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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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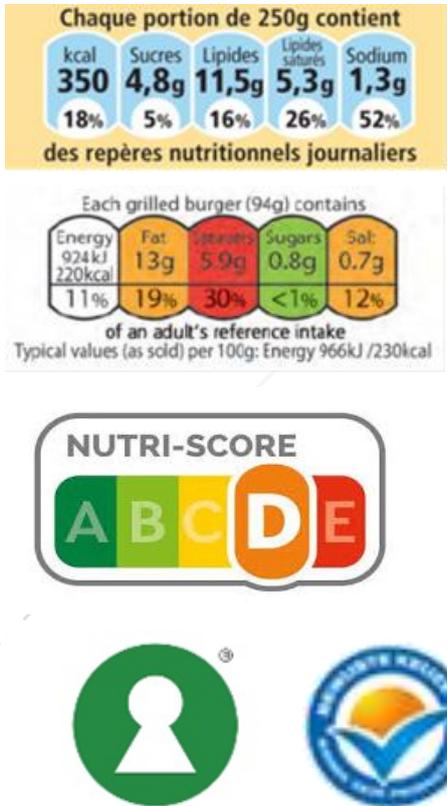
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LIST OF ABBREVIATIONS

<i>Term or acronym</i>	<i>Meaning or definition</i>
DG GROW	Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG RTD	Commission Directorate-General for Research and Innovation
DG SANTE	Commission Directorate-General for Health and Food Safety
EFSA	European Food Safety Authority
EFSA NDA Panel	EFSA's Panel on Dietetic Products, Nutrition and Allergies
EMA	European Medicines Agency
EP	European Parliament
EU	European Union
EU-NPs	EU Nutrient Profiles
FBOs	Food and feed business operators
FIC	Food Information to Consumers Regulation (Regulation (EU) No 1169/2011)
FCEC	Food Chain Evaluation Consortium
FoP	Front-of-pack
FSS	Fat, saturated fat, sugars and salt/sodium [content in foods]
GFL	General Food Law (Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)
HMPs	Herbal Medicinal Products
HMPC	Herbal Medicinal Products Committee
ISG	Interservice steering group

JRC	Joint Research Centre
Mintel GNPD	Mintel Global New Products Database
OPC	Online public consultation (also referred to as open public consultation)
PAFF	Standing Committee on Plants, Animals, Food and Feed
SG	Secretariat-General of the European Commission
SMEs	Small- and Medium-sized Enterprises
TFEU	Treaty on the Functioning of the European Union
THI	Teas and Herbal Infusions
THMPs	Traditional Herbal Medicinal Products
ToR	Terms of reference
TUR	Traditional Use Registration
USD	US Dollars
WEU	Well Established Use
WTO	World Trade Organisation

GLOSSARY FOR THE PURPOSES OF THE EVALUATION

<i>Term</i>	<i>Definition</i>
Food supplements	Concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet.
Front-of-pack (FoP) nutrition labelling schemes, including pictorial/symbolic nutrition claims	<p>A label that reports nutrition information on the food product in the principal field of vision.</p> <p>Figure 1: Examples of voluntary front-of-pack (FoP) nutrition labelling schemes, including pictorial/symbolic nutrition claims.</p> 
Health claim	<p>A health claim is any claim that states, suggests or implies a relationship between a food or its constituent and health, usually appearing on the front of the pack. The European Commission authorises different health claims provided they are based on scientific evidence and can be easily understood by consumers.</p> <p>Health claims are provided in text, e.g. <i>‘Vitamin D contributes to the maintenance of normal bones’</i></p>
Herbal medicinal products	Medicinal products exclusively containing herbal substances and/or herbal preparations as active ingredients (alone or in combination).

Negative list of plants	List of plants not permitted for use in foods, including food supplements.
Nutrient Profiles	In the context of the Claims Regulation, nutrient profiles are thresholds of nutrients such as fat, saturated fat, salt and sugars above which nutrition claims are restricted and health claims are prohibited, thus preventing a positive health message on food high in these nutrients.
Nutrients	Protein, carbohydrate, fat, fibre, sodium, as well as certain vitamins and minerals, and substances which belong to or are components of one of those categories.
Nutrition claim	<p>Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the:</p> <ul style="list-style-type: none"> • <u>energy (calorific value)</u> it (a) provides, (b) provides at a reduced or increased rate or, (c) does not provide, e.g. '<i>low energy</i>'; or • <u>nutrients or other substances</u> it (a) contains, (b) contains in reduced or increased proportions or, (c) does not contain, e.g. '<i>reduced sugar</i>', '<i>high fibre</i>'. <p>This can be provided in text (example above) or in the form of a logo.</p>

<p>Nutrition declaration</p>	<p>Detailed nutrient content indicated at the back of a product's pack in the form of a table, or if space does not allow, in linear format. This is a compulsory requirement: it should contain information stating energy value and the following nutrients: fat (of which: saturates), carbohydrate (of which: sugars), protein, and salt). It may (but not required to) also state other nutrients, e.g. fibre, vitamins and/or minerals which are present in significant amounts.</p> <p>In addition, the energy value; or the energy value together with the amounts of fat, saturates, sugars, and salt may be repeated on the front of a product's pack.</p> <p>Figure 2: Nutrition declaration (compulsory; back of pack)</p> <table border="1" data-bbox="576 696 927 1111"> <thead> <tr> <th colspan="2" style="background-color: #4F81BD; color: white;">per 100g</th> </tr> </thead> <tbody> <tr> <td style="background-color: #4F81BD; color: white; writing-mode: vertical-rl; transform: rotate(180deg);">NUTRITION INFORMATION</td> <td>energy</td> <td style="text-align: right;">kJ/kcal</td> </tr> <tr> <td></td> <td>fat</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>of which</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>— saturates</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>carbohydrate</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>of which</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>— sugars</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>protein</td> <td style="text-align: right;">g</td> </tr> <tr> <td></td> <td>salt</td> <td style="text-align: right;">g</td> </tr> </tbody> </table>	per 100g		NUTRITION INFORMATION	energy	kJ/kcal		fat	g		of which	g		— saturates	g		carbohydrate	g		of which	g		— sugars	g		protein	g		salt	g
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<p>Other substance</p>	<p>In line with Regulation (EC) No 1925/2006 'other substance' means a substance other than a vitamin or a mineral that has a nutritional or physiological effect.</p>																													
<p>Plants and their preparations / Botanicals</p>	<p>There is no official definition of botanical in EU food legislation. For the purposes of this report botanicals should be understood as plants and their preparations.</p> <p>Plants and/or their preparation in this report refer to ingredients of plant origin which would not normally be expected to be consumed in significant quantities in a balanced and varied diet (e.g. fruits and their juices, vegetables, cereals, flour, bread, rice, pasta and fibres derived from the, nuts, olives and oils, etc.). An exception is made for those substances that are subject to assessment by the European Medicines Agency's Committee on Herbal Medicinal Products.</p> <p>Examples of plants and their preparations falling under the scope of this evaluation include: <i>Camellia sinensis</i>, <i>Ginkgo biloba</i>, <i>Echinacea pallidae</i> etc., which may be used in the form of food supplements, teas, infusions and other foods.</p>																													

Positive list of plants	List of plants permitted for use in foods, including food supplements.
Traditional herbal medicinal products (THMPs)	THMPs are herbal medicinal products which are proved not to be harmful in the specified conditions of use and whose pharmacological effects or efficacy are plausible on the basis of long-standing use and experience (traditional use).
Traditional use of plants and their preparations	<p>Evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations.</p> <p>Under the medicinal law (Directive 2001/83/EC) “traditional use” refers to medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the EU. In food area, traditional use is considered as a proof of safety in the Novel Food Regulation, but it is not considered as a proof of efficacy under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods</p>

1. INTRODUCTION

1.1. Purpose of the evaluation

Food we eat can affect our health in different ways, particularly by influencing the risk of developing any of non-communicable diseases, such as cancer, cardiovascular disease and obesity. Nutrition is one of the key elements in reaching the sustainable development goals in health and the World Health Organization's disease prevention targets, on both of which Member States have subscribed to. Nutrition and health claims can play a role in dietary choices, and thus they could indirectly influence public health.

The Nutrition and Health claims Regulation ('Claims Regulation')¹ was adopted in 2006 to ensure truthful information to consumers and the facilitation of the free movement of foods bearing claims. It harmonises the use of claims in the labelling, presentation and advertising of foods. It ensures that all claims in the EU are clear, accurate and based on scientific evidence. A claim is a voluntary message² which states, suggests or implies that a food has particular characteristics. In particular, nutrition claims are statements like '*low fat*', '*high fibre*', while health claims make the link between a food constituent and health, like '*Vitamin D contributes to the maintenance of normal bones*'. In December 2012, Commission Regulation (EU) No 432/2012 establishing the list of permitted health claims³ came into application, marking the end of the transitional period for non-authorized claims.

In its Better Regulation Communication of 19 May 2015⁴, the Commission announced its intention to carry out an evaluation of the Claims Regulation. 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.

For the purpose of this document, plants and/or their preparation refer to ingredients of plant origin which would not normally be expected to be consumed in significant quantities in a balanced and varied diet (e.g. fruits and their juices, vegetables, cereals, flour, bread, rice, pasta and fibres derived from them, nuts, olives and oils, etc.). An exception is made for those substances that are subject to assessment by the European Medicines Agency's Committee on Herbal Medicinal Products. Examples of plants and their preparations falling under the scope of this evaluation include: *Camellia sinensis*, *Ginkgo biloba*, *Echinacea pallidae* etc., which may be used in the form of food supplements, teas, infusions and other foods.

This evaluation aims at assessing the impacts of two major issues in the context of the Regulation:

- a) nutrient profiles are still not established at EU level, although Article 4 of the Claims Regulation envisaged their adoption by 19 January 2009;

¹ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p.9)

² Also in the form of a picture, graph or symbol.

³ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ((OJ L 136 25.5.2012, p. 1)

⁴ 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).

- b) a long list of claims made on plants and their preparations is unregulated since 14 December 2012, when the list of permitted health claims became applicable.

In particular, this evaluation assesses whether the Claims Regulation to date has achieved, at minimum burden, its overall objectives to ensure a high level of consumer protection and the facilitation of the free movement of foods bearing claims, despite the non-implementation issues mentioned above. On the one hand, the evaluation analyses whether nutrient profiles are still *fit for their purpose*, warranted and adequate to ensure the objectives of the Claims Regulation. Nutrient profiles are thresholds of nutrients such as fat, salt and sugars above which nutrition and health claims are restricted, thus preventing a positive health message on food high in these nutrients. On the other hand, the evaluation examines: i) whether the current non-implemented rules concerning the authorisation of health claims on plants and their preparations used in foods are adequate, and ii) how the use of such claims interacts with the current applicable food regulatory framework on plants and their preparations. In line with the Better Regulation Guidelines⁵, the evaluation considers the impact of the Claims Regulation with regard to its effectiveness, efficiency, relevance, coherence and EU added value.

The results of this evaluation will be used to inform the Commission's reflection on this topic.

This Staff Working Document draws on the study and its findings prepared by the external contractor, it expresses the view of the Commission services and does not commit the European Commission. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

1.2. Scope of the evaluation

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 Union⁶. It should be noted that when the Staff Working Document refers to EU Member States in the presentation of the results, these results also include the United Kingdom.

The evaluation focuses on the following aspects:

- (a) Nutrient profiles (Article 4 of the Claims Regulation);
- (b) Health claims made on plants and their preparations (health claims submitted pursuant to Article 13 of the Claims Regulation);
- (c) The interaction of the use of health claims on plants and their preparations with the current applicable food safety regulatory framework on plants and their preparations, including other regulatory aspects, such as the possible need for safety requirements for the use of plants and their preparations in food.

The other aspects of the Claims Regulation, besides those mentioned above, are excluded from the scope of the evaluation. The reason is that an evaluation of the Claims Regulation in its entirety would not prove fruitful at this stage given that the list of authorised health claims came into application on 14 December 2012, while, most importantly, two important elements of the Regulation still remain non-implemented.

Temporal scope

This evaluation covers the period from 2005 until the end of 2015. The years 2005-2006 are included in order to enable a comparison of the situation before the adoption of the Claims

⁵ European Commission, Better Regulation Guidelines. To be found: <https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines.pdf>

⁶ The United Kingdom withdrew from the European Union and became a third country as of 1 February 2020.

Regulation (the 'baseline') to the situation following its implementation. Special attention is given to the way the EU market evolved after the application of the Claims Regulation on 1 July 2007, and after 14 December 2012, when implementing Commission Regulation (EU) No 432/2012 establishing the list of permitted health claims⁷ came into application, marking the end of the transitional period for non-authorised claims. In the light of recent developments, this staff working document also includes the years 2015 to 2018 for the assessment of some evaluation criteria.

⁷ Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ((OJ L 136 25.5.2012, p. 1)

2. BACKGROUND: DESCRIPTION OF THE INTERVENTION AND ITS OBJECTIVES

2.1. The Nutrition and Health Claims Regulation

The Claims Regulation harmonises the provisions laid down by law, regulation or administrative action in Member States which relate to nutrition and health claims in order to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. The Claims Regulation applies to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. The Claims Regulation also applies to health claims made on plants and their preparations used in foods.

The intervention logic of the Claims Regulation describing the rationale on the nutrient profiles and on health claims, including health claims on plants and their preparations, is presented in Figure 3 and described below.

Before the introduction of the Claims Regulation, nutrition and health claims on foods were proliferating in terms of the number and type of claims appearing on the labels amid a non-harmonised regulatory framework⁸. Specific legislation was introduced only in some Member States to regulate the use of claims (ranging from the complete ban of health claims to the complete absence of legislation). This resulted in different approaches at Member States' level and into numerous discrepancies: both regarding the definition of the allowed terms and of the conditions under which claims could be used. On a consultation carried out by the European Commission prior to the adoption of the Claims Regulation, the feedback received from stakeholders representing non-business interests⁹ indicated that nutrition and health claims were proliferating across the EU, due *inter alia* to the lack of a specific regulatory framework to control the market of foods with claims.

The decision to regulate the use of health and nutrition claims at EU level was linked with the concern that these discrepancies could lead to an uneven level of consumer and public health protection across the EU. That situation created also a series of obstacles to the free movement of foods across EU countries and unequal conditions of competition, thus having a direct impact on the proper functioning of the internal market.

The absence of established scientific criteria for making nutrition and health claims on foods led to a situation where consumers did not have access to truthful nutritional information and could be misled by 'false' claims. Indeed, consumers might perceive foods with claims as having a nutritional, physiological or other health advantage over other products without claims. Moreover, claims might encourage consumers to make food choices that directly influence their total intake of individual nutrients or other substances. The absence of defined principles and conditions for the use of the claims could also lead to a situation where claims were made on foods that had a high content of fat, sugar and salt and, therefore, mask the overall nutritional status of the food. At the same time, certain food business operators invested in research and development to substantiate the nutrition and health claims they made on their foods, while others

⁸ Discussion Paper on nutrition claims and functional claims, Prepared by Directorate General Health and Consumer Protection (SANCO D4), European Commission. SANCO /1341/2001. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-claims-claims_discussion_paper_en.pdf (last accessed 13 June 2018).

⁹ Consumer groups that have commented to the Discussion Paper of the Commission. E.g. Feedback from the European Consumers' Organisation (BEUC), the UK National Consumer Council, the Association of European Consumers (AEC), ALTROCONSUMO (IT) etc. To be found at: https://ec.europa.eu/food/safety/labelling_nutrition/claims/consumer_groups_en (last accessed 21 June 2018).

simply used claims as a marketing tool without ensuring that their claims were scientifically true. This led to an unfair competition amongst food business operators.

The adoption of legislation at EU level was, therefore, considered necessary to address the above-mentioned problems. In particular, the Claims Regulation was introduced to achieve the following general objectives:

- high level of **consumer protection** by providing common conditions for voluntary information, beyond the mandatory information envisaged by EU legislation, and ensure that nutrition and health claims are not misleading for consumers;
- improving the **free movement of foods** bearing nutrition and health claims within the internal market;
- increasing **legal certainty** for economic operators;
- ensuring **fair competition** for food business operators within the internal market;
- promoting and protecting **innovation** in the area of foods.

To achieve these objectives the Claims Regulation introduced the definition of nutrition and health claims, lists of permitted nutrition and health claims valid across the EU and a claim authorisation process managed at EU level. More specifically, the Claims Regulation stipulates that nutrition and health claims made on food must be based on and substantiated by generally accepted scientific evidence and that health claims should only be authorised for use in the EU after a thorough scientific assessment by an independent scientific body, the European Food Safety Authority (EFSA). The objective of high level of consumer protection was, therefore, embedded in the principle that health claims may only be used under strict conditions, following an independent scientific assessment of the '*highest possible standard*' and subsequent EU authorisation through a well-defined authorisation procedure. This would ensure that only reliable information, guaranteed by the scientific justification of nutrition and health claims, is communicated to consumers. Thus, consumers' trust in nutrition and health claims was expected to increase.

The conditions introduced by the Claims Regulation apply to all claims irrespectively to the substance or food on which they are made, such as vitamins, minerals or plants and their preparations. It was, therefore, expected that foods containing plants and their preparations would bear health claims that are scientifically justified and approved by EFSA¹⁰. At the same time, the establishment of a list of permitted health claims at EU level was expected to harmonise the use of plants substances and their preparations in the internal market.

The Claims Regulation sets general principles and conditions for the use of nutrition and health claims. These conditions include the restriction of claims on alcoholic beverages and the establishment of nutrient profiles by the Commission, after consulting EFSA. In the context of the Claims Regulation, nutrient profiles are thresholds of nutrients such as fat, salt and sugars in foods, above which nutrition claims would be limited and health claims prohibited, thus preventing a positive health message on foods high in these nutrients. As such, nutrient profiles would not appear on labels and would not be communicated to consumers. The introduction of nutrient profiles had the specific objective of avoiding a situation where nutrition or health claims

¹⁰ See Article 6(1) of the Claims Regulation.

would mask the overall nutritional status of a food product¹¹, which could mislead consumers when trying to make healthy choices in the context of a balanced diet.

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

In relation to consumers, the expected direct outcome of introducing nutrient profiles would be to restrict the use of claims on products which have a high content of such nutrients and to only allow claims on products that have, from a public health point of view, a scientifically acceptable nutrient profile. The expected impact would be to remove the risk/potential for consumers to be misled about the nutritional status of foods bearing claims, thus enabling consumers to make healthy food choices in the context of a balanced diet. The promotion of healthier dietary choices would also ensure better alignment with the broader nutritional advice provided by public health authorities.

In relation to food business operators, the expected direct outcome was that operators would a) either remove the claim on foods not complying with the criteria defining the nutrient profiles; or b) reformulate their products to reduce the fat, sugar and/or salt content, in order to maintain the claim (to the extent that reformulation is feasible).

The overall implementation of the Claims Regulation was expected to result in a common authorisation procedure for all claims and for all food business operators across the EU. With the introduction of the described harmonised legal framework, it was expected that operators in the internal market would face the same conditions for the use of claims on foods, thus ensuring a level playing field for all food business operators, with regards to the free circulation of food products, legal certainty, competition, and promotion of innovation.

Given the positive image conferred on foods bearing nutrition and/or health claims, the Claims Regulation stipulated that the nutrition declaration should become mandatory for all foods bearing nutrition and health claims. Although prior to the Claims Regulation nutrition labelling was compulsory for nutrition claims, this requirement was extended to products bearing a health claim, for which it became compulsory to provide a full nutrition declaration (for energy + seven nutrients¹²) since July 2007. The aim of this provision was to ensure that all information regarding the nutritional profile of a product was given to the consumer.

Interplay of the Claims Regulation with other food legislation

The interplay between the Claims Regulation and other legislation is summarised in Appendix 1 to this Staff Working Document. The Claims Regulation applies to nutrition and health claims made on foods. Nevertheless, food business operators, alongside with the rules comprising the use of claims, must also comply with the rules applicable to the food or food ingredient bearing the claim. Such rules include the Regulation on the principles of General Food Law¹³, the rules

¹¹ Food product which may have a high content of fat, salt or sugar; nutrients that should be consumed moderately according to scientific evidence.

¹² The amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium, as provided in Directive 1990/496/EEC (*OJ L 276, 06/10/1990, p. 40*).

¹³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*OJ L 31, 1.2.2002, p. 1*).

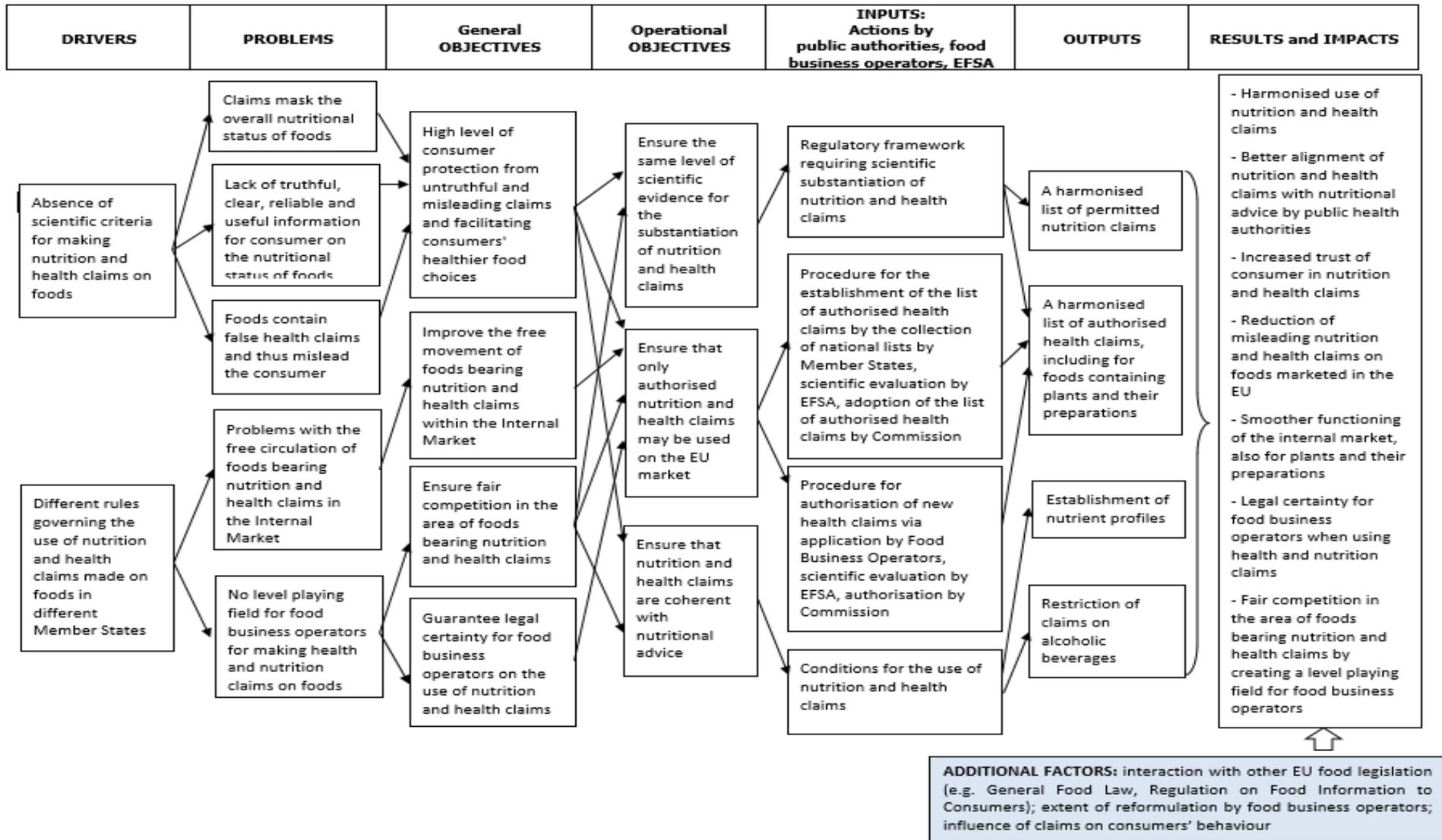
concerning the information provided to consumers¹⁴, or more specific legislation such as legislation concerning food supplements¹⁵ or food fortification¹⁶. Therefore, the interplay between the Claims Regulation and other food legislation indirectly has an influence on achieving the objectives of the Claims Regulation. At the same time, external factors play a role in the final impacts of the Claims Regulation. The main external factors are –on the supply side– the extent to which food business operators reformulate food products to improve the nutritional composition, and –on the demand side– the way consumers are influenced by claims in their dietary choices.

¹⁴ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

¹⁵ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

¹⁶ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

Figure 3: Intervention logic for the health and nutrition claims



2.2. Regulatory framework on plants and their preparations

The regulatory framework on plants and their preparations in foods

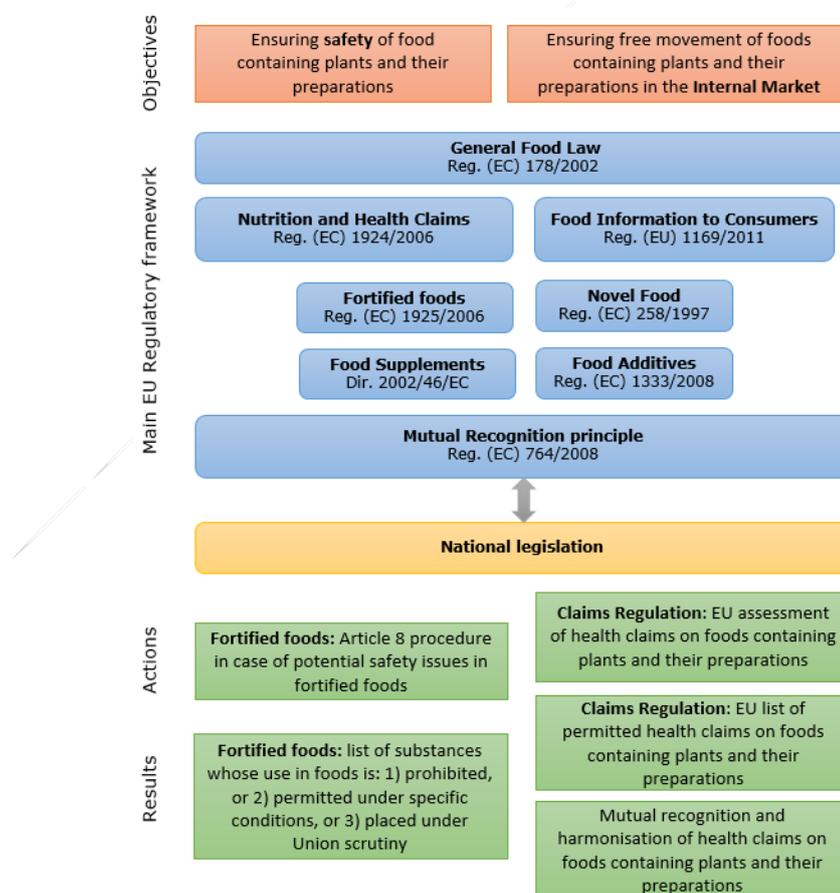
As regards the use of plants and their preparations in foods, the regulatory framework described below shall be considered as the intervention basis for the purpose of this evaluation.

The use of plants and their preparations in foods is not harmonised by means of specific legislation at EU level. These food products are covered by various EU general legislative texts applicable to all foods, such as Regulation (EC) No 178/2002 on the general principles of food law, Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC), and Regulation (EC) No 1924/2006 on nutrition and health claims made on food. Furthermore, they are also covered by other EU legislation applicable to certain categories of foods, such as Directive 2002/46/EC on the approximation of the laws of the Member States related to food supplements, and Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

The use of plant substances in the manufacture of food and of food supplements continues to be subject to the rules in force in national legislation, where relevant. National rules apply within the framework of Articles 30 to 36 of the Treaty on the Functioning of the European Union (TFEU) on the free movement of goods, without prejudice to any Union provisions of general application which may also concern them.

The main pieces of EU legislation pertaining to the use of plants and their preparations in foods, their objectives and corresponding actions are presented in Figure 4.

Figure 4: Regulatory framework for plants and their preparations used in foods



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

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

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

In addition, Article 8 of the Regulation (EC) No 1925/2006 (fortified foods) establishes a procedure to be used in case of potential risks to human health from the addition of a substance other than a vitamin or mineral to foods or food supplements, e.g. plants and their preparations. Following an assessment by EFSA of the available information on the substance, the use of the substance in foods may be prohibited, restricted or placed under EU scrutiny. This procedure was introduced to allow the regulation at EU level of substances already on the EU market and for which potential safety concerns have been raised. It was considered that the procedure of Article 8 would allow a level of harmonisation for plants and their preparations in food over time, as it would make it possible to draw up a list of substances whose use in foods is: 1) prohibited, or 2) permitted under specific conditions of use, or 3) placed under Union scrutiny for a given period where there are safety concerns but the available scientific information is insufficient. Any decision to place a substance in one of these three categories has to be taken on the basis of the results of an assessment of the available scientific information, having regard only to the safety of the substances concerned in food.

The procedure described above constitutes, on first examination, a safety net as regards health protection and could allow, with a precautionary approach, harmonisation of the possibilities or conditions of use of a certain number of substances. The Commission considered that this type of procedure is particularly well suited to plants and plant extracts, for which sufficient and appropriate scientific data are not always available, and for which the safety assessment methodology was still being developed¹⁷.

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

While all secondary EU legislation applicable to foods containing plants and their preparations overall is intended to contribute to this objective, Member States remain competent to adopt national legislation on the use of plants and their preparations in foods, including food supplements. This shall be done in compliance with the TFEU, notably with Articles 34 and 36 relating to the free movement of goods. In the field of public health, which constitutes an overriding reason in the public interest capable of justifying a hindrance to the free movement of products, Member States may determine the degree of protection which they wish to apply as well as the way in which that degree of protection is to be achieved. This may lead to differences between the Member States as to how such products are regulated and the extent of any restrictions to their use.

¹⁷ Report of European Commission to the Council and European Parliament on the use of substances other than vitamins and minerals in food supplements, COM(2008) 824 final, 2008. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-comm_2008_0824_en.pdf (last accessed 10 May 2019).

In the Claims Regulation, the decisive criterion for use of a health claim is that the health effect claimed in relation to a nutrient or substance must be assessed at EU level, based on scientific evidence. At the time of its adoption, it was thus *expected* that the legal framework applicable to health claims would ultimately constitute, directly or indirectly, an element of harmonisation of the substances benefiting from mutual recognition by the Member States, for which these claims will be authorised at EU level. Moreover, it was expected that authorisation of health claims pursuant to the Claims Regulation would constitute a presumption that the product to which they refer falls within the definition of ‘food’ laid down in the Regulation on General Food Law, thereby reducing the risk of conflicts of classification of the product. However, it has appeared that they would not make it possible to completely exclude the risk of conflict of classification in cases where the product concerned would be liable to fall within the definition of medicinal product due to its composition and its presentation¹⁸.

Overall, it was expected that the relevant provisions of food law, either applicable to all foods, or to certain categories of food, together with the expected effects of the application of the Claims Regulation and of the Regulation on food fortification, would constitute an appropriate framework for the use of plants and their preparations in foods to achieve the objectives of safety and free movement of foods in the internal market.

The regulatory framework on plants and their preparations in medicines

The EU has a long tradition of use of plants. Plants may be used both in foods and in Herbal Medicinal Products (HMPs) or Traditional Herbal Medicinal Products (THMPs), yet there are conflicting approaches particularly regarding the classification of plants as food or as medicine among Member States. EU legislation on pharmaceutical products for human use also applies to herbal medicines, including traditional ones. Herbal medicinal products are defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two.

The EU legal framework for medicinal products¹⁹ is based on the principle that medicinal products may be placed on the market only following a marketing authorisation. A large body of legislation has developed around this principle with the progressive harmonisation of requirements implemented across the whole EU. Today, herbal medicinal products are authorised by the competent authorities of Member States after an assessment of its quality, safety and efficacy to treat a particular condition.

As regards the herbal medicinal products, there are three ways of bringing an herbal medicinal products to the market:

- Normal marketing authorisation procedure applicable by default to all medicinal products;
- Well established use marketing authorisation, where in case an applicant can demonstrate using bibliographic data that products have been in well-established use in Europe for at least 10 years with recognized efficacy and safety;

¹⁸ Court case C-140/07, Hecht-Pharma, Judgment of the Court (First Chamber), 15 January 2009 - (Directive 2001/83/EC – Articles 1(2) and 2(2) – Concept of ‘medicinal product by function’ – Product in respect of which it has not been established that it is a medicinal product by function – Account taken of the content in active substances).

¹⁹ The requirements and procedures for marketing authorisation, as well as the rules for monitoring of authorised products, are primarily laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- A simplified registration procedure, introduced by Directive 2004/24/EC²⁰ (hereafter, the traditional herbal medicinal products Directive), which became applicable in October 2005. The simplified registration procedure clarifies differences and uncertainties in the status of traditional herbal medicinal products (THMPs) and facilitates the free movement of these products through harmonised rules. This registration procedure is intended for herbal medicinal products with a long tradition of medicinal use (so-called '*traditional use*' that implies at least 30 years of medicinal use, including 15 in the EU), which do not fulfil the "well established use" requirements for marketing authorisation, i.e. published scientific literature on recognised efficacy and safety. Herbal medicinal products with these characteristics can undergo a "simplified registration procedure" upon application by operators. According to legislation on THMPs, the long tradition of the medicinal product makes it possible to reduce the need for clinical trials, to the degree that the efficacy of the medicinal product is plausible on the basis of long-standing use and experience ("traditional use"). Registered THMPs bear indication of their therapeutic effect in a specific way: "*Traditional Herbal Medicinal Product used [...]*". Also, they must bear the following sentence in the labelling and package leaflet: "*The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use*".

Any herbal medicinal product remain subject to general provisions applying to all medicines such as the need for pre-market (product specific) authorisation or registration, need for an authorisation to manufacture (the necessity to comply with the good manufacturing practices and requiring a qualified person responsible for the quality), pharmacovigilance, and other application requirements for a marketing authorisation.

Given the particularities of herbal medicinal products, a Committee for Herbal Medicinal Products (HMPC) was established at the European Medicines Agency (EMA). The HMPC has been tasked with establishing monographs for traditional herbal medicinal products and proposing a list of herbal substances which have been in medicinal use for more than 30 years and are, therefore, not considered to be harmful under normal conditions of use. On the basis of the scientific opinion of the HMPC, a list of herbal substances with the indication, the posology, the route of administration and any other information necessary for the safe use of certain traditional herbal medicinal products has been established by Commission Decision 2008/911/EC²¹. Applicants can refer to this list in relation to safety and efficacy when registering a traditional herbal medicine. The quality of the specific medicinal product, object of the request of registration/authorisation, still needs to be verified prior to approval.

²⁰ Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 85).

²¹ Commission Decision of 21 November 2008, as amended, establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (notified under document number C(2008)6933) (2008/911/EC) (OJ L 328 6.12.2008, p. 42).

3. BASELINE / IMPLEMENTATION / STATE OF PLAY

This section describes the baseline and current situation concerning nutrient profiles, health claims made on foods containing plants and their preparations, as well as the current regulatory framework on plants and their preparations.

3.1. Nutrient Profiles

3.1.1. Baseline and points of comparison

The years prior to the entry into force of the Claims Regulation (i.e. 2005-2006) are considered as the baseline situation for this evaluation with regard to nutrient profiles. In assessing the evaluation criteria, existing national food schemes based on nutrient profiles are also used as points of comparison, where relevant, as they also intend to help consumers to identify the healthier option.

During the baseline period, foods bearing claims were a growing market segment, driven by increasing consumer interest in this type of foods²². Studies on consumer trends, conducted at the time, identified new drivers and needs in industrialised countries, as a result of consumers' busier lifestyle, which made it harder to meet nutritional requirements. The increasing consumer interest in functional foods²³ was fuelled by a desire for convenience, as well as health²⁴.

Applicable EU rules on nutrition labelling

Even before the adoption of the Claims Regulation, the basic provision that claims should not mislead the consumer generally applied in the context of the rules on labelling²⁵ and nutrition labelling²⁶. In line with Council Directive 90/496/EEC on nutrition labelling, the inclusion of nutrition labelling was mandatory for foods bearing nutrition claims and voluntary for other foods²⁷. However, according to Member States and stakeholders these general principles were open to different interpretations and therefore, not satisfactory for dealing with some specific claims.

Existing national initiatives/ voluntary schemes

Before the Claims Regulation, there was no EU legal framework on nutrient profiles. Nevertheless, the notion of nutrient profiling was already used to a certain extent in few of the currently existing voluntary initiatives (having a nutritional objective) before the Claims Regulation²⁸, and most commonly used in the context of the front-of-pack nutrition labelling schemes.

Front-of-pack (FoP) nutrition labelling schemes aim to help consumers with their food choices by

²² Discussion Paper on nutrition claims and functional claims, Prepared by Directorate General Health and Consumer Protection (SANCO D4), European Commission. SANCO /1341/2001. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-claims-claims_discussion_paper_en.pdf (last accessed 13 June 2018).

²³ The term '*functional*' food is often used in literature for foods bearing nutrition and health claims.

²⁴ Frewer, L. et al (2003). Consumer acceptance of functional foods: issues for the future. *British Food Journal*, 105(10): 714-731.

²⁵ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 06/05/2000, p. 29).

²⁶ Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 06/10/1990, p. 40).

²⁷ Council Directive 90/496/EEC laid down rules on the content and presentation of nutrition information on pre-packed foods. According to these rules, the inclusion of nutrition information was mandatory when a nutrition-related claim was made concerning the food.

²⁸ As they were still at early stages of development at the time of the entry into force of Claims Regulation.

providing at-a-glance nutrition information on the front side of the food package. In Sweden the Keyhole logo was already in operation, first introduced in 1989²⁹; in the Netherlands, the Choices logo was first presented as a concerted industry scheme in 2006³⁰; and, in the UK formalised preparations that eventually led to the UK traffic light label were also under way since 2004³¹.

Market aspects - Supply trends

In 2006, the food and drink industry was the single largest manufacturing sector in the EU in turnover (876 € billion), value added (188 € billion) and employment terms (4.3 million employees). It was the second leading manufacturing sector in terms of number of companies in the EU (308,000 companies). SMEs made up 99.1% of the food and drink business population; these companies generated 48.5% of food and drink turnover and employed 63% of the sectorial workforce. Large companies accounted for 0.9% of all food and drink enterprises but they provided 51.5% of the turnover, 52.9% of the value added and contributed to 37% of the employment.³²

The food and drink industry was – and still is – a pillar of the EU economy. This sector featured in the top three manufacturing activities in terms of sales in several Member States. France, Germany, Italy, the UK and Spain were the largest EU food and drink producers in 2007. Together, these countries accounted for almost 70% of the total EU turnover in this sector.

Consumer trends

Before the adoption of the Claims Regulation (February to April 2005), research on consumers' perceptions of food labelling was carried out on behalf of the European consumers' organisation (BEUC)³³ to inform the debate on the proposed Claims Regulation. The survey was conducted in five European countries: Germany, Denmark, Spain, Hungary and Poland, and 600 people were interviewed in each country³⁴.

²⁹ See external contractor's report, Annex 7.A.I, p. 22.

³⁰ See external contractor's report, Annex 7.A.II, p. 36.

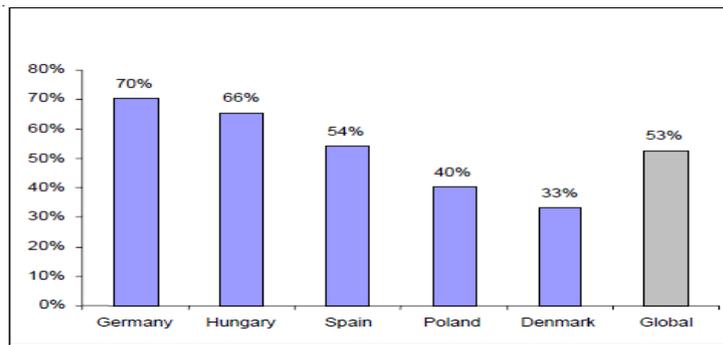
³¹ See external contractor's report, Annex 7.A.III, p. 49.

³² FoodDrinkEurope, Data & trends of the European Food and Drink Industry (2008). To be found at: https://www.fooddrinkeurope.eu/uploads/publications_documents/DataTrends2008.pdf (last accessed 21 June 2018).

³³ European Consumers' Organisation (BEUC) (2005) Report on the Consumers' Perception of Foodstuffs Labelling. Results of Consumer Research conducted on behalf of BEUC from February to April 2005. BEUC/X/032/2005, 31 August 2005. To be found at: https://www.vzby.de/sites/default/files/mediapics/beuc_foodstuffs_labelling_09_2005.pdf (last accessed 21 June 2018).

³⁴ Although five countries were selected by BEUC in order to reflect a European diversity (Mediterranean, Northern and Eastern Europe), this survey should not be considered as representative of the entire EU.

Figure 5: Do you trust nutritional claims?



Source: European Consumers' Organisation (BEUC) (2005) Report on the Consumers' Perception of Foodstuffs Labelling, p.11.

The survey results show that nutrition claims caught the attention of 59% of interviewees and that 53% of interviewees trusted nutrition claims, although this share varies considerably between countries, ranging from 33% in Denmark to 70% in Germany (Figure 5). The share of interviewees who indicated that the claim 'rich in calcium' would lead them to buy the product varied from 23% in Denmark to 59% in Poland (overall share of 47%). According to this research, the majority of consumers trusted the claims on the package, mainly because they trusted the brand, and believed they understood their meaning. However, many interviewees, who said to trust claims, did not have a good knowledge of nutritional concepts and terminology. The survey results also indicate that most consumers paid more attention to and claimed to understand better the claims made on the front of the pack of a product, particularly the nutrition claims, than the basic nutrition tables on the back of the pack, which nearly 40% of surveyed consumers were not interested in the way they were presented on food packages at the time. As bottom line of this BEUC's report, the results indicated that nutrition claims influenced to a certain extent consumers' buying patterns.

In contrast to the consumer's perception of nutrition claims shown by BEUC research, some literature suggested that consumers were sceptical towards foods bearing health claims. A study³⁵ indicated that consumers remained sceptical about the actual efficacy of health-related claims on foods, and that the success of the functional food market³⁶ depended on improving consumers' perception and trust. Similarly, other research showed that consumers' acceptance was a decisive factor in the successful marketing of functional foods, although very little research had been conducted on this topic³⁷. Another study in the literature suggested that there is some contention on the effect of health-related claims on dietary choices. In particular, it was suggested that health-related claims may increase consumption as it was observed that participants ate more of a snack food when it was described as 'low fat'³⁸. However, other studies have found that health-related claims reduce consumption as they reduce consumers' taste expectations^{39 40}.

³⁵ L. Frewer, J. Scholderer, N. Lambert, (2003). Consumer acceptance of functional foods: issues for the future. *British Food Journal* 105(10), p.714-731. To be found at:

<https://doi.org/10.1108/00070700310506263> (last accessed 21 June 2018).

³⁶ I.e. Foods claiming beneficial properties to health.

³⁷ T. Bech-Larsen, J. Scholderer, (2006). *Functional Foods in Europe: consumer reach, market experiences and regulatory aspects*. Elsevier 18(4), p. 231-234. To be found at:

<https://doi.org/10.1016/j.tifs.2006.12.006> (last accessed 21 June 2018).

³⁸ Wansink B, Chandon P. Can "low-fat" nutrition labels lead to obesity? *J Mark Res.* 2006;43:605–p. 17.

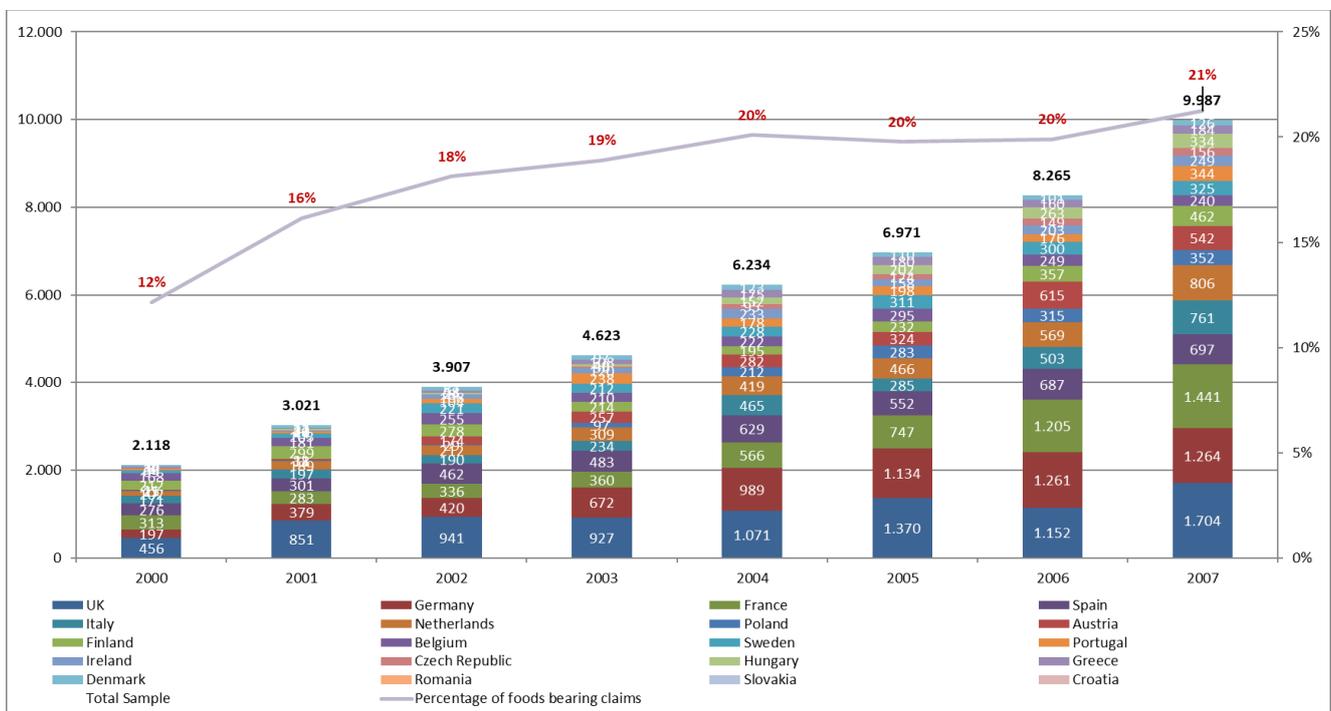
³⁹ Berning J, Chouinard H, McCluskey J. Do positive nutrition shelf labels affect consumer behavior? Findings from a field experiment with scanner data. *Am J Agric Econ.* 2010;93:364–p. 9.

Prevalence of claims

The Mintel Global New Products Database (GNPD), as described in [section 4](#) on the methodology, allowed to obtain data on new food products accessing the market on a yearly basis. While these figures cannot provide an accurate picture on the situation of the market in terms of the prevalence of nutrition and health claims, they do provide an indication of the general trend of new food products bearing claims accessing the EU market prior to the Claims Regulation.

Figure 6⁴¹, representing the number of new food products (not including food supplements) bearing claims accessing the market, shows an increasing trend over the years 2000 to 2004, while the overall percentage of foods bearing claims was stable, at approximately 20%, between 2004 and 2007.

Figure 6: Number of new products bearing claims entering the market and the percentage they represent on the food and drink market, from 2000 to 2007 (tabulated in Appendix 13)



Source: Commission analysis based on MINTEL GNPD

Note: the MINTEL GNPD covers only 20 out of the 28 EU Member States and does not include data for Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.

⁴⁰ Raghunathan R, Naylor R, Hoyer W. The unhealthy = tasty intuition and its effects on taste inferences, enjoyment, and choice of food products. *J Mark.* 2006;70:170–p. 84.

⁴¹ MINTEL GNPD searches for products where Country matches one or more of UK, Austria, Belgium, Czechia, Denmark, Slovakia, Finland, France, Germany, Greece, Hungary, Ireland, Romania, Italy, Netherlands, Croatia, Poland, Portugal, Spain, Sweden and Super-Category matches one or more of Food, Drink and Claims matches one or more of [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] as the claim and Date Published is between January 2000 and December 2007.

3.1.2. Description of the current situation

Currently, nutrient profiles are not established at EU level. The Claims Regulation stipulates that the Commission shall establish the nutrient profiles by 19 January 2009 for food or certain categories of foods by the Commission, after seeking the advice of EFSA and after having consulted with interested stakeholders, particularly food business operators and consumers. In 2008, EFSA adopted a scientific opinion on the setting of nutrient profiles⁴², and the Commission started to consult the Member States and the stakeholders on a draft Commission Regulation establishing a nutrient profiles' system. That draft legal text defined for certain categories of foods the thresholds of nutrients (fat, saturated fat, salt and total sugars), above which nutrition and health claims were to be prohibited. These thresholds are set out in detail in Appendix 2 to this Staff Working Document.

Controversy on the setting of nutrient profiles

Despite the initial progress, the work on nutrient profiles was eventually postponed given the high controversy of the topic. Member States initially supported the concept of nutrient profiles, although subsequently political considerations led to strong opposition by few Member States and requests for additional exemptions or more lenient conditions for certain categories of foods. Consumer and public health organisations advocated for a stricter system⁴³, while certain sectors of the food industry pointed to alleged economic losses and lower competitiveness that they expected from the implementation of the proposed system. Multinational companies were rather supportive⁴⁴, but certain sectors were strongly opposed, especially the chocolate, confectionary, and bakery products sectors⁴⁵.

On the basis of position papers received at the time of the nutrient profile discussions, the main arguments provided for the opposition were the following:

- the nutrient profiles would lead to a segregation of the market: traditional products, for which reformulation would be challenging, if not impossible, due to their legal composition specifications, would not be able to make claims and therefore would be perceived as non-healthy foods. On the contrary, processed foods which could be more easily reformulated and make claims, would be perceived as healthy foods;
- the proposed criteria would totally exclude the category of chocolate and cocoa-based confectionery products (100%) from the possibility to make claims⁴⁶;
- nearly all fine bakery products would be excluded from access to nutritional and health claims⁴⁷;
- the proposed value of sodium for bread was considered too low, due to technological and taste constraints⁴⁸.

Since nutrient profiles have not been set, currently all foods can bear nutrition and/or health claims that are complying with the other legal requirements of the Claims Regulation,

⁴² The EFSA Journal (2008) 644, p. 1-44. To be found at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.644> (last accessed 25 June 2018).

⁴³ Position Paper of BEUC on the setting of nutrient profiles (4 November 2008).

⁴⁴ Letter of Unilever addressed to Mr Barroso, President of the European Commission (dated 26 February 2009).

⁴⁵ *E.g.* Chocolate products containing high levels of sugars and saturated fat are enriched in calcium and bear a nutrition claim on calcium.

⁴⁶ Position Paper of Caobisco on cocoa and chocolate products and cocoa-based confectionery (6 November 2008).

⁴⁷ Position Paper of Caobisco on Cereal Products (3 November 2008).

⁴⁸ Position Paper of the Association Internationale de la Boulangerie Industrielle (31 October 2008).

independently of their content of fat, saturated fat, sugars or salt. In this context, the level of consumer's understanding, empowerment and willingness to engage into healthy dietary habits is of paramount importance in setting out priorities for future action.

Feedback received by the Commission on the Roadmap of this evaluation in October 2015, mainly from consumer and public health organisations, highlights that, in broad terms, the positions expressed in the past by these stakeholders on the issue of nutrient profiles continue to be relevant today. For example, BEUC and public health organisations still highlight the importance of the nutrient profiles for protecting consumers.

In addition, in December 2017, eight Member States asked the Commission in a letter to set the nutrient profiles arguing that they are necessary to ensure a high level of consumer protection, as well as legal certainty and equal conditions of competition for business operators in the EU.

Entry into application of the FIC Regulation

The entry into application of Regulation (EU) No 1169/2011 on the provision of food information to consumers ('FIC Regulation')⁴⁹ maintained the existing rules requiring that nutrition and/or health claims can only be made where the nutritional content of the food is labelled, particularly in relation to the nutrient for which the claim is made.

Moreover, as of December 2016, the FIC Regulation requires that the nutrition declaration is mandatory for all foods, thus providing consumers with all factual information on the nutritional value of the food in question, irrespectively of whether a food bears a claim or not. This nutrition declaration is generally presented in a table format, at the back of pack and it relates to the energy value and the content of fat, saturated fat, carbohydrate, sugars, protein and salt.

Development of national nutritional schemes/initiatives in the Member States

Simplified nutrition labelling schemes are more and more being used on the front of the pack in order to help consumers to see at a glance the essential nutrition information when purchasing foods.

Most FoP schemes are based on nutrient profile criteria that may be simple nutrient thresholds, for example to define when a scheme will attribute a green, amber or red colour (e.g. UK traffic light scheme), or more complex algorithms that result in a summary score (e.g. Keyhole, Nutri-Score). The nutrient profile criteria can be applicable to all food groups across the board, or be specific to different product groups. As such, nutrient profile criteria do not appear on labels.

During the stakeholder consultation carried out for this evaluation, Member States competent authorities reported that FoP schemes or other initiatives based on a nutrient profiling model have been adopted in 15 out of the 26 Member States that responded, with a total of 22 (implemented and/or planned) national schemes or initiatives relevant to this evaluation. The remaining 11 Member States indicated that they did not have/plan any regulatory FoP schemes/initiatives at national level.

These national schemes, as detailed in Appendix 3 to this Staff Working Document, have been developed for a variety of purposes/objectives and, on that basis, they are ultimately classified in two broad categories according to type of scheme/initiative, as follows:

⁴⁹ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304 22.11.2011, p. 18).

- a) Front-of-pack (FoP) nutrition labelling schemes, including pictorial/symbolic nutrition claims: the Nordic Keyhole in place in Denmark, Sweden and Lithuania, the Traffic Light in the UK, the Nutriscore in France and Belgium;
- b) Other initiatives to improve dietary choices, based on a nutrient profiling model:
 - a. Restrictions to advertising to children in Ireland, the UK, and Czechia;
 - b. Reformulation or food improvement initiatives (e.g. reformulation of all foods based on thresholds for each nutrient by product category, reformulation for salt content in bread) in the Netherlands, Greece and Portugal;
 - c. Application of food taxes in Hungary, Portugal and France.

With few exceptions, all the above-mentioned schemes/initiatives apply on a voluntary basis. It should be noted that none of the existing schemes has been developed because of the non-setting of EU nutrient profiles, according to the consulted national competent authorities. All FoP labelling schemes/initiatives are aimed at providing better information to consumers, thus helping them to improve their diet.

Development of private (industry-led) nutritional schemes/initiatives

A number of private schemes/initiatives, as detailed in Appendix 4 to this Staff Working Document, were identified by stakeholders⁵⁰, which were classified into different categories:

1. Front-of-pack (FoP) nutrition labelling schemes, including pictorial/symbolic nutrition claims: Reference Intakes label (these were the most frequently reported by stakeholders), SENS in Poland; Heart Symbol in Finland, Healthy Choices in Czechia and Poland.
2. Advertising to children initiatives: EU Pledge in France, UK OFCOM, advertising code in the Netherlands, Slovenia and Poland, Pledge in Belgium;
3. Reformulation initiatives: salt in bread initiative in Germany; and, food innovation in Slovenia.

Market aspects - Supply trends

Compared to the baseline period, since the adoption of the Claims Regulation, the following trends in the food sector have been observed:

- The EU food and drink industry continues to be the largest manufacturing sector in the EU, with a turnover that has increased by 1.9% in real terms between 2007 and 2017. The share of the sector's value added and employment in manufacturing have remained relatively stable. Although the number of companies in the sector dropped by 1.7%, the number of SMEs has remained relatively stable⁵¹.
- Innovation efforts in this sector are reported to be scattered, with EU business operators not being able to dominate in any field⁵². Amongst the possible reasons identified for the lack of

⁵⁰ In a total of 63 records, survey results Q2 stakeholders – see external contractor's report, Annexes, Annex 4.A, p. 18.

⁵¹ FoodDrinkEurope, Data & trends of the European Food and Drink Industry (2017). To be found at: https://www.fooddrinkurope.eu/uploads/publications_documents/DataandTrends_Report_2017.pdf (last accessed 14 September 2018).

⁵² European Commission (2014). Innovation Union Competitiveness Report. Commission Staff Working Document, Directorate-General for Research and Innovation, January 2014.

innovation are that EU consumers do not trust new technologies and that R&D investment by EU companies remains relatively low⁵³.

Consumer trends

While consumer awareness of the links between food and health has increased due to the large amount of information available, consumer trust in the food and drink industry globally has not improved⁵⁴.

A 2012 study observed that many different factors influence consumer acceptance of health-related claims and symbols: familiarity with the product, the health claim or the functional ingredient used, as well as personal relevance (e.g. motivation to live healthily, a food allergy, other nutritional requirements) appeared as the most important determinants⁵⁵.

The CLYMBOL study investigated how claims and symbols are perceived and understood by consumers and how they affect food choice and consumption. Research showed that familiarity with the nutrient/substance mentioned in the claim/symbol and the personal relevance are the primary influence factors of consumers' acceptance of nutrition and health claims. These factors varied strongly depending on the individual, making it very likely that different consumers perceive the same claim differently⁵⁶. These findings were further confirmed in other studies⁵⁷ conducted in the context of the CLYMBOL project, where it was observed that familiar or personally relevant substances could result in an "upgrade" of a statement, showing that consumers' assessments of the healthfulness of foods bearing claims does not only rely on what is actually stated in a claim. In addition, the need for information was found to be the main driver for consumers' motivation and was also higher in individuals with a strong health motivation. Subjective knowledge regarding the healthfulness of food was observed as the main factor driving consumers' self-reported ability to process health claims and symbols.

The above observations were also noted in a choice experiment that examined health claims on a fruit juice product. That experiment showed that the odds of choosing the product with a health claim varied by how health conscious the consumer was and whether they already consumed the product.⁵⁸

A systematic review of the impact of health-related claims on dietary choices showed that health-related claims have a substantial effect on dietary choices, but this effect varied according to the type of product. However, this finding was based on research mostly conducted in artificial settings (e.g. in the context of surveys), while findings from real-life experiments (e.g. in supermarkets) showed smaller effects on the dietary choices of consumers.⁵⁹

⁵³ See external contractor's report, Part Two, p. 11.

⁵⁴ Edelman Trust Barometer (2018) Global Report. To be found at: http://cms.edelman.com/sites/default/files/2018-02/2018_Edelman_Trust_Barometer_Global_Report_FEB.pdf (last accessed 19 September 2018).

⁵⁵ Wills JM, Storcksdieck genannt Bonsmann S, Kolka M, et al. (2012). European consumers and health claims – attitudes, understanding, and purchasing behaviour. *Proceedings of the Nutrition Society* 71(2):229-236.

⁵⁶ Klepacz NA, Nash RA, Egan BM, Hodgkins CE & Raats MM (2015). When is an image a health claim? A false-recollection method to detect implicit inferences about products' health benefits, accepted in *Health Psychology*.

⁵⁷ Hieke S, Cascanette T, Pravst I, Kaur A, van Trijp H, Verbeke W, Grunert KG. The role of health-related claims and symbols in consumer behaviour: the CLYMBOL project. *Agro FOOD Hi Tech* 2016, p. 27.

⁵⁸ Mohebalian P, Cernusca M, Aguilar F. Discovering niche markets for elderberry juice in the United States. *HortTechnology*. 2012;22:556 – p. 66.

⁵⁹ Asha Kaur, Peter Scarborough, Mike Rayner (2017). A systematic review, and meta-analyses, of the impact of health-related claims on dietary choices. *International Journal of Behavioral Nutrition and Physical Activity* (2017) 14:93.

Overall, it appears from the above that although nutrition and health claims do play a role, they are not the sole determining factor, in driving consumers’ dietary choices.

Prevalence of claims

The EU-funded CLYMBOL project has been conducted with respect to the prevalence of claims in the EU following the adoption of the Claims Regulation. The project analysed in 2013 a randomised sample of about 2,034 products in Germany, Netherlands, Slovenia, Spain and United Kingdom. As the research dates back to 2013, the results do not present an overview of the current prevalence of claims but are the best and latest available evidence, representing a useful point of comparison.

More than one quarter of all foods and drinks (26%) sampled in the study bore at least one claim: with 21% of the foods bearing a nutrition claim, 11% bearing a health claim and 4% bearing a health-related ingredient claim. A health-related ingredient claim was defined as a claim communicating the presence of an ingredient(s) which is not a nutrient or other substance as defined in the EU regulation but which implies health benefits, e.g. “Contains one of your five a day” or “Sweetened only with brown sugar”. However, such claims are out of scope of the Claims Regulation. On a country-level, the overall percentage of foods with at least one claim varied from 35% in the UK to 21% in Germany. The prevalence of nutrition claims varied significantly across countries (Spain: 74% Netherlands: 64%, UK: 62%, Slovenia 61% and DE: 55%); while smaller variations –in absolute terms– were observed with health claims (Slovenia and Germany: 37%, Netherlands: 31%, Spain: 24% and UK: 21%)⁶⁰.

Detailed data per product group⁶¹ indicate that the prevalence of claims also tends to vary considerably between product groups as indicated in Table 1⁶².

Table 1: Prevalence of nutrition and health claims (including symbolic ones) by food category

Food Sector	Nutrition claims	Health claims
Beverages	31%	17%
Cereals/cereal products	31%	16%
Dairy	28%	13%
Oils	26%	26%
Sugars and related products	24%	16%
Confectionery	15%;	8%
Snack foods	21%	3%
Convenience foods	9%	4%

Source: Hieke, S. et al (2016)

The findings of Mintel GNPD cannot be compared to those found in CLYMBOL study because the MINTEL GNPD includes only data on new products accessing the market while CLYMBOL is about a sample of products existing already on the market. Nevertheless, the prevalence of

⁶⁰ Hieke, S. et al (2016). Prevalence of nutrition and health-related claims on pre-packaged foods: A five-country study in Europe. *Nutrients*, 8(3).

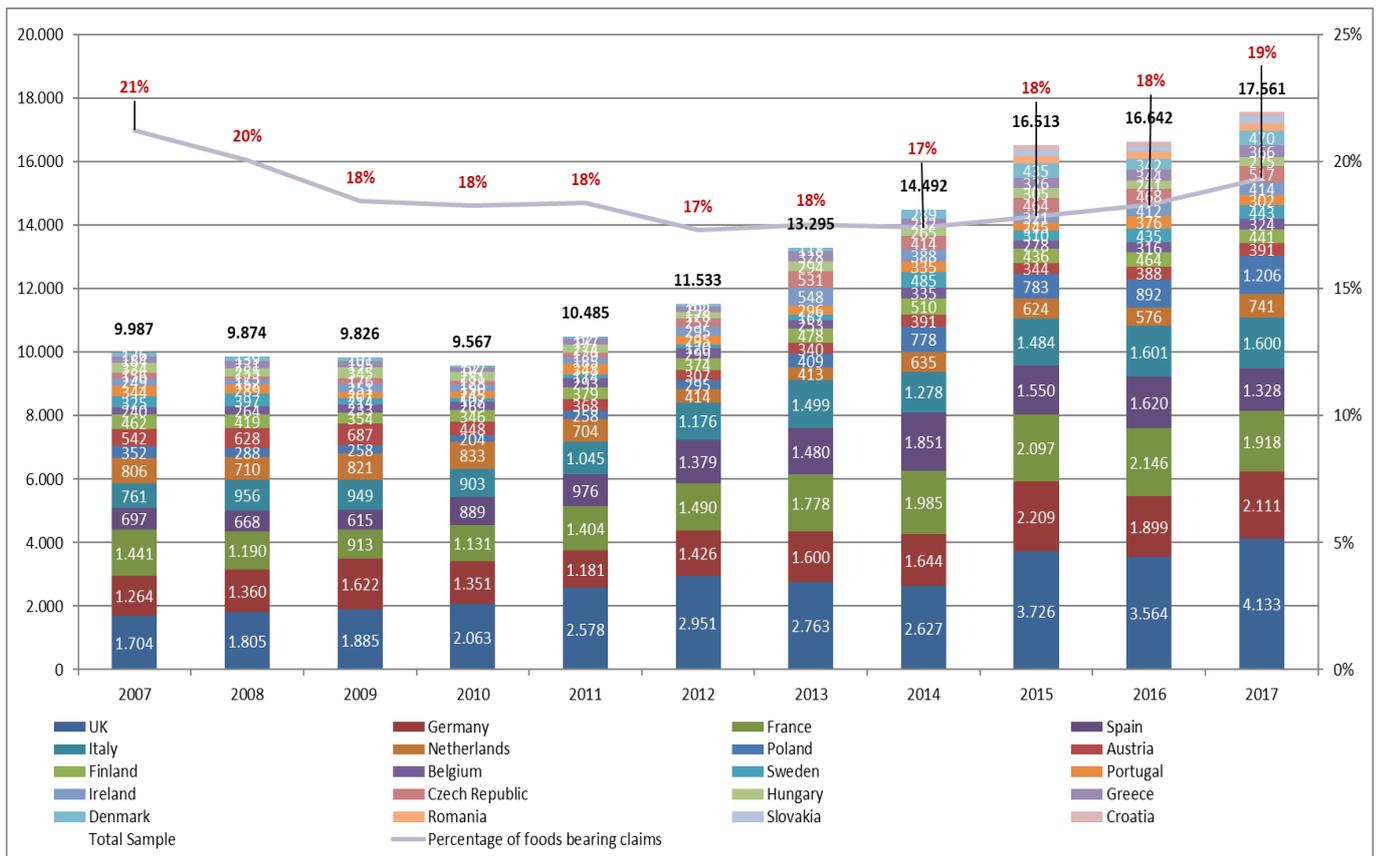
⁶¹ Similar trends were identified in another detailed study conducted in Slovenia (Pravst I. et al (2017) - *See external contractor's report, Annexes, Annex 7.D, p.100*).

⁶² Hieke, S. et al (2016). Prevalence of nutrition and health-related claims on pre-packaged foods: A five-country study in Europe. *Nutrients*, 8(3).

claims in new food and drink products from the MINTEL GNPD is presented below in Figure 7⁶³ as data from MINTEL GNPD allow for a comparison over time.

As it can be noted, compared to the baseline, the percentage of foods bearing claims dropped slightly until the moment of the establishment of the list of permitted health claims in 2012. After that point the variation of the prevalence is small, nevertheless, the actual number of products bearing claims increased on a regular basis.

Figure 7: Number of new products bearing claims entering the market and the percentage that they represent on the food and drink market, from 2007 to 2017 (tabulated in Appendix 13)



Source: Commission analysis based on MINTEL GNPD

Note: the MINTEL GNPD covers only 20 out of the 28 EU Member States and does not include data for Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia. New products considered in this analysis include all foods and drinks.

⁶³ MINTEL GNPD search for products where Country matches one or more of Slovakia, Austria, Belgium, Czechia, Denmark, Finland, France, Germany, Greece, Hungary, UK, Ireland, Romania, Italy, Netherlands, Poland, Portugal, Spain, Croatia, Sweden and Super-Category matches Drink or Category matches one or more of Bakery, Sweet Spreads, Breakfast Cereals, Dairy, Chocolate Confectionery, Sugar & Gum Confectionery, Side Dishes, Fruit & Vegetables, Savoury Spreads, Meals & Meal Centers, Processed Fish, Meat & Egg Products, Sauces & Seasonings, Desserts & Ice Cream, Snacks, Soup, Sweeteners & Sugar and Claims matches one or more of [Plus, Minus, Functional] but does not match Anti-Bacterial as the claim and Date Published is between January 2007 and December 2017.

3.2. Health Claims made on plants and their preparations

3.2.1. Baseline and points of comparison

The survey of Member States' competent authorities indicated that before the introduction of the Claims Regulation, i.e. before December 2006, the majority (21) of Member States did not have in place any specific national legislation on health claims made on plants and their preparations used in foods, while legislation in place in the remaining Member States followed different approaches. Five Member States (Austria, Croatia, Germany, Greece and Italy) had national legislation in place that limited to some extent the use of health claims on food products containing plants and their preparations. In two of these Member States (Austria and Greece) a pre-marketing authorisation procedure before using health claims on a product was envisaged. In other cases, there was no specific national legislation, although either a strict interpretation of legislation on the labelling of foods did not allow the use of medicinal claims on food products, or the overall legislation on the use of claims on foods also covered foods containing plants and plants substances. In one Member State (Italy), national guidelines listed all health claims for plants which could be used on food products⁶⁴.

Traditional Use Registrations and Well-established Use Marketing Authorisations of medicinal products

According to the European Medicines Agency⁶⁵, Traditional Use Registrations (TUR) for THMPs increased year by year, since its implementation by the Member States of the traditional herbal use procedure in October 2005. There were few registrations of new herbal medicinal products in 2004 and 2005 and mainly concentrated on the “well-established use” category rather than on “traditional use” (Figure 9 and Figure 10).

The value of the European herbal medicines market was estimated at around €4 billion in 2005, with Germany (around 37% of the total), France (25%), Italy (8%) and Poland (7%) as the leading national markets⁶⁶.

3.2.2. Description of the current situation

What progress has been made over time in the context of the legislative framework introduced by Regulation (EC) No 1924/2006? Is this in line with the initial expectations?

In 2008, Member States submitted around 44,000 health claims to the Commission, which consolidated them into a final list: the consolidated list of 4,637 health claims (including 2,078 claims for plants and their preparations). By 2010, this list of claims was sent to EFSA to assess their scientific substantiation. To streamline the evaluation process, EFSA grouped them into six batches. The publication of the first two batches of EFSA's opinions, by September 2010, revealed that no health claims (530 claims) on plant substances received a favourable assessment.

The main reason is linked with the general scientific principles applied by EFSA for the evaluation of all health claims. The Claims Regulation requires that health claims should only be

⁶⁴ See external contractor's report, Part three, page 1.

⁶⁵ European Medicines Agency (2016). Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. To be found at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf (last accessed 11 July 2018).

⁶⁶ Knöss, W. (n.d.). BfArM - Prof. Dr. Werner Knöss Presentation: Herbal and Traditional Herbal Medicinal Products – Experiences in Germany. To be found at: https://www.eiseverywhere.com/file_uploads/fe070a58abad49a6b36199c565655d6_2014_Athen_KnossPDF.pdf (last accessed 15 November 2018).

authorised for use in the EU after a scientific assessment of the highest possible standard⁶⁷. In this context, EFSA⁶⁸ considers human intervention studies as essential for the substantiation of claims, given that such studies allow the drawing of scientific conclusions at the '*highest possible standard*'. This is also confirmed in the EFSA guidance document on the scientific and technical guidance for the preparation and presentation of a health claim application⁶⁹. Hence, evidence collected solely based on experience gained over time with the actual consumption of the plants and preparations (the notion of *traditional use*) alone was not considered sufficient for EFSA as compliant with the requirements of the Claims Regulation. It should also be noted that a safety assessment is not foreseen under the framework of the Claims Regulation. However, EFSA may indicate – where relevant – restrictions of use based on safety considerations. Final decisions regarding the authorisation of health claims – including the final wording and the conditions/restrictions of use – are taken by risk managers (i.e. the European Commission and Member States), not by EFSA. In order to make such decisions, risk managers may consider other legitimate factors, such as safety aspects (e.g. to modify the conditions/restrictions of use), in addition to EFSA's scientific evaluation.

Furthermore, when the first health claims on plants received an unfavourable assessment, several stakeholders and some Member States raised concerns regarding the impact that this could have on the EU food industry, in particular to the food supplements sector. In addition, a difference in the treatment of plant substances (particularly, the consideration of the notion of traditional use) under the legislation on health claims and that on THMPs was underlined as an issue. In September 2010, the Commission announced⁷⁰ the suspension of the assessment procedure as regards claims on plants and their preparations, to reflect on a consistent treatment of these claims. This resulted in the creation of an 'on-hold' list, which currently includes a total of 2,078 health claims for plants and their preparations⁷¹. These cover claims already assessed (530 claims) and claims not yet assessed by EFSA (1548 claims).

In the absence of a definition of plants and their preparations in EU food legislation, the Commission had to apply a case-by-case approach to decide which claims in the consolidated list corresponded to claims on plants and their preparations⁷². As a first step, the Commission took into account Member States' classification when they submitted claims to the Commission, but also the definition of herbal substances and herbal preparations in the THMP legislation. From these claims, the Commission excluded those claims for which the subject of the claim would normally be expected to be consumed in significant quantities in a balanced and varied diet. An exception was made for those substances that are subject to evaluation by the European Medicines Agency's Committee on Herbal Medicinal Products.

Currently, health claims on plants and their preparations in foods that are in the 'on-hold list' can be used across the EU, under the responsibility of food business operators, provided that they

⁶⁷ Recital 23 and recital 17 and Article 6(1) of the Claims Regulation.

⁶⁸ More precisely, EFSA's Panel on Dietetic Products, Nutrition and Allergies (EFSA NDA Panel).

⁶⁹ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4680>

⁷⁰ European Commission, Press Release (IP/10/1176), Food: Commission reviews the progressive adoption of the list of permitted health claims. To be found at:

http://europa.eu/rapid/press-release_IP-10-1176_en.htm?locale=en (last accessed 13 June 2018).

⁷¹ On-hold claims are not included in the EU Register of claims but are listed in a separate document, where they are identified only through their ID number:

http://ec.europa.eu/nuhclaims/resources/docs/claims_pending.pdf (last accessed 6 June 2018).

⁷² The list of claims submitted by the Member States on the basis of Article 13(2) of Regulation (EC) No 1924/2006, corresponded to claims on plants and their preparations.

comply with the general principles and conditions of the Claims Regulation and with existing national provisions applicable to them until a final decision on these claims is taken⁷³.

Health claims on plant substances may also be submitted for an authorisation irrespectively to the on-hold list, but in such situations, should the scientific assessment be unfavourable, these claims are refused authorisation and their use is consequently prohibited on the EU market.

Use of health claims on food supplements containing plants and their preparations

The extent to which companies producing foods containing plant substances have been affected by the Claims Regulation is described below and differentiated according to the type of product, given the needs and specificities of each sector.⁷⁴

It should be noted that food supplements are marketed with claims in most cases. Consumption of food supplements is linked to a specific function and it could be reasonably expected that in most cases consumers would not buy a food supplement without a claim on it. “Communication on the properties of plants is a key element. [...] For non-medicinal use, communication focuses on nutritional and/or health benefits. For botanical food supplements it is therefore essential that such communication is possible under the form of a claim”.⁷⁵

The situation on the use of claims on teas and herbal infusions (THI)⁷⁶ is less homogenous than the situation outlined above for food supplements. According to an estimate by the THI business association, approximately 80% of THI products bore claims before the implementation of the Claims Regulation, while at the time of this evaluation THI products bearing claims can barely be found on the market. The main reason, according to the THI sector, is that the conditions set by the Claims Regulation for the use of claims refer to nutrients or other substances, while THI are composed of entire plants that contain different substances and scientific studies focus on the effects of single substances, not of whole plants.⁷⁷

Traditional Use Registrations and Well-established Use Marketing Authorisations

The situation for medicines registered under the Traditional Use Registrations (TUR) – as mapped by the European Medicines Agency⁷⁸ – indicates a total of 1,719 Traditional Use Registrations for THMPs granted between 2004 and 2016, with a peak in 2011 (374 TUR) (Figure 9). It is noted that the registrations are products specific, even though the substance with the long standing traditional medical use may be the same.

The situation with respect to well-established use marketing authorisations for medicinal products indicates a total of 859 well-established use marketing authorisations for HMPs (Figure 10). Well-established use marketing authorisations granted between 2004 and 2016, appear to be more constant over the years.

⁷³ Under transitional measures foreseen in Article 28(5) of the Claims Regulation.

⁷⁴ See external contractor's report, Part Three, pages 8.

⁷⁵ R. Anton, M. Serafini and L. Delmulle (2013), The Substantiation of Claims for Botanical Food Supplements in Relation to Traditional Use, *European Food and Feed Law Review*, 2013/5, 21 October 2013, pp. 321-328.

⁷⁶ In total, the size of the THI market amounted to around 242,200 tonnes in 2007.

⁷⁷ Interviews carried out as part of the study of the external contractor.

⁷⁸ European Medicines Agency (2016). Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. To be found at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf (last accessed 11 July 2018).

3.3. Regulatory framework on plants and their preparations

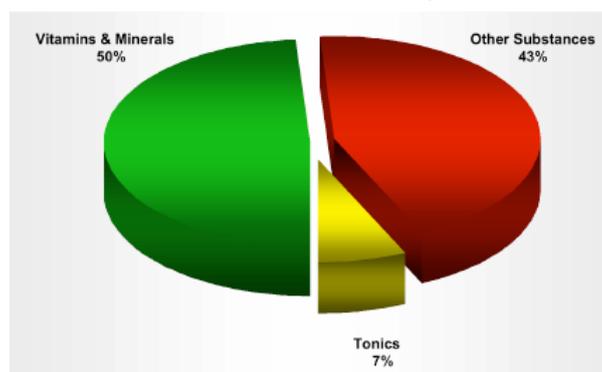
3.3.1. Baseline and points of comparison

As described above in [Section 2.2](#), the use of plants and their preparations in foods is not harmonised by means of specific legislation at EU level. Thus, the point in time after the adoption of the Commission report on the use of substances other than vitamins and minerals in food supplements⁷⁹, in 2008, is to be considered as the baseline for the regulatory framework on plants and their preparations. At that time, two important pieces of legislation, which could potentially affect the use plants and their preparations in foods, had just started to apply at the time: 1) Regulation (EC) No 1924/2006 on nutrition and health claims made on food; and 2) Regulation (EC) No 1925/2006 on the addition of vitamins, minerals, and of certain other substances to food.

Market aspects – Supply trends

The overall value of the EU market of food supplements in 2005 was estimated by Euromonitor to be at around €5 billion (Retail Selling Prices): around €2.5 billion (50% of total) consisted of vitamins and mineral products; €2.2 billion (43%) of supplements containing substances other than vitamins and minerals (including substances obtained from plants, but not limited to them); and the remaining €0.3 billion (7%) is composed of tonics and bottled nutritive drinks (Figure 8)⁸⁰. The Euromonitor data for tonics does not distinguish between tonics containing vitamins and minerals, and tonics containing other substances.⁸¹

Figure 8: Relative market share of the food supplement segments in the EU



Source: Euromonitor, 2005

⁷⁹ Report of European Commission to the Council and European Parliament on the use of substances other than vitamins and minerals in food supplements, COM(2008) 824 final, 2008. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-comm_2008_0824_en.pdf (last accessed 10 May 2019).

⁸⁰ Tonics and bottled nutritive drinks: includes liquid versions of dietary supplements, typically a combination of ingredients (such as vitamins, minerals and botanicals). Tonics and bottled nutritive drinks classified as OTC products, or marketed as functional foods are not included in Euromonitor's data (Euromonitor, 2005).

⁸¹ The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements study undertaken for DG SANCO, European Commission. Service contract Nr SANCO/2006/E4/018, European Advisory Services (EAS), 28 March 2007. To be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_nutrition-supplements-2007_a540169_study_other_substances_en.pdf (last accessed 13 June 2018).

According to Food Supplements Europe⁸², based on data of 2012, the number of new products containing plant substances launched on the market in Member States where a notification is required illustrated a highly dynamic segment, with over 3,000 products launched in Belgium and over 4,500 in Italy on a yearly basis; while 25,000 products were launched in France over the period between 2006 and 2012. It is important to note that those figures include a wide range of “new products” which contain no new plant substances. Innovation in many of those “new products” concerns packaging, dosage of ingredients, combinations of ingredients, addition of substances other than plants and their preparations (especially vitamins and minerals), etc.

3.3.2. Description of the current situation

The currently applicable regulatory framework as regards plants and their preparations used in food is the one described under [section 2.2](#) as it has been implemented at EU and national level over time. The current situation in relation to Claims Regulation has been detailed in [section 3.2.2](#).

As mentioned above, it is still possible to submit applications for the authorisation of health claims on plants and their preparations, independently to the on-hold list. In that context, one health claim on a plant substance, hydroxyanthracene derivatives, received a favourable efficacy assessment for the health claim. Even though EFSA is not asked to perform a safety assessment when assessing health claims, in its scientific opinion⁸³, EFSA drew the attention to safety concerns and advised on additional conditions/ restrictions/ warnings for the use of the health claim. In the following discussions with the Member States on the final decision on the authorisation of the health claim, a full risk assessment on the use of the substance in foods was asked for (in accordance with Article 8 of the Regulation on food fortification).

To date, this procedure has been launched for two substances⁸⁴ as a result of discussions in the context of Claims Regulation and for three substances⁸⁵, independently to Claims Regulation. For all substances, it should be noted that EFSA, in its scientific opinion, highlighted several potential problems in relation to risks to human health; while due to the scarcity of data originating from use of the substances in the food sector, the scientific opinions highlighted many uncertainties. In 2015 and 2019, the Commission prohibited the use in foods in the EU of *Ephedra* species and Yohimbe, respectively. A final decision has not yet been taken for the other substances.

National legislation

Most Member States (19) have adopted national legislation on the use of plants and their preparations in foods (*see* Appendix 5 to this Staff Working Document). The following type of provisions are the most commonly observed in such legislation:

- **Notification procedure:** Implementation of a notification procedure for the marketing of food products containing plants (15 Member States). The notification procedure can be differently implemented, but it is generally applied to the broader category of food

⁸² Food Supplements Europe, Mr Peter Loosen, Presentation at the Botanical Foundation “Towards a common approach to regulating botanical, Milan – 16 June 2016.

⁸³ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2013;11(10):3412, 12 pp. to be found at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3412> (last accessed 1 February 2019).

⁸⁴ 1) Monacolins derived from red yeast rice (i.e. rice fermented with the red yeast *Monascus purpureus*) and 2) Hydroxyanthracene derivatives.

⁸⁵ 1) Yohimbe (*Pausinystalia yohimbe* (K. Schum.) Pierre ex Beille) 2) Ephedra herb and its preparations 3) Green tea catechins, and particularly (-)-epigallocatechin-3-gallate (EGCG)

supplements and hence also, yet non-exclusively, to food supplements containing plant substances.

- **Positive lists of plant substances:** 9 Member States have developed positive lists of plant substances. Both tradition of use and scientific evidence are largely used as elements for compiling positive lists of substances. Positive lists can be linked with the use of plants in food supplements (this is the case in Belgium, France, and Italy), or serve as a support tool for the classification of products as foods or as medicines (in Germany and Slovenia), or are specifically used for other products (in Slovakia the list only includes plants that can be used to produce teas).
- **Negative lists of plant substances:** 16 Member States have developed negative lists of plant substances; negative lists are based mainly on scientific evidence but in certain cases the notion of traditional use is also considered. In certain Member States negative lists include plants which cannot be used in food supplements but can be used in medicines only. In other cases (e.g. in the Netherlands), the negative lists include plants that cannot be used at all. In other cases (e.g. Slovenia), the list classifies on a case-by-case basis whether a plant can be used for foods, for medicines, for both or if its use is not allowed at all.

As regards the classification of a product as food or as medicine, the decision is taken on a case-by-case basis by the Member States. National medicine agencies have in most of the cases a prominent role in this decision, while in other cases there is collaboration between the medicine and food agencies in order to establish whether a product should be classified as food or medicine. Special mixed competence commissions can also be set up in order to decide on specific cases. As for the timing of the assessment, it can be performed when a food supplement is notified, or when a product is already on the market.

It is important to note that where a product is classified as a “food” in a Member State, this does not preclude another Member State from classifying the same product as a “medicine”⁸⁶. For plants used both in foods and medicines, differences in the applicable legislation could lead to a different management of the same substance. The issue of classification is further discussed in [section 5.3.1](#).

Market aspects – Supply trends

The food supplements market in the EU is valued at around €10.3 billion (nearly twice as much as in the baseline situation, *see* [section 3.3](#)). Food supplements containing plant substances account for around 63% of total market value (€6.5 billion; no comparable estimate is available for the baseline situation). Four countries account for 62% of revenues from food supplements containing plants and plant substances in the EU. Germany is the most important national market with a total value of around €1.3 billion, followed by Italy (€1.1 billion), France (€1.0 billion) and the United Kingdom (€0.6 billion)⁸⁷. Another source (FSE) reports estimates of the market of food supplements with plants to be over €4 billion⁸⁸.

According to Food Supplements Europe, based on more recent data, the number of new products containing plant substances launched on the market in Member States where a notification is required illustrates a continued increase of this market. More specifically, in France, according to

⁸⁶ An extensive case-law on so-called borderline products exists. Such case law generally arises when a Member State does not allow on its territory the marketing of a food product manufactured in another Member State because it contains substances that in the destination Member State are normally used in medicinal products.

⁸⁷ Synadiet (2016). Presentation: business sector study Europe plant food supplements. May 2016.

⁸⁸ *See* external contractor's report, Part Three, page 12.

the latest available report⁸⁹ published by the “Direction générale de la concurrence, de la consommation et de la répression des fraudes” (DGCRF) on Notifications, a total of 12830 food supplements were notified of which 8376 plant-based food supplements in 2017, making botanicals the most prominent active ingredient. In Italy, the number of notifications per year is over 10000, of which over 5000 plant-based food supplements. Last, in Belgium it is assumed that the number of notified products (6000 per year, of which 3000 plant-based food supplements) is now a quite conservative estimate and has in all likelihood increased. It should be noted that not all products that are notified, are fully new products, containing new plants or plant preparations. Part of these notifications may cover re-formulation of already existing products, but a large part will indeed be new products, illustrating the dynamics of the companies.

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https://www.economie.gouv.fr/files/files/directions_services/dgcrf/securite/produits_alimentaires/Complement_alimentaire/CA_decla_Bilan2017.pdf

4. METHODOLOGY

This evaluation draws on one external study, performed by an external contractor between May 2016 and June 2018⁹⁰. The overall approach was a multi-method analysis to identify quantitative and qualitative evidence to answer the evaluation questions on effectiveness, efficiency, relevance, coherence and EU added value.

The external contractor collected primary quantitative and qualitative information and reviewed secondary data through targeted desk research. Different primary and secondary data sources were identified in an evaluation matrix⁹¹ covering all the evaluation questions. To collect data and views from the relevant stakeholders a consultation strategy (methodology – Appendix 7 to this Staff Working Document, stakeholder consultation – Appendix 8 to this Staff Working Document) was developed at an early stage of the evaluation process. A summary of the stakeholders' consultation, the number and composition of respondents and consultation outcomes are provided in the synopsis report in Appendix 9 to this Staff Working Document.

The Commission services found the external study helpful in terms of framing the issues under evaluation as a result of the gathered survey data by the contractor, but had to perform significant additional desk research to collect quantitative data in view of strengthening the overall analysis, synthesis and triangulation for the purpose of preparing this staff working document.

An interservice steering group on this evaluation was set up to steer, monitor and ensure the necessary quality of the external study and the overall process of the evaluation (Appendix 6 to this Staff Working Document)⁹². The interservice steering group was involved in all key phases of the evaluation (roadmap, terms of reference, stakeholder consultations, contractor's external study, staff working document) and provided input and information, ensuring the quality, impartiality and usefulness of the final product. The interservice steering group was composed of ten services⁹³ of the Commission.

4.1. Data collection and analysis

Primary data was collected by the external contractor through different stakeholders' consultation tools, which are summarised in Table 2 below. The main stakeholder groups identified, e.g. associations representing consumers, food and pharmaceutical industries, as well as national competent authorities (see Appendix 8 to this Staff Working Document for full list of stakeholders), were consulted through the public consultation, targeted surveys and interviews. The results of these consultations are presented in the Synopsis report (Appendix 9 to this Staff Working Document).

Table 2: Consultation activities carried out

Consultation tool	Targeted stakeholders/ participants	Time	N. contributions/ participants
First workshop	Member States' competent authorities, Stakeholders from all relevant groups	21/06/2016	25 Member States 22 Stakeholders

⁹⁰ Food Chain Evaluation Consortium, 2018, Evaluation of Regulation (EC) No 1924/2006. Link to the published report of the external study. To be found at: https://ec.europa.eu/food/safety/labelling_nutrition/claims/refit_en

⁹¹ See external contractor's report, Annexes, Annex 3.

⁹² Further details on the work of the interservice steering group together with the procedural information concerning the process to prepare the evaluation are presented in Appendix 6 to this Staff Working Document.

⁹³ SG, SJ, AGRI, GROW, MARE, JUST, RTD, TRADE, JRC, SANTE.

Consultation tool	Targeted stakeholders/ participants	Time	N. contributions/ participants
Member States survey	Member States' competent authorities	December 2016-February 2017 (8 weeks)	26 Member States
Targeted survey	FBOs, pharma business operators, public health and public interest groups/ NGOs.	December 2016-February 2017 (8 weeks)	113: 101 from business representatives, 12 from non-business organisations
SMEs survey	SMEs ⁹⁴ , including micro-enterprises, consulted through the Europe Enterprise Network SMEs Panel	April-June 2017 (10 weeks)	400 (nutrient profiles), of which 301 participants made claims and replied to the survey (84.4% SMEs ⁹⁵). 286 (plants and their preparations), of which 269 participants operating in the food and/or medicinal sector containing plants and their preparations (89.9% SMEs ⁹⁶)
Online public consultation	Individuals (potential consumers)	2/03-1/06/2017 (12 weeks)	2001 individuals
In-depth interviews	Associations of FBOs, of pharma business operators and of consumers, Commission staff, EFSA and EMA staff, Member States' competent authorities, competent authorities from US, Canada and Australia.	January-September 2017	58 interviews
Second workshop	Member States' competent authorities Stakeholders from all relevant groups	26-27/10/2017	23 Member States 36 Stakeholders

To complement the evidence collected through primary sources of information, the following secondary sources were used.

Desk research and a literature review were performed by the external contractor to fine-tune the proposed methodology, to identify quantitative and qualitative data sources, as well as the related data gaps to be addressed. The literature review drew on a wide range of relevant documentation, specific reports and other material produced within and for Commission Services, Member States as well as the body of academic literature and stakeholder position papers. The literature review carried out by the external contractor was complemented with additional literature reviewed by the Commission services.

⁹⁴ *I.e.* enterprises up to 250 employees.

⁹⁵ Nearly one third (30.2%) of respondents were micro-enterprises (1-9 employees), followed by (29.6%) medium-size companies (50-249 employees), (24.6%) small companies (10-49 employees) and 3.3% self-employed. Respondents of larger enterprises represented 11.6% (\geq 250 employees) of participants and 0.7% of respondents did not provide an answer on company size.

⁹⁶ More than one third of respondents were micro (1-9 employees) and small enterprises (10-49 employees) (31.6% and 37.9%, respectively); 20.4% were medium size (50-249 employees) and 5.9% were large enterprises (>250 employees). 4.1% were self-employed.

Existing databases: the research conducted by the external contractor highlighted that publicly available data on the prevalence of nutrition and health claims on foods and the use of a nutrient profiling model to analyse the nutritional composition of a sample of foods with and without claims are not available, with the only exception of the CLYMBOL study. The Commission services made in addition use of a private database: MINTEL's Global New Products Database (GNPD)⁹⁷, which captures and compiles data on new products (including food 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.

Case studies were designed to provide more in-depth analysis of certain issues, focussing on the advantages/disadvantages and costs/benefits of the current situation. Six thematic case studies covering nine Member States were carried out, covering both nutrient profiles and plants and their preparations used in food.

All the data and information collected were analysed by the external contractor, except for data from Mintel GNPD, which were analysed by the Commission. The same approach was taken during the analysis phase to assess the five evaluation criteria: effectiveness, efficiency, relevance, coherence and EU added value. The impacts were assessed for each group of stakeholders (Member States, consumers, food business operators).

4.2. Limitations and robustness of findings

The evaluation fully covered the scope for time period, geographical areas and target groups. The stakeholder mapping ensured that all key stakeholders were identified and addressed. However, there were selection-biases of the respondents to the online public consultation. These respondents would be expected to be more conscious and could attribute higher importance to health claims.

The methodology design was appropriate for addressing the evaluation objectives and combined several approaches (surveys, in-depth interviews, case studies, desk research). The analysis was carried out in a systematic way following established evaluation criteria. The conclusions are based on the evidence provided through the analysis.

The main limitation of this evaluation lies with the fact that it assesses two elements which have not been fully implemented, i.e. the nutrient profiles and the health claims on foods containing plants and their preparations. In particular, the exact way in which nutrient profiles might have been set is not certain, since the Commission did not finalise the initial work of 2009.

Moreover, the scarce availability of quantitative data and reliance on stakeholders' views limited the analysis performed. To mitigate such limitations, the existing literature was extensively consulted and used to verify statements from different stakeholders' groups, where possible. The scarcity of reliable quantitative data suggests that additional efforts should be made at EU level to collect data on EU consumption of different types of foods, e.g. food supplements, foods with claims, and how the dietary habits of EU consumers are affected by the different types of information provided.

Another limitation is that the Mintel GNPD data used for evaluating the absence of nutrient profiles cover only new products entering the market and therefore, do not constitute a representative sample, nor provide a complete picture of the entire market. Therefore, the analysis of these data was combined with other sources of information, such as academic literature, stakeholders' views and other data available from the literature (i.e. data from the CLYMBOL project). Lastly, it should be noted that the nutrition declaration became mandatory for all foods

⁹⁷ To be found at: <http://www.mintel.com/about-mintel> (last accessed 7 June 2018).

only as of December 2016 and between 2007 and 2016, nutritional information was mandatory only for nutrients for which a claim was made in accordance with the Claims Regulation. Thus, not all new products bearing claims listed in the Mintel GNPD provided nutritional information on the content of fat, sugar and salt prior to 2007.

Considering these limitations and corrective measures, the results of this evaluation rely mostly on a qualitative analysis and are substantiated by quantitative evidence to the extent possible. Nevertheless, the analysis and following results are presented transparently and all the sources of information are duly referenced. The views of all the consulted stakeholders are reflected in a neutral and balanced way in the Staff Working Document. Despite the limited quantitative data, the results are reliable, as the evidence was collected following a rigorous approach (e.g. definition of an evaluation matrix, mapping of stakeholders – see Appendices 7 and 8).

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1. Nutrient Profiles: answers to the evaluation questions

5.1.1. Effectiveness

Did the non-setting of nutrient profiles at EU level prevent the realisation of the objectives of the Regulation? If yes, to what extent and why? What are the objectives that are not met and to what extent?

Which main factors (e.g. actions by Member States, actions by stakeholders) have contributed to or stood in the way of achieving these objectives in relation to nutrient profiles and to what extent?

To what extent can nutrition and health claims be considered as accurate and reliable given the non-setting of nutrient profiles at EU level?

How and to what extent does the non-setting of nutrient profiles at EU level affect the trade of foods? (How do they affect the different stakeholders?)

Impacts on consumers

The assessment of whether the non-setting of nutrient profiles has achieved the consumer-related objective of the Claims Regulation (i.e. consumer protection) and the specific objective of the nutrient profiles, which is to avoid a situation where nutrition or health claims mask the overall nutritional status of a food product and could, therefore, mislead consumers when trying to make healthy choices in the context of a balanced diet, looked into two indicators. First, whether there are foods bearing claims having a high content in fat, saturated fat, sugars and salt/sodium (FSS) and second, whether, over the course of time, there has been a decrease in that number of foods.

The FSS content differs across Member States even for similar products and it is not possible to make a general statement on FSS content of products across the EU. These variations seem linked with the following:

- Different dietary patterns and FSS intake across the EU⁹⁸;
- Consumer perceptions and attitudes to the information provided on food labels and claims more generally, as these affect consumers' purchasing decisions⁹⁹;
- The prevalence of foods with claims in national markets, as well as extent to which foods have a 'high' FSS content¹⁰⁰; and,
- the different extent to which reformulation has occurred in Member States, depending *inter alia* on the extent to which national or private schemes/initiatives are in place in the various Member States and their impact.

According to a large majority of national competent authorities¹⁰¹ and BEUC¹⁰², certain foods bearing claims have a high FSS content. These stakeholders agree that this is mainly the case for

⁹⁸ For example, discrepancy between FAO recommendations that fat should make up between 15% and 30-35% of total energy intake for adults, and variations between Member States in meeting this guideline.

⁹⁹ As identified *inter alia* in research carried out in the context of the CLYMBOL, FLABEL and JANPA projects.

¹⁰⁰ There is some evidence suggesting that FSS nutrient content of the same foods may vary across the EU (irrespectively to the use of claims).

Bureau Européen des Unions de Consommateurs - BEUC (2016). Food Composition & The Internal Market. A cross-country comparison exercise by BEUC members;

JANPA (2017a) Monitoring network for food composition: A pilot study. D5.2 "Pilot study and identification of participants in a monitoring network". Work package: WP5 Nutritional information monitoring and food reformulation prompting).

certain product categories, such as breakfast cereals, soft drinks and juices, dairy, confectionery and snacks and, more generally, fortified products. There is consensus amongst national competent authorities that, in the current situation, consumers may be misled as to the overall nutritional status of products bearing claims. Consumers at the lower level of socio-economic status are more vulnerable to be misled as they are less likely to read and understand the nutrition information provided on food labels. These concerns were uniformly shared across Member States¹⁰³, even in those where nutrient profiling criteria currently apply under national schemes/initiatives¹⁰⁴, and where the available evidence shows that the prevalence of claims on foods high in FSS is relatively low (e.g. UK and NL)¹⁰⁵.

The Member States' views are corroborated by evidence available from consumer studies, which agree that consumer understanding and interest tends to be linked to socio-economic parameters¹⁰⁶. More generally, the literature agrees that the effects of food labels are subtle and multiple factors, such as socio-economic and demographic characteristics, influence consumers' behaviour.¹⁰⁷ Research shows that there is potential for consumers to be misled in perceiving foods bearing claims as healthier than they are in terms of FSS content or healthier in comparison to foods without claims.¹⁰⁸ It has been noted that, overall, motivation to process health-related information appears to be more important for European consumers than their cognitive ability to process the information provided in a claim.¹⁰⁹

National competent authorities also consider that in the current situation it is almost impossible to enforce the general principles of the Claims Regulation, that “...*the use of nutrition and health claims shall not (a) be false, ambiguous or misleading*”. In cases where authorities are faced with authorised claims on foods considered as of high FSS content, and thus potentially misleading for consumers as to their overall nutritional status, it is difficult to refuse the use of health claims on foods with a high FSS content on the basis that food information shall not be misleading (Article 7(1) of the FIC Regulation), giving way to lengthy legal disputes.

Finally, respondents to the public consultation tended to consider unacceptable that a food product with a high FSS content can bear a nutrition or health claim, although for some respondents it was acceptable.¹¹⁰

Organisations representing food business operators reported a potential ‘discrepancy’ between the claims on the package and the nutritional composition due to the nature of some products (e.g. dairy, natural fruit juices, sport and energy products)¹¹¹. On the other hand, most

¹⁰¹ Based on the targeted consultation of Member States. See external contractor's report, Part Two, page 16.

¹⁰² See external contractor's report, Part Two, page 17.

¹⁰³ Both in the feedback received from national authorities and stakeholders representing consumers.

¹⁰⁴ I.e. either on all foods (e.g. in the context of FoP nutrition labelling such as the UK Traffic light) or in the context of foods bearing nutrition claim logos (e.g. Nordic Keyhole; Dutch Choices) (see external contractor's report, Annexes, Annex 7.A).

¹⁰⁵ Both consumer associations and national competent authorities in these Member States are sceptical about the nutrient status of certain foods bearing claims (i.e. other than those conferred by the specific scheme logo). Nonetheless, CLYMBOL data (Kaur et al, 2016) showed a relatively lower percentage of foods with claims in these countries (i.e. less than 30% of foods with nutrition claims; less than 20% of foods with health claims did not pass the FSANZ NPSC model).

¹⁰⁶ See external contractor's report, Annexes, Annex 7.D, p. 106 and p. 111.

¹⁰⁷ See external contractor's report, Annexes, Annex 7.D, p. 108.

¹⁰⁸ See external contractor's report, Annexes, Annex 7.D, p. 105 and p. 107. – Grunert, K. G. (2016). How to best measure and monitor the impact of claims and symbols? *CLYMBOL final conference presentation*.

¹⁰⁹ See external contractor's report, Annexes, Annex 7.D, p. 108.

¹¹⁰ OPC question 11 (see external contractor's report, Annexes, Annex 6, p. 15).

¹¹¹ See external contractor's report, Part Two, p. 18.

respondents to the SMEs panel reported that their food products bearing claims do not tend to be high in FSS content. Less than a quarter of responding enterprises indicated that their products bearing claims are potentially high in fat (25.2%), sugar (24.3%), salt (19.6%) and saturated fat (15.6%). Around a third of respondents indicated that, since 2007, they have reduced FSS content in food products that bear nutrition/health claims, with most focusing on reducing sugar, followed by fat and salt, and least on reducing saturated fat; while around two thirds have not made any effort to reformulate their products.¹¹²

To further explore the partly contradictory views of stakeholders, additional sources of information were used: the Mintel GNDP and the CLYMBOL study. The Mintel GNDP allowed to analyse the FSS content of new food products bearing nutrition and health claims accessing the EU market on a yearly basis during the period 2005-2017. The analysis was carried out for a selection of food categories, which was based on the use of claims on these categories and their potentially high FSS content, as reported by stakeholders¹¹³. These categories are: carbonated soft drinks, juice drinks, sport and energy drinks, breakfast cereals, dairy¹¹⁴ and bakery¹¹⁵ products. Five countries were selected (i.e. UK, Italy, Poland, Sweden and France) based on their size, geographical location and use of national nutritional schemes (e.g. traffic light scheme in the UK and the keyhole logo in Sweden). Additional information about the methodology used for the analysis of the Mintel GNDP can be found in Appendix 7 to this Staff Working Document.

Table 3 and Table 4 show that, despite the adoption of the Claims Regulation in December 2006, and the anticipated establishment of nutrient profiles in 2009, the percentage of new products bearing claims that have an FSS content exceeding the thresholds proposed by the Commission in 2009 increased from 2007 to 2009, and as of 2009 remained high. The tables also indicate that the percentage of foods bearing claims and exceeding the FSS threshold is noticeable for certain categories, i.e. breakfast cereals, juice drinks, sport and energy drinks, and bakery products. However, within the same food category differences exist also between countries. For example, the percentage of breakfast cereals with an FSS content exceeding the thresholds set by the 2009 Commission's draft legal act is lower in Sweden and the UK than in France, Italy and Poland. The prevalence of cold or hot breakfast cereals might partly explain this difference as hot breakfast cereals tend to have a lower sugar content. In France and Italy, the percentages of hot cereals (out of the total number of new breakfast cereals) were, respectively, 4% and 1% on average during the period 2005-2017, while these percentages were 12% and 25% for Sweden and the UK, respectively.

¹¹² See external contractor's report, Part Two, p. 18.

¹¹³ See external contractor's report, Part Two, p. 15-18.

¹¹⁴ The following sub-categories were included: Drinking Yogurts/Liquid Cultured Milk, Fresh Cheese & Cream Cheese, Margarine & Other Blends, Soft Cheese & Semi-soft Cheese, Soft Cheese Desserts, Spoonable Yogurt.

¹¹⁵ The following sub-categories were included: Bread & Bread Products, Cakes, Pastries & Sweet Goods, Savoury Biscuits/Crackers, Sweet Biscuits/Cookies.

Table 3: New food products with claims exceeding the nutrient profile thresholds set out in the Commission’s draft legal act of 2009 on setting the criteria for nutrient profiles, 2005 to 2017*

Product category	Country	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Breakfast cereals	France	12 out of 17 71%	17 out of 25 68%	14 out of 29 48%	23 out of 32 72%	14 out of 26 54%	27 out of 44 61%	52 out of 90 58%	31 out of 62 50%	53 out of 90 59%	45 out of 99 45%	51 out of 121 42%	53 out of 142 37%	48 out of 129 37%
	Italy	5 out of 6 83%	10 out of 12 83%	4 out of 11 36%	3 out of 6 50%	6 out of 10 60%	13 out of 26 50%	13 out of 21 62%	13 out of 34 38%	28 out of 58 48%	18 out of 44 41%	11 out of 23 48%	15 out of 25 60%	11 out of 35 31%
	Poland	2 out of 2 100%	6 out of 8 75%	3 out of 4 75%	3 out of 6 50%	2 out of 5 40%	3 out of 6 50%	8 out of 13 62%	14 out of 23 61%	11 out of 26 42%	38 out of 65 58%	29 out of 71 41%	38 out of 108 35%	36 out of 106 34%
	Sweden	2 out of 7 29%	9 out of 28 32%	1 out of 5 20%	5 out of 7 71%	2 out of 10 20%	1 out of 4 25%	1 out of 4 25%	3 out of 9 33%	2 out of 15 13%	4 out of 15 27%	4 out of 37 11%	4 out of 43 9%	11 out of 38 29%
	UK	13 out of 23 57%	14 out of 38 37%	18 out of 51 35%	14 out of 38 37%	12 out of 44 27%	39 out of 88 44%	38 out of 124 31%	43 out of 126 34%	35 out of 133 26%	42 out of 140 30%	76 out of 247 31%	45 out of 194 23%	58 out of 241 24%
Margarine, drinking and spoonable yogurts	France	3 out of 14 21%	3 out of 34 9%	7 out of 37 19%	1 out of 32 3%	5 out of 27 19%	11 out of 49 22%	12 out of 59 20%	9 out of 48 19%	9 out of 68 13%	7 out of 71 10%	17 out of 62 27%	9 out of 60 15%	11 out of 61 18%
	Italy	2 out of 21 10%	2 out of 16 13%	0 out of 23 0%	2 out of 31 6%	3 out of 38 8%	9 out of 210 21%	4 out of 39 10%	9 out of 38 24%	10 out of 67 15%	6 out of 49 12%	13 out of 65 20%	10 out of 81 12%	3 out of 77 4%
	Poland	1 out of 4 25%	n.a.	5 out of 7 71%	6 out of 13 46%	3 out of 12 25%	5 out of 14 36%	4 out of 13 31%	5 out of 17 29%	6 out of 23 26%	7 out of 44 16%	7 out of 30 23%	9 out of 27 33%	7 out of 59 12%
	Sweden	1 out of 3 33%	3 out of 9 33%	4 out of 11 36%	1 out of 9 11%	1 out of 7 14%	1 out of 8 13%	2 out of 10 20%	1 out of 9 11%	0 out of 15 0%	1 out of 17 6%	1 out of 13 8%	3 out of 29 10%	4 out of 17 24%
	UK	9 out of 49 18%	7 out of 20 35%	1 out of 12 8%	8 out of 22 36%	12 out of 36 33%	19 out of 73 26%	32 out of 104 31%	27 out of 113 24%	35 out of 125 28%	32 out of 110 29%	38 out of 162 23%	38 out of 160 24%	36 out of 186 19%
Fresh, semi-soft and soft cheese	France	n.a.	0 out of 1 0%	0 out of 6 0%	3 out of 14 21%	0 out of 10 0%	1 out of 5 20%	3 out of 18 17%	3 out of 26 12%	2 out of 28 7%	9 out of 2014 33%	4 out of 18 22%	5 out of 28 18%	5 out of 19 26%
	Italy	1 out of 2 50%	0 out of 2 0%	0 out of 1 0%	3 out of 5 60%	3 out of 4 75%	0 out of 8 0%	3 out of 6 50%	3 out of 7 43%	7 out of 22 32%	10 out of 23 43%	3 out of 15 20%	3 out of 19 16%	5 out of 19 26%
	Poland	n.a.	n.a.	n.a.	1 out of 1 100%	n.a.	0 out of 2 0%	1 out of 3 33%	1 out of 6 17%	1 out of 3 33%	2 out of 8 25%	0 out of 6 0%	2 out of 18 11%	2 out of 18 11%
	Sweden	0 out of 1 89%	0 out of 2 60%	n.a.	n.a.	3 out of 4 89%	0 out of 1 0%	n.a.	0 out of 1 0%	n.a.	1 out of 10 10%	1 out of 11 9%	1 out of 7 14%	1 out of 4 25%
	UK	3 out of 5 60%	0 out of 2 0%	2 out of 2 100%	0 out of 2 0%	3 out of 10 30%	3 out of 11 27%	4 out of 27 15%	4 out of 26 15%	3 out of 25 12%	2 out of 19 11%	2 out of 26 8%	3 out of 12 25%	5 out of 33 15%
Bread & bread products	France	1 out of 4 25%	9 out of 12 75%	7 out of 10 70%	9 out of 12 75%	9 out of 12 75%	7 out of 10 70%	32 out of 44 73%	12 out of 21 57%	23 out of 34 68%	19 out of 30 63%	31 out of 47 66%	46 out of 79 58%	35 out of 45 78%
	Italy	n.a.	6 out of 7 86%	6 out of 10 60%	3 out of 6 50%	1 out of 2 50%	12 out of 21 57%	19 out of 24 79%	16 out of 24 67%	38 out of 47 81%	26 out of 31 84%	37 out of 48 77%	33 out of 45 73%	49 out of 72 68%
	Poland	1 out of 2 50%	2 out of 5 40%	5 out of 8 63%	3 out of 4 75%	0 out of 1 0%	n.a.	1 out of 1 100%	3 out of 4 75%	2 out of 7 29%	1 out of 7 14%	6 out of 12 50%	4 out of 6 67%	9 out of 10 90%
	Sweden	2 out of 13 15%	16 out of 26 62%	3 out of 6 50%	8 out of 9 89%	5 out of 8 63%	4 out of 5 80%	8 out of 14 57%	8 out of 12 67%	4 out of 8 50%	16 out of 33 48%	13 out of 18 72%	13 out of 25 52%	14 out of 35 40%
	UK	4 out of 15 27%	5 out of 14 36%	11 out of 19 58%	16 out of 36 44%	9 out of 26 35%	13 out of 34 38%	17 out of 55 31%	13 out of 58 22%	12 out of 60 20%	16 out of 69 23%	17 out of 81 21%	13 out of 93 14%	27 out of 102 26%
Cakes, pastries, sweet and savoury biscuits	France	28 out of 28 100%	31 out of 34 91%	30 out of 32 94%	27 out of 29 93%	18 out of 22 82%	33 out of 36 92%	40 out of 51 78%	43 out of 54 80%	61 out of 79 77%	93 out of 110 85%	128 out of 144 89%	138 out of 157 88%	114 out of 138 83%
	Italy	3 out of 3 100%	21 out of 23 91%	24 out of 25 96%	13 out of 14 93%	16 out of 19 84%	56 out of 73 77%	54 out of 72 75%	82 out of 101 81%	103 out of 136 76%	79 out of 113 70%	114 out of 148 77%	126 out of 163 77%	142 out of 181 78%
	Poland	2 out of 2 100%	2 out of 3 67%	3 out of 7 43%	7 out of 9 78%	10 out of 14 71%	3 out of 5 60%	1 out of 4 25%	8 out of 13 62%	19 out of 22 86%	31 out of 42 74%	31 out of 50 62%	35 out of 52 67%	51 out of 80 64%
	Sweden	4 out of 4 100%	5 out of 8 63%	7 out of 9 78%	7 out of 7 100%	3 out of 5 60%	7 out of 10 70%	3 out of 4 75%	3 out of 4 75%	11 out of 11 100%	13 out of 21 62%	9 out of 13 69%	10 out of 21 48%	24 out of 30 80%
	UK	26 out of 35 74%	25 out of 30 83%	37 out of 47 79%	29 out of 33 88%	37 out of 45 82%	34 out of 39 87%	51 out of 58 88%	67 out of 81 83%	77 out of 98 79%	76 out of 82 93%	102 out of 124 82%	76 out of 97 78%	134 out of 174 77%

Table 4: New drink products with claims exceeding the nutrient profile thresholds set out in the Commission’s draft legal act of 2009 on setting the criteria for nutrient profiles, 2005 to 2017*

Product category	Country	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Carbonated soft drinks	France	0 out of 19 0%	0 out of 8 0%	2 out of 8 25%	1 out of 9 11%	1 out of 14 7%	2 out of 14 14%	6 out of 20 30%	4 out of 33 12%	5 out of 66 8%	8 out of 51 16%	7 out of 39 18%	2 out of 54 4%	3 out of 24 13%
	Italy	0 out of 3 0%	0 out of 6 0%	2 out of 8 25%	1 out of 9 11%	0 out of 12 0%	0 out of 10 0%	0 out of 8 0%	0 out of 15 0%	0 out of 18 0%	1 out of 17 6%	1 out of 27 4%	0 out of 20 0%	2 out of 28 7%
	Poland	2 out of 4 50%	0 out of 1 0%	0 out of 2 0%	1 out of 5 20%	n.a. n.a.	n.a. n.a.	n.a. n.a.	0 out of 4 0%	2 out of 3 67%	1 out of 8 13%	0 out of 17 0%	1 out of 10 10%	1 out of 12 8%
	Sweden	0 out of 6 0%	0 out of 5 0%	0 out of 4 0%	0 out of 3 0%	n.a. n.a.	0 out of 3 0%	0 out of 1 0%	1 out of 2 50%	0 out of 2 0%	0 out of 4 0%	0 out of 3 0%	n.a. n.a.	0 out of 7 0%
	UK	1 out of 17 6%	1 out of 10 10%	1 out of 6 17%	2 out of 14 14%	1 out of 19 5%	2 out of 18 11%	4 out of 29 14%	4 out of 40 13%	7 out of 52 13%	1 out of 51 2%	2 out of 64 3%	3 out of 77 4%	2 out of 103 2%
Juice drinks	France	21 out of 26 81%	27 out of 36 75%	37 out of 47 79%	52 out of 61 85%	42 out of 54 78%	47 out of 58 81%	78 out of 95 82%	135 out of 151 89%	139 out of 173 80%	168 out of 203 83%	107 out of 145 74%	125 out of 165 76%	116 out of 167 69%
	Italy	4 out of 8 50%	6 out of 9 67%	31 out of 37 84%	43 out of 53 81%	34 out of 49 69%	33 out of 44 75%	34 out of 44 77%	34 out of 47 72%	58 out of 66 88%	33 out of 46 72%	55 out of 77 71%	32 out of 50 64%	42 out of 60 70%
	Poland	22 out of 29 76%	17 out of 23 74%	15 out of 17 88%	19 out of 25 76%	15 out of 20 75%	11 out of 14 79%	5 out of 7 71%	16 out of 24 67%	52 out of 65 80%	68 out of 101 67%	62 out of 79 78%	59 out of 89 66%	64 out of 95 67%
	Sweden	6 out of 8 75%	16 out of 18 89%	13 out of 16 81%	7 out of 9 78%	13 out of 15 87%	6 out of 7 86%	6 out of 6 100%	7 out of 11 64%	13 out of 19 68%	23 out of 33 70%	9 out of 15 60%	20 out of 25 80%	26 out of 37 70%
	UK	26 out of 45 58%	19 out of 31 61%	36 out of 51 71%	20 out of 27 74%	37 out of 55 67%	25 out of 39 64%	30 out of 52 58%	54 out of 85 64%	65 out of 130 50%	62 out of 124 50%	74 out of 208 36%	78 out of 201 39%	71 out of 203 35%
Sport and energy drinks	France	1 out of 1 100%	0 out of 2 0%	1 out of 1 100%	1 out of 3 33%	6 out of 8 75%	6 out of 9 67%	3 out of 9 33%	6 out of 13 46%	11 out of 31 35%	11 out of 21 52%	14 out of 19 74%	25 out of 33 76%	19 out of 24 79%
	Italy	2 out of 3 67%	0 out of 2 0%	1 out of 6 17%	1 out of 7 14%	4 out of 7 57%	0 out of 2 0%	0 out of 7 0%	0 out of 4 0%	5 out of 9 56%	3 out of 11 27%	6 out of 13 46%	20 out of 32 63%	18 out of 25 72%
	Poland	3 out of 4 75%	2 out of 3 67%	4 out of 8 50%	4 out of 7 57%	1 out of 3 33%	3 out of 4 75%	3 out of 4 75%	6 out of 12 50%	4 out of 14 29%	13 out of 28 46%	5 out of 17 29%	12 out of 20 60%	16 out of 33 48%
	Sweden	0 out of 2 0%	n.a. n.a.	1 out of 1 100%	n.a. n.a.	n.a. n.a.	1 out of 1 100%	1 out of 1 100%	3 out of 4 75%	3 out of 3 100%	0 out of 3 0%	0 out of 6 0%	1 out of 5 20%	0 out of 9 0%
	UK	0 out of 4 0%	2 out of 6 33%	5 out of 9 56%	5 out of 10 50%	4 out of 13 31%	7 out of 18 39%	15 out of 40 38%	14 out of 30 47%	27 out of 48 56%	13 out of 39 33%	19 out of 43 44%	11 out of 38 29%	13 out of 73 18%

* In red are highlighted the cases where more than 30% of new food and drink products with claims exceed the EU nutrient profiles’ thresholds for saturated fat and/or sugars and/or sodium set out in the Commission’s draft legal act of 2009.
‘n.a.’ indicates that there were no new products with claims for that specific year and product category.

Source: Commission calculations based on MINTEL GNPD

The CLYMBOL study¹¹⁶ is the only systematic research on the FSS content of foods bearing claims in a selection of EU countries¹¹⁷. This study used the nutrient criteria from the Australia and New Zealand nutrient profiling model¹¹⁸ to analyse the nutritional composition of a sample of foods with and without claims. The results indicate that in 2013, 43% of all foods sampled passed the Australian and New Zealand's nutrient profiling model, with foods carrying health claims and nutrition claims more likely to pass (70% and 61%, respectively) than foods that did not carry either type of claim (36%). These findings suggest that, generally, products bearing nutrition and health claims have a better FSS content than foods without any claims. Nonetheless, still 30% and 39% of foods with health and nutrition claims respectively, did not pass the nutrient profiling model criteria, although differences in nutrient content (including total sugars, total fat, and saturated fat) were in most cases reported as relatively 'modest'¹¹⁹. These data may vary depending on the nutrient profiling model, product categories and specific thresholds used in the calculations, as well as any exemptions granted¹²⁰.

Overall, the available evidence presented above suggests that the objective of nutrient profiles, i.e. protecting consumers from claims that mask the overall nutritional status of foods, is not fully achieved in the current situation. Although food products bearing claims tend to have a better nutritional status than foods without claims, a significant share of them (30% to 39% according to CLYMBOL) still have an FSS content above levels set by nutrient profiling. Bearing in mind that one of the main objectives of the Claims Regulation is to protect consumers, the non-setting of nutrient profiles has adversely affected consumers as they are exposed to claims that – in some cases – mask the overall nutritional status of foods.

Impacts on food business operators

The objectives of the Claims Regulation with respect to the Internal Market are to ensure free movement of foods bearing claims, create a level playing field and ensure legal certainty for food business operators, and promote food innovation. The effectiveness analysis investigated whether these objectives are achieved in the current situation, despite the absence of nutrient profiles.

Generally, the stakeholders from the food industry consulted during the evaluation did not report any major internal market problems arising from the absence of nutrient profiles at EU level. Foods bearing claims have been circulating freely between EU countries.¹²¹ However, the lack of a decision to set the nutrient profiles has led to some legal uncertainty. After the entry into force of the Claims Regulation, food business operators were unsure of the timing for the setting of nutrient profiles, their form (i.e. the FSS thresholds) and of how long they could keep on using the claims on non-reformulated products – where reformulation would be needed to comply with

¹¹⁶ Hieke, S. et al (2016), Prevalence of nutrition and health-related claims on pre-packaged foods: A five-country study in Europe. *Nutrients*, 8(3).

¹¹⁷ The UK, the Netherlands, Germany, Slovenia and Spain for foods selected and purchased in the same time frame (July–August 2013) for all countries.

¹¹⁸ Food Standards Australia New Zealand's Nutrient Profiling Scoring Criterion – FSANZ NPSC. The FSANZ NP model is used to restrict the use of health claims in foods in Australia and New Zealand.

¹¹⁹ Foods with health claims were found to have significantly lower levels of energy (–30 kcal/100 g), protein (–1 g/100 g), total sugars (–3 g/100 g), saturated fat (–2 g/100 g), and sodium (–842 mg/100 g), and significantly more fibre (+1 g/100 g) than foods without health claims. Foods with nutrition claims followed a similar pattern, with significantly lower levels of energy (–36 kcal/100 g), protein (–1 g/100 g), total sugars (–3 g/100 g), total fat (–4 g/100 g), saturated fat (–3 g/100 g) and significantly more fibre (+1 g/100 g). - Kaur, A. et al (2016). The nutritional quality of foods carrying health-related claims in Germany, The Netherlands, Spain, Slovenia and the United Kingdom. *European Journal of Clinical Nutrition*, 70: 1388–1395.

¹²⁰ Hieke, S. et al (2016), Prevalence of nutrition and health-related claims on pre-packaged foods: A five-country study in Europe. *Nutrients*, 8(3).

¹²¹ See external contractor's report, Part Two, p. 45.

such profiles. The Commission's work on nutrient profiles stopped in 2009, while Article 4 of the Claims Regulation that envisages the establishment of nutrient profiles has remained in place. This situation contributed to legal uncertainty for food business operators.

The absence of EU nutrient profiles (EU-NPs) has allowed neither for a comprehensive and consistent approach to reformulation throughout the food industry in the EU, nor for a level playing field across food business operators. This led to unfair competition between operators that have reformulated and operators that have not. This is due to the lack of tangible criteria against which food business operators could set product reformulation targets. Operators have reformulated in some cases for other reasons, such as the back-of-pack nutrition declaration, national or private schemes/initiatives, or response to market trends. Reformulation is done on a voluntary basis and its technical feasibility and challenges vary by sector. For example, the sugar replacement may be easier in sectors with relatively simpler ingredient composition, such as the soft drinks sector. It is also not possible to reformulate certain products due to regulatory constraints (e.g. set out by agricultural Common Market Organisation or Protected Designation of Origin / Protected Geographical Indication); however, one may question the extent to which such products use claims for marketing purposes.

Despite the above-mentioned problems, it seems that overall the absence of nutrient profiles has largely facilitated food business operators to make permitted claims under the Claims Regulation, without assessing the overall nutritional composition. Indeed, there was an increasing number of new food products with claims that entered the market between 2007 (9,987 products) and 2017 (17,561), see Figure 7.

Beyond these objectives, has the non-setting of nutrient profiles at EU level entailed negative or positive impacts, especially on the use of national or private nutrient schemes, such as nutritional logos? To what extent has the use of national or private nutrient schemes been a consequence of the non-setting of nutrient profiles at EU level? To what extent has the use of national or private nutrient schemes been effective in achieving the objectives of the Regulation, compare to the effectiveness of nutrient profiles should they have been established?

National or private schemes/initiatives

Impact on consumers

Several national regulatory and private schemes/initiatives having nutritional objectives were introduced since 2006, as described in [section 3.1.2](#). The aim of the identified schemes/initiatives is generally to improve consumers' information, restrict advertising of foods high in FSS content, improve dietary habits and promote healthier dietary choices. Therefore, their aim is not to restrict the use of claims on foods high in FSS, as the setting of the nutrient profiles was expected to do. According to the national competent authorities and stakeholders consulted, these national schemes were not developed as a consequence of the non-setting of nutrient profiles at EU level¹²². Nonetheless, they generally tend to be driven by the same broader objective of protecting consumers by enabling them to make informed and healthier food choices. In determining their relative effectiveness to meet EU-NP objectives, both for consumers and operators, it is important to consider the strengths and weaknesses of the different approaches followed by the identified schemes/initiatives.¹²³

A comparison of the objectives and scope of those schemes and the EU-NPs (*see* Appendix 10 to this Staff Working Document) indicates that, although certain schemes (e.g. FoP labelling) may feed into the same broader policy goals as EU-NPs (i.e. to help consumers make healthier food

¹²² See external contractor's report, Part Two, p. 20.

¹²³ See external contractor's report, Part Two, p. 37 (Table 7).

choices), their purpose and method of application are in practice different. The EU-NPs were to achieve their objective of limiting the use of claims without appearing on labels or being communicated to consumers, and thus without requiring the consumers' conscious decision-making on a healthy food choice; whilst the existing FoP schemes intend to communicate simplified and clear information to consumers on the nutritional composition of a food, leaving it to the consumers to make the healthy choice.

The existing voluntary front-of-pack (FoP) nutrition labelling schemes including pictorial/symbolic nutrition claims, were identified as schemes/initiatives to provide critical information on the nutritional quality of foods, including those bearing claims, and enable consumers to make informed choices. Most schemes are based on a nutrient profiling model and they aim at providing consumers with easy to read and understand information concerning the energy/nutrient content of the food or on the overall nutritional quality of the food, and help them make informed choices. However these schemes are not used to determine whether foods should bear other nutrition or health claims.

Literature¹²⁴ suggested that in the case of the Nordic Keyhole, its use on the label stimulated people to look for additional nutritional information (nutrition declaration at the back of the packaging) beyond the symbol. Studies confirm the potential of FOP schemes to help consumers make health-conscious food choices.¹²⁵ Furthermore, according to a study, consumers are more likely to buy low-fat products when they have traffic light labels.¹²⁶ Moreover, most consumers expect to find the traffic light label on pre-prepared convenience foods, ready meals and other processed products.¹²⁷ Another study indicates that consumers are more likely avoid the red category than to be attracted to the green category.¹²⁸

Last, as regards quantitative impact of FoP nutrition labelling schemes on purchasing decisions, a meta-analysis of several experimental and real-life studies¹²⁹ estimated that FoP nutrition labelling would increase the number of people choosing a healthier food option by about 18% on average (ranging from 11% to 29% depending on the scheme).

If, however, a FoP nutrition labelling scheme was to be harmonised across the EU and made mandatory for all foods bearing claims it could contribute to complement the ultimate objective of EU-NPs of providing consumers with healthier food, in particular by encouraging food business operators to reformulate their products in order to further reduce the FSS content.

Impacts on food business operators

The analysis in assessing whether, in the absence of EU-NPs, national or private nutrition schemes/initiatives entailed negative or positive impacts with respect to creating a level playing

¹²⁴ Grunert K.G, Fernández-Celemín L., Wills J.M., Storcksdieck genannt Bonsmann S., Nureeva L. (2010). Use and understanding of nutrition information on food labels in six European countries.

¹²⁵ Joint Research Centre (2020), S Storcksdieck genannt Bonsmann, G Marandola, E Ciriolo, R van Bavel, J Wollgast. Front-of-pack nutrition labelling schemes: a comprehensive review, EUR 29811 EN, Luxembourg, Publications Office of the European Union, 2020, ISBN 978-92-76-08970-4, doi:10.2760/180167, JRC113586

¹²⁶ Drescher, L. S., Roosen J., Marette S. (2014). The effects of traffic light labels and involvement on consumer choices for food and financial products. *International Journal of Consumer Studies*, Volume 38, Issue 3, March 2014. To be found at: <http://onlinelibrary.wiley.com/doi/10.1111/ijcs.12086/abstract> (last accessed 10 May 2019).

¹²⁷ UK Department of Health (2016). Guide to creating a front-of-pack (FoP) nutrition label for pre-packed products sold through retail outlets (Updated).

¹²⁸ Scarborough, P. et al (2015). Reds are more important than greens: how UK supermarket shoppers use the different information on a traffic light nutrition label in a choice experiment.

¹²⁹ Cecchini, M. and Warin, L. (2016). Impact of food labelling systems on food choices and eating behaviours: A systematic review and meta-analysis of randomized studies. *Obesity Reviews*, 17(3), 201-210.

field for food business operators looked into whether operators were prevented from using claims on foods with a high FSS content and whether operators engaged in reformulation.

With respect to the first point concerning the prevalence of the use of claims on foods high in FSS content, there are no elements to conclude whether the situation has changed due to the introduction of the national or private nutrition schemes/initiatives. On the other hand, with respect to reformulation, certain foods targeted by certain national schemes/initiatives were reformulated over the last decade¹³⁰. Business stakeholders more generally noted that reformulation efforts undertaken on their own initiative respond to emerging market trends, to actions taken by competitors and to the need to protect the brand's reputation. The case studies indicate that the Dutch Choices and the Nordic keyhole (as well as, potentially, the UK Traffic Lights) have encouraged some reformulation of participating products¹³¹. Pressure by consumers and public health NGOs has emerged more recently as an important factor. For example, Foodwatch¹³² has published a study on drinking yoghurts and their sugar content¹³³, which made companies in this sector reflect on their approach to sugar content in their products, as they would rather avoid being listed in such reports.

With respect to the remaining objectives of the Claims Regulation, it should be noted that national or private nutrition schemes/initiatives are not harmonised at EU level (compared to the setting of EU-NPs, which would have been a harmonised tool). Inherently, the national or private schemes/initiatives, due to the multitude of criteria used to define them, can create difficulties in fully achieving the objectives of legal certainty and fair competition.¹³⁴

Mandatory nutrition declaration

Impact on consumers

The Claims Regulation already obliged food business operators to provide a complete nutrition declaration as regards the nutritional composition of foods bearing nutrition or health claims. Since December 2016, the nutrition declaration is compulsory for all foods regardless of the use of claims and therefore ensures that accurate and reliable information is provided to the consumer regarding the nutritional composition of a food. However, the compulsory nutrition declaration has not changed the situation as regards information given to consumers on foods bearing claims. Nevertheless, the role of the nutrition declaration in facilitating the consumers' understanding of claims and enabling them to make informed food choices is assessed below.

The results of the public consultation suggest that the nutrition declaration is seen as a reliable source of information on the nutrient content of a food and in guiding respondents' purchasing decisions. Where there is a nutrition/health claim, respondents to the public consultation tend to look for any additional nutritional information provided on the food label when purchasing a food product, particularly the nutrition declaration which is widely used and considered the most important information, ahead of the FoP nutrition labelling¹³⁵. Furthermore, over three quarters of respondents indicated that they have been discouraged from purchasing a food because of the

¹³⁰ See external contractor's report, Part Two, p. 44 (Table 8).

¹³¹ See external contractor's report, Part Two, p. 40 and p. 44 (Table 8).

¹³² Active in NL, DE and FR.

¹³³ Foodwatch study - Food Industry Misleading Consumers with Vitamin-Fortified Junk Foods. March 2016. To be found at:

https://www.foodwatch.org/fileadmin/Themen/Health_Claims/Dokumente/2016-03-31_foodwatch_study.pdf

(last accessed 13 November 2018).

¹³⁴ See external contractor's report, Part Two, p. 45

¹³⁵ OPC questionnaire, Q8 and Q9 (see external contractor's report, Annexes, Annex 6).

high content in fat, sugars or salt indicated on the nutrition declaration¹³⁶. However, the public consultation is not a consumer survey and thus the results are prone to self-selection bias of people interested in the subject.

Consumer studies consensually identify limitations on the extent to which consumers read, understand, interpret and use the nutrition information provided on food labels to inform their food purchases¹³⁷. Nutrition and health claims might also create a health ‘halo’ effect that distorts consumer perception of the healthfulness of foods and makes them overlook the information provided in the nutrition declaration. Thus, considering that claims are usually highlighted on the front of the pack, they could have a much bigger impact than the nutrition declaration that is presented on the back of pack. The impact of the nutrition declaration on consumers’ purchases should be seen also in light of the fact that for the majority of consumers, price, taste, and marketing pressure are the predominant factors affecting choice¹³⁸.

Overall, the analysis presented above indicates that the mandatory nutrition declaration generally improves the information provided on the nutritional quality of foods. However, it is not enough on its own to ensure that consumers fully make use of this information in their purchasing decisions, particularly when comparing between foods bearing claims and foods without claims. Therefore, the nutrition declaration has its limitations towards achieving this objective of EU-NPs, i.e. to limit the use of claims on foods high in FSS nutrients, given that the nutrition declaration was not intended to have the same function as the nutrient profiles.

Impact on food business operators

Considering that the nutrition declaration was already mandatory for all foods bearing claims, the compulsory application of the nutrition declaration to all foods has not affected the current situation with respect to food business operators. In particular, reformulation of foods bearing claims has not consistently been practiced amongst food business operators, despite the nutritional declaration being compulsory on these foods; the lack of a systematic approach to reformulation was due to the absence of specific, mandatory, criteria for these foods (which would be set by EU-NPs, rather than the nutrition declaration)¹³⁹.

5.1.2. Efficiency

What are the costs and benefits and their proportionality, associated with the non-setting of nutrient profiles at EU level in the context of the application of the Regulation for consumers, food business operators and in terms of public health?

The costs and benefits identified in the current absence of EU-level nutrient profiles are summarised in Appendix 12 and presented below by stakeholder group.

¹³⁶ OPC, Q8-Q10 (*see* external contractor's report, Annexes, Annex 6). Furthermore: only half of respondents could rate the importance given to the various forms of nutrient information provided on the label (OPC Q9); with a high average level of education amongst respondents (81% of OPC respondents hold a university degree), the findings may not necessarily be representative of the EU population. Hence, these findings do not carry the same weight as evidence available from consumer studies and research which is the principal source of evidence used in the analysis here.

¹³⁷ Findings from the FLABEL, CLYMBOL, and JANPA projects - *See* external contractor's report, Part Two, p. 34, textbox.

¹³⁸ JANPA (2017b): D5.1 Best practices inventory and guidelines for improving the collection and use (both by stakeholders and by consumers) of nutritional food information. Work package: WP5 Nutritional information monitoring and food reformulation prompting.

¹³⁹ Survey results (Q11/Q12 stakeholders, Q12/Q13 Member States) – *see* external contractor's report, Annexes, Annex 4.A – SMEs panel results (Q7/Q8) – *see* external contractor's report, Annexes, Annex 5 – and interviews with business stakeholders.

Costs

Costs for consumers/public health

As discussed in [section 5.1.1](#), there is potential for consumers to be misled, leading to potential adverse effects on public health. This link may be justified by the fact that the risk of developing a non-communicable disease is significantly diet-related. However, due to the lack of data on actual consumption of foods with claims and the difficulty in linking this consumption with health effects, it is not possible to substantiate the extent to which consumers' health is negatively affected or quantify the costs for consumers stemming from the absence of EU-NPs.

The most important costs would be those stemming from the impact on consumers' health of an increased intake of FSS nutrients from consumption of high-FSS foods bearing claims, potentially arising due to the absence of EU-NPs. The assumption being that EU-NPs would on the one hand improve the nutritional composition of foods bearing claims by encouraging food business operators to reformulate and, on the other hand, would avoid that consumers are attracted by claims on foods that have a high FSS content. Such costs would comprise healthcare costs and productivity loss linked to illness. Overall, the quality of a diet plays an important role on an individual's health. For example, the evidence on the impact of high salt consumption¹⁴⁰ on the prevalence of cardiovascular diseases is convincing, resulting in costs for public health¹⁴¹. However, it is not possible to define what part of the diet and nutrient intake is sourced from foods bearing claims - in particular, foods with higher FSS content than the undefined limits that might have been imposed by EU-NPs. Causality cannot be established between the non-setting of EU-NPs and the direct and indirect effects on public health as relevant data were not available.

Costs for food business operators

As discussed in [section 5.1.1](#), the non-setting of nutrient profiles caused legal uncertainty, therefore potential constraints to innovation and an uneven playing field between companies that have reformulated products and those that have not reformulated products. These could have indirectly led to restrictions to the marketing potential, and hence loss in potential revenue. No evidence was found to support or reject this hypothesis.

Benefits

Benefits for consumers/public health

Benefits for consumers and public health were explored in terms of whether, at national level, the non-setting of EU-NPs has led to a higher level of protection, by limiting the use of claims on products high in FSS and allowing consumers to make healthier choices. The data provided in [section 5.1.1](#) indicate that foods bearing claims continue to have an FSS content that is higher than what was established in the 2009 Commission's draft legal act, based on the scientific opinion of EFSA. This situation is of no benefit to the consumers or public health, and even has a potential negative impact.

Benefits for food business operators

According to many business stakeholders, the non-setting of EU-NPs enhances the marketing potential and the free circulation of products bearing claims, all of which lead to improved gains in most sectors. These aspects are expected to deteriorate if EU-NPs were set. A range of sectors with products currently bearing claims that have a potentially high FSS content, mentioned in the

¹⁴⁰ I.e. exceeding the limits recommended by the WHO recommendations.

¹⁴¹ Collins, M. et al (2014). An economic evaluation of salt reduction policies to reduce coronary heart disease in England: a policy modelling study. *Value Health*, 17(5): 517-524.

analysis under the effectiveness [section 5.1.1](#), benefited from the current situation, such as breakfast cereals, soft drinks and juices, dairy, confectionery and snacks.

At the same time, under the current situation, product reformulation to reduce FSS content in foods bearing claims is initiated by the industry for various reasons. Most respondents to the SMEs panel indicated that they have reformulated the FSS content of products with claims due to market trends/ consumer demand or competitors' offer of 'healthier' products. Other reasons mentioned by the respondents include – by number of respondents – the mandatory nutrition declaration on the back of pack, national schemes concerning FSS content and private initiatives on FSS content¹⁴². Food business operators may make cost savings, either by not reformulating, or by following the criteria set in other voluntary (national/private) schemes/initiatives which are assumed to be less strict in action than the nutrient profile thresholds proposed by the Commission in 2009. On the basis of these above-mentioned recent developments, it could be expected that the Member States and industry would be more receptive and adaptive to the concept of nutrient profiles compared to the situation in 2009.

While the extent of actual cost savings depends on the nutrient profiling model to be used, an important component of costs would be reformulation costs (in case food business operators decide to/ can reformulate to be able to make claims) versus potential losses of market share/product value (in case the claim cannot be made). In this context, a relatively high percentage of enterprises that responded to the SMEs Panel indicated that they would probably not need to take any action to comply with potential limits on FSS content in food products bearing claims and that setting such limits would rather improve or have no impact on their business¹⁴³.

However, it has not been possible to quantify the current cost savings stemming from avoiding reformulation to reduce the FSS content of foods bearing claims in line with nutrient profiling model requirements. Such quantification could be based on figures obtained from the Mintel GNPD on the number of products on the EU market that are above the nutrient profiling model thresholds, however the calculation of the actual reformulation costs would be based on many assumptions and would be expected to be different for different products, thus not giving a reliable estimation.

The literature provides an indication of the cost of reformulating one product to reduce salt content in the UK, which is equal to EUR 34,314¹⁴⁴. It should also be noted that “many products can be reformulated within a natural product cycle”¹⁴⁵ and would therefore entail limited reformulation costs. Estimates from the evaluation of the EU Platform for action on diet, physical activity and health, indicate that the Unilever's commitment to reformulate cost the company EUR 24 million over a four year period (2002 to 2005). The costs covered the assessment of 22 204 products in total, of which 12 921 in Europe¹⁴⁶. However, no estimates were provided on how many of these products were reformulated following the assessment. If all the assessed products are considered, the cost of the research per product would be EUR 1 394 at 2018 EU

¹⁴² SMEs Panel (Q8) - See external contractor's report, Annexes, Annex 5.

¹⁴³ SMEs Panel (Q13/Q14) - See external contractor's report, Annexes, Annex 6. – A relatively small percentage of enterprises expect they would need to take some action, and that various aspects of their business would worsen.

¹⁴⁴ The cost in GBP (25,000) was converted to EUR (28,060) by using the 2009 annual average exchange rate from Eurostat [ert_bil_eur_a]. This cost was then inflated to 2018 value using the Harmonised index of consumer prices (HICP) for the UK from Eurostat [prc_hicp_aind].

¹⁴⁵ M. Collins et al. (2014), An economic evaluation of salt reduction policies to reduce coronary heart disease in England: a policy modelling study, *Value in health*, 17, pp. 717-524 (p. 520).

¹⁴⁶ European Commission, Evaluation of the European platform for action on diet, physical activity and health, Case study report: food/drink reformulation, 23 July 2010, p. 14

level prices¹⁴⁷. However, multinational companies like Unilever might be able to exploit economies of scale for research purposes, including on reformulation, while the costs per product might be higher for smaller companies.

Ultimately, while the industry in general benefits from the absence of EU-NPs, there is some discrimination against operators that have invested in reformulating their products on their own initiative compared to those that have decided not to reformulate (either due to personal choice or because such need does not exist as a result of the applicable legal framework).

Proportionality of costs and benefits

The analysis in the effectiveness of the current situation concludes that in the absence of the EU-NPs the consumer related objectives of the Claims Regulation, are not fully achieved. Thus, the lack of the EU-NPs has entailed no benefits for consumers or public health and potentially has had a negative impact.

With respect to food business operators, the absence of EU-NPs has not led to the obligation of balancing between reformulation (costs) – considering the benefits of maintaining a claim – against the costs of withdrawing a claim (and lose in value/market share). Many operators have avoided entering a situation where they would ultimately have had to decide on the question of reformulating versus discontinuing the claims currently made on their products, or even changing their product range, as indicated by SMEs Panel results¹⁴⁸. Moreover, the absence of EU-NPs has avoided a great increase in costs expected in situations where all of the above-mentioned factors would be present, i.e. products bearing claims having a high share; products not complying with nutrient content thresholds under existing national regulatory/private schemes; and, a high share of products bearing claims in which the FSS content is high.

The current situation with respect to EU-NPs has not improved the proportionality of costs to benefits. The associated costs cannot be quantified or monetised, nevertheless, whilst the industry largely benefits in the current situation, some costs are expected to stem from the impact on consumers' health by an increased intake of FSS from consumption of high-FSS foods bearing claims, potentially arising due to the absence of EU-NPs.

As a full quantification and monetisation of the costs and benefits identified above was not possible (see methodological limitations in [section 4](#)), they cannot be directly compared. It was not possible to assess the extent of the health costs borne by consumers and indirectly by public authorities, therefore making difficult any judgement on whether these costs are compensated by the benefits for the food industry (i.e. avoided reformulation and re-labelling costs, as well as possible loss of market share if claims would not be allowed).

¹⁴⁷ This cost was inflated to 2018 value using the Harmonised index of consumer prices (HICP) for the EU from Eurostat [prc_hicp_aind].

¹⁴⁸ Over a third of SMEs respondents to the SMEs panel indicated that, if limits were set on FSS nutrient content, they would probably need to reformulate their foods bearing claims. For over a quarter of enterprises it would be a case of withdrawing/removing claims on products that have nutrient content exceeding the limits, while for nearly a fifth of enterprises it would mean changing their product range (SMEs panel Q13).

What are the 'alternatives' to the setting of nutrient profiles at EU level that could achieve similar objectives but with a less burdensome measure? To what extent have national or private nutrient schemes been more or less cost effective in comparison to the potential setting of nutrient profiles at EU level in achieving similar objectives?

As discussed in the effectiveness section, the national schemes/initiatives do not aim to restrict the use of claims on foods high in FSS, as the setting of the nutrient profiles was expected to do and cannot be considered as 'alternatives' to the setting of nutrient profiles. Nonetheless, they generally tend to be driven by the same broader objective of protecting consumers by enabling them to make informed and healthier food choices.

Therefore, the cost implications of these schemes/initiatives are not directly relevant for comparison with the EU-NPs and to assess the achievement of the Claims Regulation objectives. Although operators may make some cost savings by relying on voluntary (national/private) schemes/initiatives, the costs incurred are not relevant for this analysis. If EU-NPs were to be set, the most significant costs for food business operators would be additional reformulation costs to maintain claims, and the magnitude of the costs would depend on the type of nutrient profiles. These costs would need to be balanced against the magnitude of potential market losses and relabelling costs, should a claim be withdrawn.

5.1.3. Relevance

To what extent nutrient profiles at EU level are still relevant and needed taking into account the evolution of the market and the evolution of the regulatory framework, especially following the adoption of the new EU Regulation on food information to consumers, including the development of the nutritional information on the front (logos, simplified nutrition declaration) and on the back (nutrition declaration) of pack?

The current situation described in [section 3.1.2](#) shows a relatively high prevalence of claims, and at the same time a significant number of products with a high FSS content bearing claims continue to exist on the EU market (see [section 5.1.1](#)).

The problem of existing claims that mask the overall nutritional status of foods, which was the reason for the setting of nutrient profiles remains currently at least as important as at the time when the Claims Regulation was adopted. More specifically, the only available data that allow for a comparison of the nutritional composition of foods over time show that the share of products with claims that are above the nutrient profiles discussed in 2009 has not decreased since the introduction of the Claims Regulation (see Table 3 and Table 4). Therefore, the specific objective of nutrient profiles, i.e. to avoid that nutrition or health claims mask the overall nutritional status of foods, is still relevant. Similarly, the general objective of a high level of consumer protection remains relevant in this context.

Taking into account the evolution of the market, the different schemes/initiatives and the mandatory nutrition declaration are relevant to meet the general objective, i.e. enabling consumers to make healthier food choices. However, neither of them, serve exactly the specific objectives pursued by the setting of EU-NPs, as extensively elaborated under effectiveness in [section 5.1.1](#).

Amongst the consulted parties¹⁴⁹ that considered that the nutritional declaration plays a beneficial role in providing full information on all foods, there were concerns on the extent to which this provision of full information on all foods manifests, in practice, in changes in consumer behaviour towards healthier food choices. Ultimately, it is up to consumers to read, understand

¹⁴⁹ See external contractor's report, Part Two, p. 33-34.

and make use of nutrient information in their purchasing decisions which are also influenced by other factors like price and taste.

Moreover, the existing national schemes/initiatives, intended to communicate simplified and clear information to consumers on the nutritional composition of a food, leave it to the consumers to make the healthy choice. In contrast, the nutrient profiles were to achieve their objective of limiting the use of claims on foods high in FSS content without appearing on labels or being communicated to consumers. Therefore, nutrient profiles were expected to facilitate easy and direct access to healthy food choices when consumers purchase foods bearing claims by ensuring that foods with high FSS content do not attract consumers through beneficial health claims. At the same time, nutrient profiles were expected to incentivise food manufacturers to reformulate their products to reduce the FSS content, in order to maintain the claim (to the extent that reformulation is feasible) or otherwise to remove the claim on foods not complying with the nutrient profiles. The extent to which ultimately nutrient profiles would have increased consumers' consumption of foods with low FSS content is however difficult to assess, as food choices are influenced by health considerations as well as by other characteristics such as food price and taste.

Last, it has to be noted that the opposition to the establishment of nutrient profiles by certain parts/sectors of the industry, e.g. traditional and speciality products defined under Protected Designation of Origin /Protected Geographical Indication, national regulations or others, was related to the difficulty to reformulate due to technical/legal constraints. Furthermore, these concerns currently also relate to the fact that the notion of nutrient profiling could be further used in other contexts, e.g. FoP labelling, advertising, promotional campaigns and therefore 'stigmatise' certain foods.¹⁵⁰

In conclusion, the specific objective of nutrient profiles is still relevant and needed to address current needs arising from these key drivers and trends, not addressed by the evolution of the market and the existing regulatory framework.

5.1.4. Coherence

The scope of this evaluation only focuses on the issue of nutrient profiles and thus an assessment of the internal coherence between the provision dealing with the setting of nutrient profiles and the rest of the provisions of the Claims Regulation has not been undertaken.

To what extent would the setting of nutrient profiles at EU level be considered coherent with other initiatives in the context of the EU Platform on Diet, Physical Activity and Health?

Since its launch in March 2005, the EU Platform on Diet, Physical Activity and Health, comprised of stakeholders from industry and NGOs, provides the opportunity to participants to exchange best practices and jointly develop voluntary initiatives in a number of areas related to achieving *inter alia* the objective of promoting more balanced diets and nutrition for the EU population.

The commitments made under the EU Platform have the objective to combat obesity and improve the overall nutritional choices of consumers, which is consistent with the objective of EU-NPs. The EU platform actions seek to achieve this objective via different means¹⁵¹ than the EU-NPs and can be therefore considered as complementary to EU-NPs.

¹⁵⁰ See external contractor's report, Part Two, p. 73.

¹⁵¹ In the framework of the EU platform for Action on Diet, Physical Activity and Health, Unesda, Nestlé (5%) and Danone have publicly committed to a 10% reduction of added sugars in processed foods by 2020.

A large majority of national competent authorities (18 out of 26 Member States respondents) indicated that the setting of EU-NPs would improve coherence with the initiatives taken in the context of the Platform¹⁵². The establishment of harmonised nutrient criteria for governing claims on foods is expected to allow better coordination of the various broader initiatives taken at national and industry level, to support a more consistent approach to the reformulation of foods with claims to acceptable FSS limits.

While in principle, the setting of EU-NPs would be coherent with relevant initiatives taken in the context of the Platform, in practice coherence would be determined by the format of the EU-NPs.

Coherence with the broader policy and legislative framework

Currently, the nutritional status of certain foods bearing claims can be in disagreement with national dietary guidelines and recommendations, WHO recommendations and actions, as well as broader objectives of various other initiatives pursued in the context of the EU Action Plan on Childhood Obesity 2014-2020¹⁵³ and the European Council in coordination with the rotating EU presidencies¹⁵⁴. Such recommendations ultimately aim at contributing to the same overarching goal to address the rising trends of obesity and non-communicable diseases in the EU. The establishment of nutrient profiles would provide a consistent incentive to reformulate foods bearing claims, thereby improving coherence with reformulation initiatives for foods¹⁵⁵. More precisely, nutrient profiles would improve coherence with the following:

- limiting the use of claims on high-FSS foods (either by removing the claim or by encouraging food reformulation);
- adhering to the broader recommendations to limit FSS intake;
- ensuring consistency with other initiatives to limit FSS intake by children¹⁵⁶.

Reviews have suggested that no single measure can be effective on its own to address the rising obesity and non-communicable diseases trend, whilst a more comprehensive mix of policy measures is required¹⁵⁷. Furthermore, the Council's most recent review of best practices across the EU indicates that Member States use a spectrum of activities and combination of initiatives for reaching the set goals¹⁵⁸.

¹⁵² Survey results (Q19 stakeholders and Q21 Member States) – See external contractor's report, Annexes, Annex 4.A.

¹⁵³ In 2014 the High Level Group adopted the EU Action Plan on Childhood Obesity that addresses food reformulation.

¹⁵⁴ EU Council Presidencies have sustained the work on reformulation. Council conclusions were adopted in 2014 (nutrition and physical activity), 2016 (food reformulation), 2017 (childhood obesity) and 2018 (healthy nutrition for children).

¹⁵⁵ The Member States High Level Group on Nutrition and Physical Activity agreed in 2008 on a reformulation framework that would reduce salt in food by 16% in 4 years. In 2011, the High Level Group agreed on an EU Framework for National Initiatives on selected nutrients. Work then started on reducing saturated fat by 5% before 2016 and by an additional 5% before 2020. In 2015, the High Level Group validated the Added Sugars Annex promoting a voluntary reduction of 10% in added sugars in food by 2020.

¹⁵⁶ High-FSS foods bearing claims targeted to children are present on the EU market and the experience gained from the impact of existing advertising restrictions in Member States (see external contractor's report, Part Two, p. 44 (Table 8) indicates that they are not sufficient on their own to limit the consumption of high-FSS foods by children. – See external contractor's report, Annexes, Annex 7.A.V, page 70.

¹⁵⁷ World Health Organization (2016). Ending childhood obesity. Online: http://apps.who.int/iris/bitstream/10665/204176/1/9789241510066_eng.pdf (last accessed: 12 November 2018).

The Council of the European Union (2016). Council conclusions on food product improvement (2016/C 269/04).

¹⁵⁸ Trusková, I. et al (2016). Best practices of Members States on Food reformulation – results from “trio questionnaire 2016 (NL-SK-MT)”. Public Health Authority of Slovak Republic, Ministry of Health of Slovak Republic.

Overall, the setting of nutrient profiles is considered fully coherent with the broader international policies in that field.

5.1.5. EU added value

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

The analysis of the EU added value looked into the additional value resulting from the setting of nutrient profiles at EU level compared to what is already achieved by Member States at national level, with the current implementation of the Claims Regulation and the identified schemes/initiatives.

None of the existing national measures, such as the FoP nutrition labelling schemes, reviewed in the context of this evaluation (see [section 3.1.2](#)) effectively contribute to the specific objectives of EU-NPs set for the various actors and ensure uniform consumer protection and same rules for food business operators across the EU. Approaches are non-harmonised, voluntary, dispersed, and diverse and do not specifically target foods bearing claims. Furthermore, the specific objectives of EU-NPs cannot be achieved by the compulsory back-of-pack nutrition declaration, which is not designed to limit the FSS content of foods bearing health claims, but only provide information regarding the FSS content of the food.

In contrast, the setting of nutrient profiles at EU level would provide a valid approach to address the current problems for consumers and food business operators (identified in Table 5 and in Appendix 11 to this Staff Working Document) stemming from the presence on the EU market of foods bearing claims that have a high FSS content. Starting from the objective of protecting consumers, the compulsory imposition of EU-wide specific nutrient profile criteria would ensure a direct restriction on the use of claims on high-FSS foods. In particular, the EU-NPs would lead operators, consistently across the EU, to the inevitable decision on whether to reformulate or to withdraw the claim¹⁵⁹.

Table 5: Added value of EU-NPs for the different actors, compared to the current situation

	Problems in current situation^(a):	Added value of EU-NPs:
Consumers	<ul style="list-style-type: none"> • use of claims on foods ‘high’ in FSS • potential for consumers to be misled 	<ul style="list-style-type: none"> • Limit the use of claims on products ‘high’ in FSS • Minimise the potential for consumers to be misled • Ultimately, contribute to improved trust in claims^(c)

¹⁵⁹ See external contractor's report, Part Two, page 75-76.

FBOs ^(b)	<ul style="list-style-type: none"> • lack of legal certainty to reformulate and innovate • competition between reformulated and non-reformulated products 	<ul style="list-style-type: none"> • Encourage the reformulation of foods to retain existing claims (or to bear new claims) on a consistent basis (i.e. at industry level, between food categories, and across the EU) ^(d) • Ensure legal certainty (to develop new products and ingredients for use with claims^(e); more generally, to allow FBOs to fulfil their responsibilities under the Claims Regulation) ^(d) • Ensure level playing field between operators that reformulate foods bearing claims and those that do not, to the same specifications (nutrient limits; product categories; exemptions etc.) ^(f)
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- (a) As outlined in section 5.1.1 on the impacts of the non-setting of EU-NPs on preventing achievement
- (b) The gaps were identified at the level of individual operators, rather than the industry, which – irrespective of sector/business size – is rather divided.
- (c) E.g. respondents to the OPC tend to consider unacceptable that foods with a high FSS content can make a nutrition or health claim (OPC Q11, Annex 6 of external contractor's report).
- (d) This can also contribute to facilitate innovation (although the incentive to innovate is not only constrained by the lack of EU-NPs), in the development of new products, processes and ingredients.
- (e) Also, in terms of facilitating the establishment of conditions of use for health claims, as the overall nutritional quality of the foods would no longer need to be considered case by case in the lengthy approach currently required.
- (f) It is noted, however, that to ensure a level playing field, potential distortions to competition due to technical and regulatory constraints that are inherent in some product sectors need to be taken into consideration in the design of the nutrient profiling model.

Source: External contractor's report, Part Two, page 74

The question on whether the existing EU provision on EU-NPs should be withdrawn from the Claims Regulation and what the potential consequences could be should also be explored in this context. Withdrawing the provision could mean simply continuation of the current status quo (discussed in previous sections) but could also lead to additional consequences compared to the current situation, which are described below.

Removing the legal obligation of establishing of nutrient profiles from the Claims Regulation would negatively impact consumers as they would keep being exposed to foods bearing claims despite having a high content of FSS, with the potential of being misled in their dietary choices. The removal would also undermine a regulatory approach which is coherent with national and international policy efforts to fight obesity and diet-related diseases. In addition, withdrawing the existing EU provision on nutrient profiles would give the green light to Member States to adopt measures at national level, with potential adverse consequences for the functioning of the internal market and ensuring a level playing field.

Overall, in terms of the EU added value, an EU-wide approach regarding the establishment of nutrient profiles would bring more advantages for the internal market compared to potential national approaches, given that the voluntary and partial application and the variability of the national approaches across the EU cannot guarantee a harmonised, uniform implementation, which has been one of the objectives of the Claims Regulation.

5.2. Health Claims made on plants and their preparations: answers to the evaluation questions

5.2.1. Effectiveness

Did the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods prevent the realisation of the objectives of the Regulation? If yes, which main factors (e.g. implementation by Member States, actions by stakeholders) have contributed to or stood in the way of achieving the objectives of the Regulation and to what extent? What are the objectives that are not met and to what extent?

The extent to which the absence of a decision¹⁶⁰ has resulted in deviations from the original objectives of the Claims Regulation is described below.

Impacts on consumers

Objective on ensuring a high level of consumer protection

The Claims Regulation only partly achieved its objective of ensuring a high level of consumer protection, in the light of the partial implementation of the Claims Regulation and the creation of the on-hold list of health claims.

The aim of the Claims Regulation was to protect consumers from untruthful and misleading claims, therefore allowing them to make informed food choices. To date, health claims on plant substances, which are on the on-hold list and have not been assessed by EFSA or have received an unfavourable EFSA opinion, have not been considered at risk management level but may nevertheless continue to be used on the market.

Under the current status quo, consumers are exposed to products bearing the same claim, irrespectively to whether this claim is based on robust scientific evidence, on longstanding traditional use or not science based.

Many consulted stakeholders expressed concerns about the current situation. Survey respondents representing consumers' interests commented that the current use of the on-hold list of health claims is extremely unsatisfactory from the standpoint of consumer protection, as consumers are not receiving accurate or reliable information through the use of claims included in the on-hold list and are more likely to be misled.

It can therefore be concluded that the strongest limitation in meeting the consumer-related objective of the Claims Regulation is the fact that consumers may believe that the beneficial effects communicated with claims appearing on the EU market have been assessed, risk managed and consequently authorised.

As previously pointed out, prior to the Claims Regulation, an uneven level of consumer protection from untruthful and misleading claims made on plants and their preparations used in foods was provided across the EU. Therefore, independently to the drawbacks of the current situation outlined above, it should be noted that, still, the establishment of the on-hold list of claims provides an EU-level reference for Member States and has contributed to improving consumer protection in comparison to the baseline situation. The on-hold list of claims, even if not risk assessed, it confines somehow the market with respect to the number and the type of health claims which may be made on foods.

Impacts on food business operators

Objective on improving the free movement of food products bearing claims

¹⁶⁰ I.e. the current situation as it has evolved to date, and described under [section 3.2.2.](#)

Before the Claims Regulation was adopted, only a minority of Member States had specific legislation on health claims made on plants and their preparations used in foods, with significant differences in the approaches followed, whereas most Member States (21) had no specific national legislation in place, leading to discrepancies in the marketing of plant-based products in the EU. In the current situation, the on-hold list of claims is used as an EU-level reference for Member States and food business operators face similar rules across the EU to place their food products in the market with claims on them. Thus, the establishment of the on-hold list of claims should be seen at least as an improvement in terms of free movement of food products containing plants with claims in comparison with the baseline situation. In general, the most serious limitations to the smooth functioning of the internal market emerge from the national differences in the general regulatory framework concerning the use of plants and their preparations in foods, which is further elaborated under [section 5.3](#).

The analysis of the evidence collected from different sources¹⁶¹ highlighted no significant cases of limitations to the smooth functioning of the internal market that clearly derived from the absence of a decision on the authorisation or rejection of health claims on plants and their preparations used in foods. The on-hold list of claims was established to avoid the serious disturbance of the internal market which could have derived from a massive rejection of used claims on a variety of food products containing plants and plant preparations (especially food supplements). The adoption of national instruments (e.g. guidelines) aiming at facilitating the use of claims included in the on-hold list, and/or at preventing the use of claims included in the on-hold list which are non-compliant with other relevant EU provisions, may also be seen as a factor which contributes to (or at least does not impede) a smooth functioning of the internal market.

On the other hand, in the absence of a final decision by the risk managers regarding health claims on plants and their preparations, national legislation in some Member States requires, or even imposes appropriate warnings and/or restrictions on the use of certain plant substances in foods, which could be argued that to a certain extent fragments the EU market.

Objective on increasing legal certainty for food business operators

The lack of a final decision on health claims made on plants and their preparations for use in foods was reported to create some legal uncertainty, mainly for food business operators as they are uncertain about the duration of the transitional measures. Food business operators perceive the current situation as precarious, and face challenges in planning future strategies because of this lack of legal certainty. The seriousness of the legal uncertainty experienced by food business operators also depends on the specific situation in the implementation of the on-hold list which characterises each Member State.

Several considerations on legal certainty stem from the comparison with the baseline situation. *From a national perspective*, the current situation in the implementation of the Claims Regulation can be seen as a step back by the few Member States which had specific national legislation governing the use of claims made on plants and their preparations for use in foods. However, a clear majority of Member States (21) had no such legislation in place: for these Member States, the transitional measures under Article 28 of the Claims Regulation represent an improvement in terms of legal certainty, even if they are perceived as precarious by operators. *From an EU-wide perspective*, the establishment of the on-hold list of claims provides a single reference for the Member States competent authorities and operators of the different Member States, even with its limitations. This can be seen as an improvement in terms of legal certainty for food business

¹⁶¹ Literature review (see bibliography), survey of stakeholders and Member States, in-depth interviews with stakeholders.

operators vis-à-vis the baseline situation, where operators had to deal with diverse regulatory approaches in the few Member States with specific national legislation, and with the absence of legislation in the remaining Member States.¹⁶²

It is important to note that the situation of legal uncertainty for operators producing and marketing food products containing plant substances is also related to the non-harmonised status of the general regulatory framework for the use of plant substances in foods (further discussed in [section 5.3](#)), and does not derive solely from the current status in the implementation of the Claims Regulation for plants and their preparations used in foods¹⁶³.

Objective on ensuring fair competition

In the food supplements sector, consulted stakeholders did not report significant cases of unfair competition linked to the current situation.

Moreover, Member States contribute to fair competition within the food sector by facilitating the use of claims on the on-hold list and avoiding the use of claims included in the on-hold list which do not fulfil the other requirements of the Claims Regulation and/or of other relevant legislation. This is the case, for instance, for claims in the on-hold list which are referring to properties of preventing, treating or curing a human disease and which may be similar to therapeutic indications for medicinal products. In certain Member States (e.g. Austria and Germany) food business operators should provide additional scientific data to substantiate the claim.

In fact, for these stakeholders the issues are primarily posed by the non-harmonised status of the general regulatory framework for the use of plant substances in foods ([section 5.3](#)), such as classification issues, which impedes the marketing of their products in a number of Member States. Member States where national legislation on the use of plants in food products is in force, competent authorities may link such legislation to the use of health claims on food products containing plant substances.¹⁶⁴ Unfair competition therefore arises for businesses placing on the market foods containing plants and/or their preparations, because of applicable national legislation imposing different warnings and/or restrictions on the use of certain plant substances in foods.

On the contrary, representatives of the pharmaceutical industry reported that the current situation has led to unfair competition between plant food supplements and THMPs. This, according to the sector, is because plant food supplements can bear health claims from the on-hold list that are similar to therapeutic indications, while facing less costs and regulatory restrictions than THMPs¹⁶⁵. The differences in costs between placing on the market a food supplement compared to a traditional herbal medicinal product are outlined in [section 5.2.2](#) below.

Objective on promoting and protecting innovation

Consulted stakeholders deemed that the innovation rate in the sector of food products containing plant substances has remained basically the same compared to the period before the implementation of the Claims Regulation¹⁶⁶. In general, it appears to be difficult for the food industry to launch new products and to invest in research activities when the chances to have new

¹⁶² See external contractor's report, Part Three, p. 22.

¹⁶³ It is highlighted that the implications for stakeholders of these two interlinked issues are often not differentiated in their understanding.

¹⁶⁴ See external contractor's report, Part Three, p. 14-15.

¹⁶⁵ See external contractor's report (Task 2.1), p. 26.

¹⁶⁶ See external contractor's report, Annex 4.A, p.135.

claims on plant substances positively assessed by EFSA under the current rules are perceived as extremely low¹⁶⁷. Under the current status quo, companies wishing to use claims on plant substances end up using claims featuring on-hold list. These concerns raised by the stakeholders seem confirmed by the literature, which highlights that the Claim Regulation does not appear to encourage innovation in the EU food sector¹⁶⁸. Food companies claim to struggle to inform consumers about their innovative formulas or additional functions of their products discovered in their research activities, as a result of the current requirements¹⁶⁹.

According to consulted business associations, the uncertainty on the future of the on-hold list (i.e. whether, when and how the Commission will resume the process of evaluation of claims on plants) discourages long-term investments¹⁷⁰. EU operators face serious challenges in deciding their future strategies in the current situation. This constitutes an obstacle to innovation for the operators, which believe that they cannot effectively communicate their innovation efforts to consumers without the use of claims¹⁷¹.

Factors hindering the achievement of the objectives of the Claims Regulation

Consideration of traditional evidence for the risk assessment of health claims on plants and their preparations

The Claims Regulation does not recognise the specificity of plant substances compared to other categories of substances used in foods. Therefore, the possibility to accept evidence based on 'traditional use' as sufficient to substantiating health claims on plant substances is not explored by the Claims Regulation, which stipulates that health claims should be '*based on generally accepted scientific data*'¹⁷². Because of the consideration given by EFSA to the evidence related to 'traditional use', no claim on plants or their preparations based on 'traditional use' evidence alone has obtained a positive assessment so far. 'Traditional use' is, nevertheless, an important source of evidence for plant substances and is considered in the context of the special procedure to assess the efficacy, and partly also safety, of the herbal medicinal products in the case of THMPs.

Concerns have been expressed by Member States and many stakeholders in the food sector with regards to the difference in the consideration given to the evidence on 'traditional use' under the legal framework for health claims on plants classified by the Member States as foods and the regulatory framework for plants classified by the Member States as traditional herbal medicinal products.

5.2.2. Efficiency

Comparison with full implementation has not been possible because no data could be obtained on such hypothetical situation. Therefore, the analysis has been based on a comparison of the baseline with the current situation. Due to the lack of quantitative data, a qualitative analysis of cost and benefits has been conducted ([section 4.2](#)), which does not allow for a direct comparison and conclusions on the proportionality of benefits versus costs. The costs and benefits identified in the current situation are summarised in Appendix 12 and presented below by stakeholder group.

¹⁶⁷ See external contractor's report, Part Three, p. 24.

¹⁶⁸ Bröring et al. (2017), Reviewing the Nutrition and Health Claims Regulation (EC) No. 1924/2006: What do we know about its challenges and potential impact on innovation?, *International Journal of Food Sciences and Nutrition*, 68:1, 1-9, p. 6. DOI: 10.1080/09637486.2016.1212816

¹⁶⁹ See external contractor's report, Part Three, p.24.

¹⁷⁰ See external contractor's report, Annexes, Annex 4.A, page 135.

¹⁷¹ See external contractor's report, Annexes, Annex 4.A, page 134-135.

¹⁷² Article 13(1)(i) of the Claims Regulation.

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

Costs

Costs for consumers/ public health

Most non-business stakeholders and Member States consulted agree that in the current situation, which allows the continued use of unsubstantiated health claims, reliable and adequate information to consumers is not ensured. This implies that there is risk for consumers of being misled. For example, consumers might rely on health claims presented on foods containing plants and their preparations, e.g. food supplements or herbal teas, claiming to have beneficial effects, although their efficacy has not been assessed. However, whether and the extent to which this risk translates into negative health effects for consumers and possible relative costs could not be evaluated due to the lack of data and reliable information on the effects and consumption of the purchased products.

Costs for food business operators

The current situation seems to have some negative effects on food business operators. Representatives of the food industry reported that operators are unsure of the timing for a final decision regarding health claims made on plant substances, therefore creating a situation of legal uncertainty that hinders innovation and limits long-term investments and competitiveness. These can be considered as an indirect cost for food business operators. However, the research made did not allow the collection of suitable evidence for a quantification of foregone revenues from limits to competitiveness and from hindered innovation potential due to the establishment of the on-hold list of claims¹⁷³.

On the other hand, consulted stakeholders from the food industry deemed that the situation would have been much worse if the on-hold list had not been implemented. In the absence of the on-hold list, a massive rejection of claims on plant substances was expected, which might have forced many companies – especially in the food supplements sector, where the use of claims has a critical importance in product marketing – to leave the market, leading to much higher costs¹⁷⁴.

On the basis of evidence collected¹⁷⁵, food business operators reported to face some costs (no figures provided) for the re-labelling of products in order to allow the marketing in Member States in line with the transitional measures for health claims made on plant substances, which may involve different national measures.

Food business operators reported difficulties in linking the claims in the database with plant substances and stated that they often prefer to rely on national provisions or on guidelines issued by national and EU associations.¹⁷⁶ The establishment of the on-hold list has put the teas and herbal infusions (THI) sector in competitive disadvantage compared to other sectors that make use of plant substances in foods, such as the food supplements sectors. The competitive disadvantage that this sector faces is, currently due to, THI products not being able to bear claims for two main reasons. First, claims that were generally used in the past for marketing THI

¹⁷³ See external contractor's report, Part Three, page 29.

¹⁷⁴ See external contractor's report, Part Three, page 29.

¹⁷⁵ Through the stakeholders' survey, in depth-interviews, and case studies.

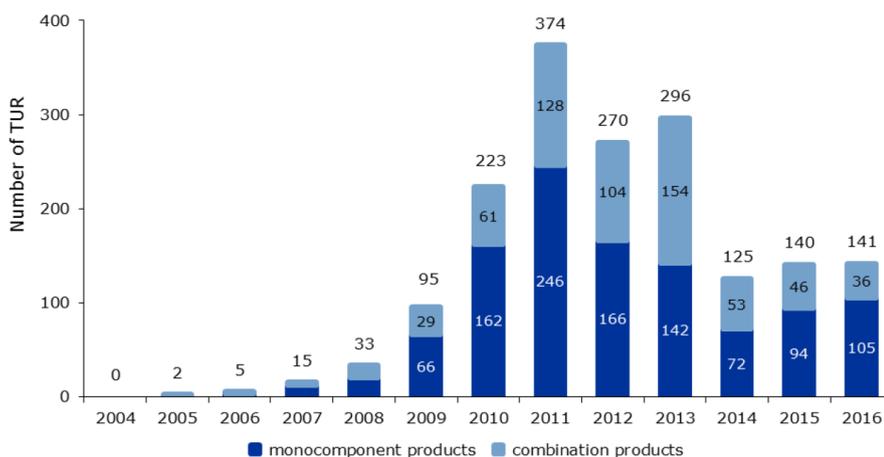
¹⁷⁶ See external contractor's report, Part Three, p. 28.

products have not been included in the on-hold list. Second, it is not always possible to identify in a certain plant the specific substance (or the combination of substances) which is responsible for the activity attributed to the plant¹⁷⁷ as THI products generally contain whole plants or parts of plants. It should be, however, noted that the use of claims on THI products appears to have a less critical role in marketing in comparison to the food supplements sector, because consumers purchase THI products also for their taste and because consumers generally know the effects of, for instance, camomile and other plants used in these products¹⁷⁸.

Costs for the pharmaceutical industry

Since plant substances may be used both in foodstuffs and in medicines, the current situation has implications also for the pharmaceutical industry. Operators in the pharmaceutical sector reported a decline in the number of applications for traditional use registrations of THMPs in Europe, in particular in those Member States with a well-developed market for food supplements containing plants and their preparations¹⁷⁹. This is illustrated by Figure 9 below on the number of traditional use registrations¹⁸⁰, which shows a clear peak in the number of THMPs registrations in 2011 and a reduction afterwards.

Figure 9: Number of traditional use registrations (TUR) for THMP in the EU grouped by year of registration for monocomponent and combination products (2004 until December 2016; total 1719)¹⁸¹



Source: European Medicines Agency, 2016

¹⁷⁷ European Herbal Infusions Associations, Statement on the “Draft proposal for a regulation of the European Parliament and the Council on nutrition and health claims made on foods” - COM (2003)xxx/June 2003.

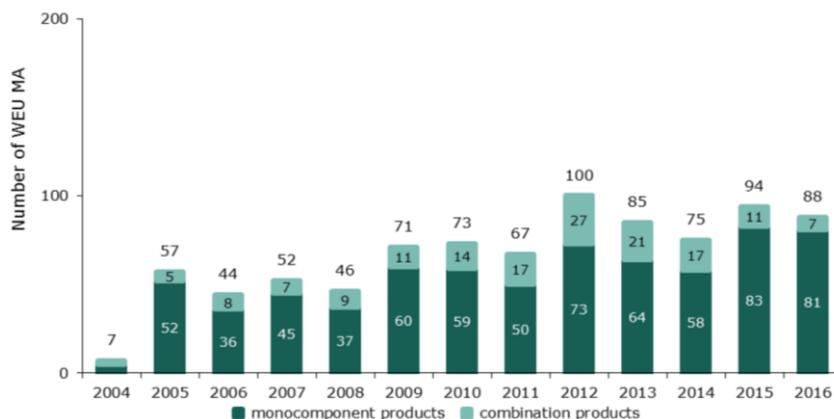
¹⁷⁸ Some consulted parties in the THI sector observed that consumers know the traditional use of these plants, whereas the notion of traditional use cannot be used as evidence for substantiating claims in the current regulatory framework.

¹⁷⁹ Interviews carried out by the external contractor.

¹⁸⁰ European Medicines Agency (2016). Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. To be found at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf (last accessed 11 July 2018).

¹⁸¹ European Medicines Agency (2016). Uptake of the traditional use registration scheme and implementation of the provisions of Directive 2004/24/EC in EU Member States. To be found at: http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106706.pdf (last accessed 11 July 2018).

Figure 10: Number of well-established use marketing authorisations for HMP in the EU grouped by year of authorisation for monocomponent and combination products (2004 until December 2016; total 859)



Source: European Medicines Agency, 2016

The year 2011 marks the favourable vote¹⁸² of Standing Committee on the Food Chain and Animal Health¹⁸³ on the list of permitted health claims and the discussions on the establishment of an on-hold list of health claims made on plants and plant preparations. At the same time, the year 2011 corresponds to the end of the transitional period to register THMPs that were already on the market on the date of entry into force of the Directive on traditional herbal medicinal products¹⁸⁴. A second, even more remarkable decrease in traditional use registrations for THMPs is noted after 2014, which coincides with the latest confirmations of the on-hold list of health claims on the market in 2014¹⁸⁵. However, as discussed in [section 5.3.1](#), it could be argued that this trend is linked both with the general regulatory framework for the use of plants in food products and with the non-application of the Claims Regulation to plants and their preparations used in foods.

Given that the requirements of the legislation on THMPs and medicinal products more broadly are stricter (e.g. requirements for pharmacovigilance, good manufacturing practices, authorisation etc.) than the ones established under the legislation on food supplements, it is expected that compliance costs are higher for THMPs than for food supplements containing plant substances. Higher compliance costs are expected to translate into overall higher production costs and consequently higher prices for THMPs compared to food supplements.

Stakeholders from the pharmaceutical industry reported that the identified costs associated with the registration/authorisation of herbal medicinal products for preparation and post-marketing activities include, *inter alia*, the following: registration/renewal fees, pharmacovigilance fees,

¹⁸² On 5 December 2011. Minutes of the meeting: https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_gfl_sum_05122011_en.pdf

¹⁸³ Section on General Food Law., currently named the Standing Committee on Plants, Animals, Food and Feed.

¹⁸⁴ W. Peschel and B. Monedero Alvarez (2018), Harmonised European standards as a basis for the safe use of herbal medicinal products and their marketing authorisation in European Union Member States, *Pharmaceutical Medicine* 2018, 32: 275-293, p. 282.

¹⁸⁵ Commission Regulation (EU) No 536/2013 of 11 June 2013 (*OJ L 160, 12.6.2013, p.4*), to be found at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0536&from=EN>
COMMISSION REGULATION (EU) No 1018/2013 (*OJ L 282, 24.10.2013, p.43*), to be found at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R1018&from=EN>

costs of maintenance and application (e.g. data on effectiveness or benefit, proof of traditional evidence, genotoxicity studies) and others.

These costs vary between THMPs and HMPs, depending also on whether monographs are already established by the European Medicine Agency and on whether the product developed is a new HMP. Rough cost estimates provided by the representatives of the pharmaceutical industry are in the range of €130,000 to €600,000, excluding clinical trials. The cost of one clinical trial is estimated between €0.5 and €1 million, and preclinical trials may be required for HMPs (including THMPs) that are not based on monographs or published clinical data. For new HMPs, the full pre-clinical testing and clinical trials data were reported to cost more than €100 million.¹⁸⁶ On the other hand, cost estimates from the literature indicate that the costs of launching a food supplement range from €89,861 to €134,791¹⁸⁷. In the presence of the ‘on hold’ list, food supplements can bear health claims that in some cases are similar to therapeutic indications made on THMPs, even if traditional use is not accepted to prove efficacy under the Claims Regulation, contrary to the THMP Directive (see [section 5.2.4](#)). Generally, it can be expected that consumers are not willing to pay more to purchase an herbal medicinal product if they can purchase a similar food supplement at a lower price, containing often the same plant substance(s) with similar properties claimed on the label. Thus, pharmaceutical companies claim to struggle to compete on this market due to much higher costs than those incurred by producers of food supplements containing plant substances.¹⁸⁸

Despite uncertainties about the future of the ‘on-hold’ list and due to the higher production costs of THMPs, the current situation could also lead producers of herbal medicinal products to change the marketing of their products and sell them as food supplements, and consequently dropping the THMPs market value. It is relatively difficult to identify a clear EU-level trend in terms of comparison of price and availability of products between food supplements and THMPs, given the different situations found at Member States’ level. Therefore, it has not been possible to verify whether since the introduction of the ‘on-hold’ list there has been a switch by companies from THMPs to food supplements. At the same time, the classification of a product as food or as a medicine, for which the national competent authorities are responsible frames all marketing activities.

During the consultation process, the pharmaceutical sector has been unable to provide evidence on a direct linkage of the above-mentioned costs with the current situation of the ‘on-hold’ list, nor was relevant information found through desk research. Therefore, it was not possible to draw firm conclusions on whether the current situation is creating unfair competition between food business operators, in particular food supplement companies, and pharmaceutical companies.

Benefits

Benefits for consumers/public health

The current situation has not brought any benefits for consumers. Consumers continue to be exposed to claims on foods containing plant substances which have been neither scientifically

¹⁸⁶ Information provided by AESGP on the requirements applicable to the registration/authorisation of herbal medicinal products (four different categories) in the EU.

¹⁸⁷ Brookes G. (2010). Economic Impact Assessment of the European Union (EU)’s Nutrition & Health Claims Regulation on the EU food supplements sector and market.
To be found: <https://www.pgeconomics.co.uk/pdf/Impact-Assessment-health-claims.pdf> (last accessed 25 September 2018).

Figures from Brookes G. (2010) were inflated to 2018 values using the Harmonised index of consumer prices (HICP) for the EU from Eurostat [prc_hicp_aind].

¹⁸⁸ See external contractor’s report, Part Three, p. 29.

assessed by EFSA nor risk-managed. With the establishment of the on-hold list, consumers may, at national level, be exposed to a greater number of claims on plant products; claims which prior to the establishment of the on-hold list did not appear on certain national markets. Nonetheless, this situation is also influenced by the existence of national lists, in particular negative lists which prohibit the use of certain plants in foods.

Plant food supplements that bear health claims from the on-hold list must comply with all relevant EU and national provisions, including those ensuring adequate information to consumers and those ensuring product safety. This counter-balances the possible negative effects of the on-hold list on consumer protection and safeguards public health.

Benefits for food business operators

The current situation has shown some benefits for the food business operators, and particularly the food supplements sector. Prior to the adoption of the Claims Regulation, certain Member States prohibited the use of the health claims on plant food products. The establishment of the on-hold list has, in the context of the functioning of the internal market, obliged some of these “strict” Member States to accept on their market health claims featuring in the on-hold list, even if their efficacy is not assessed.

The majority of consulted stakeholders in the food sector agree that the implementation of the on-hold list of claims has avoided serious negative implications for the competitiveness of food business operators, especially in the food supplements sector. Thus, putting the assessment of claims on hold has avoided for food business operators the significant costs related to label changes dictated by the need to remove rejected claims, and to the reformulation of certain products and/or to the withdrawal of a number of other products from the market. However, even in the current situation food business operators have argued that they face re-labelling and reformulation costs if they want to market their products in Member States with different national rules concerning the use of the plant substances in place.

In conclusion, the decision to put the assessment of health claims on hold was seen by most consulted food business operators as having a slightly positive overall effect on innovation and investments: it created a certain stability in the sector, safeguarding the current market situation without creating serious disturbance, but it also made it difficult for operators to plan mid- and long-term investment and innovation strategies, due to the uncertainty about the future of the on-hold list.

Benefits for the pharmaceutical industry

Given that in the current situation the pharmaceutical company remains in direct competition with the food supplements sector, consulted stakeholders from the pharmaceutical industry did not highlight any benefits stemming from the non-application of the Claims Regulation to plant substances and from the use of the on-hold list of claims.

What is the specific cost impact of authorisation procedures required for health claims, in particular on micro- small and medium sized enterprises?

The Claims Regulation initially aimed at removing untruthful claims from the market through a process where Member States submitted for review to the Commission lists of all the claims appearing on their national markets. The lists had to provide information on the wording, suggested conditions of use and list of references without preparing a full application file for each individual claim. These claims were intended for general use by any food business operator and did not entail significant cost for the scientific substantiation of claims and thus authorisation. This process was only partially completed as a list of permitted health claims was established

excluding all health claims on plants substances, which were consequently placed on the on-hold list.

Health claims that did not undergo the above procedure and thus, were not included in the list of permitted health claims or the list of on-hold health claims are not allowed to be used on the EU market. In such cases, food business operators may apply for the authorisation of a new claim through a dedicated procedure in the Claims Regulation. However, this procedure requires proof of efficacy based on human clinical studies, which are claimed by food business operators to be unavailable for plants used in foods. This procedure raises specific costs for a new authorisation procedure; thus, operators must bear the costs of conducting clinical trials, which according to the industry are expected to be elevated.

More specifically, in the food supplements sector the costs of conducting human clinical trials to provide data to support a health claim application can vary according to the scope and nature of a trial but are estimated to be in the range of €0.28 million to more than €1.1 million¹⁸⁹. These estimates are in line with the replies of food industry stakeholders to the survey carried out: the most frequently reported cost estimates for clinical trials range between €1 and €1.3 million (cost of two or three clinical trials, each one costing around €0.5 million). Total costs for food supplements companies to submit a claim under Article 13.1 of the Claims Regulation (i.e. claims which now make part of the on-hold list) were estimated between €562 and €1,123 per claim, representing about 0.6% to 0.8%¹⁹⁰ of the costs of a product launch¹⁹¹ (calculated at €89,861 - €134,791). If the work of trade associations is also considered, the administrative costs of submitting a claim under Article 13.1 is estimated to be €1,101 to €1,868¹⁹². Considering the past rejections by EFSA of health claims on plants and their preparations made under Article 13.1, it seems that if the current situation remains unchanged human clinical trials will be necessary to submit a health claim for a plant substance in foods.

Under the current situation, food business operators can either submit a new application for authorisation of a new health claim following the procedure set in the Claims Regulation, therefore facing the elevated cost of clinical trials with uncertain outcome, or use the existing health claims in the 'on-hold' list without facing additional costs.

The magnitude of the cost for human clinical trials suggests that there are important difficulties that the food industry has to face to submit new health claims on plants and their preparations, compared to the ones included in the on-hold list. More specifically:

¹⁸⁹ Brookes G. (2010). Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU food supplements sector and market.
To be found: <https://www.pgeconomics.co.uk/pdf/Impact-Assessment-health-claims.pdf> (last accessed 25 September 2018).

Figures from Brookes G. (2010) were inflated to 2018 values using the Harmonised index of consumer prices (HICP) for the EU from Eurostat [prc_hicp_aind].

¹⁹⁰ Such percentages were calculated as lower and upper bounds of the costs for submitting a claim under Article 13.1 as share of costs of launching a product (€500/€80,000 to €1,000/€120,000).

¹⁹¹ These cost estimates relate to the launch of a simple product (e.g. an extension of an existing product), with no supporting clinical trials, reliance on a general (article 13.1) health claim and limited promotion (limited to some point of sale promotions, media articles etc. but excluding TV advertising).

¹⁹² Brookes G. (2010). Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU food supplements sector and market.

To be found: <https://www.pgeconomics.co.uk/pdf/Impact-Assessment-health-claims.pdf> (last accessed 25 September 2018).

Figures from Brookes G. (2010) were inflated to 2018 values using the Harmonised index of consumer prices (HICP) for the EU from Eurostat [prc_hicp_aind].

- Most companies would simply be unable to afford these costs. In particular, SMEs would be greatly disadvantaged by the need to conduct clinical trials for presenting health claims.
- Multinational/large companies, which can probably afford to conduct such studies, would need to evaluate whether the launch of such products on the market would ensure a sufficient return to recover the related investment costs.
- In the current situation of legal uncertainty, stemming from the absence of a harmonised regulatory framework at EU level for the use of plant substances in foods, companies are unable to sell the same product in all the Member States. This limits the extent of the potential market of a product whose development costs (including the clinical trials) are in the range of €1 million. The profitability of such investments is highly uncertain and consulted food business operators deem that development costs would clearly outweigh the benefits.

The uncertainty about the outcome of an application for a claim authorisation is a strong obstacle to the submission of dossiers, even for companies which can conduct the needed research. Presenting an application with supporting clinical trials does not always guarantee a positive outcome. An example in this regard is the case of the health claim on hydroxyanthracene derivatives, which despite the favourable EFSA opinion of the health claim¹⁹³, has still not been authorised by the Commission due to other risk management considerations, such as safety concerns. Moreover, the unpredictable length of the process further increases the level of uncertainty for companies, which should plan their investments aiming to get a return within a defined time horizon. This could have detrimental effects also on innovation and the development of new products. Innovation and communication of its results would be limited to the addition of vitamins and minerals to products containing plant substances, in order to use permitted claims on those substances.

Under the currently applicable rules (i.e. requirement of clinical studies for the proof of efficacy of claims), the consulted operators indicated that they expect a remarkable loss of sales in the EU market¹⁹⁴. Only the products containing plants which are very well known by consumers for their effects (e.g. camomile) are expected to remain on the market without bearing claims. As for the possibility to expand the extra-EU market, some consulted operators warned that, given the high EU production costs, their companies cannot rely on exports to compensate for the effective loss of the EU market. It would be very difficult for producers of food supplements to shift towards the herbal medicines sector because the medicinal legislation is stricter and there are several registration and licencing procedures to be followed. Companies which already have laboratories and licenses to produce medicinal products, and well-established in the medicinal sector, would gain a competitive advantage over companies producing only food products, in particular for the SMEs.

Effects on SMEs

Considering the substantial costs of presenting a dossier, as well as the uncertainties in the outcomes of the related process, it can be assumed that SMEs would be at a disadvantage. Furthermore, product reformulation and modification of labels would also have an important economic impact for SMEs.

The substantial **costs** for conducting clinical studies, whose results should be included in the dossier, would be the main obstacle for SMEs. As for the most significant cost items for

¹⁹³ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2013. Scientific Opinion on the substantiation of a health claim related to hydroxyanthracene derivatives and improvement of bowel function pursuant to Article 13(5) of Regulation (EC) No 1924/2006. EFSA Journal 2013;11(10):3412. To be found at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3412> (last accessed 10 December 2018).

¹⁹⁴ See external contractor's report, Part Three, page 35.

including a new health claim, replies to the SMEs panel indicated the main recurrent ones as follows: production of new data and/or processing of existing data (including clinical trials) (58.2%); familiarising with the regulatory obligations, including training (if needed) (57.8%); other administrative tasks, e.g. meetings, filling in information/application templates etc. (55.1%) and buying equipment and other supplies, including for modifying labels (39.1%).

Besides the increased competitiveness, communication of innovation to consumers via the use of claims, an additional benefit of an authorisation of a new health claim on plant substances is attracting new consumers and the presentation of new products on the market figure (both options were indicated by approximately 60% of respondents).

The costs of presenting new health claims were considered higher than the benefits by around one third of respondents; only 16% of respondents in the SMEs panel indicated benefits higher than costs, and 9.4% benefits equal to costs. However, it should be considered that 39.1% of respondents replied “do not know” to this question. In line with this reply, most respondents (72.3%) would not submit any new claims for approval in the current situation.

In conclusion, the estimated costs for SMEs of submitting a dossier for the approval of a new claim (between €1.0 million and €1.3 million) in fact amount to around 3-5% of the revenue of a small company, and to around 15% of the revenue of a micro company¹⁹⁵.

What are the ‘alternatives’, to the current provisions for regulating health claims on plants and their preparations used in foods, which could achieve similar objectives to the objectives of the Regulation, but with less burdensome requirements?

An ‘alternative’ to the to the current provisions for regulating health claims on plants and their preparations used in foods for their scientific substantiation as regards their effect on health, would be the use of the notion of ‘*traditional use*’ – similar as is the case of the simplified registration procedure in the THMPs sector. However, no official definition of ‘*traditional use*’ is currently available in the food area. Generally, when referring to the notion of ‘*traditional use*’ in the food area, experts and stakeholders¹⁹⁶ refer to a history of safe use in food production for at least 25 years (this operational definition is used also in the context of this document).

According to research carried out in the context of the PlantLIBRA project¹⁹⁷, EFSA's approach in the assessment of claims cannot be applied to plants and plant preparations because such approach focuses on well-defined and pure compounds, isolated from plants. In the case of plants and plant preparations the compounds or active ingredients responsible for the effect cannot be identified, and the effects may be diffused and not linked to specific markers. For these reasons, traditional use has been suggested as a valid and essential element to substantiate health effects, should plants and their preparations used in foods bear claims.

Based on the evidence collected through the stakeholders’ survey, the use of traditional use evidence is considered less burdensome for food business operators as the absence of clinical trials would considerably reduce the overall cost for submitting a dossier. Nevertheless, how the traditional use would be introduced and implemented in the context of Claims Regulation is uncertain; thus, the costs presented below are based on assumptions. Stakeholders representing the interests of the food industry provided cost estimates for applying for the authorisation of a new health claim based on traditional use evidence. Three ranges of costs were indicated: €30,000 to €60,000; €20,000 to €50,000; and €10,000 to €20,000 (only one respondent); while no

¹⁹⁵ See external contractor's report, Part three, page 38.

¹⁹⁶ E.g. Synadiet, 2013.

¹⁹⁷ Final Report Summary – PLANTLIBRA, FP7 (PLANT food supplements: Levels of Intake, Benefit and Risk Assessment). To be found: <https://cordis.europa.eu/project/rcn/94556/reporting/en> (last accessed 6 March 2019).

stakeholders indicated costs higher than €100,000¹⁹⁸. The interviews carried out mostly confirmed these estimates. Overall, stakeholders representing food business operators are largely in favour of the inclusion of the notion traditional use as evidence for assessing the efficacy of health claims on plants and their preparations for use in foods. The main reason behind this view is that the process for assessing health claims would be much less costly and that it would offer better chances of a positive outcome.

For SMEs, it is unclear whether the inclusion of traditional use would be less burdensome in comparison with the current authorisation procedure of the Claims Regulation.¹⁹⁹

Overall, as suggested in the external contractor's report²⁰⁰ even if traditional use should be considered for the substantiation of health claims, there would still be certain plants which do not have a long history of use and their proof of efficacy could only be based on human clinical studies. In these cases, operators would need to bear the costs of such an application, as for all other claims.

According to some consulted food business operators, consideration of traditional use for substantiating claims would have a positive impact on legal certainty²⁰¹. Products which are already on the market, and are well-known among consumers, would be allowed to lawfully use claims based on tradition of use.

Most consulted parties in the food supplements sector reported that the consideration of traditional use would not provide a solution to the current lack of innovation, despite being generally strongly in favour of the consideration of the notion of traditional use in the assessment of claims. The reason is that claims would be based on history of use. In all cases, an important issue which would still need to be addressed is how a company can develop new products or improve their efficacy based on generally accepted newly developed scientific evidence.

The EU association of producers of THI indicated strong positive impacts for this sector stemming from the consideration of traditional use in the substantiation of claims. Nevertheless, it was pointed out that traditional use should be based on plants rather than on individual substances or on combinations of plants or substances. This would allow making claims based on existing studies as proof of efficacy.²⁰²

Concerning the internal market objective, concerns of unfair competition were raised by the consulted stakeholders representing the pharmaceutical industry operators. According to a German association representing the interests of the pharmaceutical industry, companies would not be able to bear the higher costs of producing THMPs when on the market there are food supplements with similar claims, but lower costs of production. Companies producing THMPs face high production costs as they must comply with demanding standards in both the quality of ingredients and the production processes (such as Good Manufacturing Practices²⁰³), which translated into higher prices than food supplements. For the associations of the pharmaceutical

¹⁹⁸ See external contractor's report, Part Three, page 41.

¹⁹⁹ See external contractor's report, Part three, page 44.

²⁰⁰ In particular from the case study Traditional use for substantiation of health claims on plants and their preparations of the external contractor's report, Annexes, Annex 8.

²⁰¹ See external contractor's report, Part Three, page 41.

²⁰² See external contractor's report, Part Three, page 42.

²⁰³ According to Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (*OJ L 262, 14.10.2003, p. 22*), 'good manufacturing practice' means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use.

industry, the simultaneous presence on the market of THMPs and of food supplements containing identical plant substances, with both products allowed to bear similar claims, would see THMPs at a serious disadvantage, due to their higher price.

As regards consumers' protection, according to the EU-level consumer association BEUC, the notion of traditional use should not be considered in the assessment of health claims in the food area, given that it does not prove the efficacy of a substance and is potentially misleading for consumers. At the same time, in the current situation consumers might already purchase products bearing health claims that are *de facto* based on traditional use as these claims have been included in the on-hold list, and most consumers have traditional knowledge of the effects of certain plants. For these reasons, several consulted parties stated that the inclusion of traditional use would improve the provision of information to consumers, confirming or clarifying practices already in place²⁰⁴. Including a disclaimer in the claims assessed based on traditional use (e.g. "*traditionally used for...*") would ensure fair competition among different operators that use different claims and transparency of information to consumers about how the claims have been assessed. According to consulted associations representing the pharmaceutical industry, consumers might be unable to fully understand the differences between THMPs and food supplements, and they would mainly base their purchasing decisions on prices. However, prices can be lower for food supplements, given the higher costs of production of medicinal products. This further implies that consumers are often unable to grasp both the differences in the quality of these products.²⁰⁵

While an assessment based on 'traditional use' alone for the substantiation of claims would facilitate the efficacy assessment of health claims on plants, issues of quality and safety of products containing plants and their preparations should also be considered in order to avoid creating an 'unequal treatment' between food supplements and THMPs. Should authorisation of health claims on the basis of "traditional use" under EU law be accepted without harmonisation of safety and quality, Member States would remain responsible for ensuring the safety and quality aspects of plants used in foods with national rules possibly applying in this regard in addition to the requirements of the EU General Food Law. Consequently, authorisation of claims on such substances would not appear to have much value if the food/food supplement itself cannot be widely commercialised across the EU, as further discussed under [section 5.3.1](#).

As for the perceptions and preferences of consumers on the inclusion of traditional use for substantiating health claims, the main evidence collected was provided by the public consultation. Romanian respondents, who accounted for 59% of total replies, are strongly in favour of considering traditional use in the assessment of health claims and would purchase such products. 43% of respondents – excluding Romania – considered as highly important the condition that health claims should be assessed on the basis of scientific evidence before marketing the products. However, around half of these respondents (49%) would purchase a food product with a health claim based on traditional use not backed by science. It should also be noted that the results of the public consultation can only give an indication of what are the general perceptions of EU consumers.

²⁰⁴ See external contractor's report, Part Three, p. 39.

²⁰⁵ See external contractor's report, Part Three, page 40.

5.2.3. Relevance

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

The analysis of the evidence collected through the surveys of stakeholders and of Member States and through interviews revealed a unanimous consensus about the relevance of the original objectives of the Claims Regulation.

Considering that the food supplements market, including plant food supplements, is a continuously growing market, the objectives of the Claims Regulation are fully pertinent to address the current needs which are to only allow nutrition and health claims on the market which have undergone a risk assessment and risk management on their claimed efficacy.

In particular, 83% of respondents (44 out of 53 respondents) to the stakeholder survey considered the original need of “*ensuring a high level of consumer protection*” as “fully relevant”. The views of stakeholders representing all interests (consumers, food industry and pharmaceutical industry) were aligned in this respect. The original need of “*giving the consumer the necessary information to make choices in full knowledge of the facts*” was considered as “fully relevant” by 88.7% of respondents (47 out of 53 respondents). Lastly, the original need of “*creating equal conditions of competition for the food industry*” was deemed as “fully relevant” by 84.5% of respondents (45 out of 53 respondents). An ample majority of surveyed Member States indicated that the three original needs addressed by the Claims Regulation in terms of consumer protection, information to consumers and fair competition are still “*fully relevant*” (69.2%, 80.8% and 80.8% of respondents, respectively).²⁰⁶

According to some stakeholders, the Claims Regulation does not ensure adequate levels of consumer protection, as quality and safety aspects are not considered in the process of assessing claims²⁰⁷. EFSA, in the context of the health claims assessment, does not proceed with a safety assessment but only carries out an efficacy assessment of the claim. It may however advise, where appropriate, on conditions or restrictions of use and/or additional warning statements that should accompany a health claim on the label, thus highlighting safety concerns even where a health claim has been substantiated.

Authorising a claim in situation where safety concerns have been raised makes the situation complicated for risk managers; as it can be reasonably expected that the authorisation of the claim can progress only once issues related to safety have been resolved amongst the Member States. Moreover, it should be noted that most often, safety concerns are raised for substances whose use is not harmonised at EU level, but it is subject to national competence. In particular for plant substances, the absence of harmonised provisions for their use has proved difficult, because a given substance may be prohibited for use in food in certain Member States, or its use may be restricted in other Member States or even allowed only in medicines.

The implementation of the Claims Regulation, in terms of the authorisation procedure of health claims, showed that safety concerns emerge in relation to claims made on plants and their preparations. Furthermore, with respect to the on-hold list, Member States on multiple occasions have stressed the importance and need of, not only looking into the efficacy of the claims on plants but also looking simultaneously into the safety and quality aspects of those plant substances. This has been also confirmed by some consulted stakeholders that stated that the efficacy assessment under the Claims Regulation should, in certain cases, also take into account

²⁰⁶ See external contractor's report, Part Three, page 47-48.

²⁰⁷ See external contractor's report, Part Three, p. 50.

safety aspects. In practice, discussions on the health claims on hydroxyanthracene derivatives, confirmed the need to also consider the safety aspect in relation to their use in foods. Thus, it appears that the consideration of issues of safety of plant substances is of great importance. This is discussed in more detail under the general regulatory framework for the use of plants and their preparations in foods, in [section 5.3.3](#).

5.2.4. Coherence

To what extent are the requirements set out in Regulation (EC) No 1924/2006 coherent with EU legislation applicable to plants and their preparations, including the part of the legislation on medicines for human use dealing with traditional herbal medicinal products?

It is important to note that part of the EU legislation in the current applicable framework predates the Claims Regulation, while the remaining part was developed and adopted successively. This implies that whereas the burden of ensuring consistency with previous EU legislation fell on the policy-making process which led to the Claims Regulation, in the case of successive provisions such burden fell on the respective policy-making processes.

With respect to the internal coherence of the Claims Regulation, it should be noted that all provisions of the Claims Regulation complement each other in order to achieve the overall objectives of the Claims Regulation. Nevertheless, it should also be noted that, given the limited scope of this evaluation, a full assessment of the Claims Regulation was not carried out (please also refer to [section 1.2](#)).

Coherence with the General Food Law (GFL)

The requirements of the Claims Regulation are fully consistent with those of the GFL. Like the GFL, the Claims Regulation explicitly establishes procedures to ensure that consumers are protected from untruthful and misleading information (e.g. Article 8 of GFL), and that operators have to comply with the same rules across the EU²⁰⁸ (Article 14, Article 11 and Article 18 of GFL). Provisions in the Claims Regulation on authorisation for the use of claims by the Commission only after a harmonised scientific assessment of the highest possible standard carried out by EFSA are consistent with the principles of the GFL concerning risk analysis (Article 28 and 29 of GFL).

Coherence with the FIC Regulation

This Regulation was developed after the Claims Regulation, and hence took into account the provisions featured in it (it actually amended Article 7 of the Claims Regulation concerning the provision of nutrition information on products on which a nutrition and/or health claim is made).

The requirements of the Claims Regulation are fully consistent with those of the FIC Regulation. Like the FIC Regulation, the Claims Regulation aims at ensuring that consumers are protected from untruthful and misleading information (Article 7 of the FIC Regulation).

Provisions in the Claims Regulation on authorisation for the use of claims by the Commission only after a harmonised scientific assessment of the highest possible standard carried out by EFSA are consistent with the principles of the FIC Regulation governing the provision of voluntary food information, and in particular with the FIC Regulation²⁰⁹, establishing that such information shall, “*where appropriate, be based on the relevant scientific data*”.

²⁰⁸ Smooth functioning of the internal market and fair competition.

²⁰⁹ Article 36 of the FIC Regulation

Coherence with Regulation (EC) No 1925/2006 on food fortification

Although the Claims Regulation does not deal with safety aspects, recital 1 of the Claims Regulation, which states that “in order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled” is consistent with Article 8 of Regulation No 1925/2006²¹⁰, also relating to plant substances.”.

Coherence with Regulation (EU) 2015/2283 on novel foods

The Claims Regulation aims to ensure the effective functioning of the internal market whilst providing a high level of consumer protection. The purpose of Regulation on novel foods and novel food ingredients is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests. It stipulates that all food and food ingredients that have not been used for human consumption in the EU before 15 May 1997 shall be considered a “*novel food*” or a “*novel food ingredient*”. A novel food catalogue lists all products of animal and plant origin and other substances subject to the Novel Food Regulation, on the basis of information provided by Member States. The catalogue is a non-exhaustive list and serves to indicate whether a product will need an authorisation under the Novel Food Regulation.

It should be noted that traditional use (i.e. human consumption in the EU before 15 May 1997) is considered as recognised proof of safety in the Novel Food Regulation. At the same time traditional use is not considered as an acceptable proof of efficacy under the Claims Regulation.

Coherence of the Claims Regulation with the legislation on THMPs

Several consulted parties²¹¹, mainly representing food industry interests, but also including some Member States' competent authorities, identified a number of inconsistencies between the THMPs legislation and the Claims Regulation. The key conflicting aspect was identified in the consideration of tradition of use in the efficacy of medicinal products, whereas tradition of use cannot be used for assessing the efficacy of foods and food supplements containing plant substances, in the context of health claims.

Several consulted parties stressed the incoherence of having a *framework for medicinal use of plant substances* which takes into account the exception of some herbal medicinal products, whose efficacy cannot be proved but can only be plausible on the basis of traditional use and, and on the other hand, a *framework for food use of plant substances* which requires proof of efficacy of claimed health effects of plants based on clinical trials, which are not available for this group of products²¹².

On the other hand, stakeholders representing pharmaceutical industry's interests and a number of Member States did not identify any inconsistencies between the THMPs Directive and the Claims Regulation, for the following reasons:

- 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; the notion of traditional use in the medicinal field implies long lasting use of specific substances in medicines for curing or

²¹⁰ Article 8 of Regulation (EC) No 1925/2006 provides for a mechanism for dealing with cases where a potential risk to human health, possibly arising from the addition of a substance other than a vitamin or mineral (and hence also of a plant substance) to foods (including food supplements), has been identified.

²¹¹ Their views emerged from the surveys of stakeholders and Member States, from interviews and from the case studies.

²¹² See external contractor's report, Part Three, page 57.

preventing a disease. There is no contradiction between recourse to the notion of traditional use for THMPs and no use of such concept in the Claims Regulation because it is not possible to transpose this concept in the food area.

- Medicinal products have a specific definition²¹³ which separates this category of products from food products, thus reducing the incoherence.
- Unlike food products, a number of other provisions apply to medicinal products, including Good Manufacturing Practices, Good Agricultural and Collection Practice, pharmacovigilance, pre-marketing authorisations, limits to advertisements and all other relevant requirements foreseen under the EU law for medicinal products. In contrast with food products, the consumption of herbal medicinal products is limited in time, while consumption of foods containing plants and their preparations has virtually no time limits. The combination of these provisions clearly differentiates the two sectors and ensures consistency between the two legislative areas.
- EMA monographs create a relationship between a well-defined quality of plant substance (whole plant/parts of plant; type of extract/form; other characteristics) and the plausible pharmacological effects. This relationship cannot be transposed in any way in the current food law, where quality is not standardised and defined.

How and to what extent does the current regulatory framework for the use of nutrition and health claims affect the trade of herbal medicinal products bearing therapeutic indications?

According to the pharmaceutical industry, the current implementation of the Claims Regulation and the establishment of the on-hold list of claims is considered unfair for the sector, as this situation allows food products to be marketed with claims that are not risk managed but are often similar to therapeutic indications used on THMPs. Moreover, food products (especially food supplements) containing plant substances are considered to overlap often with the market of THMPs and, more in general, of herbal medicinal products.

No suitable market data are available to investigate the above allegations; however, the issue of the classification of products is a clear sign of the overlapping of the two markets, at least at EU level (see also [section 5.3.1](#)). The coexistence and trade of products falling under the two legal frameworks is discussed in more detail further above, in [section 5.3.1](#).

To which extent are rules on the use of health claims on plants and their preparations used in foods coherent with other international initiatives (e.g. Codex Alimentarius)?

Of particular relevance is the work of the Codex Committee on Food Labelling, which – together with the Codex Committee on Nutrition and Foods for Special Dietary Uses – developed the *Codex Guidelines on Nutrition and Health Claims*²¹⁴.

²¹³ Article 1 of Directive 2001/83/EC states: “Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”.

²¹⁴ Three standards/guidelines have been developed on the topic of nutrition labelling to date:

- General Standard for the Labelling of Pre-packaged Foods (Codex Stan 1_1985, revised 1991, 2001)
- General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Use (Codex Stan 146_1985)
- Guidelines on Nutrition Labelling (CAC/GL 2_1985, revised 1993)
- Guidelines for use of nutrition and health claims (CAC/GL 23-1997, adopted in 1997, revised in 2004).

The Codex Alimentarius, jointly set up by FAO and WHO in 1963, is the most important international scheme dealing with health claims. Although the Codex standards, guidelines and related texts are voluntary in nature, the World Trade Organisation has recognized them as a reference in international trade and trade disputes.

The legislation in place in the EU appears to be fully coherent with the indications from the Codex, especially concerning the need for scientific evidence, the use of appropriate language and the consideration of the context of the total diet.

The guidelines for nutrition and health claims, which were adopted in 2004, define and permit “*nutrient function claims*”, “*other function claims*” and “*reduction of disease risk claims*” under certain conditions. Indications from Codex are general in nature and can be interpreted as an indicative path to be followed by national authorities in developing their own specific regulations. Further, no specific indication on health claims for plants and plant preparations is currently envisaged in the Codex.

The Codex’s guidelines were explicitly taken into account by the European Commission in the preparation of the current legislation on health claims²¹⁵. Recital 7 of the Claims Regulation indeed states that “*due consideration is given to the definitions and conditions set in the Codex Guidelines*”. The drafting of the Claims Regulation was based on the Codex guidelines, but certain areas went beyond Codex requirements; the related elements have been subsequently updated in Codex in line with EU legislation²¹⁶.

5.2.5. EU added value

What are the merits and disadvantages in terms of the EU added value of the current governance of health claims on plants and their preparations used in foods?

Added value of a decision at EU level on the authorisation or rejection of health claims on plants and their preparations used in foods

Due to the scarcity of data available, a qualitative consideration has taken place on the EU added value, paying special attention to the effectiveness of the Claims Regulation in achieving its objectives. The added value of an EU harmonised framework vis-à-vis national rules is assessed with reference to the achievement of the objectives of the Claims Regulation (as defined in [section 5.2.1](#)).

Ensuring a high level of consumer protection and facilitating healthier food choices

In the baseline situation there were serious limitations in ensuring a high level of consumer protection from untruthful/misleading claims across the EU through national legislation only. Few Member States had specific legislation on health claims made on plant substances for use in foods prior to the adoption of the Claims Regulation, but there were significant differences in terms of approaches. The majority of Member States had no specific legislation in place.

The assessment showed that the current situation does not offer significant benefits in terms of improved consumer protection and safeguard of public health. In theory, an EU-level approach of using a harmonised list of assessed and risk-managed claims could have offered significant

²¹⁵ DG Internal Policies of the Union, Policy Department: Economic and Scientific Policy, Nutrition and Health Claims: The Proposed Regulation on Nutrition and Health Claims in relation to CODEX, Briefing Note (IP/A/ENVI/OF/2005-196). To be found at: [http://www.europarl.europa.eu/RegData/etudes/note/join/2006/373586/IPOL-ENVI_NT\(2006\)373586_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/note/join/2006/373586/IPOL-ENVI_NT(2006)373586_EN.pdf) (last accessed 13 June 2018).

²¹⁶ See external contractor's report, Part Three, page 59.

benefits in terms of consumer protection. However, the actual benefit for the consumer currently depends on the level of consumer protection at national level when implementing the on-hold list.

Improving the free movement of food products bearing claims

The differences in the national legislation regulating claims made on plants and their preparations for use in foods before the development of the Claims Regulation, in combination with the absence of any specific legislation in the majority of Member States, did not ensure a smooth functioning of the internal market for products bearing claims. The limitations in the free movement of these products, together with the aforementioned issues in consumer protection and in ensuring fair competition, were actually one of the main reasons behind the development of the Claims Regulation²¹⁷. As explained in [section 5.2.1](#), the establishment of the on-hold list of claims and its implementation at national level have no significant drawbacks in terms of ensuring a smooth functioning of the internal market. The list also improved the free movement of products bearing claims vis-à-vis the previous situation, which left to Member States the decision whether to regulate or not claims made on plant substances through specific national legislation.

In principle, an EU harmonised approach to regulating claims made on plant substances for use in foods offers benefits in terms of smooth functioning of the internal market vis-à-vis national legislation.

Increasing legal certainty for food business operators

From an EU-wide perspective - which is especially important for export-oriented food business operators not operating exclusively on their own national market - a harmonised EU legislation on claims made on plant substances for use in foods offers significant benefits in terms of legal certainty compared to different national legislation (or its absence), i.e. the situation before the development of the Claims Regulation. The current implementation of the Claims Regulation for plants and their preparations has significant drawbacks in terms of ensuring legal certainty, as food business operators perceive it as precarious due to the uncertain duration of transitional measures under Article 28 of the Claims Regulation ([section 5.2.1](#)).

²¹⁷ Recital (2) of the Claims Regulation: “Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods”.

5.3. Regulatory framework on plants and their preparations: Answers to the evaluation questions

5.3.1. Effectiveness

To what extent the legislative framework applicable to plants and their preparations used in foods has allowed achieving its objectives with respect to placing of safe food on the EU market?

It was expected that the regulatory framework applicable to plants and their preparations used in foods as it stands would have allowed the objectives of safety of the use of plant substances in food and the free circulation of these products to be reached.

In relation to the first objective, i.e. ensuring that food placed on the market is safe, all products on the market must comply with the EU general rules on food safety (e.g. General Food Law Regulation, see [section 2.2](#)), existing national rules²¹⁸ (e.g. negative or positive lists with conditions of use and/or warnings²¹⁹) and, where necessary, the use of the Article 8 procedure of the Fortified Foods Regulation to assess the safety of certain plant substances in foods.

The procedure laid down in Article 8 of the fortified foods Regulation allows for a substance to be either prohibited or submitted to conditions of use where it may be harmful to health or placed under scrutiny for a given period where there are concerns that a substance may represent a potential risk to consumers, but the available scientific information is insufficient. The Commission expected that the use of the Article 8 procedure would result in the progressive setting of a harmonised list of substances, especially plant substances, the use of which in food would be prohibited or restricted.²²⁰ However, given the limited number of justified requests from Member States, the Article 8 procedure has been applied only few times, there is little experience to allow drawing definite conclusions on its effectiveness in harmonising a list of plant substances to ensure a high level of consumer protection. However, the inclusion, following requests by Member States, in the prohibited list of the fortified foods Regulation²²¹ of two plant substances (*Ephedra* species and *Yohimbe*) for which actual concerns that are considered as notoriously toxic plants for human consumption were identified, can be considered as a proof of the effectiveness of the tool. This procedure has been further used in the context of the assessment for two additional plant substances for which the decision-making process is ongoing²²². Along the same line, Member States have not been in favour of proceeding with the authorisation of claims when safety about the substance remained uncertain²²³. The increasing demand from Member States to use the Article 8 safety assessments for various plant substances²²⁴ used in foods suggests that plant substances used in food may give rise to adverse health effects and would merit a closer and more systematic scrutiny.

In the context of a set of EU legislation in place, which ensures that food is safe for consumer, a key tool to ensure the flow of information to enable swift reaction when risks to public health are detected in the food chain is the RASFF – the Rapid Alert System for Food and Feed. Vital information exchanged through RASFF can lead to products being recalled from the market. A low number of reported incidents involving food supplements containing plant substances and a

²¹⁸ National lists of permitted or prohibited plants used in foods, notified to the Commission and justified on grounds of public health protection.

²¹⁹ E.g. the BELFRIT list

²²⁰ Report of European Commission to the Council and European parliament on the use of substances other than vitamins and minerals in food supplements, COM(2008) 824 final, 2008.

²²¹ Annex III, part A, of Regulation (EC) No 1925/2006 on food fortification.

²²² Hydroxyanthracene derivatives and green tea.

²²³ E.g. in the case of hydroxyanthracene derivatives.

²²⁴ Ephedra, Yohimbe, Hydroxyanthracene derivatives, Green tea.

limited recourse to the RASFF for products containing plant substances could suggest an overall effectiveness of the current general regulatory framework. The number of RASFF notifications on food supplements (even if it has to be noted that this product category also includes dietetic and fortified foods) in the EU was 116 in 2010, 185 in 2012, 160 in 2013, and 208 in 2014. The increase in notifications could be caused by the increasing number of food supplements purchased on the internet. From an FVO analysis on RASFF data, it emerged that approximately two thirds of the notifications are related to imported products: of the 368 RASFF notifications for 2013 and 2014, 150 were related to imports from the USA, 51 to imports from China and 23 to imports from India. 158 notifications out of 208 issued in 2014 concerned the inclusion of unauthorised ingredients in food supplements. This includes plants and parts of plants ('botanicals'), but also synthetic pharmaceutical substances such as sibutramine, tadalafil and sildenafil. In 89 of the 208 RASFF notifications in 2014 (43%), the food supplement had been manufactured in another Member State or was imported via another Member State. Incidents were generally found to concern non-compliant products manufactured in third countries, marketed through specific channels (online purchases). Therefore, issues concern mainly the online sales of products, for which controls are challenging, and which can potentially raise safety concerns.

As regards the second objective related to the free movement of foods containing plants, Member States and other stakeholders consider that, as it stands, the regulatory framework applicable to the use of plants and their preparations in food failed to reach this objective. In particular, the 19 national lists adopted by the Member States to regulate the use of plants and their preparations in foods resulted in serious obstacles to the free circulation of food products containing plant substances in the internal market. Those obstacles originate also from uneven application of the mutual recognition principle at Member State level, and from diverging approaches regarding the classification of certain plant substances as "food" or "medicine", resulting in different national approaches to the authorisation of specific plants/plant substances for use in foods.

Those elements emerged from the assessment by the external contractor, with special reference to the findings of the case study on the BELFRIT project²²⁵ and other national lists of substances. Existing positive and negative lists of substances emerged as a factor which can either hinder or facilitate the achievement of the internal market objectives of the general regulatory framework. On one hand, the consulted parties agreed that positive/negative lists increased the level of legal certainty for companies which want to operate in the Member States where the lists are implemented. On the other hand, positive and negative lists are based on national traditions and reflect national practices. Therefore, they can lead to an increased fragmentation of the EU market and can be conflicting among themselves. This means that positive and negative lists can contribute to protect national specificities. In addition, the mutual recognition principle has been seldom properly applied, or requires a long period of time, and hence leading to obstacles to a smooth functioning of the internal market. Companies generally have avoided to challenge

²²⁵ The BELFRIT project is a result of a collaboration between three Member States (BE, FR, IT) which have positive lists of plant substances that can be used in food supplements. It aims at the harmonisation of plants and their preparations used in food supplements through the establishment of a commonly agreed list of plant substances by these three Member States on the basis of the work done by MS' authorities together with three high-level experts in the area of plant substances. This initiative is a spontaneous effort by the three Member States in order to facilitate the mutual recognition of food supplements containing plants and their preparations and their free circulation among their territories. The three Member States made clear that the whole project recognises the essentiality of evidence of traditional use in the area of plants both for evaluating the safety and the efficacy. The three MS, which support the development of new legislation in the area of plants and their preparations used in food, consider the BELFRIT project a first step in a longer process of harmonisation of the area.

unfavourable provisions but adapted their products to the specific requirements applying in each national market, even if this implied higher costs.

Classification of products as “medicines” or as “foods”

Besides the presentation and composition of a product and the related marketing and communication, it appears that the classification of a product as food or medicine is very different depending on the traditions and the habits of each Member State on the use of plants. It emerged from interviews with business stakeholders and Member States that certain Member States (e.g. Germany) have traditionally regulated products containing plant substances as medicines, and several products containing plants and plant preparations cannot be marketed as food supplements in those Member States. On the other side, other Member States (e.g. Italy) have a long tradition of classifying products containing plant substances as foods rather than as medicines. This is illustrated in Figure 11 and Figure 12 below for a set of botanical substances. The comparison of these two figures confirms that the divergence in the treatment of plant substances in food supplements across the EU Member States has not changed over the years.

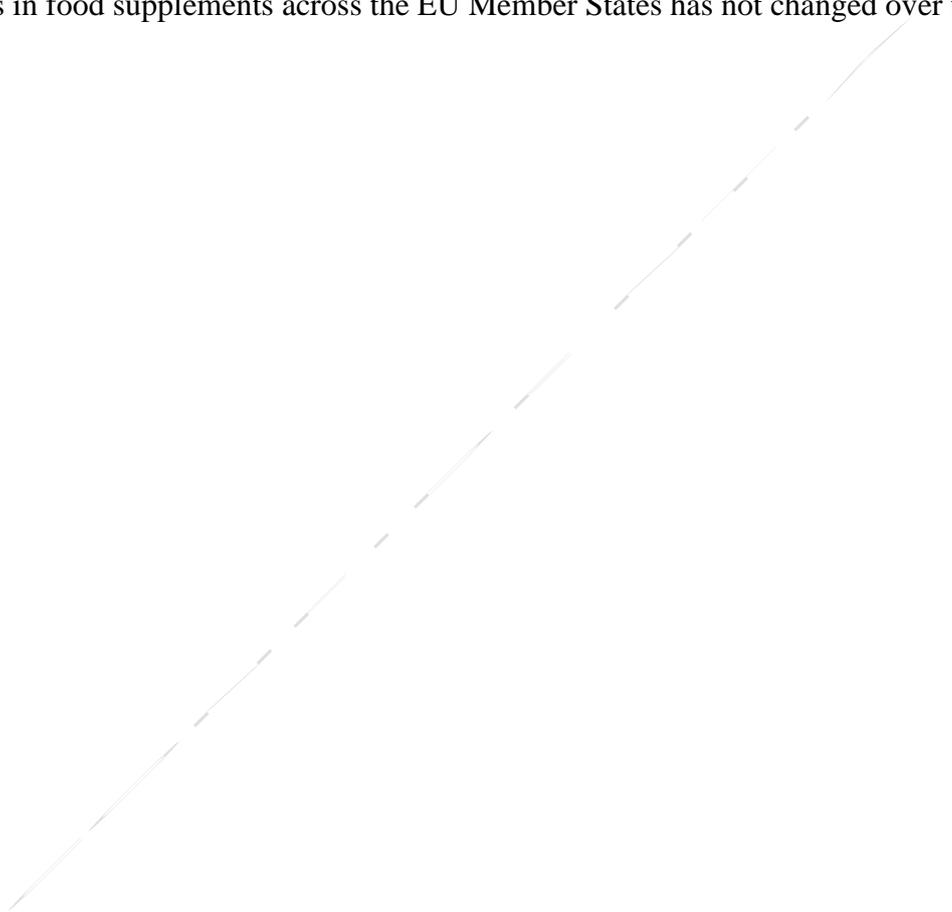


Figure 11: Regulatory status of a representative sample of “other substances” of vegetable origin in food supplements, in 2007

Symbols	✓	Permitted for use in food supplements either under national law or internal guidelines.
	L	Permitted for use in food supplements - maximum level established.
	C	Permitted for use in food supplements under specific conditions (eg type of extract, ingredients combination in the final product, etc)
	E	Permission may be given on a case by case basis following evaluation, considering issues such as ingredient function.
	A	Not currently permitted. May be permitted following a pre-marketing authorisation.
	*	Not permitted for use in food supplements, or regarded as medicinal.

		AUSTRIA	BELGIUM	BULGARIA	CYPRUS	CZECH REPUBLIC	DENMARK	ESTONIA	FINLAND	FRANCE	GERMANY	GREECE	HUNGARY	IRELAND	ITALY	LATVIA	LITHUANIA	LUXEMBOURG	MALTA	NETHERLANDS	POLAND	PORTUGAL	ROMANIA	SLOVAKIA	SLOVENIA	SPAIN	SWEDEN	UNITED KINGDOM	
Botanicals & botanical extracts	Aloe (Aloe vera (L.))	E	✓	E	E	C	L	✓	C	A	C	*	C	✓	✓	✓	E	✓	✓	✓	✓	✓	✓	C	L/C	✓	✓	C	
	Ginkgo (Ginkgo biloba)	E	L	E	E	L	✓	*	C	A	*	*	L	*	C	L	E	✓	✓	✓	✓	✓	✓	L	*	*	*	C	
	Ginseng (Panax ginseng)	E	✓	E	E	L	L	✓	C	A	*	L	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	L	✓	✓	C
	Garlic (Allium sativum (L.))	✓	✓	E	E	C	✓	✓	✓	A	C	✓	L	C	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	L	*	*	C
	Green tea extract (Camellia sinensis)	E	L/C	E	E	C	E	✓	✓	A	C/A	✓	L	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	*	✓	C
	Garcinia extract (Garcinia cambogia)	E	✓	E	E	L	*	C	✓	A	*	*	L	*	✓	✓	E	✓	✓	✓	✓	✓	✓	✓	✓	C	*	E	*
	Guarana extract (Paullinia cupana)	C	✓	E	E	C	L	✓	✓	A	C/A	*	L	C	✓	L	E	✓	✓	✓	✓	✓	✓	✓	✓	✓	*	✓	✓

Source: European Advisory Services (EAS), The use of substances with nutritional or physiological effect other than vitamins and minerals in food supplements, Study for DG SANCO, EC, 2007.

Figure 12: Regulatory status of the same representative sample of plant substances in food supplements, in 2017

Substance	AT	BE	BG	CY	CZ	DE	DK	EE	ES	FI	FR	GR	HR	HU	IE	IT	LT	LU	LV	MT	NL	PL	PT	RO	SE	SI	SK	UK
	Rec.	Leg.	Leg.	...	Leg.	Rec.	Rec.	Rec.	...	Rec.	Rec.	...	Leg.	Rec.	Rec.	Leg.	Leg.	Leg.	Rec.	Rec.	...	Rec.
Allium sativum	R	R				R					R		A			R								A	A	A		A
Aloe vera	R	R				R	R			P	R		R	R		R								A	R	R		A
Camellia sinensis		R				R					R		A			R								A		A		A
Ginkgo biloba		R			R	R		P		P	R		R		P	R								A	P	P		A
Panax ginseng		R			R	R	R			P	R		A			R								A	A	A		A
Garcinia gummi-gutta		R			R	R	P	P					A			R								A	P	R		A
Paullinia cupana (Guarana)		R				R	R				R		A			R								A		A		A

Leg.	Legislation
Rec.	Recommendation
	Leg./Rec.
A/P	Country prohibits and allows herbal at the same time based on the fact that two that two or more synonyms of the same plant are regulated differently.
A	The herbal / substance is allowed for use because the whole species/ group of nutrients is allowed.
P	The herbal / substance is prohibited because the whole species is prohibited.
R	The herbal is allowed with restrictions based on the fact that that whole species is allowed with restrictions.
A	A= The herbal / substance is allowed for use in food supplements. If "A" is replaced with a number, the number reflects the maximum level.
P	P= The herbal / substance is prohibited for use in food supplements.
R	R= The herbal is allowed with restrictions (e.g. max levels or certain parts). Please refer to original texts.

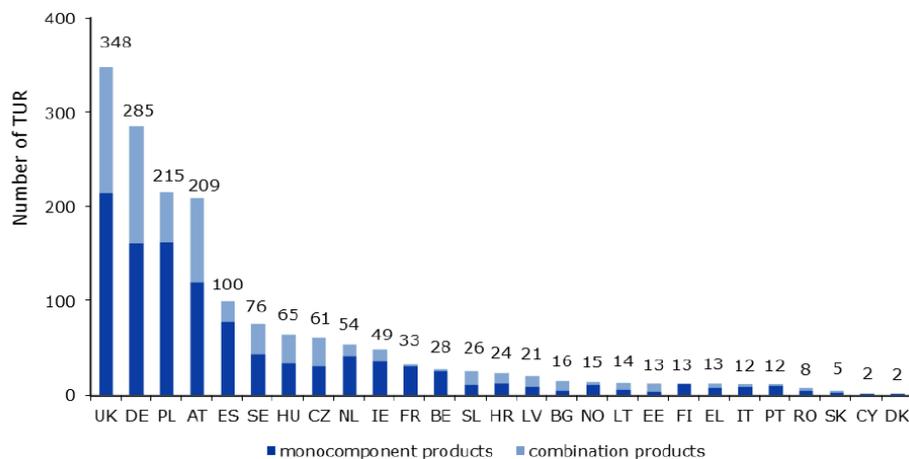
Source: AESGP, Food Supplements Data Bank, 2017.

The situation described above makes it very difficult to lawfully market the same product in multiple Member States without introducing adaptations in the formulation and/or in the label of the product, with negative practical implications for operators (limitations in exploiting scale economies, additional costs for legal consultancy, additional costs for reformulation and/or re-labelling, etc.).

The comparison of the number of traditional use registrations (TUR) and well-established use (WEU) marketing authorisations in different Member States confirms the observation about strong traditions and habits in different Member State regarding the use of plants. “Countries that already had a medicinal product category for traditional herbals show more registrations”, with the exception of the UK that did not have a national equivalent to TURs prior to the tradition herbal medicinal products directive²²⁶. Registration fees vary significantly among Member States with, for example, Germany charging approximately EUR 15,700 and Italy EUR 50,000²²⁷, and might also contribute to the differences in the number of TURs across the EU.

The United Kingdom (348), Germany (285), Poland (215) and Austria (209) between 2004 and 2016 were the leading Member States in terms of the number of granted registrations, accounting for an aggregated share of 61% of total traditional use registrations at EU level (Figure 13). On the contrary, countries like France and Belgium (of comparable size and population to Germany and Austria respectively) submitted a much lower number of registrations.

Figure 13: Number of granted traditional use registrations for monocomponent and combination THMP in the EU per Member State (since implementation of Dir. 2004/24/EC until 31 December 2016).



Total 1719: 1089 for monocomponent products, 630 for combination products (No traditional use registrations granted for IS, LI, LU and MT).

Source: European Medicines Agency, 2016

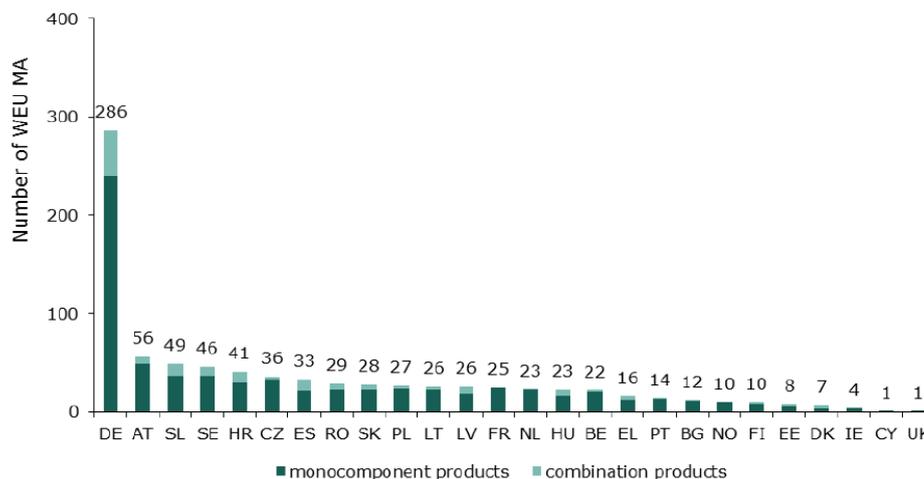
For well-established use marketing authorisations, EMA reported, for 2016, 286 authorisations in Germany, 56 in Austria and 49 in Slovenia. These three Member States accounted for an

²²⁶ W. Peschel and B. Monedero Alvarez (2018), Harmonised European standards as a basis for the safe use of herbal medicinal products and their marketing authorisation in European Union Member States, *Pharmaceutical Medicine* 2018, 32: 275-293, p. 282.

²²⁷ EUROCAM, Herbal medicinal products. To be found at: <https://cam-europe.eu/registration-herbal-medicinal-products> (last accessed on 20 March 2019).

aggregated share of 46% of total well established use marketing authorisations at EU level (Figure 14). Again, Belgium had a much lower number of registrations compared to Austria and similarly, France had eleven times less authorisations. Well-established use marketing authorisations “are mostly found in countries with a history of regulation of herbal products as medicines”.²²⁸

Figure 14: Number of granted well established use market authorisation for monocomponent and combination HMP in the EU per Member State (since implementation of Dir. 2004/24/EC until 31 December 2016).



Total 859: 704 for monocomponent products, 155 for combination products (no well-established use marketing authorisations granted for IS, IT, LI, LU and MT).

Source: European Medicines Agency, 2016

As the same plant substances can be present in the composition of both medicinal products and food products, there is the potential for differential treatment of products containing the same substance depending on whether they are classified as food or as medicine. For example, caps containing a plant substance (St John’s Wort) were reported by consumer associations to be sold as food supplement in Belgium and as medicine in France, with the same plant concentration but recommended to be consumed at different dosage (1 cap/day for food supplements, while 2-3 caps/day for medicines)²²⁹. In addition, the level of information provided to consumers for that product under each of the two categories is also different. As consequence, it could be difficult to distinguish between food supplements and medicinal products containing often the same plant substance(s) with similar properties claimed on the label (such as certain claims/indications of their physiological effect (e.g. "relief of minor articular pain" vs. "maintenance of normal joints". "Treatment of common cold" vs. "supports immune system"). This creates distortions on the market, inconsistencies and lack of clarity for food business operators and Member States' competent authorities, as well as cause confusion and safety concerns for consumers.

Finally, the results of the SMEs panel showed that the absence of harmonisation negatively affected also SMEs: almost 70% of respondents indicated that their company is affected by the

²²⁸ EUROCAM, Herbal medicinal products, <https://cam-europe.eu/registration-herbal-medicinal-products/> (last accessed on 20 March 2019).

²²⁹ Interview with BEUC carried out as part of the external study.

absence of specific harmonised rules at EU level on the use of plant substances in foods. Classification issues (foods vs. medicines) were indicated by the SMEs in the panel as a key obstacle to trading with other EU Member States (45.4% of replies), together with the absence of specific EU harmonised provisions such as positive lists of permitted plant substances (45.7% of replies).

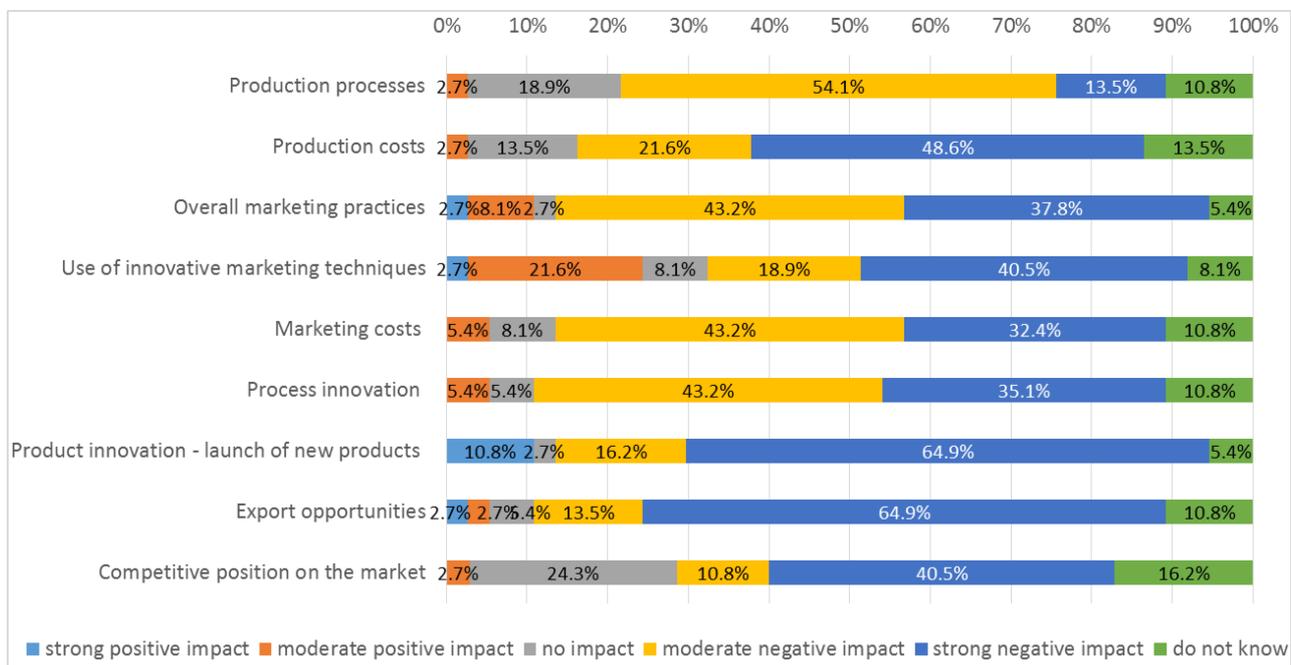
5.3.2. Efficiency

What are the costs and benefits of the legislative framework applicable to plants and their preparations used in foods?

As explained in the effectiveness section, the current general regulatory framework ensures an overall good level of consumer protection.

Concerning costs for business operators, the main source of information is the stakeholders' survey, which indicates the activities affected by the current regulatory framework (i.e. by the absence of fully harmonised provisions on the use of plants and their preparations in foods at EU level). The related survey question was targeted exclusively at stakeholders representing business interests in the food sector and in the pharmaceutical sector and the replies vary considerably between the two sectors. The consulted business operators in the pharmaceutical sector do not have a strong view on the impact of the current regulatory framework (80% replied “do not know” for all the activities, and the remaining 20% replied “no impact”), while replies of food business operators are illustrated in Figure 15.

Figure 15: Food business operators’ activities affected by the absence of a harmonised regulation on the use of plants and their preparations in foods, and related impacts



Source: External contractor’s report, Annexes, Annex 4.A, Question 3 of stakeholder survey

The results of the survey indicate that the absence of a harmonised regulation on the use of plants and their preparations in foods at EU level has mainly (strong or moderate) negative impacts on

the activities of food business operators. In particular, product innovation (launch of new products) and export opportunities are the two activities indicated by the majority of business operators to be strongly negatively impacted. The consultation of stakeholders in the food industry suggested that innovation is considered as negatively affected by the current situation, with the exception of Member states, where there is a favourable legislative environment for the launching of food supplements containing plants and their preparations. Nevertheless, it was argued by these stakeholders that new products can be developed for a specific national market, while it is basically impossible to develop new products targeting multiple national markets. These negative impacts identified by food business operators can be expected to cause them additional costs/revenue losses, which could not be quantified due to the lack of suitable data. It should, however, be noted that data from Food Supplements Europe indicate that the number of food supplements considerably increased between 2012 and 2017 (see [section 3.3.1](#) and [section 3.3.2](#)).

A majority of survey respondents reported about additional costs for food business operators caused by the lack of a harmonised framework. In particular, companies reported to bear the costs of legal consulting services to understand the legal requirements for selling a product in a specific Member State. Compliance costs were also mentioned by respondents, due to the development of multiple products with different labels and recipes that have to comply with the legislation in force in a certain national market. The issue of compliance costs is especially relevant for export-oriented companies. Although systematic cost data are not available, a respondent estimated the cost for product development as ranging between €20,000 and €100,000; the cost for launching a product in a new foreign market may amount to twice as much. For products with a complex formulation, the cost for product development (excluding production costs) may rise to €300,000. These costs should be applied for each national market that the company is targeting. This implies that the costs for the launch of a range of food products containing plants in multiple Member States can be substantial, especially for SMEs.

National control authorities indicated that the current situation of non-harmonisation is challenging for their controlling activities. However, they did not provide a quantification of additional costs - with special reference to the costs of developing national rules and monitoring their implementation (control costs) – and of the resulting increase in administrative burden.

In terms of benefits, it may be considered that the current state of play is beneficial to all the food business operators which successfully market their products containing plant substances (be they food or medicinal products) only on their domestic markets, and which are not interested in marketing their products to other Member States.

5.3.3. Relevance

To what extent is the current legislative framework applicable to plants and their preparations used in foods still relevant to deal with issues related to the evolution of the market with regard to plants and their preparations used in foods?

As mentioned in [section 2.2](#), the relevance of the current regulatory framework was a key topic addressed in the 2008 Commission Report on the use of substances other than vitamins and minerals in food supplements. The report concluded that “*the Community legal instruments already constitute a sufficient legislative framework for regulating this area and (the Commission) does not consider it opportune to lay down specific rules for substances other than vitamins or minerals for use in foodstuffs*”. The main reasons behind such conclusions are that limits exist both to the feasibility and to the necessity of such harmonisation. Regarding the feasibility, the report concluded that *unlike vitamins and minerals, the use of which is fairly similar throughout the Member States, the other substances correspond to very varied consumption habits and, in addition, also that high scientific and methodological difficulties*

would have to be overcome. As for the need for harmonisation, the EU legal instruments intended as a combination of the principle of mutual recognition, the Regulation on novel food, Claims Regulation, and Article 8 of Regulation (EC) No 1925/2006, were deemed to *already constitute a sufficient legislative framework for regulating this area*.

The existing legal provisions that led the Commission to conclude in 2008 that no further harmonisation in the field was needed, were not implemented as expected: the Claims Regulation has not been fully implemented. Moreover, the principle of mutual recognition, is claimed by food business operators, that has not been properly applied by national governments.

On the other hand the Article 8 of the Regulation on Food Fortification has been used for four plant substances, which led to the prohibition of two plant substances, while the decision-making process is still ongoing for the other two cases. Along the same line, Member States have not been in favour of proceeding with the authorisation. Furthermore, the discussion in relation to health claims on plant substances and related safety concerns have indicated that the aspect of safety cannot be ignored also in the broader context of using a given plant substance in foods.

Some stakeholders in the food sector called for laying down specific rules for the use of plants and their preparations in foods at EU level. The results of the stakeholders' survey (including both business and non-business operators) allowed identifying the following most important reasons for such call:

1. the absence of a final decision at EU level on the use of health claims (80.0% of survey respondents indicated this reason);
2. the need to grant the free circulation of these products (77.1%);
3. the issues related to the classification of products (74%) and issues related to competent authorities' controlling activities as important reasons (74%);
4. issues related to consumer protection and issues related to food safety (45.7%).

From the replies provided by 26 surveyed Member States' competent authorities, it emerged that a large majority of them links the need to lay down specific rules for the use of plants and their preparations in foods with the need to improve the free circulation of foods containing plants and their preparations (100% of Member States' competent authorities), with the need to find a solution to the current differences in the classification of products (95.7%) and with the need to enhance the efficacy of controlling activities (95.7%) and the consumer protection (95.7%).

5.3.4. Coherence

How coherent is it to have EU harmonised rules on the use of health claims on plants and their preparations while the use of those substances in foods is governed by national rules?

The Commission expected that the Claims Regulation would ultimately constitute an element of harmonisation of the substances for which a claim would be authorised at EU level; and further it was presumed that products to which claims refer would belong to the category of foodstuffs, thereby reducing the risk of conflicts of classification among Member States. In practice, the claim authorisations that raised most debate amongst Member States concerned those claims made on substances, the use of which is governed by national rules (e.g. plant substances), showing that the national traditions remain as strong as before.

A first point of disagreement between Member States was the issue of classification. In certain Member States a given substance was allowed for use in foods, and thus an authorised claim was of an added value. However, Member States where this substance was not allowed in foods feared that the authorisation of the claim would oblige them to accept it on the market; thus, opposed the authorisation. A second point of debate has been the safety of certain substances,

mainly plant substances. Member States have not been in favour of proceeding with the authorisation of health claims when safety about the substance remained uncertain. It is against this background that the Article 8 procedure has been recently initiated for a number of substances for which there were suspicions of adverse effects on health.

It is important to note that whereas in the current framework the use of health claims is harmonised at EU level through the Claims Regulation, in the absence of specific harmonised EU rules on the use of plants and plant preparations in foods, the majority of Member States adopted national rules to regulate this area. National rules, which may limit or prohibit the use of certain plant substances in foods, apply irrespectively to the presence of a health claim in the on-hold list. Therefore, national rules on the use of plant substances in foods can have implications for the use of claims and the implementation of the on-hold list at Member State level. The most straightforward implication derives from the fact that the use of certain substances on which a health claim is included in the on-hold list is prohibited for use in foods by national rules.

In particular, the different approaches in terms of classification of products, the implementation of positive and/or negative lists of substances which can be used in foods, the different traditions and practices at Member State level on several aspects related to the marketing of products containing plant substances, are just some examples of the differences in the relevant national provisions and the incoherence created between the use of claims in the on-hold list under the Claims Regulation and the use of plant substances used in foods under national legislation.

In conclusion, the assessment showed that it is not coherent to have harmonised rules on health claims while the use of plants in foods is governed by national rules. The various conflicting aspects among national rules which regulate differently the use of plant substances in foods (e.g. positive and negative lists), but also among national traditions and practices leading to different MS-level interpretations of harmonised provisions (e.g. mutual recognition, classification of products as “foods” or “medicines”) hindered the authorisation of certain claims on plant substances.

5.3.5. EU added value

What would be the merits and disadvantages in terms of the EU added value of harmonising at EU level the use of plants and their preparations in foods?

There are convergent views amongst stakeholders, that, in its current state of harmonisation, the regulatory framework applicable to the use of plant substances in food is not able to ensure free circulation of products, consumer information, or, though at a lower degree, the highest level of food safety.

For consumers, the establishment of EU lists of permitted and prohibited plant substances for use in food supplements would increase the quality of information to consumers, contribute to increased consumer protection, and would help addressing product classification issues. BEUC considers necessary the involvement of EFSA in the risk assessment part of the elaboration of such lists. The development of harmonised EU lists would need to consider also information on the quality of plant substances. Also, some Member States deemed that the harmonisation of good manufacturing practices for food at EU level could enhance consumer safety by ensuring adequate uniform standards. Last, it appears that EU harmonisation of provisions on safe doses of plant substances would be a support both for improving the safety of products and for addressing classification issues. On the other hand, the classification of substances as foods or medicines strongly depends on national traditions and habits, which sometimes can be strong and have been established for a long time.

The analysis of survey results indicated that stakeholders representing the food sector interests are strongly in favour of the development of EU-level positive lists of plant substances (61.1%)

and of the development of negative lists of these substances (55.6%). Only 2.8% of respondents expressed a strong preference for regulation at national level of positive lists, which is the current situation. According to several consulted stakeholders in the food sector, in order to offer advantages for their business the EU list should not become a tool to stop the marketing of products which are already on the market. In addition, the list should be compiled by including the largest number of plants and by respecting the traditions of use of all Member States. In other words, the list should not be compiled in a restrictive way and should not end up including only a very limited number of plants²³⁰.

Consulted parties representing the pharmaceutical sector expressed homogenous views on the development of EU lists of substances. The totality of respondents was against the development of positive lists, but in favour of the development of negative lists of substances at EU level.

As for the extent to which a harmonised framework offers advantages in terms of enforcement and control activities of Member States across the EU, most of the consulted 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 improve 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' competent authorities in the food sector.

²³⁰ E.g. BELFRIT list

6. CONCLUSIONS

This evaluation has assessed the impact of the non-setting of nutrient profiles in the context of the Claims Regulation and whether nutrient profiles are still fit for their purpose, warranted and adequate to ensure the objectives of the Claims Regulation. In addition, the evaluation has examined the impacts of the current situation concerning the use of health claims relating to plants and their preparations²³¹ used in foods. The assessment has also looked into whether adapting the rules of the Claims Regulation to recognise "traditional use" for the substantiation of such claims would ensure the objectives of the Claims Regulation. Finally, this evaluation has assessed how the use of health claims on plants interacts with the current applicable food regulatory framework on plants and their preparations, and whether this framework is sufficient in terms of their safe use in foods and the smooth functioning of the internal market. The evaluation results are based on a wide stakeholders' consultation and desk research, including a literature review and analysis of market data on foods with claims from the Mintel Global New Products Database. However, the analysis presents limitations due to the lack of quantitative data to substantiate some of the arguments put forward by the consulted stakeholders. This points to the need of stepping up efforts to collect data on EU consumption of different types of foods, e.g. foods bearing nutrition and health claims, food supplements containing plants and plant substances, and how dietary habits are affected by different types of information given to consumers and other factors that influence EU consumer's choices.

Nutrient Profiles

Nutrient profiles are thresholds of nutrients such as fats, sugars and/or salt (FSS) above which nutrition and health claims are restricted or prohibited, thus preventing a positive health message on foods high in these nutrients (nutrient profiles would apply on a mandatory basis).

The specific objective of nutrient profiles is to avoid a situation where nutrition or health claims would mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices in the context of a balanced diet. Thus, the expected direct outcome of the setting of nutrient profiles was to restrict the use of claims on products, which have a high content of such nutrients and only allow claims on products that have a widely acceptable nutrient profile. However, for important categories of foods²³² more than one third of foods bearing claims continue, to date, to have a high FSS content, which may be masked by the use of a nutrition or a health claim on the label²³³. In the past few years, other developments took place in the area of consumer information such as mandatory nutrition labelling and voluntary front-of-pack nutrition labelling schemes aimed at assisting consumers to make healthier food choices. Contrary to the nutrient profiles, such policy developments were not specifically designed to restrict the use of claims on foods high in FSS. Nutrient profiles were expected to facilitate easy and direct access to healthy food choices when consumers purchase foods bearing claims. Their objective was also to ensure that foods with high FSS content do not attract consumers through beneficial health claims. If nutrient profiles were set, consumers would have been able to rely on claims without further investigation on nutritional information provided on

²³¹ Examples of plants and their preparations falling under the scope of this evaluation include: *Camellia sinensis*, *Ginkgo biloba*, *Echinacea pallidae* etc., which may be used in the form of food supplements, teas, infusions and other foods.

²³² Such as breakfast cereals, juice drinks, breads and bakery products and cakes, pastries, sweet and savoury biscuits.

²³³ According to the Commission's analysis on the Mintel Global New Products Database. It should be noted that the Mintel Database includes only new products on the market and the analysis took into account only products for which nutritional information was available.

the package. Therefore, the specific objective pursued by the nutrient profiles is still **relevant** today.

In the absence of nutrient profiles, the Claims Regulation has not been fully **effective** to protect consumers as consumers continue to be exposed to foods bearing claims, high in FSS which could mislead consumers when trying to make healthy choices. According to the CLYMBOL study, more than one quarter of all foods and drinks (26%) sampled in the study bore at least one claim, with the majority bearing nutrition claims. Out of these foods and drinks, 30% bearing health claims and 39% bearing nutrition claims did not meet the criteria of the chosen nutrient profiling model²³⁴. The business-related objective on the level playing field between operators has not been achieved either. In particular, it was noted that some operators have reformulated their product, possibly in preparation for the establishment of nutrient profiles, while other operators have not, creating unfair competition. This was due to the lack of tangible (obligatory) criteria against which food business operators could set product reformulation targets, but also either due to technical or legal constraints for traditional foods and certain food categories or by choice.

On the **efficiency**, no quantitative data were available to allow for a quantification of costs and benefits incurred by the different stakeholders in the current situation. Nevertheless, the qualitative analysis showed that consumers continue to be exposed to foods bearing claims, high in an FSS content, and thus masking the overall nutritional status of a food product. With respect to food business operators, the absence of nutrient profiles has not led to the obligation of balancing between reformulation (costs) – considering the benefits of maintaining a claim – against the costs of withdrawing a claim (and lose in value/market share). The industry in general benefits from the absence of nutrient profiles, as food business operators have not been obliged, to date, to adapt the labelling or the composition of foods bearing claims in line with nutrient profile criteria, even if some of them have done it on a voluntary basis in preparation of the establishment of nutrient profiles. Such adaptations would have been associated with removing claims, re-labelling and/or reformulation costs.

Nutrient profiles are **coherent** with the wider EU policy as one of the tools aimed at improving public health, nutrition and preventing diet-related non-communicable diseases. Last, in terms of the **EU added value**, an EU-wide approach regarding the establishment of nutrient profiles would bring more advantages for the internal market compared to what could be achieved through potential national approaches; given that the variability of national approaches across the EU cannot guarantee a harmonised, uniform implementation, which has been one of the objectives of the Claims Regulation.

In December 2017, eight Member States asked the Commission in a letter to set the nutrient profiles arguing that they are necessary to ensure a high level of consumer protection, as well as legal certainty and equal conditions of competition for business operators in the EU. In addition, during the last years, product reformulation to reduce FSS content in foods bearing claims has already been initiated by the industry to follow market trends and consumers' demand or competitors' offer of healthier products. Furthermore, the concept of nutrient profiling has increasingly being used as part of a number of nutrition policy applications across the EU, in particular for the development of front-of-pack nutrition labelling schemes aimed at assisting consumers to make healthier food choices. On the basis of the above-mentioned recent developments, Member States and possibly the industry could prove more open to the concept of nutrient profiles compared to the situation in 2009.

²³⁴ The CLYMBOL study used the nutrient criteria from the Australia and New Zealand nutrient profiling model to analyse the nutritional composition of a sample of foods with and without claims.

Overall, the evaluation findings show that the specific objective pursued by the setting of nutrient profiles is still pertinent and necessary to meet the objective of the Claims Regulation, which is a high level of consumer protection. Therefore, the setting of nutrient profiles needs to be further considered.

Health claims on plants and their preparations and the regulatory framework on the use of plants and their preparations in foods

The objectives pursued by the **Claims Regulation** in relation to health claims on plants and their preparations i.e. to ensure the effective functioning of the internal market whilst providing a high level of consumer protection, are still **relevant** and correspond to recognised needs.

The current 'on hold' list does not provide **EU added value** compared to national approaches in terms of consumer protection as claims made on foods containing plants and plant substances have not been assessed by EFSA. The 'on hold' list has EU added value for the smooth functioning of the internal market compared to the previous situation, as it provides a list of claims that can be used in the whole EU. However, the existence of national requirements imposing different warnings and/or restrictions on the use of certain plant substances in foods create some obstacles and hampers to a certain extent the effects of the 'on hold' list. The current situation does not provide EU added value in terms of legal certainty for food business operators compared to national approaches.

On the **effectiveness** of the current situation, the **absence of a final decision on health claims on plants and their preparations** in foods has prevented the full achievement of consumer-related objective. Consumers may believe that the beneficial effects communicated with the on-hold claims appearing on foods containing plant substances have been scientifically assessed and risk managed, while this is not the case. Furthermore, the business-related objectives of legal certainty and promoting and protecting innovation have not been fully achieved as the uncertainty on the future of the on-hold list (i.e. whether, when and how the Commission will resume the process of evaluation of claims on plants) discourages long-term investments in this field. The Claims Regulation does not recognise the specificity of plant substances, nor recognises evidence based on 'traditional use' as sufficient to substantiating health claims on plant substances, which is one of the factors that has hindered the implementation of the Claims Regulation and hence the achievement of its objectives. Nonetheless, the establishment of the on-hold list allowed for an improvement in terms of free movement of food products bearing claims in comparison with the baseline situation, partially achieving one of the business-related objectives of the Claims Regulation.

Additional challenges emerge from the national differences in the **general regulatory framework** concerning the use of plants and their preparations in foods. In particular, on the **effectiveness**, the evaluation concludes that currently, the safety of foods containing plants and their preparations is adequately addressed by EU general rules on food safety (e.g. the Regulation of General Food Law), existing national rules²³⁵ (e.g. negative or positive lists with conditions of use and/or warnings²³⁶) and, where necessary, the use of the Article 8 procedure of the Fortified Foods Regulation to assess the safety of certain plant substances in foods, which represent a potential risk to consumers. To that end, following the request of Member States, the Article 8 procedure has been used to assess four plant substances, which led to the prohibition of two,

²³⁵ National lists of permitted or prohibited plants used in foods, notified to the Commission and justified on grounds of public health protection.

²³⁶ E.g. the BELFRIT list

while the other two cases are still ongoing. The fact that nineteen Member States have adopted national rules to address the issue of safety and that there is an increasing demand from Member States to use the Article 8 procedure suggest that plant substances used in food may give rise to adverse health effects and would merit a closer and more systematic scrutiny. Along the same line, Member States have not been in favour of proceeding with the authorisation of claims when safety about the substance remained uncertain.

In relation to the smooth functioning of the internal market, discrepancies in the nineteen national lists of plants and their preparations allowed for use in food to ensure consumers' health create obstacles to the intra-EU trade. This situation makes it impossible to lawfully market simultaneously the same product in multiple Member States without introducing adaptations in the composition and/or in the label of the product, with negative implications for operators.

Concerning the **efficiency** of the current situation on **health claims made on plants**, the qualitative analysis showed that there are no benefits for consumers as they continue to be exposed to unsubstantiated health claims from the on-hold list. Despite some legal uncertainty as regards the timing for a final decision on health claims on plants and costs to adapt to the current situation, overall food business operators have benefited from the current situation as they can continue using health claims on plant substances, without having to undertake clinical trials to support the application for health claims. In the current situation, the pharmaceutical industry claims to face higher production and regulatory costs than food business operators producing food supplements that can bear similar health claims, without undergoing the same requirements. THMPs need to bear the additional costs for ensuring safety and quality and to comply with the requirements for medicines, such as authorisation, pharmacovigilance, good manufacturing practices, and other requirements. Quantitative data from the food supplements sector show that the costs of preparing an application file for the authorisation of new claims under the current rules (i.e. inclusion of clinical trials) are considerably higher than the possible alternative use of the notion of “traditional use” for the use of health claims. On the **general regulatory framework on plants used in foods**, the qualitative analysis showed that the absence of a harmonised regulation on the use of plants and their preparations in foods has mainly negative impacts for food business operators, in particular, product innovation (launch of new products) and export opportunities. Stakeholders in the food industry argued that they can develop new products for a specific national market, while it is impossible to develop new products targeting multiple national markets. However, it was observed²³⁷ that the number of new food supplements in the EU increased considerably from 2002 to 2017. The current state of play is considered more beneficial to food business operators that are not interested in marketing their products to other Member States and only target their domestic markets.

The **Claims Regulation** is **coherent** with other EU legislation applicable to plants and their preparations used in foods, and with international initiatives in that field. However, in relation to the current framework on THMPs, there is a discrepancy on the consideration of tradition of use in therapeutic indications used for THMPs, as opposed to health claims used in foods. The evaluation of the **general regulatory framework on plants** showed that it is **not coherent** to have harmonised rules on health claims while the use of plants in foods is governed by national rules. The differences amongst national rules which regulate plant substances in foods (e.g. positive and negative lists), but also the divergence in traditions and practices leading to different national approaches towards plant substances (i.e. classification of products as “foods” or “medicines”) has challenged the authorisation of certain claims on plant substances.

²³⁷ According to the Commission's analysis on the Mintel Global New Products Database.

The existing legal provisions that led the Commission to conclude in 2008 that no further harmonisation in the field was needed were not implemented as expected. The list of permitted health claims regarding plant substances used in foods, which would constitute an element of harmonisation of the substances enjoying mutual recognition by the Member States, was not established. Moreover, the principle of mutual recognition, as claimed by food business operators, has not been properly applied by national governments. As regards safety, the outcome of the recent Article 8 procedure on certain plant substances suggested that plant substances used in food may give rise to adverse health effects and would merit a closer follow-up. In relation to the smooth functioning of the internal market, classification issues (foods versus medicines) were indicated as a key obstacle to trading across different EU Member States, also affecting health claims made on plants and their preparations in foods. In all cases, the objectives pursued by the general framework on plants used in foods, namely placing safe food on the market and ensuring the free movement of foods in the internal market, remain fully **relevant** today.

As for the **EU added value**, building upon the findings on coherence and relevance of the **general regulatory framework** on plants used in foods, it is concluded that although the classification²³⁸ (“food” versus “medicine”) would remain under the remit of Member States, harmonisation within the food sector with a positive or a negative list of plants would improve the situation with regard to safety and the smooth functioning of the internal market in the food sector.

Overall, the evaluation findings show that in the current situation the objectives of the Claims Regulation are not fully attained. Furthermore, the current rules of the Claims Regulation do not take into account the specific situation of plants and/or their preparations, which have a long traditional history of use linked to health benefits. It could be appropriate to explore the notion of 'traditional use' in the efficacy assessment of health claims on plants and their preparations used in foods together with the effects of the co-existence, on the EU market, of THMPs on the same plant substances. In the light of the shortcomings highlighted above about the smooth functioning of the internal market and the possible openness to the notion of '*traditional use*' to substantiate health claims on plants and their preparations, there are merits for further studying the potential harmonisation of the field of plants and their preparations, including the safety aspect.

²³⁸ To note that the existing rules on classification, as such, have not been subject of this evaluation, as they do not fall under the scope of the food legislation.