have an impact on public healthcare expenditures.	Quantitative estimates not available
Costs: lack of innovation and uneven playing field	One-off indirect economic costs	Not applicable	Not applicable	Legal uncertainty for food businesses negatively affects innovation and creates an uneven playing field between companies that have reformulated foods and those that have not.	Quantitative estimates not available.	Not applicable	Not applicable

Benefits: cost savings from product reformulation	One-off direct economic benefits (avoided compliance costs)	Not applicable	Not applicable	Medium/high Some food businesses producing foods with claims that would not comply with nutrient profile criteria avoided reformulation costs.	No overall estimate available. Example of reformulation cost to reduce salt content in UK: €34,314/product [M. Collins et al., 2014]	Not applicable	Not applicable
Benefits: avoided loss of market share	Recurring indirect economic benefits	Not applicable	Not applicable	Low/medium Some foods bearing claims cannot be reformulated, for these products food businesses have avoided possible losses of market share in case they had to remove the claims.	Quantitative estimates not available.	Not applicable	Not applicable

‘On-hold’ list of health claims and general regulatory framework on plants and their preparations in foods							
Public health costs	Recurring direct health costs	Consumers might rely on health claims whose efficacy has not been assessed/ assessed negatively by EFSA. Although safety of foods containing plants is adequately addressed by other EU and national legislations, there are indications that plant substances used in food may give rise to adverse health effects.	Quantitative estimates not available.	Not applicable	Not applicable	Impacts on consumers’ health affect public health expenditure.	Quantitative estimates not available.
Administrative costs for ‘on-hold’ list	Recurring direct administrative costs	Not applicable	Not applicable	Not applicable	Not applicable	Low National public administrations face costs (human resources) to handle queries about on-hold list	Quantitative estimates not available
Reduced long-term investments/ innovation	Recurring indirect economic costs	Not applicable	Not applicable	Medium Legal uncertainty concerning the future decision on the ‘on-hold’ list hinders long-term investments and innovation for food businesses (especially food supplement sector)	Quantitative estimates not available.	Not applicable	Not applicable

Re-labelling costs	One-off indirect compliance cost	Not applicable	Not applicable	Medium Fragmented rules for foods containing plants in Member States creates re-labelling costs to market the products in other Member States with different rules compared to the national market. These costs are relevant for exporting companies.	Quantitative estimates not available.	Not applicable	Not applicable
Missed export opportunities	Recurring indirect economic cost	Not applicable	Not applicable	Medium/ high Re-labelling costs to comply with different rules from the ones in the national market are an entry barrier for other EU markets. This can affect especially SMEs.	Food product development costs: €20,000-100,000; versus food product development for new foreign market launch cost: €40,000-200,000 [Stakeholders' consultation]		

Benefits: avoided re-labelling/ reformulation costs/ withdrawal from market	Recurring direct economic benefits	Not applicable	Not applicable	Medium/ high Avoided costs related to re-labelling and/or reformulation due to rejected claims. Food supplement companies have avoided costs linked to possible withdrawal of products from the market if claims could not be made.	Quantitative estimates not available.	Not applicable	Not applicable

APPENDIX 13: TABULAR PRESENTATION OF THE NUMBER OF NEW PRODUCTS BEARING CLAIMS ENTERING THE MARKET AND THE PERCENTAGE THEY REPRESENT ON THE FOOD AND DRINK MARKET, FROM JANUARY 1997 TO DECEMBER 2017 (FIGURE 6 AND FIGURE 7 OF THE STAFF WORKING DOCUMENT)

Country	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Total Sample
UK	34	89	499	456	851	941	927	1.071	1.370	1.152	1.704	1.805	1.885	2.063	2.578	2.951	2.763	2.627	3.726	3.564	4.133	37.189
Germany	35	106	284	197	379	420	672	989	1.134	1.261	1.264	1.360	1.622	1.351	1.181	1.426	1.600	1.644	2.209	1.899	2.111	23.144
France	11	35	131	313	283	336	360	566	747	1.205	1.441	1.190	913	1.131	1.404	1.490	1.778	1.985	2.097	2.146	1.918	21.480
Spain	28	43	108	276	301	462	483	629	552	687	697	668	615	889	976	1.379	1.480	1.851	1.550	1.620	1.328	16.622
Italy	7	15	82	171	197	190	234	465	285	503	761	956	949	903	1.045	1.176	1.499	1.278	1.484	1.601	1.600	15.401
Netherlands	7	12	86	102	189	212	309	419	466	569	806	710	821	833	704	414	413	635	624	576	741	9.648
Poland	0	2	16	15	18	29	97	212	283	315	352	288	258	204	258	295	409	778	783	892	1.206	6.710
Austria	5	5	44	21	31	174	257	282	324	615	542	628	687	448	368	307	340	391	344	388	391	6.592
Finland	1	2	4	212	299	278	214	195	232	357	462	419	354	346	379	374	478	510	436	464	441	6.457
Belgium	11	15	53	168	181	255	210	222	295	249	240	264	233	269	293	299	253	335	278	316	324	4.763
Sweden	7	2	57	69	103	221	212	228	311	300	325	397	214	107	114	120	167	485	310	435	443	4.627
Portugal	1	8	28	33	44	104	238	178	198	176	344	289	207	245	348	295	296	335	245	376	302	4.290
Ireland	5	9	18	8	20	108	120	233	158	203	249	152	251	190	185	295	548	388	321	412	414	4.287
Czech Republic	0	2	15	6	11	8	36	95	124	149	156	123	176	128	139	257	531	414	464	468	517	3.819
Hungary	0	0	0	2	32	24	49	152	202	263	334	255	345	281	274	178	294	265	305	241	275	3.771
Greece	0	6	18	30	27	58	108	175	180	160	184	231	195	127	177	192	328	282	326	344	366	3.514
Denmark	0	9	42	39	55	87	97	123	110	101	126	139	101	52	62	85	118	289	435	342	470	2.882
Romania	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	240	226	214	680
Slovakia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	196	179	232	607
Croatia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	140	153	135	428
Total Sample	152	360	1.485	2.118	3.021	3.907	4.623	6.234	6.971	8.265	9.987	9.874	9.826	9.567	10.485	11.533	13.295	14.492	16.513	16.642	17.561	176.911
Percentage of foods bearing claims	3%	3%	9%	12%	16%	18%	19%	20%	20%	20%	21%	20%	18%	18%	18%	17%	18%	17%	18%	18%	19%	18,0%