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Health claims made on foods

Findings on the implementation and application of Regulation (EC) No 1924/2006

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This European implementation assessment has been drawn up to support the work of the European Parliament's Subcommittee on Public Health (SANT) on its implementation report on Regulation (EC) No 1924/2006. Building on the Commission evaluation report published in 2020, the study assesses the implementation and application of the Regulation on nutrition and health claims made on foods. Health claims and use of health claims on foods containing botanicals are at the heart of this study, while nutrition claims and food safety are excluded from its scope.

The study is composed of three independent parts: an overview of the Nutrition and Health Claims Regulation and its evaluation report, plus two research papers. One of the papers analyses the application of the regulation through the case law of the Court of Justice of the European Union, presenting findings on the main legal issues and the European Food Safety Agency's risk assessment procedure. The other research paper examines the available literature on health implications of botanicals. It also delves into marketing practices on health claims and their impact on consumer behaviour. It then describes similarities and differences between the legal framework for health claims in the EU, the UK and the US. Both research papers provide policy recommendations on how to future-proof the rules on health claims made on foods in the EU.

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Executive summary

The Nutrition and Health Claims Regulation (EC) No 1924/2006 (NHCR) harmonised the rules on claims made on foods in the EU when it entered into force in July 2007. Adopted to ensure the highest level of consumer protection and to promote the smooth functioning of the internal market, it introduced a change, which has been found to have generated EU added value. Nevertheless, although the NHCR has increased consumer protection against false or misleading health claims presented in commercial communication and contributed positively to the effective functioning of the market its implementation remains incomplete.

According to the Commission evaluation report and the findings of this study, two issues of non-implementation remain pertinent. The setting of nutrient profiles was previewed in the NHCR, but has yet to be applied in practice. However, the 'farm to fork' strategy presented in May 2020 brought nutrient profiles back to the EU policy agenda in the context of the revision of the Regulation on Food Information to Consumers (EU) No 1169/2011 (FIC). This revision considers nutrient profiles as essential in facilitating the shift towards healthy and sustainable diets and harmonised mandatory nutrition labelling to enable consumers to make conscious food choices. The NHCR requires claims to be scientifically substantiated. Therefore, full implementation the NHCR would require a decision about the role of 'traditional use' evidence in substantiating health claims relating to botanicals i.e. plants and their preparations. Since 2012, when the Commission established the 'on hold' list of claims, which address mainly botanical products, consumers have been exposed to health claims with varying levels of scientific assessment. In addition to authorised health claims, the transitional measures allow the use of health claims on the 'on hold' list, which have not been assessed, as long as they comply with the general principles of the NHCR and with applicable national provisions.

Botanicals can be used in food products and medicines. The legal frameworks of foods and pharmaceuticals in the EU are mutually exclusive and in case of doubt regarding the status of a product, pharmaceutical law prevails. Consequently, a product is either a food or a medicinal product. The classification, which depends on the efficacy of a product, its function, and its presentation or the impression that is given about its effect, is in the remit of Member States. As noted in the evaluation report and both research papers presented in this study, the fact that products containing botanicals can be classified as both food and herbal medicinal products leads to a situation where the same product might be classified as food in one Member State and as medicine in another. Moreover, if a herbal medicinal product is used to treat a specific disease for more than one generation, evidence of this 'traditional use' can be used for both safety and efficacy substantiation. Accordingly, 'traditional use' is established when a product has been used for the treatment of a specific disease for 30 years, of which at least 15 years within the EU.

In addition to the main objectives of the regulation – to ensure the highest level of consumer protection and the effective functioning of the internal market – the NHCR sought to increase legal security for economic operators, foster fair competition in the foods sector across Member States and encourage innovation. The evaluation report reveals that the uncertainty created by non-implementation of the nutrient profiles and open questions, such as the 'on hold' list, affects business innovation negatively. Reasons listed in the literature and the reports include: the duration of the full authorisation process; the investment in research necessary to support the authorisation request; and the lack of transparency in and uncertainty of the scientific assessment.

This study is composed of three parts: an introduction to the Nutrient and Health Claims Regulation and its evaluation, which was published in May 2020, and two research papers published as annexes. Each research paper presents recommendations on the basis of its findings. The analysis of CJEU case law relating to the NHCR complements the findings of the evaluation report as it reaches beyond the topics of the evaluation report. The main issues of legal discussion highlighted in this research paper include: the definition of health claims; usage of general health claims; evidence

requirements for health claims; implementation of the transitional measures of the NHCR; commercial communication towards health professionals; and classification of products as foodstuff or as medicinal products. Questions relating to the EFSA's risk assessment procedure and issues relating to foods containing botanicals also feature prominently in the case law. In its recommendations, this research paper proposes to ensure that health claims remain well aligned with EU health policies; and to take a decision upon the use of 'traditional use' for botanical health claims. Finally, it explores ways to ensure that the NHCR can remain relevant in the online environment.

When reflecting on the implementation and application in practice of the NHCR and how to keep it fit for purpose, it is useful to look at the equivalent legal frameworks of the UK and the US, which are among the biggest non-EU trading partners in food products. The first literature review of the second research paper sheds light on the similarities and differences of the authorisation procedure for health claims in the US, the EU and the UK. It describes the types of health claims and the procedures for their authorisation and the level of scientific substantiation required.

The literature review on the impacts of health claims on foods on consumer behaviour raises several issues with regard to consumers' attitudes and food choices. Issues, such as correct understanding of the claim; attraction towards the food product and perception of the overall healthiness of the product figure high in the academic discussion. This review also looks at marketing practices used to circumvent the Nutrient and Health Claims Regulation. The recommendations seek to provide concrete policy options on how to encourage consumers to make healthier food choices.

The literature review on beneficial effects and health risks of botanicals on human health explains that currently there is no common EU-level positive list on permitted botanicals across the EU and no comprehensive source or list of beneficial or adverse health effects of botanicals, although several separate lists or databases exist. Consequently, it encourages a reflection on the possibility of establishing such a positive list and setting up an EU surveillance system for adverse health effects.

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List of abbreviations

Abbreviation	Explanation
BECA	European Parliament Special Committee on Beating Cancer
CJEU	Court of Justice of the European Union
EC	European Commission
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EP	European Parliament
EPRS	European Parliamentary Research Service
EU	European Union
FBO	Food business operator
MEP	Member of the European Parliament
NHCR	Nutrition and Health Claims Regulation (Regulation (EC) No 1924/2006)
REFIT	European Commission's regulatory fitness and performance programme
SME	Small and medium-sized enterprise
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
THMP	Traditional herbal medicinal products
UN	United Nations
UK	United Kingdom
US	United States of America
WHO	World Health Organisation

1. Introduction

The exact number of health-related claims in food products is hard to grasp. According to statistics, at least 18 % of new products entering the EU food and drink market carry nutrition or health claims.[1] Although the amount of food products bearing health claims varies between EU Member States, approximately a quarter of all foods is estimated to bear some sort of nutritional or health-related claim.[2] According to Eurobarometer studies, consumers have become increasingly interested in the information appearing on food labels during recent years[3]. This makes it all the more important that information about the nutritional or health values of foods appearing on labelling and used for presentation, marketing and advertising is accurate and meaningful. Regulation (EC) No 1924/2006 on Nutrient and Health Claims (NHCR) applies to voluntary statements made in commercial communication on the nutrition content or implied health effects of foods. It seeks to ensure that such claims are based on generally accepted scientific evidence. Its twofold objective is to provide a high level of consumer protection and ensure effective functioning of the internal market.

On 9 May 2023, the subcommittee on public health (SANT) of the Committee on the Environment, Public Health and Food Safety (ENVI))[4] decided to launch an own-initiative implementation report regarding Regulation (EC) No 1924/2006.[5] To inform the committee's work on that file, the Ex-post Evaluation Unit of the Directorate for Impact Assessment and Foresight within the Directorate General for Parliamentary Research Services (DG EPRS) was asked to prepare an analysis to underpin the evidence base of the committee's work.

This European implementation assessment study seeks to offer insight into the most pertinent questions relating to the implementation and application of the NHCR to date, with a focus on health claims and the legislative framework for the use on botanicals in foods. It builds on the evaluation report by the European Commission, published in May 2020. While it does not constitute a fully fledged evaluation of the Regulation (EU) No 1924/2006, it aims to provide added value in various forms by shedding light on the effectiveness, efficiency, relevance, coherence and EU added value of the regulation. However, issues of food safety and nutrition claims are not within the scope of this study. Nutrient profiles are examined only in relation to their interface with health claims.

In this context, the EPRS commissioned two research papers from external experts. This study, which is composed of three parts, offers first an overview of the NHCR and the findings of the Commission evaluation report of May 2020 and the research papers as annexes. All three parts can be read separately, meaning that some repetition is unavoidable.

The paper entitled 'Health claims made on foods: Analysis of the Court of Justice of the European Union case law on Regulation (EU) 1924/2006' (Annex 1) examines the case law of the Court of Justice of the European Union (CJEU) in relation to the NHCR. It helps to identify the major legal issues surrounding the implementation and application of measures relating to health claims made on foods. It places a special focus on the legal issues stemming from the judgments on the requests for preliminary rulings, under Article 267 TFEU. The risk assessment procedure of the European Food

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1 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 food, SWD(2020)95, Part 2, Appendix 13.

2 Final Report Summary – CLYMBOL (Role of health-related claims and symbols in consumer behaviour).

3 Special Eurobarometer 505 'Making our food fit for the future: Citizens' expectation', 2020 and Special Eurobarometer Wave EB97.2, 'Food Safety in the EU', 2022.

4 European Parliament decision of 14 February 2023 on setting up a subcommittee on public health (2023/2565(RSO)), P9_TA(2023)003.

5 Implementation report on Regulation (EC) No1924/2006 on nutrition and health claims made on foods, 2023/2081(INI).

Safety Authority (EFSA) and its application to foods and food supplements containing botanicals have been prominent subjects in the Court's case law. Drawing on the analysis of the relevant case law of the CJEU, the research paper concludes with policy recommendations.

The research paper titled 'Implementation, application and impact of health claims made on foods: Literature reviews' (Annex 2) presents three literature reviews, each with its own scope and applying a different method. Drawing on relevant publications from academia, international organisations and think tanks it analyses various dimensions of the implementation and application of the NHCR and makes policy recommendations based on its findings. First, it describes the regulatory framework for health claims made on foods in the EU, the UK and the US and looks in particular to their authorisation procedures and level of scientific substantiation. Then, it analyses the literature available on marketing and advertisements of health claims on foodstuffs and the impact on consumer behaviour. Finally, it provides an overview of the scientific (medical) evidence on the health implications of botanicals.

1.1. Road to the Regulation on Nutrient and Health Claims

The regulation of health claims on foods in the EU started in the late 1990s in the context of a wider reform of food labelling and other rules. In 1997, the Commission put forward a green paper on food law[6] in order to propose and consult on a new legal framework covering the whole of the food chain. In the aftermath of the BSE crisis,[7] the aim was to establish a high level of consumer health protection and clearly attribute primary responsibility for safe food production to industry, producers and suppliers with a system of controls and rapid response to health emergencies. Subsequently on 12 January 2000, the Commission published a white paper on food safety where it considered whether to introduce specific provisions to govern nutrition claims and functional claims made on foods, in order to foster free movement of foodstuffs between Member States and a high level of consumer protection.[8]

In its resolution on the green paper, the European Parliament[9] called on the Commission to propose legislation on food claims to ensure that 'health claims are only authorised if they are tested and confirmed by an independent body within the European Union'. The Parliament continued along the same line, in its resolution on the white paper,[10] where it encouraged the Commission to address as a priority issue 'enhanced function claims and disease reduction claims'.

Following the consultations on the white paper and prior to the proposal, Commission published a discussion paper in 2001 where it announced a plan for a proposal, which would however exclude health claims.[11] The subsequent comments received from stakeholders convinced the Commission not to postpone the inclusion of health claims, but to set the conditions for nutrition and health claims in one legislative proposal. The proposal for the NHCR came out in 2003.[12] It set the following general objectives for the harmonisation of rules on nutrition and health claims at EU level:

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6 Commission Green Paper on the general principles of food law in the European Union, COM(90)176.

7 Bovine spongiform encephalopathy (BSE) is also referred to as 'mad cow disease'. Its human equivalent is the Creutzfeldt-Jakob disease.

8 Commission White Paper on food safety of 12 January 2000, COM(99)0719.

9 European Parliament, resolution on the green paper on the general principles of food law in the European Union of 10 March 1998.

10 European Parliament, resolution on the Commission white paper on food safety25 October 2000.

11 DG SANCO discussion paper on nutrition and functional claims, 2001.

12 Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods, COM(2003)424.

- to achieve a high level of consumer protection by setting out common conditions for voluntary information, beyond the mandatory information envisaged by EU legislation, and to ensure that nutrition and health claims are not misleading for consumers;
- to improve the free movement of foods bearing nutrition and health claims within the internal market;
- to increase legal certainty for economic operators;
- to ensure fair competition for food business operators within the internal market;
- to promote and protect innovation in the area of foods.

As regards the potential positive or negative impacts of the proposal, the impact assessment attached to the proposal concluded that the regulation would not have an impact on economic operators if they did not provide any additional information in the labelling, presentation or advertising of foods, as the NHCR is complementary to existing rules and concerns only voluntary claims. It also assumed that the regulation would bring significant benefits for consumers by clarifying the legislation describing which claims are admissible and the conditions under which such claims can be made. The assumption was that the NHCR would educate the consumer to be more capable of making better choices in the context of a balanced diet. Moreover, the economic operators were expected to benefit from increased legal security as 'the rules for making a nutrition claim will be the same for all economic operators and only those health claims that are scientifically based and meaningful to the consumer will be allowed'. Finally, the impact assessment noted the risk arising from there being no common EU-level rules, which would leave the consumers in a situation of an unregulated market where claims could be presented in a false, misleading or deceptive manner without scientific substantiation.

The proposal was dealt under the co-decision procedure in two readings.[13] The NHCR has been in force since 1 July 2007 and amended three times. The Commission published a compliance guide for Regulation (EC)1924/2006 in 2007.[14] The Commission Delegated Regulation (EU) 2019/343 of 28 February 2019 allowed certain derogations from Article 1(3) of the NHCR for the use of certain generic descriptors listed in its annex.

1.2. Legal framework for nutrient and health claims in the EU

The legal framework for nutrient and health claims in the EU is composed of mandatory and voluntary rules on food labelling, horizontal food law, and regulation targeting either specific groups of consumers or foods. As regards food labelling, the NCHR applies to voluntary claims made in commercial communications targeting the final consumer, whether in the labelling or the presentation, whereas the Regulation on Food Information to Consumers (FIC) targets mandatory information on labelling and advertising of foods in the EU.[15] At the core of the horizontal legal framework is the General Food Law Regulation (EU) No 178/2002, which introduces the basic principles and rules of EU food law, including its enforcement.[16] Regulation (EU) 882/2004 on official controls provides a general framework for official controls performed by Member States' competent authorities to verify compliance with feed and food law, animal health and animal welfare.

[13] Procedure 2003/065(COD), legal base Article 95 of the Treaty establishing the European Community (Nice consolidated version) on approximation of laws and Article 251 of the Treaty establishing the European Community (Nice consolidated version) on the co-decision procedure.

[14] Guidance on the implementation of Regulation No 1924/2006 on nutrition and health claims made on foods - Conclusions of the Standing Committee on the Food Chain and Animal Health.

[15] Regulation (EU) No 1169/2011 of 25 October 2011 on the provision of food information to consumers.

[16] Regulation (EC) No 178/2002 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.

Legislation on specific types of foods determines the rules applicable to these foods by regulating their content and other aspects specific to them. EU Regulation (EU) 2015/2283 on novel foods[17] and Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements seek to protect consumers against potential health risks from those food products, and to ensure that consumers are not provided with misleading information. For example, Directive 2002/46/EC lays down a harmonised list of vitamins and minerals that may be added for nutritional purposes in food supplements, and a list of permitted sources from which those vitamins and minerals may be manufactured. Regulation (EC) No 1925/2006,[18] adopted at the same time as the NHCR, regulates the addition of vitamins and minerals and certain other substances to foods. In terms of authorisation procedures, Regulation (EC) No 1331/2008 establishes a common authorisation procedure for food additives, food enzymes and food flavourings.

When it comes to laws on the use of plants and their preparations in foods, there is no harmonised EU legislation. Directive 2004/24/EC, which amended Directive 2001/83/EC, includes provisions on the classification and authorisation process for traditional herbal medicinal products (THMPs)[19]. Food products containing botanicals are covered by EU acts of general application, such as the General Food Law Regulation, and other legal acts applicable to certain categories of foods. In this context, Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods plays a key part. Its Article 8 sets out a procedure whereby the use of other substances in foods may be prohibited restricted or placed under EU scrutiny if a harmful effect on health emerges.

The introduction of the farm to fork strategy and its action plan in 2020 launched a reform of the EU legal framework on food. The planned framework for sustainable food systems (FSFS) initiative and the revision of the Food Information for Consumers Regulation will have an impact on the NHCR.[20]

[17] Regulation (EU) 2015/2283 of 25 November 2015 on novel foods.

[18] Regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods.

[19] Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

[20] Commission website on the legislative framework for sustainable food systems and website on the revision of the Regulation on Food Information to Consumers (FIC). Nutrient profiles: A 'farm to fork' strategy initiative takes shape, Tarja Laaninen, EPRS briefing 2022.

Box 1: Definitions of terms

A claim: 'any message or representation, which is not mandatory under Community of national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that food has particular characteristics' (Article 2 of the NHCR).

A nutrition claim: any claim that states, suggests or implies that food has particular beneficial nutritional properties due to the energy it provides or does not provide or provides at a reduced or increased rate. This includes claims on the nutrients or other substances the food contains or does not contain or contains at reduced or increased proportions (Article 2).

A health claim: 'any claims that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health'. In the same vain, a reduction of disease risk claim refers to 'any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease'. A wide range of substances, such as vitamins, minerals, amino acids, essential fatty acids, fibre and herbal extracts, have a nutritional or physiological effect that might be present in a food and be the subject of a claim. The Claims Regulation also applies to health claims made regarding plants and their preparations used in foods (Article 2).

A food supplement: 'foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities' (Directive 2002/46/EC).

Botanicals: 'all botanical materials e.g. whole, fragmented or cut plants, plant parts, algae, fungi and lichens'. Botanical preparations are 'all preparations obtained from botanicals by various processes e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation' (EFSA guidelines: 'Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements', 2009).

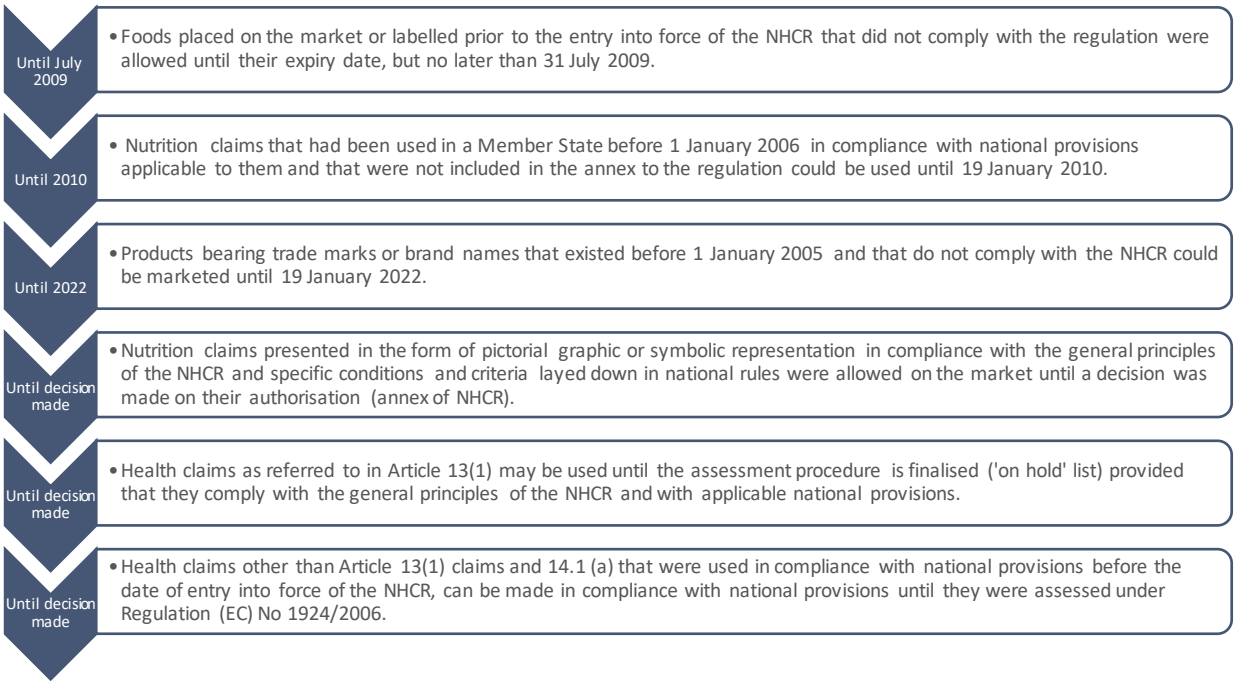
2. Nutrition and health claims in the EU

Europeans have become more aware of and interested in the composition of food and its relationship with health, and the implications of different diets. Recent Eurobarometer studies reflect this development by reporting that citizens considered the healthiness of food as the most important aspect of a sustainable diet and that concerns relating to health impact are most often spontaneously mentioned when citizens are asked to think about problems or risks associated with food.[21]

2.1. Regulation on nutrition and health claims made on foods

Regulation 1924/2006 on nutrition and health claims made on foods (NHCR) has been in force for more than 15 years, since July 2007. Certain transitional arrangements were adopted in Article 27 in order to provide time for the market operators to adapt to the new rules. Some of the transitional measures are still in use as the pending decisions relating to their execution are still pending.

Figure 1 – Timeline of transitional measures set out in Article 27 NHCR



2.1.1. Scope and objectives

The objective of the NHCR is to provide high level of consumer protection and to ensure effective functioning of the internal market (Article 1). As stated above, the Commission proposal for the regulation identified three other objectives: to increase legal certainty for economic operators; secure fair competition for food business operators, and to promote and protect innovation in the area of foods.

The NHCR applies to voluntary statements made on the nutrition content or implied health effects of foods in commercial communication. In addition to nutrition or health claims in written form, it covers expressions presented in other formats, such as in pictures, graphics or symbols, namely, any trademark, brand name or fancy name appearing in the labelling, presentation or advertising of a

[21] Special Eurobarometer 505 'Making our food fit for the future: Citizens' expectation', 2020 and Special Eurobarometer Wave EB97.2 'Food Safety in the EU' 2022.

food that may be construed as a nutrition or health claim. The regulation ensures that nutrition claims and health claims on foods are based on generally accepted scientific evidence and can be expected to be understood by the average consumer.

NHCR defines the types of nutrition and health claims that can be made on foods and lays down general principles and conditions for them. As only pre-authorised claims are allowed in the EU, the NHCR provides rules on the scientific substantiation for claims and their authorisation procedure.

2.1.2. Nutrition claims and health claims

The conditions introduced by the NHCR apply to all claims irrespective of the substance or food on which they are made, such as vitamins, minerals or plants and their preparations. Nutrition and health claims must comply with the general principles set out in the NHCR. Thus, a claim should not be false, ambiguous or misleading. It should not give rise to doubt about the safety or nutritional adequacy of other foods, encourage excess consumption; or suggest that a balanced and varied diet cannot provide appropriate quantities of nutrients. A claim should neither suggest that health could be affected by not consuming the food, refer to a rate or amount of weight loss, or refer to recommendations of individual health professionals (Articles 3 and 12). Moreover, the use of nutrition and health claims is allowed only if the presence, absence or reduced content in a food of a substance has been shown to have a beneficial effect and this is substantiated with accepted scientific data. The amount of such substances in the food product must be in quantities that can be reasonably consumed and in an amount that gives the claimed effect (Article 5).

A nutrition claim states, suggests or implies that food has particular beneficial nutritional properties due to the energy it provides or does not provide or provides at a reduced or increased rate. In addition, nutrition claims give information about the nutrients or other substances a food contains or does not contain or contains at a reduced or increased proportions (Article 2). They can be used for all types of food with the exception of specific requirements for alcoholic beverages that contain more than 1.2 % volume alcohol. However, claims about a reduction in alcohol or energy content are allowed. In contrast, such alcoholic beverages cannot bear health claims (Article 4).

Health claims are statements implying that consuming a specific food or ingredient has health benefits or supports the health of the consumer. Generic non-specific claims (Article 10(3)) like 'Healthy for you' must be accompanied by a specific health claim under Articles 13 or 14, which must be substantiated with scientific evidence. The evidence has to confirm the causal connection between the intake of the ingredient and the claimed favourable effect on health. The NHCR identify the following types of health claims:

- Function claims relying on generally accepted scientific evidence (Article 13(1))
- Function claims based on newly developed scientific knowledge (Article 13(5))
- Claims referring to reducing a risk factor in disease development (Article 14(1a))
- Claims referring to the growth and development of children (Article 14(1b))

Table 1 – Health claims under Regulation (EC) No 1924/2006: Types of claim and number of authorised and non-authorised claims as of 18 August 2023

Health claims under Regulation (EC) No1924/2006		
Type	Example	Number of claims (18 August 2023)
Article 13 (1) **Function claims** supported by generally accepted scientific evidence	Walnuts contribute to the improvement of the elasticity of blood vessels	Authorised: 229 Non-authorised: 1841
Article 13 (5) **Function claims** supported by newly developed scientific research and/or including a request for protection of proprietary data	Cocoa flavanols help maintain the elasticity of blood vessels, which contributes to normal blood flow	Authorised: 13 Non-authorised: 144
Article 14 (1a) **Reduction of disease risk claims**	Oat beta-glucan has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in development of coronary heart disease.	Authorised: 15 Non-authorised: 30
Article 14(1 b) **Claims referring to children's health and development**	Calcium and vitamin D are needed for normal growth and development of bone in children	Authorised: 12 Non-authorised: 47

Data source: EU Register of Health Claims (online).

2.2. Authorisation procedure for nutrition and health claims

As stated above, the NHCR stipulates that nutrition and health claims made on food must be substantiated by generally accepted scientific evidence. Health claims should only be authorised for use in the EU after a thorough scientific assessment by an independent scientific body of the European Food Safety Authority (EFSA) (Articles 5 and 6).

All **nutrition claims** on foods authorised in the EU are placed on a positive list of authorised claims published as the annex of the NHCR. New nutrition claims may be added to this list through Commission regulation. As regards **health claims**, the NHCR lays down rules for two types of procedure for health claims included on the Community list of permissible health function claims:

1) the establishment of a Community list of permitted health claims for claims that existed at the time of its adoption and that are based on generally accepted scientific evidence for claims under Article 13(1);
2) the authorisation of new claims substantiated by scientific evidence for claims under Articles 13(5).

The reduction of disease risk claims and claims on children's development and health under Article 14 (1) undergo a separate authorisation procedure.

2.2.1. Community list of permitted health claims already in use

According to Article 13 of the NHCR, existing function claims based on generally accepted scientific evidence had to be submitted by Member States for an assessment and authorisation procedure by January 2008. Subsequently, the EFSA was to assess whether the expert reports and consensus documents underpinning the health claims provided enough evidence for a positive opinion in order to enter them on the Community list of permitted claims that was to be established by 31 January 2010. In total, over 44 000 claims for authorisation were submitted by the deadline, many of which related to botanicals. A number of these dossiers referred to 'traditional use' as evidence to substantiate the link between the food or ingredient in question and the suggested health effect. The 44 000 claims submitted to the EFSA for authorisation were grouped to 4 600 putative claims. The deadline was set for the end of January 2010, but it was not reached because of the large number of claims, and procedural difficulties.[22]

By December 2011, the EFSA had reviewed 2 500 claims. These scientifically substantiated health claims were then proposed for authorisation by the Commission, if successful to be added to the Community list of permitted health claims as authorised. Following this procedure, under Article 13(1), 222 health claims were authorised and added to the Community list of permitted health claims, published in an annex of the Commission Regulation (EU) No 432/2012 and in the Union Register of Health Claims. The claims that were assessed and considered not to fulfil the requirements of scientific substantiation were listed in the register to indicate transparently the reasons for the refusal.[23]

Eventually, the fact that only a few – and in 2009 none – of the health claims for plant substances used in foods had received a favourable assessment from EFSA led to the suspension of the authorisation procedure under Article 13(1). The lack of sufficient scientific evidence on the health effects of botanicals used in foods, notably the lack of human intervention studies, was the main argument underpinning this outcome. In 2012, the Commission established an 'on hold' list for more than 2 000 outstanding health claims mostly relating to botanicals.[24] According to the transitional measures set out in Article 27, these health claims – both those negatively assessed and those and those not yet reviewed – can be used until a decision on the 'on hold' list is taken on the EU market, under the responsibility of the food business operator, provided they act in compliance with the general principles and conditions of the NHCR and the relevant national rules.

2.2.2. Authorisation of new claims

Any manufacturer can request the inclusion of a new claim on the list of permitted health claims by submitting an application to a national health authority of an EU Member State, which reviews the eligibility of the claim and then forwards it to the EFSA for an assessment and an independent scientific opinion. Following its considerations, the EFSA Nutrition, Novel Foods and Food Allergens (NDA) Panel gives a positive or negative opinion about the claim(s) and sends it on to the Commission. The opinion may include specific conditions on the consumption pattern or wording of the health claim. The Commission then decides whether to authorise the claim, on the basis of the EFSA's opinion (Article 18).

Scientific substantiation of a health claim requires evidence to support the causal relationship between consuming the food (ingredient, substance or compound) and the suggested beneficial physiological effect for a healthy population. The experts on the NDA Panel assess whether all available scientific evidence has been considered in the dossier. According to the NHCR (Article 15),

[22] Commission press release 28 November 2011, IP/11/1460.

[23] Questions and answers on the list of permitted health claims 5 December 2011, MEMO/11/868.

[24] Questions and answers on the list of permitted health claims on food products, 16 May 2012, MEMO/12/346.

Commission Regulation (EC) No 353/2008[25] and the EFSA guidance,[26] the essential elements are as follows:

- The ingredient must be well characterised.
- The health effect must be well-defined and established in a healthy population.
- The causal link must be underpinned by trials in humans.
  There must be evidence on the quantity and consumption pattern of the ingredient to obtain the claimed health benefit within a balanced diet.

Although no pre-defined number of studies is required to demonstrate the causal link between the ingredient and the health benefit, in practice at least two independently conducted human intervention studies have been deemed necessary.[27] Business operators gathering extensive and detailed information to fulfil the requirements set out in Article 13(5) may request and receive 'protection of proprietary data' i.e. an exclusive right to use the claim for the first 5 years of its authorisation. When the exclusive usage period lapses or if it is never granted, the claim is treated as a standard health claim. Consequently, all products meeting the conditions of use for the authorised claim may apply it.

In practice, the Commission tends to follow the EFSA's opinion closely in its own decision-making on whether or not to authorise health claims. However, deviation from the EFSA's scientific opinion is possible on the basis of relevant EU legislation or other legitimate factors.[28] Authorised health claims under Articles 13(1) and 13(5) are published in Commission Regulation (EU) No 432/2012, which is updated regularly in accordance with the procedure compatible with the implementing powers delegated to the Commission in the NHCR (Article 25). [29]

Disease reduction claims and claims on children's development and health falling under Article 14 undergo an EFSA risk assessment procedure followed by a Commission authorisation procedure in accordance with the implementing powers delegated to the Commission in the NHCR. The authorisation decision (positive or negative) is published as a Commission act in the EU Official Journal and is available on the Union Register of Health Claims (Articles 15-17 and 25). The applicant may request 'protection of proprietary data'. Health claims under Article 14 are by definition 'standard claims' meaning that food business operators that produce equivalent products can use them.

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25 Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006.

26 EFSA Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3), 26 March 2021.

27 Alie de Boer, 'Fifteen years of Regulating Nutrition and Health Claims in Europe: The Past, the Present and the Future', *Nutrients*, Vol. 13(5), 2021, p. 1725.

28 Idem.

29 The procedure for adopting implementing measures involves consultation of the standing committee composed of representatives of EU Member States' competent authorities, and scrutiny of the draft decision by European Parliament and the Council.

In terms of the wording used in marketing purposes in food labelling, some flexibility in the wording is considered acceptable in order to present the health claim in an attractive way compared to the wording in which the claim was approved, which might be technical. The claim can be altered as long as the meaning stays the same. Moreover, a more general claim can be made about a product that fulfils the conditions set for a specific claim. However, a general claim (Generic non-specific claims under article 10(3)) must always be accompanied by a specific health claim.

Box 1: Where to find authorised nutrition and health claims

A list of permitted nutrition claims is published as an annex of the NHCR whereas health claims under Articles 13(1) and 13(5) are published in the Commission Regulation (EU) No 432/2012, which is regularly amended to update the list of newly authorised health claims. New health claims filed under Articles 14(1a) and 14(1b) are applications for an individual authorisation request with authorisation decisions published in the Official Journal in a Commission act.

Information on authorised and non-authorised health claims is also available online. Commission provides a list of permitted nutrition claims online, and a portal on the Union Register of Health Claims. The portal provides information on authorised health claims and their conditions of use and applicable restrictions. It also includes non-authorised health claims and information about the reasons for their rejection. The register does not provide information on individual authorisation procedures that are pending decision, applications for claims submitted as Article 13(1) 'function claims' but that do not qualify as such, or those on the 'on hold' list.

2.2.3. Specific issues relating to botanicals used in foods

The substantiation of health claims on foods containing botanicals, the classification of botanicals as foods or as medicines, and botanicals in food supplements are currently open issues in the implementation and application of the NHCR. They are recognised in the evaluation report on the NHCR as major shortcomings in the implementation of the NHCR (findings summarised below in Chapter 3. The issues as such and their implications for consumers, market operators and food policies in general have been thoroughly analysed in academic literature.

The use of plants as foods is governed by EU general food law and specific national rules. However, the use of health claims on plants as foods is harmonised at EU level by the NHCR. Therefore, health claims presented on plants or their preparations and their use in foods fall under the categories of claims determined in the NHCR, which means that they can be authorised by the Commission only after a scientific assessment of the European Food Safety Authority (EFSA), which requires human intervention studies.

It is noteworthy that there is no commonly agreed definition of botanicals, i.e. plants and their preparations. The EFSA defines botanicals as 'all botanical materials e.g. whole, fragmented or cut plants, plant parts, algae, fungi and lichens'. It defines botanical preparations as 'all preparations obtained from botanicals by various processes e.g. pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation'.[30]

The double standards currently in use in relation to the level of **scientific evidence** underpinning health claims made on foods containing botanicals creates a peculiar situation where consumers are exposed to health claims based on varying levels of scientific assessment. Some might have undergone the EFSA/Commission authorisation procedure while others are made under the transitional measures of the NHCR. Consumers may not be able to distinguish these claims from one another. In practice, these diverging levels of scientific substantiation mean that today over 2 000

[30] EFSA guidelines 'Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements', 2009.

health claims made on foods containing botanicals may be made without a thorough scientific assessment or authorisation.[31]

Plants and their preparations are widely available on the EU internal market as foods or as herbal medicines. Therefore, another pertinent issue is the **classification** of plants and their preparations as food or as medicinal products, which falls within the remit of Member States. Classification of botanicals as foods or medicines can differentiate considerably between Member States and is commonly done on a case-by-case basis, depending on the composition and presentation of the product. Thus, a plant substance classified as a 'food' in one Member State, can be classified as 'medicine' in another Member State.

Herbal medicinal products are considered pharmaceuticals and are subject to medicinal legislation whereas food supplements made with botanicals are considered foods and have to comply with food law. Therefore, the safety, quality and efficacy of the two types of product differ. A herbal medicine has to be authorised according to the procedure(s) of the European Medicines Agency (EMA) before it can be placed on the EU market. Medicinal products may refer to pharmacological effects while foods may only claim nutritional or physiological effects. If herbal medicines meet the criteria for 'traditional use', they can use a simplified registration route applicable to traditional herbal medicinal products (THMP), where evidence of 'traditional use' is accepted to substantiate safety and efficacy of the product.[32] If a herbal medicinal product has been used to treat a specific disease for more than one generation, evidence of this 'traditional use' can be used for both safety and efficacy substantiation. Accordingly, 'traditional use' is established when a product has been used for the treatment of a specific disease for 30 years, of which at least 15 years within the EU.[33] As highlighted in academic literature, the international approach towards allowing evidence on 'traditional use' to substantiate the efficacy of botanicals varies greatly. As explained above, the European Union allows the use of such evidence, but only for herbal medicines.[34]

The EMA has established an extensive body of monographs covering the traditional use of botanicals. The Community Herbal Monographs are based on the scientific opinions on safety and efficacy data for herbal substances and their preparations of the Committee on Herbal Medicinal Products (HMPC). The HMPC evaluates all available information, including non-clinical and clinical data, and documents long-standing use and experience in the EU (EMA).[35] In contrast, there is no EU-level harmonisation of the lists of **plants allowed in food supplements**. Several EU Member States have published their own positive and/or negative lists of botanical ingredients allowed or prohibited in food supplements.[36]

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31 N. Collins and H. Verhagen, 'Nutrition and health claims in the European Union in 2022' *Regulatory Focus*, published online, 3 September 2022.

32 F. Colombo et al., 'Botanicals in Functional Foods and Food Supplements: Tradition, Efficacy and Regulatory Aspects', *Applied Science Review*, Vol. 10, 2020, p. 2387.

33 Article 16(c)(c) of 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.

34 K. Lenssen et al., 'The complexity of providing health effects with data on 'traditional use': A critical perspective on supporting botanical health claims', *Trends in Food Science & Technology*, Vol. 120, 2022, pp. 338-343; A. Kušar and I. Pravst, 'Exploitation of the traditional evidence for botanical health claims on foodstuff in Europe', *Journal of Functional Foods*, Vol. 89, 2022, pp. 104936.

35 EMA website, European Union monographs and list entries.

36 S. Geurts, 'Health Claims and Botanicals: How to Proceed with European Union Harmonisation?', *European Food and Feed Law Review EFFL*, Vol. 13(1), 2018, pp 29-33.

EFSA has published a guideline for the identification of possible risks for consumers stemming from botanicals in the 'Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health'.[37]

The above-mentioned specific issues relating to the use of botanicals in foods are also reflected in written parliamentary questions, used by Members of the European Parliament to scrutinise the work of the Commission.[38] For example, on 5 October 2020, Esther de Lange (PPE) asked the Commission about the 'on hold' list on health claims regarding herbal and plant substances.[39] Referring to the fact that a decision on the status of a significant number of health claims has been pending for a substantial amount of time, she asked whether the Commission intended to resume the evaluation of substances, and if not, if it planned to ban unverified health claims on foods. The current situation might result in consumers being provided with unverified information. In its answer, the Commission explained that it was considering exploring the introduction of a 'traditional use' rating for certain substances, which seemed justified based on the evaluation of Regulation (EC) No 1924/2006 launched in 2016, and published in May 2020. The Commission confirmed that it was in the process of reflecting on how to proceed in the matter.

On 9 April 2021, Dan-Ştefan Motreanu (PPE) asked[40] the Commission about plans to clarify the distinction between medicinal products and food supplements, which was reported to be causing confusion among consumers. In its reply, the Commission did not see a need for such clarification. It noted that classification of a product as a food supplement or a medicinal product is under the remit of Member States. Moreover, at EU level, food supplements and medicinal products fall under different directives, which include provisions clarifying their divergent status as medicinal products or food supplements. The Commission also noted that on food supplements, the permitted health claims were defined under Regulation (EC) No 1924/2006.

37 EFSA Compendium of botanicals report to contain naturally occuring substances of possible concern for human health when used in food and food supplements, revised 2012 version.

38 Rules of Procedure of the European Parliament, Rule 138.

39 Question for written answer E-005449/2020 to the Commission - Rule 138, 5 October 2020, Esther de Lange (PPE).

40 Question for written answer E-001918/2021 to the Commission - Rule 138, 9 April 2021, Dan-Ştefan Motreanu (PPE).

3. Evaluation report on the Nutrition and Health Claims Regulation

3.1. Fitness check programme and evaluation report

The evaluation clause of the NHCR provided for an evaluation report on nutrition and health claims in the EU food market with a focus on consumers' understanding of claims already before January 2013 (Article 26). In 2015, the European Commission announced an evaluation of the NHCR as part of a the regulatory fitness and performance programme (REFIT) in order to ensure food policies remained fit for purpose.[41] The European Parliament responded to the Commission by welcoming the REFIT programme and its implementation in the context of simplifying legislation as well as avoiding and reducing red tape.

The purpose of the REFIT evaluation was to examine whether the NHCR had so far achieved its general objectives regarding truthful information for consumers and the facilitation of the free movement of foods bearing claims. The scope and content of the evaluation was set to assess to what extent the act remained 'fit for purpose' regardless of its incomplete implementation. The evaluation focused on two elements deemed complex and problematic, namely the nutrient profiles, which the Commission was required to set by January 2009; and the health claims on plants and their preparations used in foods, which remained unregulated at EU level. In this context, the evaluation also examined how the use of health claims on plants and their preparations in foods interacted with the applicable general regulatory framework on foods. It excluded other aspects of the NHCR because it considered a full evaluation premature given that the list of authorised health claims came into application only in December 2012.

The evaluation report covered the years 2005 to 2015. It was underpinned by a rich supply of analytical evidence, including the following:[42]

- Alongside the Commission proposal and impact assessment of the original NHCR, the Green and White Papers contributed to the evaluation.
- An external study was published in July 2008 with the title 'Study supporting the evaluation of: a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regards to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods'.
- In order to collect primary data from various stakeholder groups and citizens, the Commission conducted a set of online surveys, workshops, in depth interviews, a survey of small and medium-sized enterprises and an open public consultation.
- Secondary data collection instruments included desk research and a literature review, case studies and MINTEL's Global New Products Database.
- Commission reported 20 feedback notes from stakeholders on the REFIT roadmap.
- Previous reports and other reports, such as the Commission report of December 2008 on the need for and feasibility of EU-level positive lists on categories of nutrients or of substances with a nutritional or physiological effect other than vitamins and minerals.[43]

[41] Communication on better regulation for better results – An EU agenda, COM(2015)215.

[42] Commission evaluation report, SWD(2020)95, Part 2, Annexes 6 and 7.

[43] Report by Commission to the European Parliament and the Council on advisability of establishing specific rules for the use of substances with a nutritional or physiological effect other than vitamins and minerals, COM(2008)824.

3.2. Findings of the evaluation report

While acknowledging that the objectives of the NHCR to ensure a high level of consumer protection and effective functioning of the EU internal market are still relevant and correspond to recognised needs, the evaluation report was critical on the issues of non-implementation. Nutrient profiles – which were foreseen in the NHCR but have yet to be implemented – were seen as a still pertinent and necessary objective. As regards health claims on botanicals and their regulatory framework, the existing legislation was considered sub-optimal on the specific situation of plants and their preparations. The report highlighted the impact of the co-existence of non-authorised health claims on foods containing botanicals and legitimate traditional herbal medicinal products on the same plant substance(s) and the shortcomings of this situation for the effective functioning of the EU internal market. It brought forward the notion of exploring 'traditional use' to substantiate health claims on plants used in foods and in assessment of their efficacy. The report also concluded that harmonisation with a positive or negative list of plants allowed in foods in the EU would improve the current situation. While the classification (as food or as medicine) would remain within the remit of Member States, such a harmonised list could have a positive impact on the safety and smooth functioning of the internal market in the food sector.[44]

Nutrient profiles were designed to prevent a positive health message on food high in certain nutrients harmful for health if consumed extensively. Consumers should be able to rely on nutrient and health claims without examining the nutritional composition of the product. The idea of nutrient profiles would mean that clearly unhealthy foods with high amounts of unfavourable ingredients, such as fat, sugar and salt, could not carry authorised nutrition or health claims. According to Article 4 of the NHCR, the Commission should have established nutrient profiles by 19 January 2009. They have yet to materialise however.

As regards this specific objective of the NHCR to establish nutrient profiles, the evaluation report considered that that the NHCR could not be considered fully effective. The report found the situation where consumers continue to be exposed to positive nutrient or health claims for foods high in fat, salt or sugar incompatible with the objective of high consumer protection. Regarding business operators, the evaluation reported that some had reformulated their products in preparation for the establishment of nutrient profiles where as others had not, which was considered to lead to an unbalanced situation in the market. However, the evaluation did not identify quantitative rates of costs and benefits for different stakeholders as the absence of nutrient profiles 'has not lead to the obligation of balancing between reformulation (cost) – considering the benefits of maintaining a claim – against the costs of withdrawing a claim (and lose in value/market share)'. It considered the adaptation of labelling or the composition of food bearing claims in line with the nutrient profile criteria a cost that some food business operators had taken on voluntary basis. The evaluation concluded that the introduction of nutrient profiles would bring added value to the EU internal market, as varying approaches across EU Member States could not ensure harmonised and uniform implementation of nutrient profiles.

Although the nutrient profiles were not established in the period indicated in the NCHR, the report concluded that it remained a relevant objective not only for the NHCR but also in the context of general food policy. Setting nutrient profiles is in line with EU policies aimed at improving public health and preventing diet-related non-communicable diseases.[45]

[44] Evaluation report SWD(2020)95, Part 1 p. 87

[45] Evaluation report SWD(2020)95, Part 1, p. 84

Box 2: Nutrient profiles

With the nutrient profiles, the NHCR aimed to avoid the situation where nutrition and health claims would mask or mislead the consumer in the assessment of the overall nutritional status of a food product when seeking to make healthy choices in the context of a balanced diet. Another aim was to manage consumers' behaviour, which might directly influence their total intake of individual nutrients or other substances. This is based on the idea that foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added (Recitals 10 and 11 of NHCR).

Despite these initial steps towards establishing nutrient profiles according to Article 4, they have still to be approved. In 2008, the Commission asked the EFSA for scientific advice on nutrient profiles, which led to the adoption of an EFSA scientific opinion on the topic. In parallel with the non-implementation of the nutrient profiles under the NHCR, other developments took place in the area of consumer information on foods, such as mandatory nutrition labelling and voluntary front-of-pack nutrition labelling schemes. Contrary to nutrient profiles, these voluntary initiatives do not seek to restrict or ban health claims on food products considered unhealthy, but to indicate a positive message relating to the healthiness of a food product.

In 2020, the farm to fork strategy and its actions plan brought nutrient profiles back to the EU policy agenda in the context of the revision of front-of-pack labelling under the Food Information to Consumers Regulation (FIC). In this context, the Commission has published two inception impact assessments and organised public consultations: 1) Food labelling – revision of rules on information provided to consumers and 2) Facilitating healthier food choices – establishing nutrient profiles. Moreover, EFSA put forward in March 2022 'Scientific advice related to nutrient profiling for the development of harmonised mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods'.

Sources: Regulation (EC) No 1924/2006; Commission Communication on A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system COM(2020)381; EFSA scientific advice relating to nutrient profiling, 2022, EFSA-Q-2021-00026; EFSA scientific opinion on the setting of nutrient profiles for foods bearing nutrition and health claims, 2008, EFSA-Q-2007-058.

In its assessment of **health claims made on plants, their preparations, and their regulatory framework** the evaluation report noted positively that the NHCR is coherent with other EU legislation applicable to foods containing botanicals and with corresponding international initiatives. Although the NHCR does not recognise the specific nature of plant substances or evidence based on 'traditional use' as sufficient to substantiate health claims on plant substances, the report noted some EU added value compared to the previous unregulated situation. The EU lists of permitted health claims lists the claims that can be used throughout the EU.

Regarding the complex issues surrounding the 'on hold' list, the evaluation report noted significant shortcomings in terms both of consumer protection and of a well-functioning internal market. The effectiveness of the NHCR was overshadowed by the fact that under the current circumstances consumers may falsely assume that the beneficial effects communicated with the claims on the 'on hold' list and used on foods containing botanicals have been scientifically assessed and risk managed. Moreover, the 'on hold' list was seen to hamper the effective implementation of the objective to promote and protect innovation, as the uncertainty of the situation discourages long-term investments in this field.

Related to the 'on hold' list of health claims made on foods is the absence of a final decision on health claims on foods containing botanicals. Furthermore, additional challenges stem from national differences in the general regulatory framework concerning the use of plants and their preparations in foods.[46] According to the report, severe inconsistency prevails between the legal

[46] Evaluation report SWD(2020)95, Part 1 p. 85-87

framework applicable to THMPs, namely 'traditional use' in therapeutic indications, and the substantiation of health claims. The evaluation report also pointed out that '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'.

On the question of establishing an EU positive or negative list of plants, the evaluation refers to the previous evaluation by the Commission dating back to 2008 and based on Article 4(8) of Directive 2002/46/EC. It examined the questions of EU-level positive lists and concluded that laying down specific rules applicable to substances other than vitamins and minerals for use in food supplements was not justified at that time. Consequently, the list of permitted health claims regarding plant substances used in foods, which would have harmonised the substances enjoying mutual recognition by Member States, was not established.[47]

While the evaluation report considered the EU-level regulatory framework on the safety of foods adequate, it drew attention to certain issues creating barriers to the effectiveness of the overall general regulatory framework concerning the use of plants and their preparations in foods. The evaluation report pointed out that in 2020, numerous Member States had adopted national rules addressing safety issues (positive and/or negative lists of botanicals used in foods with conditions of use and/or warnings).[48] It also referred to the use Article 8 of Regulation 1925/2006 on the assessment of the safety of plant substances in foods presenting a potential risk to consumers, and stated that Member States have been reluctant to proceed with the authorisation of claims owing to the lack of recognition on the safety of the substance(s). In relation to the smooth functioning of the EU market, the national lists create barriers to trade, as marketing a product on different Member States requires adaptations in its composition and/or labelling with negative implications for business.

The efficiency analysis of the NHCR, focusing on costs and benefits, gave mixed results. The report explained that while food business operators were considered to suffer from a degree of legal uncertainty as regards timing of the final decision on health claims made on plants and adaptation of costs, they benefited from the possibility of continuous use of health claims on the 'on hold' list without undertaking clinical trials in order to substantiate the claim. The pharmaceutical industry arguably suffers higher production and regulatory costs than food business operators producing food supplements. However, the evaluation report showed that the cost of preparing an application file for the authorisation procedure for a new claim in accordance with the current rules, which require clinical trials, is considerably higher than the cost of the possible alternative use of traditional use to substantiate health claims made on botanicals. Owing to this issue, the existing regulatory framework on plants used in foods was deemed to influence negatively innovation and trade on the internal market.

3.3. Recent EU developments in health claims made on foods

Even though the evaluation report published in May 2020 did not lead to immediate revision of the NHCR, its findings have contributed to various policy developments on EU food policies during the ongoing ninth legislature (2019 to 2024). At the beginning of the current legislature, the REFIT evaluation of the NHCR was ongoing.[49] Currently, nutrient profiles feature prominently in the farm

[47] Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements, COM(2008)824.

[48] Evaluation report, SWD(2020)95 part 1, p. 28.

[49] N. Pushkarev, F. Godfrey et al., EU Public Health Policies: State of play, current and future challenges, European Parliament, September 2009.

to fork strategy, which is an essential part of the European Green Deal.[50] In Europe's beating cancer plan, which is a pillar of the European health union, one of the objectives is to use policy tools to promote health awareness, access to healthy diets and improved availability of healthy foods.[51] Together with the FIC Regulation, the NHCR is at the heart of these debates on future food policies. As regards information delivered to consumers on foods, there is a strong link between the FIC Regulation, which defines rules on mandatory labelling and the NHCR, which governs the use of voluntary nutrition and health claims on foods made in commercial communication.

The farm to fork strategy[52] aims to make food systems fair, healthy and environmentally friendly and announced in its action plan the introduction of a proposal on setting the nutrient profiles by the end of 2022. As explained above, work on proposal is pending. The European Parliament supported this initiative in its own-initiative resolution of 20 October 2021 on the farm to fork strategy when it called on the Commission to ensure a mandatory and harmonised EU front-of-pack nutritional labelling based on scientific evidence and demonstrated consumer understanding to support accurate information on foods and healthier alternatives.[53]

In a wider context, health claims made on foods play a role also in the Europe's beating cancer plan.[54] It tackles the entire disease pathway from prevention of cancer to detection, diagnosis, treatment and finally quality of life of patients and survivors. The plan sees improved access to healthy foods as a way to reduce mortality for non-communicable diseases. Hence, it promotes sustainable food consumption and facilitating the shift to more healthy diets through informed consumer choices. Provisions on clear and trustworthy information about foods is key in achieving these goals. The European Parliament's Beating Cancer Special Committee (BECA) called for the EU to strengthen the fight against cancer and to move towards a comprehensive and coordinated strategy. In its own-initiative resolution of 16 February 2022, the European Parliament stressed in particular the role of healthy diets in preventing and limiting the incidence of cancer and encouraged the adoption of harmonised front-of-pack nutrition labelling.[55]

These initiatives on future EU food and health policies introduce a change to the status quo. Regulation on commercial communication to consumers on nutrient and health claims made on foods, among other issues, is an important policy instrument and an essential part of the policy debate. Though the NHCR has been marked by issues of non-implementation, its objectives remain pertinent and necessary. The new initiatives place high consumer protection and effective functioning of the internal market at the core of their goals.

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50 T. Laaninen, Nutrient profiles: A 'farm to fork' strategy initiative takes shape, EPRS briefing, European Parliament, April 2022.

51 L. Amand-Eeckhout, Strengthening Europe in the fight against cancer, EPRS, European Parliament, October 2022.

52 European Commission, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM(2020)381.

53 European Parliament resolution of 20 October 2021 on a farm to fork strategy for a fair, healthy and environmentally-friendly food system, 2020/2260(INI)).

54 Europe's Beating Cancer Plan, COM(2021)44.

55 Strengthening Europe in the fight against cancer – towards a comprehensive and coordinated strategy (EP/2020/2267(INI)).

4. Presentation of the research papers

4.1. Health claims on foods: Analysis of the case law of the Court of Justice of the European Union on Regulation (EC) No 1924/2006

Building on the findings of the evaluation report on Regulation (EC) No 1924/2006, this research paper presents findings on the implementation and application of the NHCR in practice. It analyses the implementation of the NHCR through desk research into case law and literature. It identifies the following main issues of legal discussion:

- the definition of health claims;
- usage of general health claims;
- evidence requirements for health claims;
- implementation of the transitional measures of the regulation;
- commercial communication towards health professionals;
- classification of products as foodstuff or as medicinal products; and
- other issues.

The research paper also looks at questions relating to the EFSA's risk assessment procedure and issues relating to foods containing botanicals. Finally, it offers an analysis of the impact of CJEU case law on the development of the legal framework and sheds light on the open questions relating to nutrient profiles and botanical claims.

The research paper analyses the 22 cases listed in table here below, retrieved from the EUR-Lex and CURIA databases. The paper analyses all relevant proceedings relating to the NHCR with a focus on requests of national courts for preliminary rulings (Article 267 TFEU).[56] In this regard, other relevant proceedings are appeals from the ruling of the General Court (to the Court of Justice); and claims on failure to act (Article 265 TFEU) as well as claims on actions for annulment (by the General Court) (Articles 263 and 256 TFEU). Although it is not a legal analysis, this approach sheds light on the variety of issues brought before the CJEU by either national courts through requests for preliminary rulings or by individuals holding a 'locus standi' in other types of proceedings.

The cases that have emerged during the 15 years of implementation and application in practice of the NHCR complement the findings of the evaluation report. The evaluation report covers notably the question of the nutrient profiles, the use of botanicals in health claims and the general legal framework on plants and their preparations. This analysis of case law clarifies issues raised by divergent interpretations or views, to the extent that they have been brought before the CJEU. These include: usage of general health claims; implementation of the transitional measures of the regulation; and commercial communication towards health professionals. Moreover, the legality of the EFSA's risk assessment procedure and the Commission decision to establish the 'on hold' list have been challenged and upheld before the CJEU. The judgments in these cases highlight the Court's reasoning and create a solid case law on the matter.

[56] R. Manko, Preliminary reference procedure, EPRS, European Parliament, 2017; and 60 years of *Da Costa en Schaake* – Asserting the binding authority of European Court of Justice case law, EPRS, European Parliament, 2023.

Table 2 – CJEU case law analysed in the research paper

Requests for preliminary rulings (Article 267 TFEU)
Judgment of 14 July 2016, *Verband Sozialer Wettbewerb eV* v *Innova Vital GmbH*, Case: C-19/15
Judgment of 23 November 2016, *Nelsons GmbH* v *Ayonnax Nutripharm GmbH and Bachblütentreff Ltd*, Case: C-177/15
Judgment of 17 December 2015, *Société Neptune Distribution* v *Ministre de l'Économie et des Finances*, Case: C-157/14
Judgment 5 November 2014, *Herbaria Kräuterparadies GmbH* v *Freistaat Bayern*, Case: C-137/13
Judgment of 18 July 2013, *Green Swan Pharmaceuticals CR, a.s.* v *Státní zemědělská a potravinářská inspekce, ústřední inspektorát*, Case: C-299/12
Judgment of 10 April 2014, *Ehrmann AG* v *Zentrale zur Bekämpfung unlauteren Wettbewerbs eV*, Case: C-609/12
Judgment of 6 September 2012, *Deutsches Weintor eG* v *Land Rheinland-Pfalz.*, Case: C-544/10
Order of the President of the Court of 6 November 2012, *Schutzverband der Spirituosen-Industrie eV* v *Sonnthurn Vertriebs GmbH*, Case C-51/11
Judgment of 10 September 2020, *Konsumentombudsmannen* v *Mezina AB*, C-363/19
Judgment of 30 January 2020, *Dr. Willmar Schwabe GmbH & Co.KG* v *Queisser Pharma GmbH & Co. KG*, Case: C-524/18, EU:C:2020:60
Judgment of 15 January 2009, *Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg*, Case: C-140/07 *)
Appeals, actions for annulment and actions for failure to act
Judgment of 30 April 2014, *Moritz Hagenmeyer and Andreas Hahn* v *European Commission*, Case: T-17/12
Order of 17 September 2014, *Asociación Española de Fabricantes de Preparados alimenticios especiales, dietéticos y plantas medicinales (Afepadi) and Others v European Commission*, Case: T-354/12
Judgment 12 June 2015, *The Health Food Manufacturers' Association and Others* v *European Commission*, Case: T-296/12
Judgment of 12 June 2015, *Plantavis GmbH and NEM, Verband mittelständischer europäischer Hersteller und Distributoren von Nahrungsergänzungsmitteln & Gesundheitsprodukten eV* v *European Commission and European Food Safety Authority*, Case: T-334/12
Order of 16 September 2015, *Bionorica SE* v *European Commission*, Case: T-619/14 and Judgment of 23 November 2017 *Bionorica SE and Diapharm GmbH & Co. KG* v *European Commission*, joined cases: C-596/15 and C- 597/15
Order of 16 September 2015, *Diapharm GmbH & Co. KG* v *European Commission*, Case: T-620/14
Order of 16 September 2015, *VSM Geneesmiddelen BV* v *European Commission*, Case: T-578/14
Judgment of 16 March 2016, *Dextro Energy GmbH & Co. KG* v *European Commission*, Case: T-100/15
Order of 25 October 2016, *VSM Geneesmiddelen BV* v *European Commission*, Case: C-637/15

*) This request for a preliminary ruling is not directly about the Regulation (EC) No 1924/2006, but it is closely related and relevant as regards the classification of products as foodstuff or medicinal products.

Sources: Eur-Lex database and case law on the CJEU website.

4.2. Implementation, application and impact of health claims made on foods: Literature reviews

Each chapter of this research paper provides a small-scale literature review applying different methods. Many of its findings confirm remarks and conclusions already presented in previous studies.

4.2.1. Comparison of the regulatory frameworks of the European Union, the United States and the United Kingdom

The first chapter of this research paper provides a comparison of the regulatory frameworks of the European Union, the United States and the United Kingdom as regards the risk assessment and authorisation of health claims. Based on desk research, it describes the types of health claims and the procedures for their authorisation as well as the required level of scientific substantiation. While it is not a comparative study, but rather a description, this chapter offers insight into the main similarities and differences between these three regimes.

The research paper identified differences between the EU and US systems in the types of health claims made on foods and their scientific substantiation. The current legislative frameworks in the EU and the UK since Brexit are relatively similar, but about to diverge further as a revision in the UK has recently been announced. Most importantly, the rules on health claims in the EU and the current rules in the UK following Brexit entail a separation between risk assessment and the risk management i.e. authorisation of the claim. In the US, the FDA deals with both assessing the scientific substantiation of the new claims and issuing the authorisation for most of the claims.

4.2.2. Literature review on the impact of health claims in advertisements on consumer behaviour

The second chapter outlines a literature review on the impacts of health claims on foods on consumers' attitudes and food choices. The results of this analysis show that several factors influence consumers' decision making when choosing food. These factors include: the understanding of the claims, which varies according to consumers' education level, socioeconomic status and personal motivation to follow a healthy diet and lifestyle. The analysis reveals also that risk reduction claims and positive nutritional claims are most attractive to consumers; and that taste is still the main determinant of consumers' food choices. It also recognises the so called 'halo effect' where consumers are prone to overconsume food products bearing positive claims. Contrasting results are available regarding willingness to pay more for foods having a nutrition or a health claim. This chapter offers also insight into literature on marketing practices used to circumvent the provisions of the NHCR.

The small-scale desk research performed in this chapter is based on a systematic review of the scientific literature published since 2010 and available in the databases Scopus, Embase and Pubmed on the effects of nutrition and health claims on consumers' attitudes and food choices. The data set comprises 23 qualitative/mixed studies analysed according to the SPIDER methodology[57] and two quantitative studies examined with the PICO methodology.[58]

Among the previous studies performed in this field, CLYMBOL (2012-2016)[59] was conducted for the Commission under the seventh framework programme and fed in the evaluation of the NHCR. The

[57] SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) and PICO (Population, Intervention, Comparison, Outcome), https://researchguides.gonzaga.edu/qualitative/spider.

[58] PICO (Population, Intervention, Comparison, Outcome), https://guides.mclibrary.duke.edu/ebm/pico.

[59] CLYMBOL, https://cordis.europa.eu/project/id/311963/reporting and FLABEL, https://www.flabel.org/.

CLYMBOL project was set up to develop a better understanding of consumer behaviour in relation to claims and symbols on food products. CLYMBOL, which ran from 2012 to 2016, had a broad scope covering both nutrition and health claims in all EU countries and used a multidisciplinary approach, including extensive collection of primary data. The impact of health claims on consumer understanding, purchase and consumption behaviour were at the heart of its research questions. CLYMBOL preceded FLABEL, which was a three-year project on food labelling and consumer understanding of health claims and symbols (2008-2011).

The small-scale desk research presented in this study does not compare with the CLYMBOL project. Nevertheless, the findings of this literature review, though much narrower in scope and scale, reaffirm the findings presented in the CLYMBOL project.

The recommendations based on the findings of the literature review presented in Chapter 2 emphasise the need to raise the level of knowledge of and familiarity with the information delivered in health claims and the impact of dietary choices on health and thus enable consumers make healthy food choices.

4.2.3. Scientific evidence on health effects of foods containing botanicals

The literature review on beneficial effects and health risks of botanicals on human health reports that currently there is no common EU-level positive list on permitted botanicals across the EU nor a common comprehensive source or list of beneficial and adverse health effects of botanicals. The analysis lists the existing patchwork of such databases.

Consequently, the recommendations of this literature review encourage reflecting on the possibility of establishing such a comprehensive positive list and setting up an EU surveillance system of adverse health effects of foods containing botanicals.

One of the examples of the existing databases is the Eurofir PlantLIBRA[60] project conducted between June 2010 and May 2014. The findings of the PlantLIBRA project contributed to the evidence base for the evaluation report. Plant LIBRA compiles quality-reviewed scientific information from peer-reviewed publications on the composition, beneficial and adverse effects of food supplements, botanicals and food plants. It seeks to support science-based decision-making and notes that in order to make informed decisions, competent authorities and food businesses operators need quality-assured and accessible information and accessible databases. PlantLIBRA project and its online databse ePlantLIBRA aim to develop, validate and disseminate data and methodologies for risk and benefit assessment.

[60] PlantLIBRA https://cordis.europa.eu/project/id/245199 and database https://eplantlibra.eurofir.org/Default.asp.

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Annex I: Health claims made on foods

Analysis of Court of Justice of the European Union case law on Regulation (EC) No 1924/2006

Since 2007, the Nutrition and Health Claims Regulation has dealt with commercial communication on the nutritional aspects and health effects of foods. The regulation aims to ensure the effective functioning of the internal market, while offering the highest level of consumer protection. Claims must therefore be scientifically substantiated. The multidisciplinary analysis of CJEU case law presented in this research paper identified seven main issues of legal discussion in case law relating to the regulation, including substantiation requirements for claims, and the use of transitional measures for botanical claims – claims for which the assessment and authorisation process is currently on hold.

The results of this analysis highlight that in case law, consumer protection is understood as ensuring that consumers are only exposed to non-ambiguous and substantiated information. The two main issues of non-implementation of the regulation, nutrient profiles and the on-hold botanical claims, need to be addressed if this aim of offering the highest level of consumer protection is to be met. Even though the use of claims under two regimes is not seen to create legal uncertainty for business operators, the transitional regime does create fragmentation of the market. A decision on the role of 'traditional use' for substantiating botanical claims, together with further harmonisation of safety considerations for botanicals in foods, will contribute to the effective functioning of the market and will further optimise consumer protection.

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Executive summary

Conducted at the request of the European Parliamentary Research Service to underpin the deliberations of the European Parliament's SANT subcommittee, this research paper presents a multidisciplinary analysis of case law relating to Regulation (EC) No 1924/2006 on nutrition and health claims. It examines current issues raised by the implementation and application of the regulation. By conducting desk research into CJEU case law, it was possible to identify general trends from the rulings and analyse the impact of case law on the development of the legal framework and on open questions.

The research paper provides an overview of developments around nutrition and health claims since the regulation entered into force in July 2007. The analysis of CJEU case law – which includes both questions referred for preliminary rulings, and appeals, actions for failure to act and actions for annulment – addresses seven main issues of legal discussion. The main issues are: (i) the definition of 'health claims', (ii) the use of general health claims (Article 10(3)), (iii) evidence requirements for substantiating both general and specific claims, (iv) the transitional measures for trademarks and brand names as well as botanicals, (v) commercial communication with healthcare professionals, (vi) classification of foods versus medicine, and (vii) other relevant issues. This analysis highlights that the concept of 'health claims' should be understood broadly, covering all commercial communication about nutritional or health aspects of food products, which must be substantiated with generally accepted scientific evidence. Consumers should be protected from ambiguous, potentially misleading claims. Nutrient profiles, which remain to be implemented, are an important tool to support the alignment of health policies with claims, to further foster consumer protection.

Another pertinent issue is claims on botanicals, which are currently used under transitional measures, awaiting a decision on how to proceed with the (non-)use of traditional evidence in substantiating the efficacy of botanical-containing foods. Consumers are therefore exposed to two types of claim: claims that have undergone a rigorous assessment, and claims that have not. This has a negative impact on achieving the regulation's aim of a high level of consumer protection. The on-hold list of botanical claims under the transitional measures in the regulation is not considered to create legal uncertainty for food business operators (FBOs), but claims are treated differently under the definitive versus the transitional regime. The fact that the termination of these measures is unpredictable has a negative impact on strategic business decisions. National provisions that botanical claims must live up to – often relating to safety – cause further fragmentation of the market. The ongoing use of claims under the transitional measures therefore negatively impacts both consumer protection and the effective functioning of the market.

In line with the evaluation of Regulation (EC) No 1924/2006 presented in 2020, this multidisciplinary analysis highlights that the Nutrition and Health Claims Regulation (NHCR) offers EU added value and, in general, functions effectively in protecting consumers from false and misleading claims, while ensuring the functioning of the internal market, even though the impact on innovation is questionable. However, the two main issues of non-implementation need to be addressed if these objectives are to be fully achieved. The Commission has published considerations on setting nutrient profiles in the context of the planned revision of the Food Information to Consumers Regulation (FIC). It is essential to also decide upon the role of 'traditional use' evidence in substantiating health claims on botanicals. As the regulation currently requires claims to be scientifically substantiated, it needs to be decided whether evidence on traditional use can be seen as a specific type of scientific substantiation, or whether a new category needs to be developed for such claims, especially when aiming for the highest level of consumer protection with substantiated claims. When determining the approach to claims on botanicals, EU harmonisation of safety considerations for botanicals in foods should be investigated.

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List of abbreviations

AG	Advocate General
CJEU	Court of Justice of the European Union
EFSA	European Food Safety Authority
EU	European Union
FBO	Food business operator
FIC	Regulation (EU) No 1169/2011 on the provision of food information to consumers
NDA Panel	The EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA)
NHCR	Regulation (EC) No 1924/2006 on nutrition and health claims

List of CJEU case law

CJEU Preliminary rulings (Article 267 TFEU)

Case C-363/19 *Konsumentombudsmannen v Mezina AB* [2020] ECLI:EU:C:2020:693

Case C-524/18 *Dr Willmar Schwabe GmbH & Co.KG v Queisser Pharma GmbH & Co. KG* [2020] ECLI:EU:C:2020:60

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Case T-334/12 *Plantavis GmbH and NEM v Commission and EFSA* [2015] ECLI:EU:T:2015:376

Case T-296/12 *Health Food Manufacturers' Association and Others v Commission* [2015] ECLI:EU:T:2015:375

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Case T-620/14 *Diapharm* v Commission [2015] ECLI:EU:T:2015:714

Case T-354/12 *Afepadi and Others v Commission* [2014] ECLI:EU:T:2014:798

Case T-17/12 *Hagenmeyer & Hahn v European Commission* [2014] ECLI:EU:T:2014:234

1. Introduction

1.1. Background and objective

1.1.1. Regulating nutrition and health claims in the EU

Regulation (EC) No 1924/2006, also known as the Nutrition and Health Claims Regulation (hereafter abbreviated as NHCR), entered into force in July 2007. The NHCR regulates all voluntarily provided commercial communication related to the nutritional content or health effects of foods. The regulation aims to provide a high level of consumer protection, by ensuring that consumers are not exposed to unsubstantiated information about foods or to medical claims on food products; while ensuring the effective functioning of the internal market[1].

Prior to the adoption of the NHCR, various research projects and policy documents that addressed advertisements and commercial information provided to consumers about functional foods had been drafted since the 1990s[2]. In particular, the 1995 Functional Food Science in Europe FUFOSE[3] and 2001 PASSCLAIM[4] projects were key in this development. In 1999 and 2005, the final reports suggested developing specific categories for different types of claims on foods and provided criteria for their scientific substantiation. The White Paper on Food Safety in 2000[5] already described the Commission's intention to regulate nutrition and health claims, and the subsequent policy documents that were informed by the research projects resulted in the final regulation being adopted in December 2006[6].

Nutrition and health claims are prohibited within the EU 'unless they comply with the general and specific requirements described' in the NHCR[7]. Only pre-authorised claims are allowed for use[8] and additional information must be provided[9] about, e.g. the quantity of the food to obtain the claimed beneficial effect. One of the main conditions for pre-market authorisation of a claim is the scientific substantiation of the beneficial nutritional or physiological effect[10]. Food business operators (FBOs) are required to justify the claims they use[11]. Evidence must be provided that a healthy population benefits from the food product or ingredient, to support the causal relationship between consuming a food (ingredient) and the consequential beneficial physiological effect[12].

In the NHCR, claims are understood as '*any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form,*

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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, p. 9. (Consolidated version: 13 December 2014) (hereafter: NHCR), Art. 1(1).

2 A de Boer, E Vos, A Bast (2014). 'Implementation of the nutrition and health claim regulation - The case of antioxidants', *Regulatory Toxicology and Pharmacology* 68(3), pp. 475-487.

3 AT Diplock, PJ Aggett, M Ashwell, F Bornet, EB Fern, MB Roberfroid (1999). 'Scientific concepts of functional foods in Europe: consensus document', *British Journal of Nutrition* 81, S1–S27; FUFOSE: https://ilsi.eu/eu-projects/fufose/ (Last accessed 25 August 2023).

4 PJ Aggett, J-M Antoine, N-G Asp, F Bellisle, L Contor, JH Cummings, J Howlett, DJG Müller, C Persin, LTJ Pijls, G Rechkemmer, S Tuijtelaars, H Verhagen (2005). 'PASSCLAIM* Consensus on Criteria', *European Journal of Nutrition* 44, i5-i30; PASSCLAIM: https://ilsi.eu/eu-projects/passclaim/ (Last accessed 25 August 2023).

5 COM/99/0719 final Commission White Paper on Food Safety.

6 de Boer *et al*. (2014) *supra* note 2; A de Boer (2021). 'Fifteen years of regulating nutrition and health claims in Europe: the past, the present and the future', *Nutrients* 13(5), 1725.

7 Art. 10(1) NHCR.

8 *Ibid*.

9 Art. 10(2) NHCR.

10 Arts. 5(1)(a) and 6(1) NHCR.

11 Art. 6(2) NHCR.

12 de Boer (2021), *supra* note 6.

which states, suggests or implies that a food has particular characteristics'[13]. This definition highlights that the regulation on nutrition and health claims not only covers communication about particular characteristics of a food product through textual information provided on the label, but it also covers other forms of explicit and implicit suggestions about nutritional or health effects. It thus touches upon elements such as brand names, slogans used in advertising, etc[14].

Two categories of claims are defined within the NHCR: nutrition claims[15], which are statements, suggestions, or implications that a food has particular beneficial nutritional properties due to the specific amount of nutrients that the food does or does not contain; and health claims[16], statements, suggestions, or implications that there is a relationship between consuming a food (ingredient, product or category) and a health benefit. Permitted nutrition claims and their conditions of use are specified in the Annex of Regulation (EC) No 1924/2006[17]. Health claims can be further subdivided into four types, being:

- Article 13.1 claims: general function claims[18]. These claims are based on generally accepted scientific evidence (scientific consensus) that supports the association between a food ingredient, product or category and the maintenance or support of a certain physiological function.
- Article 13.5 claims: function claims based on newly developed scientific evidence and/or including a request for protecting proprietary data[19]. These claims similarly address the relationship between consuming a food ingredient, product or category, but these relationships are substantiated by newly developed scientific evidence. For a period of five years, food business operators may request the protection of any proprietary data that was deemed necessary to substantiate this relationship[20]. The authorised claim is then also restricted for use to only the applicant[21].
- Article 14.1(a) claims: reduction of disease risk claims[22]. This category of claims allows for linking the intake of a food ingredient, product or category and the reduction of a risk factor for the development of a disease.
- Article 14.1(b) claims: claims referring to children's development and health[23]]. All claims related to the health benefits of food (ingredient, product or category) for children, such as the role of calcium in bone development in children, are dealt with in this category.

To allow FBOs time to deal with the impact of the NHCR and implement the new regulatory requirements, specific transitional measures were described in Article 28 of the NHCR. These addressed measures for:

- Marketing foods not complying with nutrient profiles
- Until 2022, marketing foods using trademarks or brand names existing before 2005 that do not comply with the regulation[24];

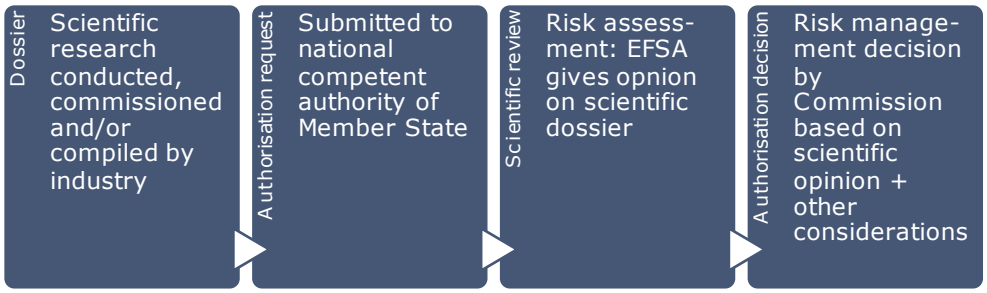
13 Art. 2(2)(1) NHCR.
14 Art. 1(3) NHCR.
15 Art. 2(2)(4) NHCR.
16 Art. 2(2)(5) NHCR.
17 Art. 8(1) NHCR.
18 Art. 13(1) NHCR.
19 Art. 13(5) NHCR.
20 Art. 21 NHCR.
21 Arts. 13(5) and Art 18 NHCR.
22 Art. 14(1)(a) NHCR.
23 Art. 14(1)(b) NHCR.
24 Art. 28(2) NHCR.

- Until 2010, nutrition claims previously authorised in Member States but not authorised under the NHCR[25];
- Until the moment that decisions were made about nutrition claims, those nutrition claims that are not authorised under the NHCR, which are complying with the general principles laid down in the NHCR and were used following specific conditions and criteria laid down in national rules and provisions[26];
- Until the adoption of the positive list described in Article 13(3), those health claims that are submitted for evaluation under Article 13(1) but for which the assessment is not finalised[27]; and
- Health claims other than Article 13(1) and Article 14.1(a) claims that were used in compliance with national provisions prior to the entry into force of regulation, until they are evaluated under the NHCR[28].

Authorisation procedure for health claims

Following from the provisions in the NHCR, all claims need to be supported by scientific evidence. With their request for authorising a specific health claim, food business operators need to provide a scientific dossier to support the beneficial nutritional or health effect of a compound that they want to make a claim about[29]. This request is submitted to the national competent authority of a Member State, which shares the request and any supplementary information with the European Food Safety Authority (EFSA) (figure 1).

Figure 1: Overview of the process for health claim authorisation requests



Source: adapted from de Boer (2021).

Under the NHCR, EFSA acts as the risk assessor and offers its scientific opinion about a proposed health claim[30]. This scientific opinion addresses whether the claim is substantiated by scientific evidence and whether the wording of the claim 'complies with the criteria laid down' in the NHCR[31]. This opinion, which is made public, is subsequently forwarded to the Commission, the Member State and the applicant. Within 2 months of receiving EFSA's positive scientific opinion, the Commission proposes their draft decision to the Standing Committee on the Food Chain and Animal Health (following the regular procedure for authorising new claims) in which the opinion is considered, as

25 Art. 28(3) NHCR.
26 Art. 28(4) NHCR.
27 Art. 28(5) NHCR.
28 Art. 28(6) NHCR.
29 Arts. 15 and 18 NHCR.
30 Art. 16 NHCR.
31 Art. 16(3) NHCR.

well as 'any relevant provisions of Community law and other legitimate factors relevant'[32]. When the decision of the Commission is different from the scientific opinion issued, this difference needs to be explained[33].

The authorisation procedure described above applies to all authorisation requests today, for Article 13.5 claims, Article 14.1(a) claims and Article 14.1(b) claims. However, applications for health claims now always concern individual authorisation requests for claims. The authorisation of Article 13.1 claims could only be requested until 31 January 2008 via Member State authorities[34]. This procedure differed slightly from the procedure described above: Member States offered lists of claims to the Commission before this date, together with 'the conditions applying to them' and with 'references to the relevant scientific justification'[35]. As described in Article 13(3), the Commission would adopt a Community list of permitted claims[36].

A total of 44 000 claims were submitted by January 2008, which were grouped into 4 600 putative claims that needed to be assessed by EFSA[37]. The supportive evidence for these entries to the Community list – which could for example include consensus documents and expert reports – was critically reviewed by EFSA to establish whether these sources indeed supported the suggested health benefits of nutrients or other food components or ingredients[38]. By December 2011, 2 500 claims proposed for inclusion on the Community list were reviewed, which resulted in a total of 222 authorised health claims. While the scientifically substantiated claims were proposed to be authorised and thus listed in the Annex of Regulation (EU) No 432/2012, the claims not considered to be sufficiently substantiated were also listed in the Union Register, to show why these were not authorised[39].

For the other approximately 2 000 claims, the authorisation procedure was not yet completed in 2011. These claims[40] mainly addressed the putative health benefits of botanical products, which are plant and herbal substances and extracts thereof. As described in the 2011 Memo of the Commission, the Commission had already asked EFSA to discontinue the assessment for these botanical claims in September 2010[41]. Even though some of the claims had been already assessed, the authorisation process for all proposed claims on botanicals was put on hold because of potential clashes between legal requirements for botanicals in food products versus botanicals in pharmaceutical products, authorised as traditional herbal medicinal products (THMP)[42]. The procedure was suspended at the request of the Commission because of concerns that were raised by different Member States and stakeholders, with regard to the different treatment of these products under both regulatory frameworks[43]. These 'on hold' claims continue to fall under the

32 Art. 17(1) NHCR; de Boer (2021) *supra* note 6.
33 Art. 17(1) NHCR.
34 Art. 13(2) NHCR.
35 Art. 13(2) NHCR.
36 Art. 13(3) NHCR.
37 European Commission (2011) Memo/11/868: Questions and Answers on the list of permitted Health Claims. Brussels, 5 December. Available via: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_11_868. (Last accessed 3 August 2023); European Commission (2012) Memo/12/346: Questions and answers on the list of permitted Health Claims on food products. Brussels, 16 May. Available via https://ec.europa.eu/commission/presscorner/detail/en/MEMO_12_346 (Last accessed 3 August 2023).
38 de Boer (2021) *supra* note 6, de Boer *et al*. (2014) *supra* note 2.
39 Memo/11/868, *supra* note 38.
40 The full list of the submitted 2 078 claims is available under their submission ID numbers, via https://ec.europa.eu/food/food-feed-portal/backend/claims/files/claims_pending.pdf (Last accessed 3 August 2023).
41 Memo/11/868, *supra* note 38.
42 Memo/11/868, *supra* note 38.
43 Joined Cases C 596/15 P and C 597/15 P, *Bionorica SE (C 596/15 P) and Diapharm GmbH & Co. KG (C 597/15 P) v European Commission* [2017] Opinion of Advocate General Bobek delivered on 25 April 2017, para., 12.

transitional measures described in Article 28[44]. This means that they can still be used on the market under the responsibility of the food business operator, as long as the claims comply with the NHCR and existing national provisions[45]. The authorisation procedure for these on hold claims has not yet resumed.

All Article 13 claims that are authorised, and which are not restricted for use, are added to the Community list of permitted claims[46]. This positive list of Article 13 claims is found in the Annex to *Commission Regulation (EU) No 432/2012 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*[47]. Together with the claims described in the Annex, other authorised health claims are also publicly accessible via the Community Register[48], now known as the Union Register[49]. As put forward above, for transparency reasons, the Union Register also includes entries of finalised authorisation requests for claims that are not authorised.

In July 2023, a total of 269 health claims[50] has been authorised for use in the European Union. Commission Regulation (EC) No 432/2012 entered into force in December 2012, listing 222 authorised health claims. Today, 229 Article 13.1 claims are authorised; as well as 13 Article 13.5 claims (of which one with the protection of proprietary data); 15 Article 14.1(a) claims including also one with the protection of proprietary data; and 12 Article 14.1(b) health claims.

Scientific substantiation

The scientific opinion issued by EFSA is key in the authorisation decision of the Commission. In January 2008, when all putative Article 13.1 claims needed to be submitted, the procedure underlying EFSA's risk assessment was not known[51]. After issuing the first scientific opinions and subsequently the publication of guidance documents[52] for food business operators, this procedure has been clarified further. It is now known that there are four key elements to be addressed in the

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44 Art. 28 NHCR.

45 Memo/11/868, *supra* note 38.

46 Art. 13(3) NHCR.

47 Commission Regulation (EU) No 432/12 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, p1. Consolidated version: 17 May 2021. (Hereafter Reg No 432/2012).

48 Art. 20 NHCR.

49 The Union Register is currently available via https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/eu-register-health-claims_en (Last accessed: 3 August 2023). The Register not only includes the permitted claims described in the positive list in Reg (EU) No 432/2012, but also details authorised Article 14(1) claims and links to Article 13(5) and 14(1)(a) claims for which protection of proprietary data is granted.

50 Identified via Reg (EU) No 432/2012 (consolidated version 17 May 2021) and Union Register, *supra* note 50.

51 A de Boer, A Bast (2015). 'Stakeholders' perception of the nutrition and health claim regulation', *International Journal of Food Sciences and Nutrition* 66(3), p. 321-328; KGM Lenssen, A Bast, A de Boer (2018). 'Clarifying the health claim assessment procedure of EFSA will benefit functional food innovation', *Journal of Functional Foods* 47, pp. 386-396.

52 A working group of the Standing Committee on the Food Chain and Animal Health issued a guidance document for the implementation of the NHCR in 2007, which mainly addressed the classification of claims. Available via: https://food.ec.europa.eu/system/files_en?file=2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf (Last accessed: 3 August 2023). Administrative, technical and scientific guidance has been issued by EFSA's NDA Panel since 2011. The general administrative and technical guidance document was last updated following the entry into force of the Transparency Regulation (*Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain OJ L 231, p.1*) in March 2021: D Turck, *et al*. (2021). Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3). *EFSA Journal* 19(3):6554. Most importantly, the general scientific guidance document provides details related to the scientific requirements for health claims: EFSA NDA Panel (2021). General scientific guidance for stakeholders on health claim applications (Revision 1). *EFSA Journal* 19(3):6553. Six scientific guidance documents for specific health effects are available via EFSA's website on Nutrition Applications: regulations and guidance. Available via https://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance#health-claims (Last accessed 3 August 2023).

scientific dossier submitted by the applicant, to contain information on the causal relationship between the consumption of the ingredient and the beneficial nutritional or physiological effect[53]. Firstly, the ingredient needs to be characterised well; the well-defined effect needs to be a beneficial effect and it needs to be established in a healthy population; and the causal link between consumption and effect should be substantiated ideally with well-designed trials in humans (that are randomised, double-blind, and controlled)[54]. Finally, both Commission Regulation (EC) No 353/2008 and EFSA's general guidance document supporting health claim applications describe that the dossier should contain information regarding the quantity of consuming the ingredient and the consumption pattern, which should be achievable within a balanced diet[55].

The dossier is reviewed by independent experts within EFSA's NDA Panel, to assess whether all available scientific evidence has been considered in the application and to establish whether the dossier is complete[56]. The NDA Panel can add scientific literature which they believe to be 'pertinent to the claim' but is not expected to undertake additional literature reviews for this purpose[57]. If needed, the Panel can request additional information from applicants, e.g. when ambiguities are identified when reviewing the dossier. Even though there is no pre-defined number of studies that would be needed to be automatically considered sufficient to support a health claim, studies have shown that providing at least two – independently conducted – human intervention studies of high quality, which support the causal relationship described in the claim, is often deemed necessary[58]. When all available evidence is considered supportive of the proposed claim, the EFSA Panel will issue a positive opinion about the claim and share this with the Commission. This opinion may include specific conditions of use, as well as comments on the proposed wording of the claim, to ensure that the scientifically substantiated relationship is well reflected in the claim[59].

All authorised nutrition and health claims can be used on food products throughout the EU[60], although the claims authorised under the protection of proprietary data are limited to the use of the applicant. For the use of an authorised claim, it is essential that the product, ingredient or food category aligns with the conditions of use of a claim. Even though it is essential that these conditions of use are met, it is not necessary for the – often technically phrased – health claims to use the exact wording by which the claim was approved when using the claim in commercial communication: as long as the statement has a similar meaning, it is considered to fall under this authorisation[61]. This 'flexibility of wording' allows food business operators to present a health claim in a more attractive way for marketing purposes, as long as the wording still reflects the scientific evidence underlying the causal relationship between the consumption of a product and the health effect, as was authorised[62]. Even though national enforcement authorities in MS may differ in their interpretation

53 de Boer (2021), *supra* note 6.
54 Art. 5 in Commission Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. OJ L 109 2008, 11–16 (hereafter Reg No 353/2008); Lenssen *et al*. (2018), supra note 52; de Boer (2021), *supra* note 6.
55 de Boer (2021), *supra* note 6, Art. 6 Reg No 353/2008.
56 Scientific and technical guidance EFSA revision 3, *supra* note 53.
57 *ibid*, p11.
58 de Boer 2021, *supra* note 6, de Boer & Bast (2015), *supra* note 52, Lenssen *et al*. (2018), *supra* note 52.
59 de Boer (2021), *supra* note 6.
60 de Boer (2021), *supra* note 6.
61 Art. 5(2) NHCR; L González Vaqué, S Romero Melchor (2014). Chapter 18: 'A Yankee in King Arthur's Court: A Lawyer's Perspective of EFSA'. p. 279-294. In: *Foundations of EU Food Law and Policy*, eds A Alemanno, S Gabbi. ISBN: 978-1-4094-6721-2. Oxon: Ashgate Publishing.
62 de Boer (2021), *supra* note 6.

of the exact flexibility[63], it has become clear that words such as 'normal' and 'maintenance' must be well reflected in reworded and translated claims[64].

Next to this flexibility of wording, authorised health claims also provide the opportunity for food business operators to make use of more general well-being claims, claims that were initially foreseen to be no longer allowed for use on food products because of the NHCR[65]. When a product meets the conditions of use for an authorised claim, based on Article 10(3) of the NHCR, a more general claim can be made about the product, as long as this claim is accompanied by the authorised Article 13 or 14 claim. Still, the use of terminology in these statements is restricted, as the NHCR only allows the use of general statements that refer to overall good health or health-related well-being[66]. Similar to such general statements, also other sources of voluntarily provided information about nutritional content or health effects are considered claims[67]. This means that also online information, information in advertisement and campaigns, as well as symbols and graphics that describe or imply to influence the nutritional intake or health, are regulated as claims.

1.1.2. Evaluation of the Regulation (EC) No 1924/2006

In 2015, an evaluation under the European Commission's Fitness Check[68] was proposed for the NHCR. This evaluation addressed whether the current legislation was 'fit for purpose' to deal with the then current, as well as future food safety and food policy issues. The conclusions published in 2020 highlighted that the objectives of the NHCR have not been fully attained[69]. This is firstly influenced by the fact that botanical claims have not yet been assessed – claims on plants and plant preparations[70] that have a long history of use for specific health benefits[71]; and secondly, by the lack of nutrient profiles (which were proposed in Article 4 of the NHCR) which means that also on products that are considered less healthy – as these foods exceed thresholds of specific nutrients such as fat, sugars, and salt – can still make use of health claims[72].

In the initiative to revise Regulation (EU) No 1169/2011 on the provision of food information to consumers, the Commission took up the issue of investigating nutrient profiles that can be used to

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63 A de Boer, MJE Urlings, E Vos, A Bast (2015). 'Enforcement of the nutrition and health claim regulation', *European Food and Feed Law Review* 10, pp. 334-344.

64 de Boer (2021), *supra* note 6.

65 Paragraph rewritten for clarification from de Boer (2021). *supra* note 6; SR Melchor, L Timmermans (2010). 'Article 10(3) of Regulation (EC) 1924/2006-The Road to Salvation', *European Food and Feed Law Review* 5, pp. 22-27.

66 Melchor, Timmermans (2010). *supra* note 66; Commission Implementing Decision (2013/63/EU) adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council. OJ L 22, pp. 25-28

67 de Boer *et al* (2015). *supra* note 64; Report from the Commission to the European Parliament and the Council regarding the use of additional forms of expression and presentation of the nutrition declaration (COM/2020/207 final).

68 Commission Staff Working Document: A Fitness Check of the Food Chain – State of play and next steps (SWD(2013) 516); Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2015). Better regulation for better results —An EU agenda (COM(2015) 215 final)

69 Evaluation of 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. Part 1. SWD(2020) 95 final pt 1.

70 There is no official definition for 'botanicals' in EU legislation. In this research paper, we use the definition of botanicals put forward in SWD(2020) 95 final, pt 1, introduction.

71 The term 'traditional use' is often used to describe this. There is no formal definition for the term, but in this research paper, it is understood as 'evidence collected on the basis of experience gained over time with the actual consumption of the plants and preparations' (SWD(2020) 95 final, pt 1). Whilst it is a notion used in the regulatory framework for medicinal products, in the food regulatory framework it can only be considered in substantiating safety of novel foods (under Regulation (EU) No 2015/2283), but not for proving efficacy under the NHCR.

72 de Boer (2021), *supra* note 6.

restrict the use of nutrition and health claims on foods high in fats, sugars and/or salt[73]. The issue of botanical health claims has, however, not yet been addressed further, although a discussion paper[74] was circulated on health claims on botanicals used in foods in 2012. In that discussion paper, the on hold status of botanical claims was further addressed and it provided two options to move forward from the impasse experienced since that time. These two options are (i) to continue the evaluation as it was, without issuing special conditions for botanical health claims; or (ii) to recognise evidence on traditional use in the evaluation of the botanical health claims. Even though this discussion paper has led to an open consultation within the European Union[75], and has been the subject of various publications in scientific journals[76], so far, no formal decision has been made on how to proceed with the evaluation of the claims that currently fall under the transitional measures.

As a result, two types of claims can be found on the internal market: those claims that have been authorised following the rigorous evaluation and authorisation procedure (as described in Articles 15 and 18 of the NHCR); and those claims that await such an authorisation decision but can be made under the transitional measures, as long as they comply with the provisions of the NHCR and national law. This, therefore, creates uncertainty for consumers, who cannot easily distinguish those claims that are based on scientific substantiation (Arts 13 and 14) versus those falling under the transitional measures of Art. 28(5) and (6). For food business operators, on the other hand, a lack of harmonisation of measures may prevail as national provisions in Member State law can impose different requirements on those claims falling under transitional measures. In addition, there is uncertainty as to when the authorisation procedure will commence and how this will impact their competitiveness on the market.

1.2. Research aim and scope

Over 15 years after the entry into force of the NHCR, it has become clear from the evaluation report published in May 2020[77] that the regulation cannot currently fully meet its objectives: providing a high level of consumer protection by requiring that claims on foods are scientifically substantiated; and ensuring the effective functioning of the internal market[78]. In particular, the fact that approximately 2 000 claims have been on hold since 2010 requires attention.

In this research paper, we analyse the implementation of the NHCR through desk research into case law and literature, with the aim to present relevant findings on its implementation and application in practice. The analysis builds on the findings of the evaluation report on the effectiveness, efficiency, relevance, coherence and EU added value of the Regulation (EC) No 1924/2006.[79] In that

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73 Roadmap for 'facilitating healthier food choices – establishing nutrient profiles, i.e. revision of Regulation (EU) No 1169/2011 on the provision of food information to consumers. Available via https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12748-Facilitating-healthier-food-choices-establishing-nutrient-profiles_en (Last accessed 12 August 2023).

74 Discussion Paper on Health Claims on Botanicals used in Foods (2012).

75 KGM Lenssen, A Bast, A de Boer (2020).'Should botanical health claims be substantiated with evidence on traditional use? Reviewing the stakeholders' arguments', *PharmaNutrition* 14, 100232.

76 R Anton, M Serafini, L Delmulle (2012). 'Traditional knowledge for the assessment of health effect for botanicals – a framework for data collection.', *European Food and Feed Law Review* 7, pp. 74-80; S Geurts (2018). 'Health claims and botanicals: how to proceed with European harmonisation', *European Food and Feed Law Review* 13, pp. 29-33; A Kusar, I Pravst (2022). 'Exploitation of the traditional evidence for botanical health claims on foodstuffs', *Journal of Functional Foods* 89, 104936; Lenssen et al. (2020). supra note 76; and KGM Lenssen, A Bast, A de Boer (2022). 'The complexity of 'traditional use' to prove health effects: a critical perspective on botanical health claim substantiation', *Trends in Food Science & Technology* 120, pp. 338-343.

77 SWD(2020) 95 final, pt 1.

78 Art. 1(1) NHCR.

79 SDW(2020)95 final, pt 1.

respect, we focus mainly on the botanical claims currently falling under the transitional measures, as well as the risk assessment requirements for health claims.

The Court of Justice of the European Union exercises its function through references preliminary ruling references and in various other categories of proceedings. In terms of this research paper, the relevant proceedings analysed are requests for preliminary rulings, appeals from the ruling of the General Court (by the Court of Justice); and claims on failure to act as well as claims on actions for annulments (by the General Court).

Following Article 267 TFEU, national courts may refer an issue to the CJEU for a preliminary ruling. Requests for preliminary rulings can be made on questions related to the interpretation of the EU Treaties or the validity and interpretation of acts of the EU institutions, bodies, offices or agencies when such a question is raised in a case pending before that national court or tribunal. A national court determines the need for a request for a preliminary ruling to the CJEU. National courts can do so when they consider that such a decision is necessary for this court to give a judgement, but – unless there is well-established case law on the point or there is no reasonable doubt about the correct interpretation of EU law – courts are required to bring a request for a preliminary ruling before the Court when a question is raised in the context of a case that is pending before a court or tribunal against whose decisions there is no judicial remedy under national law[80]. The CJEU provides its ruling on the specific issue of EU law addressed to it and they are delivered to the particular national court that posed the request. The judgements given in response to requests for preliminary rulings in one Member State are considered to have a harmonising influence on the interpretation and application of EU law in other Member States[81], as they are binding both on the referring court and on all courts in Member States[82].

Article 263 TFEU deals with the review of the legality of EU acts and deals with claims that directly challenge the legality of EU acts. For a claim to be successful, it has to meet five conditions: (i) the body must be amenable to judicial review; (ii) the type of act in question must be open to challenge; (iii) the claimant must have a standing to act in that position ('locus standi'); (iv) the illegality must be in the scope of Article 263 TFEU; and (v) the time limits set in Article 263 TFEU have to be respected. The claims on failure to act are based on Article 265 TFEU, which defines the corresponding requirements for standing and time limits. A failure to act can be raised only against an institution, body or agency that has been called upon to act[83]. The statute of the Court of Justice of the European Union determines the conditions under which an appeal on the ruling of the General Court may be brought before the Court of Justice[84].

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80 Recommendations to national courts and tribunals in relation to the initiation of preliminary rulings proceedings (2019/C 280/01). *OJ C 380*, pp. 1-9; Article 267 TFEU (para 2 and 3).

81 P Craig, G de Burca (2020). Chapter 13: 'Preliminary rulings', pp. 442-484. In: *EU law – Text, cases, and materials*, eds P Craig, G De Burca. ISBN: 9780198856641. Oxford: Oxford University Press; B Schima (2019). 'Article 267 TFEU'. pp. 1822-1840. In: *The EU Treaties and the Charter of Fundamental Rights: A Commentary*, eds M Kellerbauer, M Klamert, J Tomkin. ISBN: 9780198794561. Oxford: Oxford University Press.

82 2019/C 280/01, *supra* note 81.

83 B Schima (2019). 'Article 263 TFEU'. pp. 1798-1813. In: *The EU Treaties and the Charter of Fundamental Rights: A Commentary*, eds M Kellerbauer, M Klamert, J Tomkin. ISBN: 9780198794561. Oxford: Oxford University Press.

84 Statute of the Court of Justice of the European Union (consolidated version), accessible via https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-08/tra-doc-en-div-c-0000-2016-201606984-05_00.pdf (Last accessed 27 August 2023).

1.3. Methodology

Desk research was conducted for the analysis described in this research paper. First, judgments of the CJEU were searched in the EUR-Lex and CURIA databases and analysed[85]. This resulted in the identification of 22 cases referred for a preliminary ruling, or concerning appeals, actions for failure to act or annulment, further discussed in subsequent sections. The judgments as well as CJEU Annual reports, opinions of the Advocate Generals, case law commentaries and other scientific papers written about the included cases were analysed. Additionally, discussions, commentaries and other grey literature were used to deepen the analyses.

Evidence was collated by conducting literature searches to identify relevant academic literature addressing either Regulation (EC) No 1924/2006 and EFSA's assessment procedure; or Regulation (EC) No 1924/2006 and the (national) enforcement, implementation and application in Member States; both providing general insights and, in particular, identifying information on regulating botanical-related health claims. Scientific papers from different domains were included, to allow for an interdisciplinary approach to conducting the study. Included papers were for example written by legal scholars, nutritional scientists, economic scholars, and others; and included case notes, opinion papers, as well as studies discussing the effectiveness, efficiency, relevance, coherence and EU-added value of the NHCR and the impact of case law on the development of the legal framework. Additionally, other relevant sources addressing these topics were included in the systematic analysis, including, e.g. monographs, working papers, and white papers. This desk research approach resulted in a systematic analysis of case law and a narrative review of the literature, as presented in this report. This research paper does not seek to provide a legal analysis of the CJEU case law. Its multidisciplinary approach offers findings on the implementation and application of the NHCR in practice throughout the more than fifteen years it has been in force.

[85] EUR-Lex, https://eur-lex.europa.eu/homepage.htm; CJEU website > Access to online Reports of Cases > Search for, https://curia.europa.eu/juris/recherche.jsf?language=en.

2. Overview and analysis of CJEU case law

2.1. Main issues of legal discussion at EU level and in Member States

Since 2009, the CJEU has issued rulings on several cases that affect the interpretation and implementation of the NHCR. So far, Court judgments have addressed: (i) the definition of a health claim; (ii) the use of general health claims; (iii) evidence requirements for (a) general health claims and (b) specific health claims (with EFSA's role specifically); (iv) the application of transitional measures for (a) trademarks or brand names and (b) botanicals; (v) the application of the NHCR in governing commercial communication directed towards health care professionals; (vi) the classification of products as foodstuffs or medicinal products; and (vii) other relevant issues. These rulings will be briefly discussed in this chapter.

2.1.1. Defining the concept of health claims

Up to July 2023, Member State courts have referred a total of 10 cases to the CJEU related to the NHCR for preliminary rulings, of which one case was withdrawn[86]. Two of these cases, Cases C-544/10 and C-299/12, addressed the definition of 'health claims' under Article 2(2)(5) and Article 2(2)(6) of the NHCR. In the Deutsches Weintor case[87], the CJEU was requested to issue a preliminary ruling *inter alia* on whether the statement 'gentle acidity/easily digestible' used on wine would be considered a health claim under Article 2(2)(5) of the NHCR. While Land Rheinhald-Pfalz issued a broad interpretation of the definition of claims, the producer believed that this was not a health claim as it referred to 'general well-being and not health'. The referring court wondered whether this broad interpretation was indeed appropriate; and whether a health claim could relate to something being less harmful when compared to other products. While some scholars had expected the definition to be interpreted narrowly because it is a restrictive measure[88], the CJEU confirmed a broad interpretation of what constitutes a health claim as defined in the NHCR. Next to longer-term effects originating from the consumption of certain foods or food ingredients, short-term 'relationships' were also considered by the Court to fall under this definition: 'The definition [of a health claim in the NHCR] provides no information as to whether that relationship must be direct or indirect, or as to its intensity or duration. In those circumstances, the term 'relationship' must be understood in a broad sense'[89]. Also, the term refers to 'both temporary or fleeting effects […] and those of the repeated, regular, even frequent consumption of such a food'[90]. Since such a statement could positively influence a consumer to choose and consume this product[91], the Court confirmed that this should be seen as a health claim, also following the recitals of the NHCR[92]. The 'relationships' highlighted by the Court do not merely cover relationships describing health benefits of consumption, it was also deemed to encompass the absence of negative effects that can follow from consuming a certain product as is the case with wine – it is considered a beneficial nutritional or

86 Reference for a preliminary ruling from the Bundesgerichthof (Germany) lodged on 4 February 2011. *Schutzverband der Spirituosen-Industrie eV v Sonnthurn Vertriebs GmbH* (Case C-51/11) [2011] OJ C 139, p. 12.

87 Case C-544/10 *Deutches Weintor eG v Land Rheinland-Pfalz* [2012] ECLI:EU:C:2012:526.

88 M Inglese (2013). 'Do Consumers Have the Right to Drink Healthy Wine? An Appraisal of the Deutsches Weintor Case', *European Journal of Health Law* 4, p. 409.

89 Case C-544/10, para. 34.

90 Case C-544/10, para. 36.

91 Case C-544/10, para. 37.

92 T Mylly (2013). 'CJEU Approves Ban on Health Claims Related to Alcoholic Beverages', *European Journal of Risk Regulation* 2, pp. 271-274.

physiological effect[93]. Finally, the Court judged that the consequence of prohibiting claims on wine was proportionate. While some scholars suggest that this 'right to health' – and the Commission's efforts to restrict alcohol consumption in line with this – thereby overrules the right of consumers to be protected from false, ambiguous or misleading information[94], as well as the right to freedom of expression[95]; the Commission sees this as a proportionate measure. The restriction of using health claims on alcoholic beverages merely prohibits the marketing of a product on the basis of health effects but does not affect the right to general marketing or sales of such products[96]. The Deutsches Weintor case is seen as a landmark decision in the interpretation of defining health claims, confirming the broad scope of application of the NHCR[97] and restricting the possibility to provide information about less harmful or healthier substances in alcoholic beverages[98] to protect consumers' health.

In the Green-Swan Pharmaceuticals case[99], the Court provided a preliminary ruling in three questions of the Czech Supreme Administrative Court regarding (i) the interpretation of a claim under Article 2(2)(6) referring to reducing disease risk, without explicitly mentioning the reduction of a risk factor in the disease described in the claim; (ii) whether commercial communications on a product's packaging also fall under the transitional measures of Article 28(2) and thus should be seen as a trademark or brand name; and (iii) whether all trademarks on foods on the market could benefit from the transitional measures in Article 28(2). The CJEU confirmed that when reference is made to a risk factor in commercial communications by using 'helps to …' in that communication – even though it does not state whether there is a ''significant' reduction of a risk factor in the development of a disease'[100] – the suggestion or implication of such an effect[101] makes it a health claim under Art 2(2)(6). Secondly, the Court confirmed that commercial communications cannot, in general, be seen as trademarks or brand names[102]. As Verhoestraete (2013) described, the CJEU thereby *'clarifies that the provision – obviously! – does not apply to all foods which were on the market prior to 1 January 2005 or to all foods which were on the market with a trademark or brand name which existed before 1 January 2005'*[103]. Only when such communications are indeed protected, which is for national courts to ascertain[104], can they fall under the transitional measures of Article 28(2). For the third question, the CJEU stipulated that the NHCR applies to commercial communications on foods, and not to food products themselves[105], and only to trademarks and brand names that can be 'construed as a nutrition or health claim'[106]. The transitional measures of the NHCR[107], were

93 *Ibid.*

94 Case C-544/10, paras 52-53; Inglese (2013), *supra* note 89.

95 Mylly (2013). *supra* note 93; A Meisterernst (2012). 'No Oil on Carrots! 5 Years of Regulation (EC) No. 1924/2006 on Nutrition and Health Claims Made on Food', *European Food and Feed Law Review* 7(4), p. 170.

96 Case C-544/10, para. 57.

97 Mylly (2013). *supra* note 93 González Vaqué, Romero Melchor (2014). *supra* note 62; K Verzijden (2013). 'How Easily Digestible Wine and Health Chocolate Attempt to Seduce Consumers - Recent Decision on Health Claims', *European Food and Feed Law Review* 8(1), pp. 67-69.

98 Mylly (2013). *supra* note 83.

99 Case C-299/12 *Green – Swan Pharmaceuticals CR, a.s. v Státní zemědělská a potravinářská inspekce, ústřední inspektorát* [2013] ECLI:EU:C:2013:50.

100 Case C-299/12, para. 14.

101 Case C-299/12, para. 24.

102 Case C-299/12, paras 27-32.

103 F Verhoestraete (2013). 'The Court of Justice of the European Uniform Confirms the Obvious and Clarifies the Trade Marks and Brand Names Derogation', *European Food and Feed Law Review* 8(5), pp. 338-343, p. 343.

104 Case C-299/12, para. 31.

105 Case C-299/12, para. 34; Verhoestrate (2013), *supra* note 104.

106 Case C-299/12, paras 35-37; Verhoestrate (2013), *supra* note 104.

107 Verhoestrate (2013), *supra* note 104, p, 343: in the development of the NHCR, the European Parliament tried to exclude brand marks and tradenames from the scope of the NHCR but the Commission and Council believed that everything that can be understood as nutrition or health claim should be addressed by the NHCR. The transitional measures

confirmed by the Court to only relate to those brand names and trademarks on the market before 1 January 2005, which should be seen as a nutrition or health claim[108]. In line with the Deutsches Weintor case, this case confirms the broad interpretation of health claims and the broad coverage of the NHCR[109]. The Green-Swan Pharmaceutical case is thereby seen as an important case for defining disease risk reduction claims – and thus affecting consumer protection. As the case further clarifies the application of transitional measures for trademarks and brand names, it has also supported the functioning of the internal market by ensuring that these measures will be understood in the same way throughout Member States when enforcing the NHCR.

In addition to both cases referred for a preliminary ruling, an additional case related to the interpretation of health claim definitions was presented to the Court. In Case T-17/12[110], two applicants appealed the decision to reject the application for authorisation of a disease risk reduction claim submitted to the Commission. The applicants thereby applied for the annulment in part of the Commission Regulation describing the rejection[111]. This rejection was based on the interpretation of health claims under Article 2(2)(6), the category of disease risk reduction claims. The proposed health claim submitted by the applicants, *'Regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance'*[112] was not considered to be sufficiently linked to the reduction of a risk factor[113]. The applicants argued that the NHCR did not require the designation of a risk factor[114]. As there are specifics laid down in Articles 14(1)(a) and 15(3) for 'risk factors'[115], in line with other broad interpretations of health claims as such (as in Case C-299/12, discussed previously), the applicants claimed that 'any reduction of disease risk' should be included[116] and thus, their claim should be considered to fall under the category of disease risk reduction claims. The CJEU, however, disagreed and ruled that the ''risk factor' element of the concept' [of disease risk reduction claims] could 'not be ignored'[117]. To allow for authorisation of a claim under Article 14(1)(a), claims thus needed to include 'a designation of a risk factor in the development of a disease', next to the designation of a disease as such, and a relationship should be established between consuming the food and the risk factor[118]. Such clear designation of risk factors was also considered to support the distinction between food products, that can claim to affect one of the multiple risk factors in disease development[119], and medicinal products, which can be used to prevent, treat or cure a disease[120]. Furthermore, the other eight pleas presented in this case, including the argument that such a decision should not be a regulation but a decision, following Article 17 of the NHCR[121], were rejected by the CJEU. The CJEU thus confirmed the rejection of the authorisation of the putative disease risk

described in Art. 28(2) can therefore be seen as 'a compromise to respect acquired rights' in the move towards a harmonised system.

108 Case C-299/12, para. 38; Verhoestrate (2013). *supra* note 104; L Evans (2014). 'Recent Judgments on the Health Claims Regulation: A Journey through the Colourful World of Health Claims Made on Food Stopping at Luxembourg and Karlsruhe', *European Food and Feed Law Review* 9, pp. 233-240.

109 Evans (2014), *supra* note 109.

110 Case T-17/12 *Hagenmeyer & Hahn v European Commission* [2014] ECLI:EU:T:2014:234.

111 Commission Regulation (EU) No 1170/2011 of 16 November 2011 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk, *OJ L* 299, p. 1.

112 Recital 5 Commission Regulation (EU) No 1170/2011.

113 Recital 6 Commission Regulation (EU) No 1170/2011.

114 Case T-17/12, para. 64.

115 Case T-17/12, para. 69.

116 Case T-17/12, para. 70.

117 Case T-17/12, para.71.

118 Case T-17/12, para. 73.

119 Case T-17/12, para. 75.

120 Case T-17/12, para. 76.

121 Case T-17/12, para. 64; M Liebmann (2013). 'The Water Claim Proceedings: Questions of Justification of the Claim – And Even More on Questions of Admissibility', *European Food and Feed Law Review* 8(5), pp. 344-348.

reduction claim, and most importantly, clarified the definition and subsequent requirements for these Article 14.1(a) claims.

2.1.2. Using general health claims

A preliminary ruling was requested by the German Federal Court of Justice in the Schwabe case[122], to gain insights into how specific health claims needed to be provided when using general, non-specific health-related benefits on labels and whether evidence should be provided on such general health claims (addressed in the next section). The Court highlighted that the NHCR requires Article 10(3) or general health claims to be 'accompanied by' a specific health claim that is found in the list of authorised claims[123]. In this case, a general claim was provided front-of-pack, the specific health claim was described on the back of the pack. The average consumer, being reasonably well-informed, reasonably attentive and circumspect, should be enabled to understand the link between the general claim front-of-pack and the more specific claim described back-on-pack, both via the content and the context of the claim: the 'accompanying' concept should be understood as having a substantive and a visual dimension[124]. Implementing Decision 2013/63[125] also stipulates that 'accompanying' is understood as 'next to' or 'following'[126]. Since general health claims are seen as exceptions to the general prohibition of claims unless they are explicitly allowed, the Court judged that the 'accompanying' requirement should be interpreted strictly[127]. Therefore, if such a link between claims cannot be observed because there is no spatial link, with the claims being presented next to each other, a visual link should be used (e.g., an asterisk) to support the connection between the claims[128]. This specification of requiring something alike an asterisk has been debated upon in literature[129]: the Implementing Decision adopting guidelines for the specific conditions for health claims in Article 10 of the NHCR seemed to have provided a stricter interpretation of the 'accompanied by' concept than the interpretation of the Court in this case. This requirement seems to have been disregarded by both the Court and the Advocate General, while the Commission had already provided clarification in an implementing act, which is legally binding[130]. In literature, Dr. Schebesta makes a critical note that this reasoning may lead to a situation where *'even when traders follow a legally binding guidance this does not provide legal certainty that compliance with the regulatory framework is ensured'* [131]. Next to creating legal uncertainty, this is described to potentially undermine the value of EU secondary legislation, such as implementing acts.

2.1.3. Evidence requirements for health claims

For general health claims

Even though the Court did not issue a preliminary ruling for one of the questions referred by the German Federal Court of Justice in 2015 (in Case C-177/15[132], see section 2.1.4 for a full discussion), Advocate General Bobek[133] did answer the question of whether direct evidence should be provided

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122 Case C-524/18 *Dr Willmar Schwabe GmbH & Co.KG v Queisser Pharma GmbH & Co. KG* [2020] ECLI:EU:C:2020:60
123 C-524/18, para. 34.
124 Case C-524/18., para. 40.
125 Directive 2013/63/EU.
126 Case C-524/18, para. 39.
127 Case C-524/18, para. 38; H Schebesta (2020). 'On Legal Value of Implementing Acts at the CJEU', *Journal of European Consumer and Market Law* 9(6), pp. 248-252.
128 Case C-524/18, paras 47-48.
129 Schebesta (2020). *supra* note 128.
130 Schebesta (2020). *supra* note 128.
131 Schebesta (2020). *supra* note 128, p. 251.
132 Case C-177/15 *Nelsons GmbH v Ayonnax Nutripharm GmbH and Bachblütentreff Ltd* [2016] ECLI:EU:C:2016:888.
133 Case C-177/15 *Nelsons GmbH v Ayonnax Nutripharm GmbH and Bachblütentreff Ltd* [2016] ECLI:EU:C:2016:888. Opinion of Advocate General Bobek delivered on 22 June 2016.

when referring to general, non-specific health benefits that are seen as general health claims under Article 10(3) of the NHCR. He highlighted that because Article 10(3) should be accompanied by specific, pre-authorised health claims under Article 13 or 14[134], references to general benefits are indirectly supported by evidence of those authorised claims[135]. He stipulated that even though general references are too general to be specifically evaluated on their scientific merit[136], a general exception to such evidence requirements would be problematic[137] as the NHCR aims to protect consumers and specifically aims to ensure that no misleading claims – that 'have no basis in science' – are found on foods[138]. Article 10(3) therefore cannot be read as a 'general exemption to the evidentiary requirements' for health claims laid down in the NHCR[139], but thanks to the link with the specific health claims, these general, non-specific benefits are supported with indirect evidence.

In the Schwabe case[140], Advocate General Hogan highlighted in his opinion[141] that he considered that the second request for a preliminary ruling had already been addressed by Advocate General Bobek in Case C-177/15 Nelsons GmbH – described in the previous paragraph – even though in that case, no judgement had been provided to answer the question related to evidence requirements for general claims[142]. In line with AG Bobek, AG Hogan concluded that for Article 10(3) health claims, no direct scientific evidence was required, but indirect evidence – the evidence supporting the related Article 13 or Article 14 claim – is essential[143]. The Court indeed ruled that such Article 10(3) claims are sufficiently substantiated with generally accepted scientific evidence – requirements laid down in Articles 5(1)(a) and 6(1) of the NHCR – when the specific health claims that accompany the general, non-specific claim are supported by evidence 'which has been verified and authorised, provided that the latter claims are include in the list provided for in Article 13 or Article 14'[144]. Article 10(3) claims are therefore already considered sufficiently supported – albeit indirectly – by the generally accepted scientific evidence that has been used for authorised Article 13 or 14 claims. No separate evidence thus needs to be provided for the more general claim made.

For specific health claims

One of the important arguments in Case T-296/12[145] to request the annulment of Commission Regulation (EU) No 432/2012, and the list of on hold claims raised by the Health Food Manufacturers' Association and others argued that the scientific opinions requested stem from 'applying improper assessment criteria'[146]. The CJEU ruled, however, firstly that requesting these scientific opinions does not infringe Article 13 of the NHCR[147]. The evaluation criteria were not considered erroneous for focusing on 'significant effects' while Article 5 of the NHCR requires that 'a' beneficial physiological

134 Opinion AG Bobek, supra note 134, para. 73.
135 Opinion AG Bobek, *supra* note 134, para. 113.
136 Opinion AG Bobek, *supra* note 134, para. 68.
137 Opinion AG Bobek, *supra* note 134, para. 69.
138 *Ibid*.
139 Opinion AG Bobek, *supra* note 134, para. 70.
140 Case C-524/18.
141 Case C-524/18 *Dr Willmar Schwabe GmbH & Co.KG v Queisser Pharma GmbH & Co. KG* [2020] ECLI:EU:C:2020:60 Opinion of Advocate General Hogan delivered on 12 September 2019.
142 Schebesta (2020), *supra* note 128.
143 Opinion AG Hogan, *supra* note 142, paras 71-72; Schebesta (2020), *supra* note 128.
144 Case C-524/18, para. 58.
145 Case T-296/12 *Health Food Manufacturers' Association and Others v Commission* [2015] ECLI:EU:T:2015:375
146 González Vaqué, Romero Melchor (2014). *supra* note 62, p. 291: 'In case T-296/12 the applicants mainly argue that the non-inclusion of many health claims in the permitted list infringes the Claims Regulation by applying improper assessment criteria. For instance, it infringes the principle of good administration, legal certainty and the duty of collaboration with national food authorities, the obligation to provide adequate reasons, in addition to procedural flaws and general principles of law.'
147 Case T-296/12, para. 132.

effect is shown by generally accepted scientific evidence[148]. This is considered to follow from Article 5(1)(b) and (d)[149], in which it is stated that the expected quantity consumed contains a significant quantity of the nutrient or substance that elicits the nutritional or physiological effect. Secondly, the applicants criticise the overemphasis on the cause-and-effect relationship[150], but the Court[151] describes that this results from Reg 1924/2006 and how 'health claims' are understood in Article 2(5)(5): as a relationship between a food and a beneficial effect. To determine that a claim is justified, this cause-and-effect relationship should be determined from the evidence. Thirdly, explicit characterisation of the food (challenged by the applicants[152]) is believed to be important to allow for determining 'whether the scientific substantiation for the claim is relevant'[153]. The applicants fourthly challenge that the Commission has not correctly reviewed the requirement that claims must be well understood by the average consumer, following Art 13(1)(ii), as it 'permitted claims worded in complex scientific language'[154]. The Court rejects this argument because the applicants try to annul the list of authorised claims, and only claims on that list need to be well understood by the average consumer. The evaluation criteria applied by the Commission and EFSA during the evaluation are thus not deemed erroneous by the CJEU[155].

The applicants in this case finally also alleged that the principles of good administration and legal certainty were infringed with these scientific assessment procedures[156]. The CJEU ruled that legal certainty is not infringed by the timing nor the approach to issuing the guidance documents (after the deadline of submitting Article 13(1) claims), and thus the assessment criteria[157]. The CJEU also ruled that the principle of good administration could not be infringed in this situation, as it is a measure of general application and not an individual decision[158]. The applicants' complaints related to the assessment criteria were therefore also rejected[159]. As discussed in section 2.1.4 below, the CJEU finally ruled that the applications to annul Regulation (EU) No 432/12 and the list of claims on hold was deemed inadmissible[160].

In Case C-296/16[161], Dextro Energy GmbH & Co appealed the decision of the General Court in Case T-100/15[162]. In the original case, Dextro applied for the annulment of Commission Regulation 2015/8[163], in which the refusal to authorise five health claims made on foods was described. Under Article 13(5), Dextro had requested the authorisation of five health claims related to glucose and the energy-yielding metabolism. In spite of positive scientific opinions issued on the scientific substantiation of these claims, the Commission decided to not authorise the claims based on general nutrition and health considerations: the claims could result in conveying 'a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which […] national and international authorities inform the consumer that their intake should be reduced. Therefore, such a claim does not comply with [the NHCR] which foresees that the use of claims

148 Art. 5(1)(a) NHCR.
149 Case T-296/12, para. 136.
150 Case T-296/12, para. 137.
151 Case T-296/12, para. 138.
152 Case T-296/12, para. 139.
153 Case T-296/12, para. 140.
154 Case T-296/12, para. 141.
155 Case T-296/12, para. 142.
156 Case T-296/12, paras 144-156.
157 Case T-296/12, para. 152.
158 Case T-296/12, para. 155.
159 Case T-296/12, paras 153 & 156.
160 Case T-296/12, paras 182-183; 191-192; 194-197; 203-205; 210-212.
161 Case C-296/16 *Dextro Energy GmbH & Co. KG v Commission* [2017] ECLI:EU:C:2017:437.
162 Case T-100/15 *Dextro Energy v Commission* [2016] ECLI:EU:T:2016:150.
163 Commission Regulation (EU) No 2015/8 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. OJ L 3, pp. 6-9.

should not be ambiguous or misleading'[164]. The applicant pleaded, *inter alia,* that such a rejection was not proportionate, as 'advertising is protected by freedom of expression, freedom of communication or information, and freedom to conduct a business, as defined and protected by the Charter of Fundamental Rights of the European Union'[165]. They further claimed that the principle of proportionality was infringed by the General Court in Case T-100/15: as the NHCR aims to objectively inform interested consumers about 'scientifically established links between the consumption of the products in question and health and, more specifically, about the physiological effects of consuming those products'[166]. A rejection of these applications 'would be contrary to that objective'[167] as it does not allow the food business operator to provide scientifically substantiated information[168]. The CJEU however disagrees; it does not believe that there are contradictions[169], because 'information which proves to be incomplete, ambiguous or misleading and which may mislead the consumer cannot be protected under the freedom of expression and information of the entrepreneur and the freedom to do business', as previously ruled in the Neptune Distribution case, Case C-157/14[170] on claims on mineral waters (discussed in section 2.1.7). It thereby confirmed that the scientific opinion issued by EFSA is only one of the elements considered when deciding on the authorisation of a health claim, as described in Article 18(4) of the NHCR[171]. The CJEU also confirms[172] the position of the General Court that the Commission does not infringe the principle of proportionality, as 'the Commission has a wide discretion in an area, such as that provided for by regulation No 1924/2006, which involves political, economic and social choices on its part, and in the context of which it is called upon to carry out complex assessments.'

Case T-344/12[173], further discussed in section 2.1.4, addresses the role of EFSA's scientific opinions. The applicants challenged the evaluations. The Court however ruled that these should be seen as 'intermediary steps in the procedure which are not capable of affecting the legal situation of third parties' that do not produce legal effects[174], and thus could not be subject to an action[175]. This case thereby clarifies the position of EFSA's scientific opinions as being 'intermediary steps'[176]. The Court also specifies that the opinions are published following the procedure described in the NHCR in Article 13(3), and thus 'acts in the capacity of an authority performing scientific and technical tasks with no possibility of adopting acts having legal effects on the legal situation of third parties'[177]. These cannot be subject of an action for annulment, as they are excluded from the scope of Article 263 TFEU[178]. This ruling thereby confirms the separation of the risk assessment and risk management procedures under the NHCR. Consequently, legal actions cannot be taken against scientific opinions, but only against a subsequent authorisation decision of the Commission.

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164 Commission Regulation (EU) No 2015/8, recital 14.
165 Case C-296/16, para. 38.
166 Case C-296/16, para. 39.
167 Case C-296/16, para. 40.
168 Case C-296/16, para. 41.
169 Case C-296/16, para. 55.
170 Case C-296/16, para. 54.
171 Case C-296/16, paras 79-80; N Carbonelle & C Lindenthal (2017). Health Claims: CJEU confirms a claim can be refused on grounds of generally accepted nutrition and health principles despite scientific substantiation. Available via https://www.twobirds.com/en/insights/2017/global/health-claims-cjeu-confirms-a-claim-can-be-refused (Last accessed 11 August 2023).
172 Case C-296/16, para. 44.
173 Case T-334/12 *Plantavis GmbH and NEM v Commission and EFSA* [2015] ECLI:EU:T:2015:376.
174 Case T-334/12, para. 63..
175 Case T-334/12, para. 65
176 Case T-334/12, para. 63.
177 Case T-334/12, para. 60.
178 Case T-334/12, para. 61.

2.1.4. Transitional measures

Both questions referred by national courts to the CJEU for a preliminary ruling and appeal cases and other cases were addressed by the CJEU related to the transitional measures in Article 28, specifically related to trademarks and brand names (Article 28(2)), and related to claims awaiting an authorisation decision (Article 28(5) and 28(6)).

Article 28(2) – trademarks and brand names

The Green-Swan Pharmaceuticals case[179] included two questions related to the understanding of the transitional measures for trademarks and brand names (under Article 28(2) of the NHCR). The questions referred for a preliminary ruling addressed firstly whether these transitional measures also covered commercial communication provided on the packaging of a product and whether these covered all trademarks on foods in general. As described in section 2.1.1, the CJEU confirmed 'the obvious'[180]: generally speaking, commercial communications cannot be seen as trademarks or brand names and the transitional measures merely covers those trademarks and brand names that can be understood as nutrition or health claims[181].

The Federal Court of Justice in Germany decided to refer different questions to the Court for a preliminary ruling in the case against Nelsons GmbH[182]. Together with questions about whether liquids with an alcohol content of 27 % by volume, from which drops are used, should be seen as beverages containing more than 1.2 % by volume of alcohol – and thus, whether the NHCR prohibits the use of claims on such products or whether evidence must be provided when referring to general, non-specific benefits (following Article 10(3) of the NHCR), the case addressed the question as to whether the transitional measures for brand names and trademarks merely applied to products marketed as 'food' or whether they should also apply to products that were first marketed as a medicinal product before 1 January 2005. The Court confirmed that if the substantive characteristics, the physical characteristic of the product and the trademark or brand name, remained the same, the product should be covered by the measures as this article refers to 'products bearing a trademark or brand name 'existing' before 1 January 2005'[183]. In this case, this change to the legal categorisation of the product followed from a Court decision issued by the Upper Regional Court in Hamburg[184]. Because the products had already been marketed as foods since 2007 and were no longer considered as foods at the time of the proceedings, and because the product's name and its characteristics remained the same, the transitional measures applied[185]. The Court determined that, 'given the nature of the main proceedings', merely answering this third question was relevant[186]. This case highlighted that the transitional measures applied in this specific case, as the change of product category happened because of a legal requirement and the product itself did not change: the NHCR applied to the product.

Article 28(5) and 28(6)

In Case C-609/12[187], the German Bundesgerichtshof asked the Court whether information requirements when using claims, laid down in the NHCR[188], should already be complied with in 2010.

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179 Case C-299/12.
180 Verhoestraete (2013), *supra* note 104.
181 Case C-299/12, paras 27-32.
182 Case C-177/15.
183 Case C-177/15, paras 46-47.
184 Opinion AG Bobek, *supra* note 134, para. 80.
185 Opinion AG Bobek, *supra* note 134, para. 48.
186 Opinion AG Bobek, *supra* note 134, para. 49.
187 Case C-609/12 *Ehrmann AG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV* [2014] ECLI:EU:C:2014:252.
188 Art. 10(2) NHCR.

A food business operator advertised their product to be 'as important as a daily glass of milk'[189] but believed this merely addressed the quality of their product[190]. Also, due to the transitional measures described in Article 28(5) of the NHCR, the requirement of Article 10(2) was believed not to be applicable at the time of using the slogan[191]. The referring court confirmed that the statement did fall under the definition of a health claim (under Article 2(2)(5)), as did Advocate General Wathelet[192], but wondered whether the food business operator was already obliged to provide the information requested in Article 10(2) in 2010. The Court confirmed the opinion of the Advocate General[193] on the need for this information to ensure consumer protection, 'also where [a] claim is made in accordance with the transition measure under Article 28(5)'[194]. Even though transitional measures are thus provided for in the NHCR, claims have to live up to other requirements listed in the NHCR as the regulation has been in force since 1 July 2007.

In Case C-363/19[195], the Patent and Market Court in Stockholm, Sweden, referred questions to the Court of Justice of the EU to gain an understanding of whether specific function (Article 13) claims as well as related general health claims (Article 10(3)), falling under the transitional measures of Article 28(5), should be substantiated by scientific evidence, as detailed in Articles 5 and 6 of the NHCR; and if so, with whom the burden of proof should lie and whether the NHCR governs the specific evidence requirements for such claims. The CJEU confirms that food business operators can use claims that await further decisions of the Commission – the 'on hold' botanical claims under Article 13 – but these must live up to the other requirements laid down in provisions of the NHCR and potentially existing national provisions[196]. In Article 28(5), reference is only made to the claims provided for in Article 13(1), and thus, Article 10(3) claims are not dealt with under these transitional measures. Articles 5 and 6, in particular, stipulate that evidence is needed to firstly support that certain substances are present in a product and secondly substantiate the relationship between consuming a substance and a beneficial nutritional or physiological effect, food business operators 'should be able to justify, by means of generally accepted scientific evidence, the claim which it uses'[197]. As the claims are made 'under the responsibility of food business operators'[198] and these organisations 'shall justify the use of a claim'[199]: the burden of proof for these claims lies with the operator[200]. Finally, the Court stipulates that there are no requirements found in the NHCR governing 'how evidence is to be provided or the methods of obtaining that evidence' and thus, national law deals with these questions[201]. In news items[202], this ruling has been described as a 'win' for using 'traditional use' evidence to support their botanical claims, as the CJEU has not specified any evidence requirements. So far, this has not been further commented upon in literature.

189 Case C-609/12, para. 15.
190 Case C-609/12, para. 18.
191 Case C-609/12, para. 18.
192 Case C-609/12 *Ehrmann AG v Zentrale zur Bekämpfung unlauteren Wettbewerbs eV* [2014] ECLI:EU:C:2014:252 Opinion of Advocate General Wathelet delivered on 14 November 2013, para. 62.
193 Opinion AG Wathelet, *supra* note 193, paras 90, 97, 98.
194 Case C-609/12, para. 41.
195 Case C-363/19 *Konsumentombudsmannen v Mezina AB* [2020] ECLI:EU:C:2020:693.
196 Case C-363/19, para. 41.
197 Case C-363/19, para. 54.
198 Art. 13(3) NHCR.
199 Art. 6(2) NHCR.
200 Case C-363/19, paras 48, 52.
201 Case C-363/19, para. 53.
202 K Askew (2020). Could latest health claims ruling boost botanicals? 'It's time for the European botanicals industry to use these opportunities'. Available via https://www.foodnavigator.com/Article/2020/10/05/Could-latest-health-claims-ruling-boost-botanicals-It-s-time-for-the-European-botanicals-industry-to-use-these-opportunities# (Last accessed 12 August 2023).

As well as different requests for preliminary rulings, other Court actions have addressed the transitional measures. Firstly, Case T-354/12[203] in which Afepadi, the Spanish association of special foods manufacturers, together with four other companies addressed two elements[204]: firstly, they request that recitals 11, 14 and 17 in the preamble to Commission Regulation (EU) No 432/2012 be annulled; secondly, they challenge the Union Register. The recitals address the on hold claims under Article 28(5) and (6): the establishment of the Union Register in Article 20(1) of the NHCR and the classification of products as foodstuffs or medicinal products'. The applicants believed that these recitals were detrimental to their interests[205]. Moreover, the applicant argued that 'in the interest of legal certainty [the authorised list of Article 13 claims] must result from a legislative act'[206]. The CJEU however ruled that the claims were inadmissible: recitals do not produce legal effects[207] and can therefore not be challenged in court. And while the second request could be interpreted in three different ways[208], all three interpretations would lead to an inadmissible request[209].

Similarly to the above mentioned claims, Case T-296/12[210], also dealt with a request to annul Commission Regulation (EU) No 432/2012 on the positive list of Article 13 claims, as well as the Commission Decision of 16 May 2012 that resulted in the adoption of a list of permitted claims and the list of on hold claims. The Health Food Manufacturers' Association and others argued, *inter alia*, that due to the on-hold status of the botanical health claims, the aim to develop one list had not been achieved and this was considered to lack a legal basis[211]. The Court, however, ruled[212] that the fact that this list was not adopted at once but rather gradually was not prohibited in Article 13 of the NHCR. The Court added that in spite of not making the timeline[213], this process did not infringe the principles of good administration[214] nor the principles of equal treatment and non-discrimination[215]. Similarly, the Court ruled that the adoption of the list did not create any legal uncertainty[216]: while legal certainty requires 'legal rules [to be] clear and precise, and their consequences foreseeable'[217], according to the Court this concept should not be understood as not allowing a situation that may be challenging to navigate. This for example is seen in the difference between the list of ID numbers representing the on hold claims, versus a clear-cut list of authorised claims. A second important issue addressed by the applicants in this case, is that the scientific opinions requested stem from 'applying improper assessment criteria'[218]. This is discussed in section 2.1.3 above. The Court finally considered that the applications to annul Regulation (EU) No 432/12 and the list of claims on hold inadmissible[219]. In particular, the Court highlighted the lack of clarity and precision on the grounds on which the second challenge was made, as it 'considers that the line of argument relied on by the applicant […] is manifestly insufficient to enable the complaints made by the applicants against the

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203 Case T-354/12 *Afepadi and Others v Commission* [2014] ECLI:EU:T:2014:798.
204 Action brought on 3 August 2012. *Afepadi and Other v Commission (Case T-354/12)* [2012] OJ C 29, p. 30.
205 González Vaqué, Romero Melchor (2014), *supra* note 62.
206 Action Case T-354/2012, *supra* note 205.
207 Case T-354/12, para. 33.
208 Case T-354/12, para. 38: 'firstly, as a claim that the Commission be ordered to adopt a normative act, or, secondly, as an action for omission, or, thirdly, as a ground of appeal in support of the claim for annulment that constitutes the first of the claims in the application.'
209 Case T-354/12, paras 37-46.
210 Case T-296/12 *Health Food Manufacturers' Association and Others v Commission* [2015] ECLI:EU:T:2015:375.
211 Case T-296/12, para. 55.
212 Case T-296/12, paras 67-68.
213 Case T-296/12, para. 74.
214 Case T-296/12, paras 94, 102, 103, 111.
215 Case T-296/12, para. 95.
216 Case T-296/12, paras 85-87.
217 Case T-296/12, para. 86.
218 González Vaqué, Romero Melchor (2014), *supra* note 62, p. 291.
219 Case T-296/12, paras 182-183; 191-192; 194-197; 203-205; 210-212.

Commission as the author of that list to be identified in a precise manner'[220] and thus the action was deemed inadmissible[221].

In Case T-334/12[222], Plantavis GmbH and NEM argue that the situation with some claims being on hold and others being rejected or authorised, is unclear and thus, Regulation (EC) No 1924/2006 should be deemed inapplicable and Commission Regulation (EU) No 432/2012 should be annulled. The applicants also challenged the Union Register and the evaluations conducted by EFSA. The Court ruled that the applicants did not show that they were directly concerned by Regulation (EU) No 432/2012[223]. The CJEU highlighted that on hold claims, pending evaluation, could still be used under the transitional measures of Article 28(5) and (6) (para 36) and disagreed with the applicants that the list of these claims was difficult to identify and thus, their complaint for a lack of clarity was rejected[224]. Following this dismissal, the request to declare the NHCR illegal is also dismissed[225]. As the Union Register (based on Article 20 of the NHCR) is not legally binding[226] and the evaluations of EFSA are merely 'intermediary steps in the procedure which are not capable of affecting the legal situation of third parties' that do not produce legal effects[227], both cannot be subject to an action and the requests of the applicants are considered inadmissible[228].

In Case C-637/15 P[229,] VSM Geneesmiddelen appealed the decision of the General Court in Case T-578/14[230] that their action[231] for 'failure to act' was inadmissible[232.] In Case T-578/14, VSM had claimed that 'the Court should declare that the Commission has unlawfully failed to initiate the assessment of Health Claims on Botanical Substances by EFSA', following Article 13(3) of the NHCR; or alternatively, 'annul the decision, allegedly contained in the Commission's letter of 29/06/2014, not to initiate the assessment of Health Claims on Botanical Substances by EFSA through the procedure foreseen by Article 13'[233]. The applicant argued that the Commission had failed to establish a complete list of permitted claims and the NHCR was considered not to allow the Commission to 'alter the procedural steps nor to extend the timelines'. In T-578/14, the General Court however agreed with the Commission that the action was inadmissible[234].The Court stipulated that the concept of 'failure to act', as defined in Article 265 TFEU, should be understood as 'a failure to take a decision or to define a position'[235]. Even though the reply of the Commission did not satisfy the applicant, this was deemed 'immaterial': when 'a measure different from that desired by the persons concerned has been adopted', this cannot be regarded as 'failure to act'[236.]. 'For the sake of

[220] Case T-296/12, para. 210.
[221] Case T-296/12, para. 212.
[222] Case T-334/12 *Plantavis GmbH and NEM v Commission and EFSA* [2015] ECLI:EU:T:2015:376.
[223] Case T-334/12, para. 45.
[224] Case T-334/12, paras 37-38.
[225] Case T-334/12, paras 52-53.
[226] Case T-334/12, para. 59.
[227] Case T-334/12, para. 63.
[228] Case T-334/12, para. 65.
[229] Case C-637/15 P *VSM Geneesmiddelen BV v Commission* [2016] ECLI:EU:C:2016:812.
[230] Case T-578/14 *VSM Geneesmiddelen v Commission* [2015] ECLI:EU:T:2015:715.
[231] Action brought on 1 August 2014. VSM Geneesmiddelen v Commission (Case T-578/14) [2014] OJ C 339, p. 26
[232] In their action (*supra* note 225), the applicant argues that following Article 13(3), the Commission had the obligation to adopt a list, latest by 31 January 2010, with all claims submitted by Member States. In a letter in 2014, the applicant called upon the Commission 'to instruct EFSA to resume without delay the assessment of health claims on botanical substances used in food, since it is strongly affected by the present legal backlog and uncertainty in the field of Health Claims on botanical substances used in food'. Even though the Commission responded that the assessment of botanical claims would not be initiated due to different concerns raised by Member States and stakeholders, the applicant set a deadline for resuming the assessment in a subsequent letter.
[233] Action Case T-578/14, *supra* note 225.
[234] Case C-637/15 P, paras 15-32.
[235] Case C-637/15 P, para. 20.
[236] Case C-637/15 P, para. 20.

completeness'[237], the Court analysed the arguments raised by the applicant. The Court judged that VSM could not substantiate why there would be an advantage to resuming the evaluation and authorisation procedure for botanical claims[238:] authorised claims are permitted following Regulation 432/2012 and those claims submitted can be made under the transitional measures of Article 28(5) and (6)[239]. The Court thus held that even if there were consequences for the applicant's legal certainty, still being allowed to make the on hold and potentially unsubstantiated health claims was an advantage for the applicant[240]. Secondly, the Court ruled that even though the Commission had not given a complete, definite decision on whether or not certain claims would be allowed, there were 'no unequal conditions of competition and no legal uncertainty on the market'[241]. The Court also highlighted in its ruling that the letter sent by the Commission in answering VSM 'could not be regarded as a challengeable act', it merely explained the reason to suspend the authorisation procedure[242]. As there are no clear rules in the NHCR for the Commission in adopting the positive list, and this is a complex technical assessment to be undertaken, the Commission 'enjoys a broad discretion'[243]. In the appeal case C-637/15 P, the applicant claimed *inter alia* that the order should be set aside, and repeated their claims made in the previous case[244]. The CJEU ruled that all six grounds of appeal were inadmissible[245.]. The CJEU for example ruled that the argument raised by VSM that the General Court erred in law by 'holding that the Commission enjoys broad discretion in its courses of action in the adoption of that list'[246,] this appeal was insufficiently coherent, clear and relevant and their 'line of argument does not specifically refer to the reasoning set out by the General Court'[247]. Even though both cases were considered inadmissible, the rulings highlight the Commission's wide discretion in the complex, technical assessments that need to be undertaken under the NCHR. It also highlights the position of the Court in determining that the 'on hold' list did not create legal uncertainty, and stipulates that having these claims on hold could lead to a more advantageous situation from having the claims assessed for authorisation.

The most recent appeals related to the NHCR are Joined Cases C-596/15 P and C-597/15 P[248], appealing the General Court's decisions in Cases T-619/14[249] and T-620/14[250]. Similar to Case T-578/14 discussed above, the applicants in Cases T-619/14[251] and T-620/14[252] argued that the

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237 Case C-637/15 P, para. 23.
238 Case C-637/15 P, para. 24.
239 Case C-637/15 P, paras 25-26.
240 Case C-637/15 P, para. 27.
241 Case C-637/15 P, para. 28.
242 Case C-637/15 P, para. 31.
243 Case C-637/15 P, para. 32.
244 Case C-637/15 P, para. 33.
245 Case C-637/15 P, para. 85. The six grounds of appeal raised by the applicant (para. 37) were: 'The first four grounds allege errors of law committed by the General Court in the assessment of: (i) compliance by VSM with the time-limits for actions for failure to act under Article 265 TFEU; (ii) its interest in bringing proceedings in the procedure before the General Court; (iii) the insufficient protection given to VSM and other food business operators by the transitional measures provided for in Article 28 of Regulation No 1924/2006; and (iv) the Commission's broad discretion under Article 13(3) of that regulation. The fifth ground alleges that the Commission, in failing to act, infringed its obligations under that regulation, Article 41 of the Charter of Fundamental Rights of the European Union ('the Charter'), Article 168 TFEU, the principle of effectiveness of that same regulation and the principle venire contra factum proprium. Lastly, by its sixth ground of appeal, VSM criticises the General Court for having infringed its own procedural rules in deciding not to include its letters of 22 and 24 July 2015 in the case file.'
246 Case C-637/15 P, para. 66.
247 Case C-637/15 P, para. 69.
248 Joined Cases C-596/15 P and C-597/15 P *Bionorica and Diapharm v Commission* [2017] ECLI:EU:C:2017:886.
249 Case T-619/14 *Bionorica v Commission* [2015] ECLI:EU:T:2015:723.
250 Case T-620/14 *Diapharm* v Commission [2015] ECLI:EU:T:2015:714.
251 Action brought on 14 August 2014. Bionorica v Commission (Case T-619/14) [2014] OJ C 409, pp. 48-49.
252 Action brought on 14 August 2014. Diapharm v Commission (Case T-620/14) [2014] OJ C 409, p. 49.

Commission had infringed Article 13(3) of the NHCR by 'failing to entrust the EFSA with'[253] or 'did not request EFSA'[254] for the assessment of botanical claims to support the drafting of a positive list of permitted claims. As in Case T-578/14, the General Court considered both actions inadmissible: the applicants were both held to not have an interest in bringing the actions and in Case T-620/14, the applicant was found to not have locus standi, a direct concern to bring such an action. Specifically, in Case T-619/14, the Court ruled that there was no failure to act because the Commission needed more time to take a decision, which was deemed to have been explained sufficiently[255]. The Court agreed with the Commission that the applicants (Bionorica) did not have sufficient interest in moving forward with the assessment: the acceptance of the definite list of authorised claims would not necessarily be advantageous for the applicants and on hold claims could be used under the transitional measures[256]; the transitional measures do not negatively affect the level playing field in the market for those business operators using botanical claims[257]; and there is no legal uncertainty[258]. Similarly, in Case T-620/14, the claim for failure to act by the applicant (Diapharm) was inadmissible[259]. In both cases, the Court found shortcomings in the applicant's substantiation of their interest in the adoption of a definitive list[260]. The applicant was also viewed to lack *locus standi*, as they did not manufacture or market foods but offered advisory and support services[261]. This was upheld in the ruling in the joint cases: Diapharm (Case T-620/14 and C-597/15 P) lacked *locus standi* and their appeal was dismissed[262]. In the same vain, in the appeal case also Bionorica (in Case T-619/14) was not considered to have locus standi, as they 'did not carry on business as a manufacturer of food or food supplements on the European market' but rather manufactured herbal medicinal products, which are not in remit of the NHCR[263]. The appeal was therefore ruled inadmissible[264].

In their ruling on the appeal cases, the CJEU clarified different considerations for using botanical health claims under the transitional measures. Advocate General Bobek argues that due to these transitional measures, 'the most that the Appellants could hope for would be the continued right to use the relevant claims' and that the adoption of the list may worsen the situation for them[265]. In line with previous cases, they agree that the failure to adopt the list 'in no way creates unequal conditions of competition'[266] and that this does not create legal uncertainty 'because it was clear which rules applied during the transitional regime'[267]. They do, however, disagree[268] with the Court that the Commission's letter had sufficiently defined the Commission's position: it 'simply describes the status quo'[269] and is 'at best ambiguous'[270]. The Commission is not clear in refusing the

253 Action Case T-619/14, *supra* note 252.
254 Action Case T-620/14, supra note 253.
255 Case T-619/14, paras 22-26.
256 Case T-619/14, paras 28-45.
257 Case T-619/14, paras 46-48.
258 Case T-619/14, paras 49-52.
259 Case T-620/14, paras 22-26.
260 Being that a definitive list is not necessarily advantageous for the business operator (paras 30-39 Case T-620/14), the transitional measures allowed for using the claims (paras 40-44), the applicant is not affected by a potentially created uneven level playing field (paras 45-47), and no legal uncertainty exists due to the lack of a final decision for the list (paras 48-52).
261 Case T-619/14, para. 56.
262 Joined Cases C-596/15 P and C-597/15 P, paras 105-108.
263 Joined Cases C-596/15 P and C-597/15 P, para. 113.
264 Joined Cases C-596/15 P and C-597/15 P, para. 116.
265 Opinion AG Bobek, *supra* note 44, para. 18
266 Opinion AG Bobek, *supra* note 44, para. 19
267 Opinion AG Bobek, *supra* note 44, para. 20
268 Opinion AG Bobek, *supra* note 44, paras 31-32
269 Opinion AG Bobek, *supra* note 44, para. 33
270 Opinion AG Bobek, *supra* note 44, para. 37

Appellants' request to act[271]. In their final ruling, the CJEU rules that the General Court did indeed 'commit an error of law' and thus agrees with the Advocate General that the Commission did not bring an end to the 'failure to act' by issuing a letter in 2014[272].

A second important element described by the AG and considered by the CJEU is whether the claims made under the transitional measures should be seen as having the same position as those claims authorised in Regulation (EU) No 432/2012. The AG compares the transitional and permanent regimes[273]. Whereas the General Court set out that the 'Appellants could not derive any benefit from the adoption of the botanicals claims list' because the transitional regime applies and this 'is in practice as good as it would be if the claim were to be authorised'[274], the AG disagrees[275] as legally speaking, both regimes are not equivalent[276]. National provisions may create certain conditions for claims made under the transitional regime, but those claims addressed by EU rules are not subject to such rules anymore. 'As a matter of principle, there would be a clear benefit from authorisation as compared with the transitional regime'[277]. Even if the possibility for refusal of these claims could be more negative for the applicants compared to the traditional regime – although this is seen as an oversimplification[278] – the AG believes that such potential consequence is not sufficient to refuse the interest of these parties to act[279]. Failure to act should not be limited to a possible positive outcome[280]. The CJEU agrees that the 'transitional and definite regimes' are not equivalent[281]: they 'are subject to different requirements and do not benefit from the same conditions'. They, therefore, recall that for claims made under the transitional measures, national provisions may apply[282]. As these national provisions may differ, especially when it comes to considering whether such products are seen as safe by Member States[283], the CJEU disagrees with the General Court's assessment that both regimes are equivalent as stipulated in cases T-619/14 and T-620/19[284]. Arguing that the parties would not benefit from a decision on the list, as their claims of interest may be rejected, was therefore not upheld by the CJEU: it could lead to a benefit 'in terms of legal clarity'[285]. As both parties were however deemed to not have a personal interest in these proceedings, their action was deemed inadmissible[286] or the appeal was dismissed[287].

CJEU's ruling on these appeals clarifies that using authorised claims and using claims from the on-hold list cannot be regarded as using claims under similar conditions. The applicants were ruled to not have an interest in the procedures and thus, the different appeals were dismissed. Still, the argumentation of the Court in their rulings did show that they deemed that legal certainty could be further increased for FBOs when the assessment and authorisation procedure for on hold claims would be finalised[288]. Clarification of how claims are handled when the procedure is finalised can

271 Opinion AG Bobek, *supra* note 44, para. 36
272 Joined Cases C-596/15 P and C-597/15 P, para. 59
273 Opinion AG Bobek, *supra* note 44, para. 59
274 Opinion AG Bobek, *supra* note 44, para. 60
275 Opinion AG Bobek, *supra* note 44, para. 61
276 Opinion AG Bobek, *supra* note 44, para. 62
277 Opinion AG Bobek, *supra* note 44, para. 62
278 Opinion AG Bobek, *supra* note 44, para. 66
279 Opinion AG Bobek, *supra* note 44, para. 63
280 Opinion AG Bobek, *supra* note 44, paras 67-75
281 Joined Cases C-596/15 P and C-597/15 P, para. 87
282 Joined Cases C-596/15 P and C-597/15 P, para. 88
283 Joined Cases C-596/15 P and C-597/15 P, para. 90.
284 Joined Cases C-596/15 P and C-597/15 P, para. 92.
285 Joined Cases C-596/15 P and C-597/15 P, para. 96.
286 Joined Cases C-596/15 P and C-597/15 P, para. 116.
287 Joined Cases C-596/15 P and C-597/15 P, para. 108.
288 Joined Cases C-596/15 P and C-597/15 P, para. 96.

subsequently support commercial strategies, as it will affect the planning and strategy of economic operators in the food or food supplement industry[289].

2.1.5. Governing commercial communication towards healthcare professionals

In response to the request for a preliminary ruling from the German court, the judgment of the Court in Case C-19/15[290] clarified that the NHCR also applies to commercial communication directed towards healthcare professionals and is not only directed towards end-consumers. In this case, healthcare professionals received a general communication from the director (and doctor) of a company producing supplements that contain vitamin D, about the positive aspects of vitamin D consumption. As this concerns commercial communication, communication to 'promote goods, services or image of a company'[291] – including the promotion of foods[292] - and the NHCR deals with claims made in commercial communications in labelling, presentation or advertising[293] , the NHCR was considered also applicable to this type of information sent to healthcare professionals. While the information in this case was addressed to healthcare professionals and not to consumers directly, Article 1(2) describes that it addresses 'claims made on commercial communications of (…) foods to be delivered as such to the final consumer'. Advocate General Saugmandsgaard interpreted this as the foods being delivered to the final consumer, *not* the communication[294]. The Court agreed that the subject matter was not the communication necessarily aimed at the consumer, but rather the product itself[295]. Also, the NHCR does not clearly exclude covering this type of communication[296]. As it is one of the objectives of the NHCR to provide a high level of consumer protection[297], consumers should be provided with 'the necessary information to make choices in full knowledge of the facts'[298]. Even though healthcare professionals 'may be considered to have scientific knowledge superior to that of (…) an average consumer (…)', it cannot be assumed that they always have up-to-date knowledge that allows them to evaluate nutrition and health claims made on foods[299]. Healthcare professionals may thus be misled by 'false, deceptive or even mendacious' claims[300]. Because information is provided to professionals but in practice indirectly aimed at the final consumer[301], the NHCR covers claims made in such information[302]. The Court's ruling has thereby further elucidated the scope of the NHCR, as it also covers the indirect communication to final consumers through healthcare professionals. Such communication should therefore comply with the requirements set out in the NHCR or food business operators should ensure that they merely provide information that is qualified as non-commercial communication, as this is not

289 Joined Cases C-596/15 P and C-597/15 P, para. 96.
290 Case C-19/15 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH* [2016] ECLI:EU:C:2016:563.
291 Art. 2(f) of Directive 2001/31/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, p. 67-128. (Consolidated version 1 January 2022).
292 Case C-19/15, para. 29.
293 Art. 1(2) NHCR.
294 Case C-19/15 *Verband Sozialer Wettbewerb eV v Innova Vital GmbH* [2016] ECLI:EU:C:2016:563 Opinion of Advocate General Saugmandsgaard delivered on 18 February 2016.
295 Case C-19/15, para. 31.
296 Case C-19/15, para. 36.
297 Case C-19/15, para. 38.
298 Case C-19/15, para. 39.
299 Case C-19/15, para. 43; J Lazíková, L Rumanovská (2022). Nutrition and health claims on foods in the EU legislation. *Tribuna Juridica* 12(2), pp. 283-311.
300 Case C-19/15, para. 44; Opinion AG Saugmandsgaard, *supra* note 295, para. 4.
301 Opinion AG Saugmandsgaard, *supra* note 295, para. 57.
302 Case C-19/15, para. 51.

covered by the NHCR[303]. While some scholars note that this judgment may have increased legal uncertainty as no criteria were provided by the Court to assess whether the information is of commercial or non-commercial nature[304] and it thus may limit the exchange of scientific information[305], others deemed that the judgment has put an end to the uncertainty of general practices of information sharing in the food industry[306]. The ruling has been described as a 'major breakthrough' for consumer protection[307].

2.1.6. Classifying products as foodstuffs or medicinal products

Even though not directly related to the NHCR, Case C-140/07[308] is relevant for determining for which products health claims can be used. It addresses the classification of a foodstuff based on its active substance and effect. A judgment was issued by the Court in 2009 in response to a case referred for a preliminary ruling by the Bundesverwaltungsgericht in Germany, concerning the classification of a product with fermented red rice as food or as a medicinal product. This was based on the potential, but uncertain pharmacological effects the product, containing relatively low amounts of monacolin k as the active substance, could elicit. The Court judged that the definition of a medicinal product by function[309] should be interpreted narrowly as covering those products 'the pharmacological properties of which have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions'[310]. The Court stipulated that 'all characteristics', including those 'of the manner in which a product is used'[311] should be taken into account when determining whether a product should be considered a medicinal product or a food product[312]. Because not all products that could affect physiological functions should immediately fall into the definition of 'medicinal product by function', when the amount of the active substance in the product's prescribed use is lower than providing a significant effect, a product does not need to be defined as a medicinal product[313]. While this case contributed to the classification of medicinal products versus foodstuffs (food supplements in particular)[314], it did not impact the NHCR, its implementation nor its effectiveness directly.

Also, the Nelson Distribution case[315] addressed whether transitional measures described in the NHCR applied to products that had previously been marketed as medicinal products but that were now considered foodstuffs. As highlighted in the previous section, in this specific case, the product's categorisation was adjusted due to a Court decision in Germany, without resulting in any changes to the substantive characteristics of the product[316]. The NHCR, therefore, applied to a product that

303 Case C-19/15, para. 52; M de Morpurgo, P Carmona Botana (2016). 'The Nutrition and Health Claims Regulation Applies to Commercial Communication Addressed to Health Professionals', *European Journal of Risk Regulation* 7(3), pp. 634-641.

304 S Romero Melchor (2016). 'Now What, Doc? Regulation 1924/2006 Applies to Communications to Health Professionals (Case C-19/15)', *European Food and Feed Law Review* 11, pp. 415-423.

305 AM Conea (2017). Health Claims' Notion in the Case Law of the European Court Of Justice. *Challenges of the Knowledge Society*, pp. 426-431.

306 De Morpurgo, Carmona Botana (2016). *supra* note 304.

307 Conea (2017). *supra* note 306.

308 Case C-140/07 *Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg* [2009] ECLI:EU:C:2009:5.

309 Art 2(2) Dir 2001/83/EC.

310 Case C-140/07, para. 25.

311 Case C-140/07, para. 37.

312 Case C-140/07, para. 36.

313 Case C-140/07, paras 43-44.

314 K Purnhagen (2010). 'On How to Assess a Medicinal Product By Function'. *European Journal of Risk Regulation* 1(1), pp. 90-92.

315 Case C-177/15.

316 Case C-177/15, paras 46-47.

had been marketed as a medicinal product before 1 January 2005 but was re-categorised as a foodstuff in 2007[317].

2.1.7. Other relevant issues

In the preliminary ruling requested by the Bavarian Administrative Court in Case C-137/13[318], the Court judged whether living up to the requirements for using nutrition or health claims on products would allow food producers to add substances of non-organic origin while still labelling these products as organic following Regulation (EU) No 889/2008 governing organic production and labelling[319]. Even though this regulation provides a restricted list of substances that can be used in the processing of food products that are marketed as organic[320], this merely refers to situations in which the inclusion of such substances is legally required[321]. As nutrition and health claims can voluntarily be used for commercial communication and cannot be considered, the addition of vitamins and minerals of non-organic origin would merely be a voluntary consideration to allow FBOs to use a claim in the marketing of such a food product[322]. Thus, the exemption in the Regulation for organic production to add substances of non-organic origin does not concern a 'legal requirement'[323]. Even though this ruling does not affect the implementation or effectiveness of the NHCR directly, as put forward by González Vaqué[324], it does show the intertwined nature of the EU regulatory framework on foods.

In their preliminary ruling issued in 2015 on the Neptune Distribution case[325] the CJEU confirmed which substances should be included in calculating the requirements for a nutrition claim on salt. On their mineral waters, the distributor highlighted that the sodium in this product was sodium bicarbonate and not sodium chloride – and thus should be considered as less harmful. The CJEU however ruled that when determining the sodium or salt content, all chemical forms of sodium must be considered so as to not mislead the consumer in suggesting that the product would be low in sodium[326]. Also, in reviewing the effect of sodium bicarbonate on arterial tension, EFSA did not issue a positive scientific opinion on the less harmful effect of sodium bicarbonate versus sodium chloride as the study that should support this claim was not of sufficient methodological quality[327]. Thus, 'it does not appear' that a health risk of consuming high levels of sodium bicarbonate 'may be excluded'[328]. With the precautionary principle in mind[329], the Court, therefore, judged that in light of the freedom of expression and information, restricting communication about sodium bicarbonate is proportionate 'to the objectives pursued'[330], the protection of human health in Europe.

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317 Case C-177/15, para. 48.
318 Case C-137/13 *Herbaria Kräuterparadies GmbH v Freistaat Bayern* [2014] ECLI:EU:C:2014:2335.
319 Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. OJ L 250, pp. 1-84. (Consolidated version 1 January 2022).
320 Art. 27(1)(f) Reg No 889/2008; L González Vaqué (2015). 'Case Herbaria Kräuterparadies', *European Journal of Consumer Law* 2015(1), ISBN: 978-2-8044-9024-9.
321 Case C-137/13, para. 48.
322 Case C-137/13, para. 47.
323 Case C-137/13, para. 51.
324 González Vaqué (2015), *supra* note 321.
325 Case C-157/14 *Société Neptune Distribution v Ministre de l'Economie et des Finances* [2015] ECLI:EU:C:2015:823.
326 Case C-157/14, paras 55-56.
327 Case C-157/14, para. 30.
328 Case C-157/14, para. 83.
329 Case C-157/14, para. 81.
330 Case C-157/14, para. 85.

2.2. Summarising the evidence on the impact of case law on the implementation of the regulation's objectives

As highlighted in the sections above, various rulings of the Court have further clarified the application and implementation of the NHCR. In particular, the rulings in cases C-544/10, C-299/12 and T-17/12 have provided clarity as to what should be understood as a health claim. According to the rulings and literature reflecting upon these rulings, this has provided greater certainty with regard to ensuring a high level of consumer protection. The fact that health claims on alcoholic beverages, even though they may be factually correct, are completely prohibited (Case C-544/10) also clarifies that alcohol consumption is always discouraged. Furthermore, the ruling in C-296/16 supports this interpretation: even when scientific evidence supports a cause-and-effect relationship, the Commission can decide to not authorise a claim on a compound if it may confuse consumers as it could be ambiguous or lead to misunderstandings, when public health messages are targeted towards decreasing the intake of such a compound (in this case, glucose).

Similarly, the ruling (C-524/18) that Article 10(3) claims have to be supported with evidence[331] – albeit indirectly – highlights that only claims that are based on scientific evidence, which are not misleading, can be made in the commercial communication for food products. Again, this can be understood as contributing to the high level of consumer protection, which is one of the main objectives of the NHCR. This requirement also exists for claims made under the transitional measures of Article 28(5), the on hold claims currently awaiting an authorisation decision.

In Case C-19/15[332], the Court clarified that commercial communication of FBOs to healthcare professionals falls under the remit of the NHCR. In order to protect the consumer from potentially incorrect, incomplete or even false information, claims in communications exclusively targeted at healthcare professionals – which may indirectly reach the consumer through these professionals – have to comply with the provisions laid down in the NHCR.

Finally, in the Schwabe case (C-524/18), the Court defined that in order to ensure that consumers can understand the link between a general (Article 10(3)) and a specific (Articles 13 or 14) claim, FBOs need to consider the visual dimension of presenting claims[333]. The general claim and the specific claim should be presented within the same field of vision and the wording of the general claim should be well-aligned with the specific claim. If this positioning is not possible, national courts may determine whether other ways of linking both claims, e.g. by using an asterisk, provide sufficient clarity for consumers.

In particular, various cases (including C-609/12 and C-363/19 referred for preliminary rulings, and actions in T-354/12, T-296/12, T-334/12, C-637/15, and Joined Cases C-596/15 and C-597/15) addressed the transitional measures of Article 28(5) under which the on hold claims (mostly on health benefits of botanicals) can be made on food products. This topic is discussed in the subsequent chapters. According to the Court's considerations, these transitional measures do not create legal uncertainty for FBOs. In this context, the principle of legal certainty was understood as requiring 'rules to be clear and precise and their consequences to be foreseeable'[334]. The Court did recognise that the fact that decisions regarding the assessment procedure of a significant number of health claims are pending cannot be seen as a sustainable situation. In its rulings, it recognised that a decision on the 'on hold' list would further increase the legal certainty of business operators[335].

331 Case C-524/18, para. 58.
332 Case C-19/15, para. 54.
333 Case C-524/18, para. 40.
334 Case T-578/14, para. 63.
335 Cases C-596/15 P and C-597/15 P, para. 96.

Transitional measures are also addressed in different appeal cases and actions for annulment of Regulation (EU) No 432/2012 on the 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. The Court did recognise that claims made under the definite versus the transitional regime were treated slightly differently. However, the argument challenging the gradual approach taken by the Commission as regards the setting of the list were deemed inadmissible[336].

Under the current rules, two types of claims are now found on the internal market: claims that are authorised following the NHCR provisions, and those claims that are currently still on hold but can be used under the transitional measures of Article 28(5) as long as they comply with national provisions. According to the evaluation report, the current situation, which creates ambiguity for both consumers and FBOs, may negatively affect the smooth functioning of the market and hamper a high level of consumer protection – the two main objectives of the NHCR[337].

[336] Cases C-596/15 P and C-597/15 P, para. 87.
[337] SWD(2020) 95 final, part 1.

3. Health claim issues emerging from the CJEU rulings

3.1. General trends emerging from CJEU rulings

The CJEU preliminary rulings, together with the other cases brought to the Court, highlight that the Court considers the broad interpretation of the health claim regulation mostly proportional. In various cases [338], the freedom of expression, the freedom of information, the freedom to choose an occupation and the freedom to start or conduct a business – all defined in the Charter of Fundamental Rights of the European Union – were put forward by applicants as issues that were negatively impacted by the NHCR. They therefore believed that claims and their requirements as laid down in the NHCR should be interpreted narrowly, to ensure that these freedoms would not be obstructed disproportionately. As shown in the judgment on C-296/16 [339], the Court agrees that such measures 'should be suitable for achieving the objective pursued and not go beyond what is necessary to achieve it'. In all issued rulings, however, these freedoms were not considered to have been disproportionately restricted by the means implemented by the provisions of the NHCR. As the NHCR merely governs the use of nutrition and health-related information in advertising a food product or other forms of commercial information [340], it does not negatively affect the freedom to advertise such products in a disproportionate manner, nor does it negatively affect the possibilities to start a business or choose an occupation to produce or sell foods. FBOs can still place products on the market and can advertise certain aspects of these products. It is not 'an absolute prohibition of advertising' [341], they are merely unable to advertise upon any nutrition or health considerations of their products as these may be considered to potentially mislead the consumer [342].

As put forward in section 2.2, protecting consumers' health is considered more important than – perhaps well-founded – information on substances that can be harmful or unhealthy when consumed in excessive amounts, such as alcohol or sugar. Information on the beneficial nutritional or physiological effects of a specific product could contribute to choosing these products, and thus encourage their consumption. Meanwhile, EU policies are aimed at reducing alcohol

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338 Including C-544/10, C-157/14, C-19/12, , T-100/15 and C-296/16.

339 Case C-296/16, para. 44.

340 T-100/15, para. 93: *'[…] while it is true that the prohibition of the health claims at issue imposes certain restrictions on the applicant's business activity in one specific respect, compliance with those freedoms is nonetheless assured in the essential respects. Far from prohibiting the production and marketing of the applicant's products or the advertising of those products, the contested regulation merely controls, pursuant to Article 1(2) of Regulation No 1924/2006, the presentation of the foods in question and the advertising of those products, with the aim of protecting public health, which constitutes an objective of general interest justifying a restriction of a fundamental freedom (see judgment in Deutsches Weintor […]). Thus, the refusal to authorise the health claims at issue does not in any way affect the actual substance of the freedoms recognised by Articles 6 and 16 of the Charter of Fundamental Rights and must be regarded as complying with the requirement that is intended to reconcile the various fundamental rights involved and to strike a fair balance between them […].'*

341 Case T-100/15, para. 82.

342 In Case C-296/16, the Court judges that information that may mislead the consumer (because it 'proves to be incomplete, ambiguous or misleading') 'cannot be protected under the freedom of expression and information of the entrepreneur and the freedom of enterprise of the latter' (para. 54, C-296/16). Similarly, in Case C-544/10, the Court highlights that 'restrictions may be imposed (..) when [this] corresponds to objectives of general interests' without forming 'disproportionate and intolerable interference' with rights to the freedom of choosing an occupation, conducting a business, trade or profession (para. 54, C-544/10). In Case C-544/10 this therefore also results in the Court acknowledging that the prohibition of claims results in 'certain restrictions on the professional activity of the economic operators concerned in one specific respect' (para. 56), but the legislation merely controls labelling and advertising of the products in a 'very clearly defined area' (para. 57) and thus strikes a 'fair balance' between the fundamental rights of choosing an occupation and to conduct a business and the objectives of the NHCR (paras 56-59).

consumption[343] and improving public health through healthy diets[344]. The Court rulings have thereby clarified these priorities. Ambiguous or incomplete information, which may contribute to misleading consumers, would not be in compliance with the NHCR[345]. Consequently, the restrictions to freedom of expression imposed by the NHCR are considered to be in line with the 'objectives of general interest pursued by the EU'[346], such as protection of health in all policies.

3.2. Foods and food supplements containing botanicals

As previously highlighted in the 2020 evaluation of the NHCR, one of the elements proposed in the NHCR that is not yet implemented[347], is the authorisation of health claims on plants and their preparations, often referred to as botanicals. Over 2 000 claims are currently on hold: 530 claims have been assessed by EFSA and received a negative scientific opinion; the other claims have not yet been assessed[348]. By putting the authorisation on hold, both the negatively assessed as well as those non-reviewed claims can be used for foods under the transitional measures described in Article 28(5) of the NHCR. Following this Article, claims made need (a) to comply with national measures and (b) need to be justified by food business operators.

The CJEU rulings highlight that firstly, the transitional measures as such provide sufficient legal certainty for food business operators[349], as they allow for the use of the on hold claims throughout the EU. Whereas food business operators put forward that it may be challenging to identify which claims exactly are on this list, the Court determines that this does not create uncertainty: the law itself is clear as is, and the claims can be found through their ID number online[350]. In addition, the Commission's approach to conduct the assessment of claims in different phases was considered to be in conformity with its legal basis[351], and aligned with the principles of good administration and non-discrimination and equal treatment[352]. In certain actions, the Court ruled that a plea to annul Regulation (EU) No 432/2012 was inadmissible when applicants did not have an explicit benefit to this[353], and as the on hold situation allowed for marketing products with claims based on that on-hold list, no benefit could be derived from such annulment[354]. In the ruling on the appeal in Joined Cases C-596/15 P and C-597/15 P, the CJEU disagreed with the General Court and highlighted that deciding upon the authorisation requests of claims could indeed lead to increased legal clarity – even when claims of interest would not be authorised. The CJEU recognised[355] that there was a difference between claims made under the transitional regime and those made under the definitive regime: the first need to potentially address national provisions, as well as other provisions in the NHCR (requiring these claims to be substantiated); the definitively authorised claims can be made when the FBO complies with the conditions of use described in Regulation (EU) No 432/2012. Such

343 Point 3.3 'Reducing harmful alcohol consumption', p10 in Europe's Beating Cancer Plan. Communication from the European Commission to the European Parliament and the Council. Available via https://health.ec.europa.eu/system/files/2022-02/eu_cancer-plan_en_0.pdf (Last accessed 5 August 2023).

344 Point 3.4 'Improving health promotion through access to healthy diets and physical activity', p11 in Europe's Beating Cancer Plan, *supra* note 344.

345 Case C-296/16, para. 54.

346 Conea (2017), *supra* note 306.

347 SWD(2020) 95 final, part 1, p. 1-2.

348 SWD(2020) 95 final, part 1, p. 23.

349 Case T-296/12, para. 90.

350 E.g., in Case T-296/12, paras 87-89.

351 Case T-296/12, paras 77, 95.

352 Case T-296/12, paras 98, 100, 106-111, 113-118.

353 Case T-296/12, para. 208.

354 Case T-296/12, paras 209-212.

355 Cases C-596/15 P and C-597/15 P, para. 87.

a case-by-case analysis in Member States could result in 'diverging' outcomes[356] which can partially be attributed to differences in addressing the safety of botanicals in Member States[357]. As the applicants, however, were ruled to not have a personal interest in these proceedings, the Court did not further address this. Case law has therefore not resulted in the annulment of Regulation (EU) No 432/2012 and the transitional measures in Article 28(5) and (6) have been considered to allow food business operators sufficient clarity and certainty. Nevertheless, the lawfulness of the transitional measures as such was challenged[358]. In literature, this question has sparked a discussion. According to Professor Di Fabio, the Commission should request EFSA to commence the assessment immediately, to ensure that the objectives of the NHCR can be attained[359].

The Court finds that the transitional measures only apply to previously submitted Article 13(1) claims and not Article 10(3) claims related to general health and well-being based on such submitted claims[360]. Under these transitional measures, claims must be compliant with the other requirements laid down in the NHCR and potentially in national legislation[361]. This means that claims need to be substantiated with 'generally accepted scientific evidence' that should be provided by the food business operator[362]. Even though the Court did not lay down specific requirements for scientific evidence, in C-363/19 the CJEU explicitly mentioned that such scientific evidence 'cannot consist solely of beliefs, hearsay derived from popular wisdom or observations coming from individuals outside science and the scientific community'[363].

The rulings clarify that legal certainty is not an issue according to the Court, as the on hold claims can be used across the internal market under clear conditions of use, even though food business operators do believe that the uncertainty of when to expect a final decision – and what such a decision might entail - creates legal uncertainty[364]. In spite of this legal certainty, in practice, the NHCR's objectives of providing a high level of consumer protection while ensuring the effective functioning of the internal market are considered to be affected negatively, e.g. as reported in the evaluation report in 2020[365]. Today, two types of claims are found on the market: firstly, those claims that have undergone the rigorous assessment and authorisation procedure; and secondly, those claims that have not been assessed – or have been assessed negatively – and no authorisation decision has been made. Claims in this second category may be science based, could be based on traditional use, or have no scientific substantiation at all[366]. Consumers may thus be insufficiently protected from potentially false and misleading claims. As argued in literature by Dr. Schebesta (2020), when the scientific quality of claims is safeguarded, authorised health claims do not merely

[356] Cases C-596/15 P and C-597/15 P, para. 89.
[357] Cases C-596/15 P and C-597/15 P, para. 90.
[358] U Di Fabio (2022). Does EFSA's lack of re-instruction by the Commission on the assessment of botanicals under Regulation (EC) 1924/2006 violate companies' rights and can companies continue to rely on the transitional provision under Art. 28 para. 5 HCR? Legal opinion commissioned by EUCOPE and BPI. Available via https://www.eucope.org/wp-content/uploads/2023/04/legal-opinion-prof-di-fabio-botanicals-health-claims-translation.pdf (Last accessed 7 August 2023); EUCOPE (2022). Assessment of botanical health claims violates rule of law. Available via https://www.eucope.org/suspension-in-assessment-of-botanical-health-claims-violates-eu-rule-of-law/ (Last accessed 7 August 2023).
[359] Di Fabio (2022), *supra* note 359.
[360] Case C-363/19, para. 41.
[361] Case C-363/19, para. 41; Joined Cases C-596/15 P and C-597/15 P, paras 68, 87, 92.
[362] Case C-363/19, paras 48, 52, 54.
[363] Case C-363/19, para. 46.
[364] SWD(2020) 95 final, pt 1, p. 53.
[365] SWD(2020) 95 final, pt 1.
[366] SWD(2020) 95 final, pt 1, p. 52.

'provide accurate information to consumers, they also contribute to consumer education about scientifically proven effects of nutrients on health'[367].

In scientific literature, the effect of having two types of claims on businesses has also been discussed: it was suggested that this creates an uneven playing field, in which botanical-selling food operators can still use claims that are considered insufficiently substantiated, while other rejected health claims can no longer be used[368]. As explained above, the CJEU has considered that this situation does not infringe the principle of equal treatment[369]. Moreover, the evaluation report concludes that there is more certainty on the internal market with the on-hold list as compared to the pre-2012 situation of merely national provisions – or a lack thereof – for botanical claims[370], national provisions still may be applied to these claims. Whilst the national guidelines are considered to potentially help the functioning of the internal market, at the same time, such provisions may lead to a further fragmentation due to specific requirements that are issued by individual Member States[371].

Indeed, Member States are shown to provide different types of information in issued guidelines when it comes to dealing with botanical on hold claims. For example, in the Netherlands, FBOs are allowed to make on hold claims when they either have evidence supporting the claim or when they combine this on hold claim with a disclaimer that the claim is currently on hold[372]. In Belgium, the guidance document defines that scientific evidence is required for on hold claims and that 'the fact that a claim is "on hold" does not necessarily mean that the claim may be used'[373]. Next to fragmentation, such differences in requiring evidence or not do not seem to align with the Court's judgment in Case C-363/19 that claims need to be substantiated (addressed further in the next section). Secondly, the Court specified that the transitional measures in Article 28(5) only address Article 13(1) claims and do not apply to Article 10(3) claims[374]. Still, some Member States suggest that also Article 10(3) claims can be used when they are supported by on hold claims[375]. Such differences create further fragmentation in the internal market that may hamper the functioning of the internal market.

Next to the legal uncertainty perceived by business operators, the uncertainty with regards to the resumption of the assessment and authorisation procedure for the on hold claims has been considered to negatively affect innovation in this field[376]. Food operators are free to submit new claims on health effects of botanicals in foods, but the lack of recognising (a) the use of full plants (instead of specific components from plants) and (b) evidence on traditional use, and the associated

367 Schebesta (2020), *supra* note 128, p, 251.
368 Geurts (2018), *supra* note 77.
369 Case T-296/12, paras 77, 95; Joined Cases C-596/15 P and C-597/15 P, para. 92.
370 SWD(2020) 95 final, pt 1, p. 53.
371 SWD(2020) 95 final, pt 1, p, 53-54; Joined Cases C-596/15 P and C-597/15 P, para. 90.
372 Nederlandse Voedsel- en Warenautoriteit (2022). Handboek Voedings- en Gezondheidsclaims (versie 3.0). Available via https://www.nvwa.nl/binaries/nvwa/documenten/consument/eten-drinken-roken/etikettering/publicaties/handboek-voedings--en-gezondheidsclaims/handboek-voedings-en-gezondheidsclaims.pdf (Last accessed 15 August 2023), p. 69-70.
373 Federale overheidsdienst Volksgezondheid, veiligheid van de voedselketen en leefmilieu (2022). Vragen en antwoorden over sommige bepalingen omtrent voedings- en gezondheidsclaims. Available via https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/2022_01_faq_claims_final_nl.pdf (Last accessed 15 August 2023), p. 4
374 Case C-363/19, paras 40-41, 54.
375 Federale overheidsdienst Volksgezondheid, veiligheid van de voedselketen en leefmilieu (2022), *supra* note 374.
376 Lenssen et al. (2020), *supra* note 76; SWD(2020) 95 final, pt 1, p. 85.

uncertainties regarding the use and substantiation of such claims, are considered to hinder innovation in that regard[377].

3.3. EFSA's risk assessment procedure

Together with the clarified interpretations of what constitutes a health claim, case law[378] has clarified how a 'relationship' between consuming food and the subsequent beneficial nutritional or physiological effect should be understood – and subsequently, substantiated. Article 2(2)(5) of the NHCR defines that a 'health claim means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health'. Article 2(2)(6) similarly describes that reduction of disease risk claims are those claims linking the consumption of a food (constituent) 'to a significant reduction of a risk factor in the development of a human disease'. Cases C-544/10 and C-299/12 clarified that this relationship should be understood as **any** direct or indirect relationship that can be of varying intensity or duration since the NHCR's definitions provide no further information upon that[379].

Because these definitions of claims also cover statements that suggest or imply a relationship[380], claims that do not immediately assert or suggest a significant reduction of a disease risk factor also have to be understood as falling within this definition. In line with these cases, the Court stipulates in T-296/12 that the fact that EFSA's scientific assessment focuses on significant effects logically follows from Article 5(1)(b) and (d) from the NHCR[381]. In different cases, applicants argued that requesting scientific opinions is erroneous and infringes Article 13[382] but the Court did not agree. They ruled that all claims have similar evidence requirements[383], for which it is deemed logical that scientific opinions are requested from EFSA on suggested claims[384]. Also, even though the guidance documents were issued only *after* Article 13(1) claims had been submitted for authorisation, the risk assessment procedure has not been considered as infringing the principle of legal certainty[385].

The emphasis on providing evidence for a cause-and-effect relationship is seen by the Court as logically following from the NHCR[386]. As Article 2(2)(5) relates to statements stating, suggesting or implying a relationship, this translates to requiring evidence that can show a cause-and-effect relationship between a food (constituent) and the effect that is referred to in such a claim. The focus of EFSA on evidence substantiating such cause and effect[387] has been on evidence that can support scientific conclusions 'at the highest possible standard'[388]. Following the hierarchy of evidence pyramid[389], human intervention studies are considered key in substantiating causal relationships

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377 SWD(2020) 95 final, pt 1, p 85; E Hoogenraad, B Duivenvoorde (2016). 'Health Claims for Botanicals: 'On Hold', Yet Forbidden? *European Food and Feed Law Review*, 11, pp. 58-59; Lenssen et al. (2020), *supra* note 76; Geurts (2018), *supra* note 77.

378 In particular, Cases C-544/10, C-299/12, T-296/12 and C-363/19.

379 Case C-544/10, para. 34; Case C-299/12, para. 22.

380 Case C-299/12, para. 24.

381 Case T-296/12, para. 136.

382 Case T-296/12, para. 122.

383 Case T-296/12, para. 129.

384 Case T-296/12, para. 132.

385 Case T-296/12, paras 152 and 153.

386 Case C-299/12, para. 138.

387 Scientific guidance EFSA revision 1 (*supra* note 53), de Boer *et al.* (2014), *supra* note 2; Lenssen *et al.* (2018), *supra* note 52

388 SWD(2020) 95 final, pt 1, p, 23

389 In the hierarchy of evidence pyramids, study designs that produce a higher relative strength of evidence are placed on top, starting with meta-analysis and systematic reviews, immediately followed by human intervention studies (or trials). Intervention studies are therefore considered the main type of experimental study design to support causal

between the consumption of a product and its subsequent nutritional or physiological effect described in health claims. *In vitro* and animal studies can only be used to support applications, not to substantiate them as such[390].

Evidence originating from the consumption of botanicals, following the notion of traditional use (also referred to as 'evidence on traditional use'), was however not considered sufficient to support such causal relationships[391]. This has been exemplified by the 530 claims on botanicals that were assessed negatively and are currently on hold awaiting a risk management decision. As explained above, Case C-363/19 determined that 'generally accepted scientific evidence' should be used to substantiate claims and that such evidence 'should not be limited to hearsay derived from popular wisdom, or the observations or experiences of persons outside the scientific community'[392]. The Court however did not provide any *specific* requirements for the evidence that should underlie the claims made under transitional measures. This was left in the remit of national legislation. As described in section 3.1.2, however, national provisions and requirements may differ between Member States, resulting in different interpretations for evidence requirements. Next to different stakeholders such as consumer organisations and industry associations, various scholars have addressed the potential use of evidence on traditional use, based on longer-term exposure to a product, to support health claims on botanicals[393].

Finally, the rulings of the CJEU[394] have confirmed that a positive opinion on the scientific evidence underlying the proposed health claim does not guarantee authorisation of a claim. In this vain, the Commission can decide, based on other relevant considerations[395], not to authorise a claim that EFSA has considered sufficiently substantiated[396]. The Court stipulates that 'scientific risk assessment alone cannot provide all the information on which a risk management decision should be based (…). The Commission must be recognised as enjoying broad discretion in an area which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments[397].' According to the CJEU, the Commission was therefore required to take generally accepted nutrition and health principles into account, when determining whether claims should be authorised on glucose[398].

relationships. (from A de Boer (2022). Chapter 17: 'Nutrition and health'. In BFW Wernaart, BMJ van der Meulen (eds.) *Applied Food Science*. Wageningen: Wageningen Academic Publishers, pp. 385-406.)

390 Scientific guidance EFSA revision 1 (*supra* note 53), de Boer *et al*. (2014), *supra* note 2.

391 SWD(2020) 95 final, pt 1, p. 24.

392 Case C-363/19, para. 46.

393 Most recently, this was done in two papers: A Kusar, I Pravst (2022), *supra* note 77; Lenssen *et al*. (2022), *supra* note 77.

394 E.g., in Case T-100/15.

395 Art. 18(4) NHCR.

396 Case T-100/15, para. 25.

397 Case T-100/15, para. 30.

398 Case T-100/15, para. 34.

4. The impact of case law on health claims made on foods

4.1. The impact of case law on the development of the legal framework

4.1.1. The impact of case law on the interpretation and application of the regulation

The CJEU rulings, in particular, the preliminary rulings issued by the Court of Justice, have provided increased certainty on the interpretation and application of the regulation across Member States. In particular, as put forward in chapter 3, the CJEU has specified (i) the definition of 'health claims' is interpreted relatively widely[399]; (ii) the NHCR and its provisions apply to commercial communication with healthcare professionals[400]; (iii) showing evidence for cause-and-effect relationships is key in the scientific substantiation[401]; and (iv) the transitional measures are lawful and provide legal certainty[402]. Most cases referred to the CJEU for a preliminary ruling originated from German courts. A 2015 analysis[403] already indicated that enforcement activities across Member States may differ, but systematic research into enforcement actions has so far not been conducted.

The main objectives of the regulation are to ensure the highest level of consumer protection and the effective functioning of the internal market[404]. The introduction of the NHCR also foresaw the objective of increasing legal security for economic operators, which would contribute to fair competition in the foods sector across Member States and foster innovation[405]. The extent to which this secondary objective of supporting and stimulating innovation in the food sector has materialised in practice has been questioned in literature[406]. In this context, the duration of the full authorisation process[407], the required investments for research supporting the authorisation request[408] and the lack of transparency in and uncertainty regarding the scientific assessment[409] have been named as the main issues hampering innovation. In literature, the extensive requirements imposed by the NHCR have been described as 'obstacles to food innovation'[410].

399 Cases C-544/10, C-299.12, T-17/12.
400 Case C-19/15.
401 Cases C-177/15, C-524/18, T-296/12, T-344/12.
402 Cases C-609/12, C-636/19, T-354/12, T-296/12, T-334/12, T-578/154, C-637/15 P, T-619/14, T-620/14, Joined Cases C-596/15 P and C-597/15 P.
403 de Boer et al. (2015), *supra* note 64.
404 Art. 1(1) NHCR.
405 Opinion of the Commission on the European Parliament's amendments to the Council's common position regarding the proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods amending the proposal of the Commission (COM 2006/0368 final), para. 3; SWD(2020) 95 final, pt 1, p. 4.
406 *Inter alia* in JL Buttriss (2015). 'Nutrition and health claims in practice', *Nutrition Bulletin* 40, pp. 211-222; S Bröring, S Khedkar, S Ciliberti (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, pp. 1-9; S Khedkar, S Bröring, S Ciliberti (2016). 'Exploring the Nutrition and Health Claims Regulation (EC) No. 1924.2006: What is the impact on innovation in the EU food sector?', *International journal of food sciences and nutrition* 68, p. 10-17; Lenssen *et al.* (2018), *supra* note 52.
407 de Boer & Bast 2015 *supra* note 52.
408 Khedkhar *et al.* (2016). *supra* note 407; de Boer & Bast 2015 *supra* note 52.
409 Lenssen *et al.* (2018). *supra* note 52; Khedkhar *et al.* (2016) *supra* note 407.
410 EHM Moors (2012). 'Functional foods: regulation and innovations in the EU. Innovation', *The European Journal of Social Science Research,* 25(4), pp. 424-440.

As the food and beverage industry largely consists of SMEs (99.2 %) that generate approximately 40.5% of the industry turnover[411], and that have limited resources for R&D, the required resources for innovation seem to be an important issue. Another point of interest regarding the effect of the NHCR on innovation is the aspiration to 'promptly' revise the positive list, and a simple and accelerated procedure with implementing acts is expected from the Commission[412]. As the authorisation procedure is now known to be lengthy[413] – with submissions of claims under Article 13(5) of the NHCR having a success rate of 10 % and a processing time of 2 to 3 years[414] – it may be questioned whether this desire can be fulfilled with the current regulatory framework. Finally, the 2020 evaluation of the NHCR also concluded[415] that the uncertainty on the on-hold list negatively contributes to the objective of promoting and protecting innovation. In the botanicals sector particularly, it is deemed challenging to launch new products and to obtain a claim on these types of products, which 'discourages long-term investments'[416].

4.1.2. The impact of case law on the high level of consumer protection

Different rulings specify that health claims have to be interpreted broadly, and thus, any statement or suggestion that a food affects health in the short or long term is considered a claim that should be substantiated with scientific evidence[417]. This is also the case for Article 10(3) claims, general statements related to health and well-being[418]. Even though this requirement for scientific evidence is considered to support the high level of consumer protection aimed for by the NHCR, Dr. Schebesta (2020) argues that Article 10(3) claims should be interpreted more restrictively by national courts, even though the wide interpretation of 'general' statements is described as rather common[419]. She describes that a narrower interpretation may contribute to a high level of consumer protection, by enabling consumers to make a well-considered purchasing decision, as the '(scientific) quality of information [would be] better safeguarded' when health claims provide accurate information and contribute to consumer education[420].

Furthermore, CJEU rulings analysed in this research papernote have specified that health claims should not result in conflicting, confusing, ambiguous or even false messages towards consumers[421]. The Commission as risk manager may therefore deviate from the positive scientific opinions issued on certain cause-and-effect relationships when general nutrition and health considerations may be in conflict with these proposed claims. Case law thereby confirms that the NHCR can be seen as taking a precautionary approach, focusing on consumer understanding[422]. Even though substantiated information may thus be withheld from consumers, this does allow for

411 FoodDrinkEurope (2021). Data & Trends of the European Food and Drink Industry 2021. Available via https://www.fooddrinkeurope.eu/resource/data-trends-of-the-european-food-and-drink-industry-2021 (Last accessed 15 August 2023).
412 Recital 26 NHCR.
413 I Pravst, A Kusar, K Zmitek, K Miklavec, Z Lavrisa, L Lähteenmäki, V Kulikovskaja, RN Malcom, C Hodgkins, MM Raats, the REDICLAIM Consortium (2018). 'Recommendations for successful substantiation of new health claims in the European Union.',*Trends in Food Science & Technology*, 71, pp. 259-263.
414 A Meisterernst, B Haber (2019). 12 Years of a Learning Process – What Has the HCR brought? European Food and Feed Law Review, 14(4), pp. 310-322.
415 SWD(2020) 95 final, pt 1, p. 85
416 SWD(2020) 95 final, pt 1, p. 54-55; Meisterernst, Haber (2019), *supra* note 406; Hoogenraad, Duivenvoorde (2016), *supra* note 378.
417 Cases T-296/12, C-296/16.
418 Opinion AG Bobek, *supra* note 134, paras 73, 113, 68-70 ; Case C-524/18.
419 Schebesta (2020), *supra* note 128; Evans (2014), *supra* note 109.
420 Schebesta (2020), *supra* note 128.
421 Cases C-296/16, T-100/15.
422 Conea (2017), *supra* note 306.

protecting consumers from potentially confusing information that may be misunderstood[423]. The NHCR and the case law discussed are thereby contributing to consumer protection.

The transitional measures of Article 28(5) under which on hold claims on botanical products can be used do not support meeting this objective[424]. As put forward in section 3, consumers are exposed to potentially unsubstantiated claims next to carefully reviewed claims. Furthermore, the lack of nutrient profiles to limit the use of claims on products that have a favourable profile decreases the effectiveness of the NHCR to achieve the highest level of consumer protection[425]. Claims can still be made on products that may be considered less healthy – and these may stimulate consumers to consume more of these products[426]. The strict conditions and scientific requirements of the highest standard were meant to ensure that consumers would only see 'reliable information', subsequently increasing trust in nutrition and health claims[427]. Due to the on hold claims and the lack of nutrient profiles, however, consumers are still exposed to unverified claims and to claims on products that are less healthy. The Court rulings discussed in this research paper do not touch upon the consumer protection aspects related to these issues, but as put forward below, these are key issues that need to be tackled to further ensure that the NHCR can achieve this objective.

4.1.3. The impact of case law on the effective functioning of the internal market

As well as contributing to achieving the NHCR's aim of consumer protection, case law has contributed to the effective functioning of the internal market. Most importantly, the CJEU has ruled on the possibility of the Commission to derogate their authorisation decision from positive scientific opinions issued[428], even though scientific substantiation of the cause-and-effect relationship is key for authorising health claims[429].

Secondly, the scope of the NHCR is confirmed to affect commercial communication towards healthcare professionals[430]. Prior to the CJEU's ruling, food business operators across Member States took different approaches when addressing healthcare professionals with information, and this ruling created a more level playing field as to under what conditions information can be shared and when the provisions of the NHCR have to be considered[431]. Member State interpretation differences are thereby also reduced.

Thirdly, the rulings on the transitional measures for trademarks and brand names[432] which were applicable until July 2022 offered clarity on what types of communication were covered by these provisions, and how these should be enforced by competent authorities. While the trademark and brand name requirements have been described as potentially negatively affecting intellectual property rights of food companies[433], the CJEU judgments again supported decreasing interpretation differences of these provisions across the single market.

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423 Lenssen et al. (2020), *supra* note 76.
424 SWD(2020) 95 final, pt 1.
425 *Ibid.*
426 Recital 14 Commission Regulation (EU) No 2015/8.
427 SWD(2020) 95 final, pt. 1, p. 5.
428 Cases C-296/16, T-100/15.
429 Art. 6 NHCR.
430 Case C-19/15.
431 Lazíková, Rumanovská (2022), *supra* note 300.
432 Cases C-299/12, C-177/15.
433 MS Cohen (2020). 'Balancing Public Health and Intellectual Property Rights: The Impact of the EU Nutrition and Health Claims Regulation on Trademarks in the Weight Loss Industry', *European Food and Feed Law Review* 15, pp. 108-116.

Finally, in different cases[434], the CJEU ruled that the functioning of the internal market was not negatively affected by the transitional measures of Article 28(5) and the on hold claims list. The on-hold list is not judged to create legal uncertainty, and in different actions brought before the Court, the approach taken by the Commission to gradually adopt a list of authorised claims was upheld[435]. As put forward in section 4.2.2, the Court did however acknowledge, e.g. in Joined Cases C-596/15 P and C-597/15 P, that the national provisions to which on hold claims must comply may actually give rise to different requirements and varied approaches to the burden of proof for on hold claims. This was also found in the NHCR's evaluation: the on-hold list does not create legal uncertainty, but especially national provisions related to safety requirements for botanicals in food to which operators have to comply under the transitional measures, could negatively affect the internal market[436].

4.2. Open questions

4.2.1. Nutrient profiles

The rulings of the Court in Cases C-544/10, C-299/12, C-177/15, and C-296/16 showed that whenever claims may become ambiguous, for example, if they contradict general nutrition and health considerations, these claims are not allowed. The potential to confuse or mislead consumers through such ambiguous messages is not allowed. Consumers may thereby miss certain information that could be factually correct, e.g. on the specific type of sodium in a product or that a specific alcoholic beverage is more easily digestible. They are however protected from ambiguity as such claims may initiate increased consumption of these products which would go against the general aims of the EU to protect consumers' health. Without the adoption of nutrient profiles, different products that are high in fats, sugar and/or salt can carry nutrition and health claims, as long as they do comply with other provisions of the NHCR. However, this may likewise result in ambiguous messages, for example when sodas with high sugar and energy content are being advertised for their vitamin content, or when the amount of fibre is highlighted with a claim on a cookie containing high levels of fats and sugar. Research has shown that even though foods with claims may be healthier than their regular counterparts, approximately 25 % of the products using health-related claims do not meet the criteria of different profiling schemes[437]. With the possibility to use claims on products that have an unhealthy composition, a high level of consumer protection cannot be guaranteed. This was also recognised in the NHCR evaluation[438]. And even though nutrient profiling and front-of-pack labelling may seem like two separate topics in food law – and are currently dealt with under different regulatory schemes – the NHCR and the FIC – the increased attention for front-of-pack nutrition labelling with the development of NutriScore[439] has stimulated

[434] On *i.a.*, cases C-609/12, C-363/19.

[435] Cases T-354/12, T-296/12, T-334/12, T-578/14, C-637/15 P, T-619/14, T-620/14, C-596/15 P, C-597/15 P.

[436] SWD(2020) 95 final, pt 1, p. 53, 54, 71, 73

[437] S Hieke, N Kuljanic, I Pravst, K Miklavec, A Kaur, KA Braun, BM Egan, K Pfeifer, A Gracia, M Rayner (2016). Prevalence of Nutrition and Health-Related Claims on Pre-Packaged Foods: A Five-Country Study in Europe. *Nutrients* 8(3), 137; A Kaur, P Scarborough, S Hieke, A Kusar, I Pravst, M Raats, M Rayner (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, p. 1388-1395; B Franco-Arellano, M-E Labonte, J Bernstein, M L'Abbe (2018). Examining the Nutritional Quality of Canadian Packaged Foods and Beverages with and without Nutrition Claims. *Nutrients* 10, 832; U Pivk Kupirovic, K Miklavec, M Hribar, A Kusar, K Zmitek, I Pravst (2019). Nutrient Profiling Is Needed to Improve the Nutritional Quality of the Foods Labelled with Health-Related Claims. *Nutrients* 11, 287.

[438] SWD(2020) 95 final, pt 1.

[439] NutriScore is a colour-coded front-of-pack nutrition label that summarises the nutritional quality of a product with one of its five colours (from dark green to dark orange) and associated letters (from A to E). The logo is based on an overall score of nutrients that should be limited (energy, saturated fats, sugars and salt) or which are encouraged

the discussion on nutrient profiling and labelling of healthy foods[440]. Therefore, in the revisions to Regulation (EU) No 1169/2011, nutrient profiles, also linked to nutrition and health claims, were included for analysis in the inception impact assessment[441]. The inception impact assessment recognises nutrient profiles as essential instruments in informing consumers about the healthiness of products and decreasing the risk of ambiguous messages to consumers when making their dietary decisions[442].

4.2.2. Botanical claims

The evaluation of the scientific dossiers underlying the submitted botanical health claims is yet to be resumed. The CJEU rulings so far have highlighted that the transitional measures are currently considered sufficient for the health claims on hold. Any pleas of legal uncertainty due to the applicable transitional measures on the on hold claims were dismissed. As recognised by the Court in Joined Cases C-596/15 and C-597/15, the claims made under these two different regimes, however, cannot be seen as dealing with the same requirements.

Two major consequences follow from the current situation. Firstly, as put forward in sections 4.1.2 and 4.1.3 above, it cannot be established whether the NCHR is fully meeting its objectives. As the underlying evidence of botanical claims has not been evaluated, it is not known how many misleading claims are currently present on the market. Additionally, with FBOs being subject to both the general requirements of the NHCR as well as national provisions, there is a chance for different rules among Member States, with a potentially negative impact on the market in the future. Secondly, it is currently unknown what the future evidence requirements for botanical claims will be. This can potentially hinder innovation and research, as it is unclear what to invest in for product development and research. Even though the provisions described in the NHCR refer to 'scientific evidence of the highest possible standard'[443], the ongoing debate addresses the potential role of evidence on traditional use in the assessment to determine whether claims have been sufficiently substantiated.

When the Court ruled that generally accepted scientific evidence should not merely entail experiential evidence as in Case C-363/19, it can, however, be questioned how 'traditional use' could ever fulfil such a requirement. As science prevails in scientific assessment, it should then be determined whether traditional use can be considered 'scientific': from a life science perspective, merely experimental studies or grouped experimental studies (in meta-analyses and systematic reviews) that analyse cause-and-effect relationships are considered of sufficient quality to support health claims, whereas other disciplines including, e.g. history, may give a wider interpretation to the concept[444].

(fibre, protein, fruits, vegetables, pulses, nuts, and rapeseed, walnut and olive oils). NutriScore was developed by a team of researchers at Université Sorbonne Paris Nord. The algorithm underlying NutriScore is based on the UK Food Standards Agency's nutrient profiling system, the FSE score. More information on NutriScore can be found on https://www.santepubliquefrance.fr/en/nutri-score (last accessed 27 August 2023) and https://nutriscore.blog/category/papers-in-english (last accessed 27 August 2023).

440 de Boer (2021), *supra* note 6, L Dréano-Trécant, M Egnell, S Hercberg, P Galan, J Soudon, M Fialon, M Touvier, E Kesse-Guyot, C Julia (2020). 'Performance of the Front-of-Pack Nutrition Label Nutri-Score to Discriminate the Nutritional Quality of Foods Products: A Comparative Study across 8 European Countri',*Nutrients* 12, 1303.

441 European Commission (2021). Facilitating healthier food choices – establishing nutrient profiles. Available via https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12748-Facilitating-healthier-food-choices-establishing-nutrient-profiles_en (Last accessed 15 August 2023).

442 de Boer (2021), *supra* note 6.

443 SWD(2020) 95 final, pt 1, p. 5.

444 KGM Lenssen (2023). The role of non-scientific data in risk analysis: the case of botanical health claims. Maastricht: Maastricht University. https://doi.org/10.26481/dis.20230525kl

The evaluation process for botanical claims was put on hold because many claims would be rejected[445], as they were not supported by scientific evidence substantiating the causal link between product and effect. In different applications, 'traditional use' evidence, evidence collected based on the experiences with consuming a botanical, was used as substantiation of a health effect. In the discussion to determine the extent such evidence could or should play a role in the substantiation of health effects within the NHCR, both Member States and stakeholders[446] have referred to the regulatory framework for medicinal products. Indeed, botanicals can be used in food products and medicines[447]. Their classification depends on both the efficacy of a product, its function, and the way it is presented or the impression that is given about its effect[448]. The legal frameworks of foods and pharmaceuticals are mutually exclusive: a product is either a food or a medicine, and pharmaceutical law prevails when there is doubt about the status of a product[449]. However, this classification is determined at the Member State level, and in this, culture and tradition can play an important role[450]. As illustrated in *Hecht Pharma*[451] described in this research paper, products can be classified differently.

Following Directive 2004/24[452], there is the possibility to substantiate the safety and efficacy of 'traditional herbal medicinal products' (THMPs), with evidence on experience or 'traditional use'. If it can be shown that the product has been used safely in the treatment of a specific disease for 30 years of which 15 years within the EU, it can be authorised as a THMP[453]. Whereas the evidence base for regular medicinal products is based on intervention studies, 'bibliographic or expert evidence' can be used to substantiate the safety and efficacy of a THMP. General information should be provided in the authorisation request, which should also include quality studies. Although several stakeholders[454] argue that such evidence should then also be able to be used to substantiate the health effects of botanicals in food, the THMP approach does not seem to translate one-to-one to health claims. Indeed, THMP assessments address both the safety and health effects of a product with a specific dosage[455]. Information can also be given about the instructions for use, possible interactions, and vulnerable groups can be warned about possible side effects by means of a package leaflet. In addition, through vigilance, potential adverse events are detected, analysed and mapped by both market authorisation holders and vigilance centres. For food products, and thus also food supplements containing botanicals, no such risk information is to be provided nor is there

445 SWD(2020) 95 final, pt 1, p. 23.
446 SWD(2020) 95 final, pt 1; Lenssen et al. (2020), *supra* note 76.
447 Bert Schwitters (2012).' Want to Harmonize "Botanicals"? Take the Broader Perspectives of "Traditional Health Claims" and "Other Substances"!', *European Food and Feed Law Review* 7, pp. 328-340.
448 A de Boer (2015). *Interactions between nutrition and medicine in effect and law*. Maastricht: Maastricht University. https://doi.org/10.26481/dis.20151106ab; KGM Lenssen, A Bast, A de Boer (2019). 'International Perspectives on Substantiating the Efficacy of Herbal Dietary Supplements and Herbal Medicines Through Evidence on Traditional Use.', *Comprehensive Reviews in Food Science and Food Safety* 18, pp. 910-922.
449 V Silano, P Coppens, A Larrañaga-Guetaria, P Minghetti, R Roth-Ehrang (2011). Regulations applicable to plant food supplements and related products in the European Union. *Food & Function* 2, pp. 710-719; C Quintus, HG Schweim (2012). European regulation of herbal medicinal products on the border area to the food sector. *Phytomedicine* 19(3-4), pp. 378-381; Lenssen *et al.* (2019), *supra* note 443.
450 Silano *et al.* (2011), *supra* note 450; Lenssen *et al.* (2020), *supra* note 76.
451 Case C-140/07.
452 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, pp. 85-90.
453 Lenssen *et al.* (2019), *supra* note 443.
454 Lenssen *et al.* (2020), *supra* note 76.
455 Art. 1(2) Dir 2004/24/EC.

planned vigilance. Products placed on the market are presumed to be safe[456]. While information can be given on the dosage and instructions for use of a product should be described, it is assumed that no package leaflet is needed and there is no organised system (vigilance framework) to detect possible adverse events[457]. Because it is known that the use of botanicals in food supplements can carry risks, several Member States use positive or negative lists for these substances, which describe the explicitly authorised or explicitly prohibited substances respectively for use in food products[458]. This is not a harmonised approach, again potentially causing fragmentation in the internal market. In addition, several Member States require dietary supplements to be notified, in an effort to contribute to food safety[459]. In this too, however, Member States determine their own approach, again leading to different strategies[460]. The Commission considered in 2008[461] that at that time it was not essentially needed or feasible to adopt new legislation for the safety of botanicals in food[462]. Back then, the then existing provisions and procedures[463] were considered to be enough to regulate substances other than vitamins or minerals for use in foodstuffs. This conclusion was based on the expectation that the NHCR would lead to a number of products with approved claims and that such a list of approved claims would indirectly harmonise the use of botanicals in the internal market[464].

As shown, consumer protection and the functioning of the internal market may not be fully attained when on hold claims can be made on botanicals. However, it remains a political decision to determine how to move forward from this impasse. The Court confirmed (C-363/19) that evidence cannot merely be provided based on anecdotal experiences with a product. 'Generally accepted scientific evidence' has so far been understood as relating to human (intervention) studies, suggesting that under the NHCR, 'traditional use' evidence as such may not easily meet this evidence requirement to support the relationship between a food (ingredient) and a health effect. This seems to suggest that not merely would the risk assessment strategy need adjustments, but the provisions of the NHCR would need to be revised to allow for such use. This could, however, be an option, should it be decided that the use of traditional use evidence for substantiating botanical claims in foods should be aligned with its use in the risk-benefit assessment of medicinal products, in THMPs[465]. But this would also require further harmonisation of other national provisions, such as how to deal with the safety of botanicals.

Both decisions, allowing or not allowing botanical claims to be substantiated with evidence on traditional use, will have consequences for consumer protection and (the functioning of) the market. When not allowed, only scientifically substantiated claims will be available to consumers. In such case, FBOs in the food supplement industry will be particularly impacted, as these products – which

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456 Regulation (EC) No 178/2002 of the European Parliament and of the Council 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, p. 1-24. (Consolidated version: 1 July 2022), Art. 14.

457 A de Boer, L Geboers, S van de Koppel, F van Hunsel (2022). 'Nutrivigilance in the Netherlands: reporting adverse events of non-registered products', *Health Policy* 126(8), pp. 731-737.

458 SWD(2020) 95 final, pt 2, Annex V.

459 TC Wallace (2015). 'Twenty years of the dietary supplement health and education act-how should dietary supplements be regulated?', *Journal of Nutrition* 145, pp. 1683-1686.

460 de Boer *et al*. (2022), *supra* note 452.

461 Report of the 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. Available via https://food.ec.europa.eu/system/files/2016-10/labelling_nutrition-supplements-comm_2008_0824_en.pdf (Last accessed 27 August 2023).

462 SWD(2020) 95 final, pt 1, p. 12, 13

463 SWD(2020) 95 final, pt 1, p. 9, 10: Through TFEU art 30-36, among others, free movement of goods can be determined; the procedure in Art 8 of Reg 1925/2006 by which substances can be banned; and mutual recognition.

464 SWD(2020) 95 final, pt 1, p. 5

465 Directive 2004/24/EC.

often contain botanicals – are mainly sold for their beneficial health effects[466]. If traditional use evidence could be used in the substantiation of botanical claims, manufacturers of THMPs may move towards the food (supplement) market as this category of products is known to be less strictly regulated[467]. When no distinction is made in the wording of claims[468], consumers may however not understand the different levels of evidence supporting the claim.

4.2.3. Other issues

Increasingly, food products are promoted through communication on social media. While Case C-19/15 clarified that commercial communication towards health care professionals on foods dealing with nutrition and health aspects of products intended for the final consumer is covered by the NHCR, communication on social media, e.g. by influencers is not always clearly commercial or non-commercial. As described in the 2022 Position Paper of the UK Academy of Nutrition Sciences, already for healthcare professionals working in commercial settings, who are interested in referring to authorised health claims, it may be challenging to understand to what extent they are allowed to use certain authorised claims in their communications[469]. Celebrity endorsements as such, as long as they fall under non-commercial communication, do not seem to be prohibited under the NHCR[470]. The UK Academy of Nutrition Sciences highlights that celebrities or influencers have great effects on the public. When non-professionals with limited or no professional nutrition training do make such impactful endorsements, these may lead to using 'potentially unsafe or misleading claims'[471]. The new use of social media for food (supplement) marketing and sales may thereby present 'the potential to undermine the main principles' of the NHCR: protecting consumers from false and misleading claims[472]. So far, no cases have reached the CJEU dealing with food-related influencer communication, but more research is needed to analyse the grey area of health-related online communication about foods and how this impacts the implementation of the regulation.

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466 SWD(2020) 95 final, pt 1, p. 25, 28

467 SWD(2020) 95 final, pt 1; Lenssen et al. (2020), *supra* note 76.

468 Some stakeholders (e.g., Synadiet, the French union of food supplements) have suggested that a graded approach to claims would be suitable. Claims would then reflect the level of evidence that supports the relationship between the ingredient and the beneficial nutritional or physiological effect. Consumer research has however shown that consumer understanding such graded claims seems limited, as e.g., written by Verhagen et al (2010).

469 M Ashwell, M Hickson, S Stanner, A Prentice, CM Williams (2022). 'Nature of the evidence base and strengths, challenges and recommendations in the area of nutrition and health claims: a position paper from the Academy of Nutrition Sciences', *British Journal of Nutrition* 130(2), pp. 221-238.

470 Ashwell et al. (2022), *supra* note 470, p. 233; Department of Health & Social Care (2022). 'Nutrition and health claims: guidance to compliance with Regulation (EC) 1924/2006'. Available via https://www.gov.uk/government/publications/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-1924-2006-on-nutrition-and-health-claims-made-on-foods/nutrition-and-health-claims-guidance-to-compliance-with-regulation-ec-19242006. (Last accessed 27 August 2023).

471 Ashwell et al. (2022), *supra* note 468, p. 233.

472 Ashwell et al. (2022), *supra* note 468, p. 233.

5. The added value of the existing legal framework

The NHCR was adopted to ensure that consumers could be better protected from potentially false and misleading claims, while promoting the functioning of the internal market. The NHCR, therefore, harmonised national provisions related to commercial communication made on foods about the nutritional content and health benefits of these nutrients. The analysis of CJEU rulings, legal opinions and related literature presented in this research paper has provided insights into the implementation and application of the regulation.

From the different cases analysed, it becomes clear that the NHCR is seen as proportionate for achieving the aims of consumer protection and it has in many ways contributed positively to the effective functioning of the internal market. In the rulings, the precautionary approach taken within the NHCR to consumer protection is confirmed. Consumers should only be exposed to scientifically substantiated claims – which can stimulate the consumption of healthier food products – when these claims are used on products that fall within a healthy diet[473]. The current approach to nutrition and health claims thereby fosters a high level of consumer protection. As highlighted in the NHCR evaluation[474], however, nutrient profiles will provide an important tool to further optimise the alignment of claims with products with a more favourable nutritional profile to further reduce the risk of consumer confusion. From the evaluation report, it was clear that a harmonised, and thus EU-wide approach to nutrient profiles would be a tool to further improve consumer protection and to support the development of a level playing field on the internal market. For consumers, it could limit the use of claims on products that have a less favourable nutritional profile, which 'minimises' the potential for consumer misleading and this can further support consumer trust in claims[475]. FBOs would benefit from an EU-level approach as this would not only support reformulation, both legal certainty for new product developments and a level playing field between operators would be ensured[476].

The ongoing revision of the FIC highlights the importance of nutrient profiles when informing consumers. It shows the interlinkages between nutrient profiles and harmonised mandatory front-of-pack nutrition labelling as four out of the five options presented in the inception impact assessment include the establishment of nutrient profiles. As put forward in this inception impact assessment, 'for reasons of coherence and consistency (…), the nutrient profiling model for restricting claims is based on the nutrient profiling model underpinning the harmonised front-of-pack scheme'[477].

The evaluation report also highlighted that having the botanical claims on hold for assessment and authorisation negatively impacts the objective of consumer protection[478]. Consumers are exposed to claims that have undergone a rigorous assessment, as well as to claims that may not be substantiated by scientific evidence. The main question before the assessment can be resumed, is whether there is a role for traditional use evidence or experiential evidence. Diverging views have been presented as to whether or not this notion, which has a specific role in the risk assessment of safety and efficacy of THMPs, should play a role in the efficacy substantiation of botanicals in

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473 Claims are therefore not found on alcoholic beverages, and no health claims are authorized which may result in ambiguous messages to consumers.

474 SWD(2020) 95 final, pt 1, p. 49

475 SWD(2020) 95 final, pt 1, p. 50, 84.

476 SWD(2020) 95 final, pt 1, p. 51, 84.

477 Inception Impact Assessment: Proposal for a revision of Regulation (EU) No 1169/2011 on the provision of food information to consumers. Ares(2020)7905364, p. 4.

478 SWD(2020) 95 final, pt 1, p. 52.

foods[479]. From the analysed CJEU rulings, it can be questioned whether the provisions of the NHCR would allow for implementing 'traditional use evidence' immediately as supportive evidence for claims. If the legal framework were to be adjusted to also allow for claims on botanicals being supported by experiential evidence instead of scientific evidence as such, this could be considered as a separate category within the NHCR. Whether this is sufficiently aligned with the precautionary approach to consumer protection, remains to be determined.

The provisions of the NHCR are mostly seen as contributing to the effective functioning of the market. The most important exception to this is the list of on hold claims on botanicals used in food products, under the transitional measures of Article 28(5) of the regulation. The on hold claims list is already a first step towards increased harmonisation of allowing the use of claims on botanical-containing substances in foods[480]. In their rulings, the CJEU has noted that there is not necessarily legal uncertainty arising from these measures. FBOs however do experience such legal uncertainty, as they do not have certainty as regards how this situation will be dealt with in the future, and within what time frame. This uncertainty may negatively affect decisions related to innovation and business strategy. From the analysis presented in thisresearch paper, it becomes clear that using claims under the transitional regime cannot be seen as a similar situation to using claims under the definitive regime, the claims that are found on the positive list. They are not legally equivalent, as national provisions apply to the on hold claims. For botanical claims, national provisions often also address safety considerations. The current transitional measures for botanical claims were deemed to not offer EU-added value, as the provisions are not sufficiently harmonised[481]. It was assumed that the NHCR would result in indirect harmonisation of safety and health aspects of botanicals, but the continued use of the transitional regime has not contributed to such harmonisation.

The evaluation of the NHCR showed that when addressing claims on botanicals and the potential role of traditional use evidence in supporting the efficacy of botanicals in foods, the safety framework for botanicals in foods should also be considered. Back in 2008[482], the Commission decided not to address the legal framework for botanicals in foods on an EU level. Meanwhile, Member States and other stakeholders have highlighted that national rules governing the safety of botanicals are highly divergent. National rules range from the use of positive lists, negative lists, warning systems, guidance documents or no rules at all[483]. This contributes to the fragmentation of the market[484]. The regulatory framework thereby 'is not able to ensure free circulation of products, consumer information, or, though at a lower degree, the highest level of food safety'[485]. It is therefore deemed important to address the safety and efficacy questions for botanicals on an EU level[486]. This confirms the findings previously shared in section 4.2.2: a decision on how to move forward with the on hold botanical claims would increase certainty for business operators and will influence the extent to which the NHCR can meet its objectives.

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479 In the evaluation of the NHCR (p. 68/69 SWD(2020) 95 final, pt 1), it is highlighted that there are differences between both categories and both legal frameworks, making the concept of traditional use not transposable to food. Also, they highlight that the category of medicinal products and THMPs are well defined, which is not the case for foods; that other provisions also apply to medicinal products (including, but not limited to Good Manufacturing Practices); and that EMA monographs have supported 'the relationship between a well-defined quality of plant substance(s) 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'.

480 SWD(2020) 95 final, pt 1.

481 SWD(2020) 95 final, pt 1, p. 81.

482 COM(2008) 824 final, *supra* note 462.

483 SWD(2020) 95 final, pt 2, Annex V.

484 SWD(2020) 95 final, pt 1, p. 78-79.

485 SWD(2020) 95 final, pt 1, p, 80-81.

486 SWD(2020) 95 final, pt 1, p. 50-51, 80-82.

6. Recommendations

The analysis of CJEU rulings, legal opinions and (grey) literature on the Nutrition and Health Claims Regulation presented in this research paper specify that the NHCR offers important provisions that support consumer protection and that have contributed to the harmonisation of legislation across EU Member States. The following recommendations build on analysed cases the, the evaluation of the NHCR published in 2020 and related literature as presented in previous sections.

Recommendation 1. Health claims should remain well-aligned with EU health policies. The regulation of nutrition and health claims has been shown to contribute to consumer protection. The CJEU rulings have confirmed that all messages stating, suggesting or implying a relationship between consuming a food and a potential beneficial nutritional or physiological effect, should be understood as such claims. Thus, they should be substantiated with scientific evidence. Different cases have further confirmed that in light of consumer protection from potentially ambiguous messages, scientifically substantiated relationships may not be authorised on specific types of products. For relationships substantiated by scientific evidence, when such claims can confuse consumers, they are not allowed under the provisions of the NHCR. As this strict interpretation is seen to contribute to consumer protection, the continued use of such broad interpretations of what constitutes a claim and how this should be aligned with other public health policies remains essential.

Recommendation 2. Decide upon the use of 'traditional use' for botanical health claims. A decision needs to be made on whether claims should always be substantiated with scientific evidence, and if this is the case, whether 'traditional use' should be considered part of this. Interestingly, in academic literature this decision has so far mostly been linked to deciding upon an adjusted risk assessment procedure in which evidence on traditional use may also play a role. The analysis presented highlights that it is however essential to link a decision on the role of traditional use evidence to the risk management considerations of the NHCR. Prior to potentially adjusting any risk assessment requirements, a discussion needs to be held on if evidence on traditional use should be considered in determining whether a claim is sufficiently substantiated. A careful decision-making process will then ensure that the risk assessment criteria are well aligned with the legislative requirements laid down in the provisions of the NHCR, and that these are not disproportionate. In that regard, it should be noted that the CJEU rulings have highlighted that the freedom of expression and information, an argument often raised by scholars in favour of substantiating botanical health claims based on evidence of traditional use or experiential proof, is not necessarily infringed when restricting information provision as is the case in the NHCR.

A decision on the role of 'traditional use' for substantiating botanical claims will allow for a next step in harmonisation. Currently, these claims must live up to both the provisions in the NHCR as well as national requirements. This immediately brings forward the safety considerations that play a role in the use of botanicals in foods. National provisions often address the safety, and efficacy of botanicals. A decision on the use of 'traditional use' evidence for botanical claims can therefore not be made in isolation from the other regulatory considerations addressing botanicals in foods, such as (national) provisions relating to safety of botanicals in foods.

Recommendation 3. Study whether the NHCR remains future-proof in an online environment. The NHCR was adopted at a time when social media did not yet play such a large role in advertising and sales of foods and food supplements. Today, influencers and celebrities use social media to generate income and have a large reach towards the public through these channels. It is however unclear to what extent health-related online communication about foods is governed by the NHCR, and how

the implementation and application of the NHCR contributes to protecting consumers from false and misleading claims found online.

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Annex II: Implementation, application and impact of health claims made regarding foods

Literature reviews

Conducted at the request of the European Parliamentary Research Service, this research paper examines the implementation and application of the Nutrition and Health Claims Regulation (NHCR) and its impact on consumers' attitudes and food choices.

Chapter 1 begins with a description of the legal framework for nutrition and health claims in foods and food products currently in force in the European Union (EU), the United Kingdom (UK) since it left the EU, and the United States (US), with an emphasis on regulations on botanicals. The chapter concludes with a discussion on similarities and differences between legislation in these three settings.

Chapter 2 contains a systematic review of the scientific literature describing the influence of nutrition and health claims on consumers' attitudes, behaviours and choices, with a focus on advertising messages through traditional and new media that are often used to circumvent the limits of the NHCR and to deliver misleading and unauthorised messages.

Finally, Chapter 3 provides an overview and examples of the positive and adverse health effects of botanicals permitted in food supplements. In addition, it presents the difficulty of collecting evidence to substantiate claims for botanical food supplements and the overlapping classification of food supplements and traditional herbal medicinal products.

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Executive summary

This document starts with an analysis and comparison of the implementation and application of the legal framework for food business operators that want to make nutrition and health claims regarding their food products in the European Union (EU), the United Kingdom (UK) and the United States of America (US).

In the EU, the European Commission (EC) adopted Regulation (Reg.) (EC) 1924/2006 in 2006 to ensure messages on food products to consumers regarding nutritional and heath claims are scientifically substantiated and not misleading. It has been in force since July 2007. According to the above-mentioned regulation, the nutritional claims permitted on foods are those listed in Annex of the regulation and can be used by the producers without previous authorisation, provided that the nutrient composition of the food product complies with the rules established in the regulation. There are three types of health claims: 1) **functional** (Articles 13[1] and 13[5]); 2) **reduction of a risk of disease** (Article 14(a)); and 3) **development and health of children** (Article 14(b)). Claims are not permitted to attribute to any food the property of preventing, treating or curing any human disease. Other than nutrition and health claims, Reg. (EC) 1924/2006 allows for the use of a 'generic descriptor', which is information traditionally used to indicate particular classes of food products that might affect human health (e.g. 'digestive'). When authorised, the generic descriptor must be written in the same words used for at least 20 years. An application for a new health claim must be submitted to the EC, which forwards it to the European Food Safety Authority (EFSA) for an opinion on the scientific substantiation. The EC updates the EU Register of Health Claims with permitted claims, their conditions of use and claims proposed but not authorised due to denial of authorisation.

The UK left the EU in 2020, and the powers the EC held regarding food legislation have been transferred to the national competent authorities of England, Wales and Scotland through the UK-wide Common Framework for Nutrition Labelling Composition and Standards. Some articles of Reg. (EC) 1924/2006 are under review by the UK legislators, and a consultation on some proposed amendments is on course. Currently, the authorisation process for nutritional and health claims in the UK is similar to that of the EU.

In the US, three types of claim are permitted by the enforced legislation, the 1990 Nutrition Labeling and Education Act and the 1997 Food and Drug Administration Modernization Act: **1) nutrient content claims, 2) authorised and qualified health claims and 3) structure/function claims**. Nutrient content claims are equivalent to European nutrition claims. Authorised and qualified health claims are claims that the US Food and Drug Administration (FDA) has authorised with a different scientific evaluation. Function/structure claims that do not require scientific assessment and authorisation by the FDA are traditionally used.

Regulation (EC) 1924/2006 applies also to claims for foods containing botanicals. However, the risk assessment and authorisation procedure for more than 2 000 claims mostly concerning botanicals is currently on hold owing to the difficulty in characterising the composition of plants and the lack of human studies necessary to substantiate the claims scientifically.

Legislation on botanicals in foods and food products is not harmonised at EU level. The EU Member States (MSs) also have different lists of permitted and/or non-permitted plants in foods. These national lists overlap for several plants with traditional medicinal value. Therefore, a plant might be authorised as a food supplement in a MS and as traditional medicine in another or be permitted as food ingredients in an MS and forbidden in another.

The systematic review of the scientific literature published since 2010 and available in the databases Scopus, Embase and Pubmed on the effects of nutrition and health claims on consumers' attitudes and food choices includes 25 papers. The data from these studies were extracted from 23 qualitative/mixed studies according to the SPIDER methodology and two quantitative studies with the PICO methodology. The results of this analysis show that 1) the understanding of the claims varies depending on consumers' education level, socioeconomic status and personal motivation to follow a healthy diet and lifestyle, 2) risk reduction claims and positive nutritional claims (e.g. 'high in….') are the most attractive to consumers, 3) food's taste is still the main determinant of consumers' food choices and 4) consumers are prone to overconsume food products that have positive claims (the so-called halo effect). Contrasting results are available regarding consumers' willingness to pay more for foods bearing a nutrition or health claim. The link between the implementation of nutrition and claim regulations affecting consumers' health has not been studied.

Currently, there is no common EU-level list on the health effects of botanicals. There are some national lists of permitted botanicals and their parts as ingredients in food supplements, with health effects indicated for some botanicals on those lists. Those effects are based mostly on traditional use rather than the available scientific evidence. Some agencies have compiled documents to inform consumers of the health effects of the consumption of selected botanicals as foods, and the European Medicines Agency has developed a list of herbals approved as medicines through the traditional use procedure, with the indication of use that is mandatory for medicinal products. Clinical trials on healthy individuals, which are required for the authorisation of a health claim per the EFSA scientific framework, seldom confirm claims regarding botanicals set by traditional use.

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List of abbreviations

DSHEA	Dietary Supplement Health and Education Act
EC	European Commission
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
FBO(s)	food business operator(s)
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act
MS(s)	Member State(s)
NHCR	Nutrition and Health Claims Regulation
NLEA	Nutrition Labelling and Education Act
PICO	population, intervention, comparison, outcome
RCT	randomised clinical trial
Reg.	regulation
RYR	red yeast rice
SPIDER	sample, phenomenon, design, evaluation, research type
SSA	significant scientific agreement
THMP(s)	traditional herbal medicinal product(s)
UKNHCC	United Kingdom Nutrition and Health Claims Committee
WHO	World Health Organization

1. Normative framework on health claims made on foods in the European Union and their comparison with those in the United States and the United Kingdom

1.1. Introduction and methodology

In this chapter, the European Union (EU) legal framework on nutrition and health claims on food is presented, with a focus on the assessment of the scientific substantiation of claims by the European Food Safety Authority (EFSA). The legal framework is the set of laws, regulations and rules that apply in a particular country or the European Union regarding a specific topic. The main similarities and differences between the EU normative framework and United Kingdom (UK) and the United States of America (US) are presented at the end of this chapter.

Desk research was conducted using the following keywords: EU OR European Union, UK or USA AND health OR nutritional claim AND regulation OR normative OR regulatory framework. The databases searched were Google (for the search on the websites of the competent authorities in the studied countries and the corresponding legal database), PubMed, Embase and Scopus.

Due to time and resource constraints, the analysis is limited to the existing published literature. This research paper is not a legal or a comparative analysis. It describes the legal frameworks and offers an examination of the findings as presented in the literature.

1.2. The normative framework in the EU

1.2.1. The normative on nutrition and health claims

According to Regulation (EC) 1924/2006 (Nutritional and Health Claim Regulation, NHCR),[1] a 'claim' is any non-mandatory message or image made based on community or national legislation, including figurative, graphical and symbolic representations stating, suggesting or implying in any form that a food has specific characteristics.
A nutrition claim is any claim stating, suggesting or implying that a food may have particular beneficial nutritional properties, depending on

- the energy (caloric value) that the foo
  - provides,
  - does not provide and/or
  - provides at a reduced or increased extent or
- the nutritional substances that the food
  - contains,
  - contains at a reduced or increased extent or
  - does not contain.

A health claim is any claim that states, suggests or implies a relationship between a food category, a food or one of its components and health. There are three types of health claims:

- functional (Articles 13(1) and 13(5)),
- reduction of a risk of disease (Article 14A) and

[1] Article 2 of Regulation (CE) 1924/2006.

- development and health of children (Article 14 (1b)).

Claims that attribute to any food the property of preventing, treating or curing a human disease or refer to such properties are prohibited.
Another piece of voluntary information Regulation (EC) 1924/2006 addresses is the 'generic descriptor', traditional information used to indicate particular classes of food products that might affect human health (e.g., 'digestive'). For this type of claim, 20 years of usage must be proven.[2]

The use of nutrition and health claims shall not[3]

- be false, ambiguous or misleading;
- give rise to doubt about the safety and/or the nutritional adequacy of other foods;
- encourage or condone excessive consumption of a food;
- state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general; or
- refer to changes in bodily functions, which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.

The use of nutrition and health claims shall be permitted only if the following conditions are fulfilled[4]:

- the presence, absence or reduced content in a food or food category of a nutrient or other substance for which the claim is made has been shown to have a beneficial nutritional or physiological effect, as established by generally accepted scientific evidence;
- the nutrient or other substance for which the claim is made
  - is contained in the final product in a significant quantity as defined in community legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence or
  - is not present or is present in a reduced quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence;
- where applicable, the nutrient or other substance for which the claim is made is in a form the body can use;
- the quantity of the product that can reasonably be expected to be consumed provides a significant quantity of the nutrient or other substance to which the claim relates, as defined in community legislation or, where such rules do not exist, a significant quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence; and
- compliance with the specific conditions set out in Chapter III or Chapter IV, as the case may be.

The use of nutrition and health claims is permitted only if the average consumer can be expected to understand the beneficial effects as expressed in the claim. Nutrition and health claims shall refer to food ready for consumption.

The commission maintains a register of permitted nutrition claims in the EU and a register of authorised health claims and their conditions of use or applicable restrictions. The EU register on

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2 Article 1(4) of Regulation (EC) No 1924/2006 and Commission Regulation (EU) No 907/2013 on setting the rules for applications concerning the use of generic descriptors (denominations).

3 Article 3 of Regulation (EC) No 1924/2006.

4 Article 5 of Regulation (EC) No 1924/2006.

Health Claims includes information on authorised health claims and rejected health claims together with the reasons for their non-authorisation.[5] Due to their broad scope, it is important to notice that a number of health claims submitted to the commission are not available in the register. For example, information on claims submitted under Article 13(1) but that do not qualify as such and claims not related to human health are excluded from the register. Similarly, functional claims referring to botanical substances and pending an EFSA assessment procedure or deliberations of the Commission are not within the register's scope. Health claims for which a protection of proprietary data applies are recorded in the register.[6]

Nutrition Claims

Nutrition claims are permitted only if they are listed in the Annex of Regulation (EC) 1924/2006 and conform with the conditions set out in this regulation for a specific food product.[7] In the case of comparative claims, a comparison may be made only between foods of the same category, taking into consideration the range of foods in that category. The difference in the quantity of a nutrient and/or the energy value has to be stated, and the comparison should relate to the same quantity of food.[8]

Health Claims

Basic criteria for the acceptance of health claims include the[9]

- characterisation of the food and its constituents,
- beneficial role for human health,
- evidence of a cause–effect relationship,
- knowledge of the food amount needed for the indicated effect,
- representativity of available data for the target population and
- need to consider the globality of available scientific data and to evaluate all available evidence.

General-Function Health Claims Already in Use[10]

The claims based on Article 13(1) are the general functional claims authorised with an ad hoc procedure among all those already in use at the time Regulation (EC) 1924/2006 entered into force. A complex procedure was established to gather and evaluate a very large number of claims in use, in all the languages of the EU.

It should be noted that a considerable number of health claims already in use (e.g., those regarding botanicals or probiotics) have not received a positive evaluation by the EFSA. In 2010, after the EFSA's rejection of about 500 applications for botanical health claims due to a non-adequate characterisation of the botanical preparations or the non-demonstrated correlations between the use in humans of the botanical preparation and the beneficial health effects asserted, it became clear that substantiating the approximately 2,000 remaining claim applications for botanicals required more stringent proof of efficacy than was required for traditional herbal medicinal products. The EFSA put these claim evaluations 'on hold' while it deliberated how to resolve this

5 EC Register of permitted nutrition claims and their conditions of use and for Health claims

6 Article 19 of Regulation (EC) No 1924/2006.

7 Article 8 of Regulation (EC) No 1924/2006.

8 Article 9 of Regulation (EC) No 1924/2006.

9 Article 10 of Regulation (EC) No 1924/2006.

10 Article 13.1 of Regulation (EC) No 1924/2006.

persisting dilemma.[11] The on-hold claims can still be used in the EU market as long as they comply with Regulation 1924/2006 and relevant national measures.[12]

Annex of Regulation (EU) 432/2012 establishes 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.[13]

General-Function Health Claims Based on New Data Subject to Protection[14]
The procedure of Article 13(5) is for the same kind of claims as that of Article 13(1) except new data are necessary for the authorisations for which data protection may be requested. Therefore, these are health claims based on newly developed scientific evidence and/or applications that include a request for the protection of proprietary data. Article 13(5) claims are authorised under the procedures detailed in Article 18 of Regulation (EC) 1924/2006. The application to be presented by the FBO to a competent authority in the Member State must include the following information:

- the nutrient or other substance, the food or the category of food in respect of which the health claim is to be made and its particular characteristics;
- a copy of the studies, including, where available, independent, peer-reviewed studies that have been conducted regarding a health claim and any other material that is available to demonstrate that the health claim complies with the criteria provided in Regulation (EU) 1924/2006 on nutrition and health claims;
- where appropriate, an indication of the information that should be regarded as proprietary accompanied by verifiable justification;
- a copy of other scientific studies that are relevant to that health claim;
- a proposal for the wording of the health claim for which authorisation is sought, including, as the case may be, specific conditions for use;
- a summary of the application; and
- the reasons for the request.[15]

The competent authority will send the application and any information in MS to the EFSA for a scientific assessment and to the commission and the other MSs for information.
To prepare its opinion, the EFSA will verify that the health claim is substantiated by scientific evidence and that the health claim's wording complies with the criteria laid down in the regulation. The EFSA will forward its opinion to the commission, the MSs and the applicant, including a report describing its assessment of the health claim and stating the reasons for its opinion based on its guidance regarding the submission of claims under Article 13(5) and the information on which its opinion was based and will be made public.

Standing Committee on the Food Chain and Animal Health of the EC bases its decision to authorise a claim or not on the EFSA's opinion.[16] As described in Article 17 of the NHCR, the commission might deviate from the EFSA's opinion because of 'relevant provisions from EU legislation' or other 'legitimate factors'.[17] The EC has very rarely not authorised claims the EFSA has approved. Five claims on glucose supporting the human metabolism were considered inconsistent with generally accepted principles in nutrition and health.[18] In addition, four claims referring to increased alertness

11 EC List of pending authorisations on botanicals

12 EC Questions and Answers on the list of permitted Health Claims on food Products

13 Regulation (EU) No 432/2012

14 Article 13.5 of Regulation (EC) No 1924/2006.

15 EFSA Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3)

16 EC Standing Committee on the Food Chain and Animal Health

17 Article 17 of Regulation (EC) No 1924/2006

18 Regulation (EU) 2015/8

from caffeine consumption, which the EFSA approved and the EC authorised, were rejected after members of the European Parliament expressed concerns regarding the potential effect of allowing caffeine claims on drinks targeted to adolescents and containing large amounts of sugar.[19]

Table 1: Data to be provided with applications for authorisation ex Articles 13(5) and 14 Claims[20]

Part 1 – Technical and administrative data 1.1. Table of contents 1.2. Form for the presentation of the application 1.3. General information 1.4. Description of the health claim 1.5. Summary of the application 1.6. References
Part 2 – Characteristics of the food/ingredient 2.1. Food ingredient 2.2. Type or category of food 2.3. References
Part 3 – Global summary of relevant scientific data 3.1 Tabular summary of all the relevant studies identified 3.2.Tabular summary of the data derived from relevant studies on human beings 3.3. Written summary of the data derived from relevant studies on human beings 3.4. Written summary of the data derived from relevant studies not carried out on human beings 3.5. General conclusions
Part 4 – Global summary of all relevant scientific data 4.1. Tabular summary of all relevant studies carried out on human beings 4.2. Tabular summary of data derived from relevant studies carried out on human beings 4.3. Written summary of data derived from relevant studies carried out on human beings 4.4. Written summary of data derived from relevant studies not carried out on human beings 4.5. General conclusions

[19] EP Document 2016/2708(RPS) Resolution on the draft Commission regulation amending Regulation (EU) No 432/2012

[20] EFSA Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3)

Table 2: Types of Nutrition and Health Claims, according to the EU regulation

<table>
<tr><th colspan="2">Nutrition Claims</th><th colspan="3">Health Claims</th></tr>
<tr><th>Art. 8
Content Claims</th><th>Art. 9
Comparative Claims</th><th>Art. 10(3)
Comparative Claims</th><th>Art. 13(1)
Function Claims</th><th>Art. 14(1a)
Claims on reduction of disease risk</th></tr>
<tr><td>Refer to the nutritional composition of a food that meets a specific amount criterion</td><td>Comparison of the nutritional composition of a range of foods within the same food category</td><td rowspan="3">Reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being. It may only be made if accompanied by a specific health claim included in the lists provided for in Article 13 or 14.

ie: healthy</td><td>Health claims

- based on generally accepted data,
- well understood by the average consumer;

describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body, or

(b) psychological and behavioural functions; or

(c) slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet

ie: "Calcium contributes to normal muscle function"</td><td>Direct link between a nutrient and the reduction of a risk factor for a disease

ie: "Calcium helps to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures"</td></tr>
<tr><td>ie: source of Vitamin D</td><td>ie: reduced content of fat</td><th>Art. 13(5)
Function Claims</th><th>Art. 14(1b)
Children's Health Claims</th></tr>
<tr><td colspan="2">Commonly used description for Nutrition Claims:
- Contain/source of
- High in
- Reduced/Increased
- Light
- Low
- Free
- Not added
- Natural</td><td>Any claims based on newly developed scientific data and/or which include a request for the protection of proprietary data

"Sugar beet fibre contributes to an increase in faecal bulk"</td><td>Claims referring to children's health and development

ie: Calcium is needed for normal growth and development of bone in children.</td></tr>
</table>

Source: modified from Collins and Verhagen[21]

[21] Collins N, Verhagen H., Nutrition and health claims in the European Union in 2022. Regulatory Focus. Published online 3 September, 2022, www.raps.org/news-and-articles/news-articles/2022/9/nutrition-and-health-claims-in-the-european-union

Health Claims Regarding Reduction of Disease Risk and Children's Health and Development[22]

Article 14 (1a) accounts for claims of reduced disease risk (e.g., '*Calcium/ vitamin D and reduction of the risk of osteoporotic fractures through a reduction of bone loss*'). Reduction of disease risk claim is any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in a human disease's development. Article 14 (1b) concerns the health and development of children.

In the evaluation of a health claim, it is very important to consider the detailed characterisation of the food and its ingredients, as this makes it possible later to check that the product present on the market is the one effectively authorised to the benefit of the claim. Other essential steps of the evaluation of health claims include the identification of

- the cause–effect relationship between the food and the benefit for human health,
- the amount of food needed to obtain the benefit and
- the representativeness of the target population.

> It is also necessary to show that all available data have been examined, not only the favourable data. If the essential data to support the application are protected as 'industrial property' and have not been published, it is possible to apply and obtain the 'protection of proprietary data'. If granted it provides an exclusive use of the claim for five years.

One of the more problematic aspects that emerged regarding the authorisation of claims ex article 13.5/14 has been the high costs of the supporting scientific data that are needed for the applications of this type of claim.

An impact assessment analysis of the EU NHCR showed that the cost of an application ex article 13.5/14 might be as high as one million euros if newly developed human studies are required.[23] A relevant part of this kind of application is the provision of data to substantiate any claimed health effect scientifically. This activity starts with conducting a detailed literature search and review, filling in an elaborate template of relevant information and collecting and collating a complete copy of such references. In addition, proprietary data from human clinical trials may be commissioned and reported on a support application submission. The literature review is estimated to cost an average of €6,750 (range €6,400 to €8,000), mainly for the consultants that conduct it. The following preparation of the application is estimated to cost between €10,000 and €23,000. When proprietary data to support the health claim are provided, the cost of the randomised clinical trials (RCTs) on humans typically ranges from €0.25 million to €1 million.

Nutrient Profiles

According to Article 4 of Regulation (EC) 1924/2006, the EC should adopt specific 'nutrient profiles' applicable to foods or some categories of food to make nutrition or health claims and set conditions concerning the use of nutritional and health claims in relation to nutrient profiles.[24]

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22 Article 14A and 14B of Regulation (CE) 1924/2006.

23 Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU food supplement sector and market, Graham Brookes GBC Ltd, UK, September 2010. www.pgeconomics.co.uk/pdf/Impact-Assessment-health-claims.pdf

24 Article 4 of Regulation (CE) 1924/2006.

Nutrient profiles are thresholds of energy, fats, sugar and salt above which nutrition and health claims are restricted or prohibited. They should take into account:

- the amounts of specific nutritional or other constituents in the food product (e.g., saturated fats, saturated fatty acids, trans fatty acids, sugars and salt/sodium);
- the role, importance and contribution of the food or food category in the diet of the general population or, when appropriate, of specific population groups at risk;
- the global nutritional composition of the specific food as well as the presence of nutritional substances with recognised health effects.

In the years following the implementation of the NHCR, nutrient profiles were not developed. In 2020, the EC's conclusion regarding the NHCR reaffirmed the need to develop nutrient profiles as a tool to protect consumers from being exposed to claim-bearing foods with poor nutritional composition.[25]

The farm to fork strategy, adopted by the EC in 2020, considers that nutrient profiles should be set to restrict the marketing and the promotion (via nutritional and health claims) of foods high in saturated fats, sugars, salt and energy, so as to facilitate the shift to healthier diets and stimulate food reformulation.[26]

In 2022, the EFSA issued an opinion on nutrient profiles for the development of harmonised front-of-pack labeling and to restrict the use of nutrition and health profiles for foods with high salt, sugar and/or saturated fat content.[27]

The regional Office for Europe of the WHO developed a model nutrient profile, updated in 2023.[28]

1.2.2. The normative framework on botanicals as food

As stated in the previous chapter, the Commission put the health claims regarding botanicals as foods, including food supplements, on hold. In 2009, no health claim regarding botanicals as food ingredients received a favorable opinion from the EFSA, mainly due to the absence of the substance characterisation and lack of evidence of the link between the substance and the health effect. Therefore, in 2012, the commission established an 'on-hold' list of 2,078 health claims regarding plant substances. However, these plants may still be used on the EU market under the responsibility of the FBOs and provided that they comply with the general principles and conditions of the NCHR and the relevant national legislation.[29]

This matter, along with the classification of botanicals as food or medicine, currently falls within the remit of the Member States. Therefore, a plant substance classified as a 'food' in one MS can be classified as 'medicine' in another.
At EU level, the following horizontal normative rules for food are applicable to botanical ingredients of foodstuff and food supplements:

- Regulation (EC) No 178/2002 (the General Food Law Regulation)
- Novel Food Regulation (EU) 2015/2283
- Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

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25 Summary of the EC evaluation of the Regulation (EC) No 1924/2006 (REFIT)

26 EC, Farm to fork strategy, 2020

27 EFSA panel on NDA. Scientific advice related to nutrient profiling for the development of harmonized mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods. *EFSA Journal*, Vol. 20(4), Wiley, 2022, pp 7259.

28 WHO Regional Office for Europe Nutrient profile models 2nd edition,

29 Summary of the evaluation of the Regulation (EC) No 1924/2006 (REFIT), SWD(2020)96.

- Food Information to Consumers Regulation (EU) 1169/2011
- Food Hygiene Regulation (EC) 852/2004
- Pesticide Residues Regulation (EC) 396/2005
- Contaminants Regulation (EC) 1881/2006
- Food Additives Regulation (EC) 1333/2008
- Food Irradiation Directive 1999/2/EC and Directive 1999/3/EC

Directive 2002/46/EC partially harmonises the legislation applicable to the marketing of food supplements on the market in the MSs; however, this directive describes the requirements for labeling information and notifications that apply to all food supplements regardless of their composition (vitamins, minerals, botanicals, other molecules with physiological effect), and the detailed rules of the directive are only applicable to vitamins and minerals used in food supplements.[30]

In the effort to conduct the risk assessment of botanicals in food systematically, the EFSA produced a compendium in 2009.[31] This botanical compendium is a hazard database containing the following information:

- botanical scientific name and synonyms,
- botanical family,
- plant part(s) containing the substance(s) of concern and
- substance(s) of possible concern regarding human health because they belong to one of the chemical groups considered 'of concern' by default by the ad hoc working group or known to the ad hoc working group to be of concern for other reasons.

A web-based version of the Compendium of Botanicals is online and is a work in progress. It is expected to include:

- characterisation of the toxicity of the large number of substances listed in the EFSA Compendium regarding possible concerns for human health, partially also covered by the Open Food Tox database;
- systematic review of the scientific literature and consultation of EFSA partner databases (NTP, JECFA, EMA, ECHA, etc.), gathering information on toxicity, genotoxicity, mutagenicity and outcome of conducted safety assessments; and
- liaising with data colleagues to ensure that tox data coded for the compendium are compatible with the Open Food Tox (see section 3).

Some MSs have adopted national legislation on botanicals used as foods through lists of authorised or banned plants or their parts. Usually, those lists are based on the tradition of use and/or longstanding production of botanicals in the country and are rarely supported by scientific evidence.

1.2.3. Practices in EU Member States

The following country cases are examples of practices in the EU Member States that have established positive or negative lists of permitted plants on the basis of the available evidence on their safety when used as foods.

Italy

[30] Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

[31] EFSA Compendium of botanicals

The Italian Ministry of Health has issued a positive list of plants and their parts allowed as ingredients in food supplements with the physiological effect(s) that might be claimed in 2012. This list constitutes the Annex 1 of the Ministry Decree of 10 August 2012.[32] And it has been built on the BELFTRIT list that is not legally binding list, jointly developed by Belgium, France and Italy (see next paragraph). This annex is regularly updated according on the technical advice of the Section on Dietetic Food and Nutrition and the Istituto Superiore di Sanità - Italian National Institute of Health; last updated was in July 2022, when a mandatory warning for the food supplements containing curcumin/turmeric was set.

Italy does not require an ad hoc authorisation for each food supplements to be introduced on the market, but only a notification of the labeling at the Ministry of Health.

BELFRIT project

The BELFRIT is a project carried out by the competent authorities of Belgium, France and Italy and was aimed at establishing a common list of plants allowed as ingredients in food supplements among this three MSs. This project started in 2011 and resulted in a first list of plants after a year and half of activities. The inclusion criteria of the plants in the list were the tradition of use and the evidence available on their safety. The BELFRIT list, that was updated several times in the following years, is not legally binding (it requires a national legislative act to be adopted), but it is meant to offer a tool for the risk assessors, risk managers and FBOs. Despite the result of the BELFRIT project, Belgium, France and Italy today still have different lists of permitted botanicals in food supplements.[33]

The following MSs have adopted a **positive** list of admitted botanicals in food supplements: Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Italy, Romania and Slovenia. The following MSs have adopted a **negative** list of plants: Austria, Belgium, Bulgaria, Croatia, the Czech Republic, the Netherlands, Romania and Sweden. The other MSs have not implemented any list, and authorisation is given on a case-by-case basis: Germany, Greece, Finland, Hungary, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Slovakia and Spain (as of 2018).[34]

1.3. The normative framework in the UK

1.3.1. The normative framework on nutrient and health claims

Following the UK's departure from the EU on 31 January 2020, the UK entered a transition period that lasted until 31 December 2020. Now that the transition period has ended, food regulation is an autonomous matter for the UK. Food business operators (FBO)s are required to send the documentation for the authorisation of health claims to the Department of Health and Social Care of England, that will share the documentation with the Competent Authorities of Wales, Scotland and then with the scientific expert committee.[35] Each of these authorities holds the power to authorise claims in their administrative territory. The Nutrition Regulations 2019 also provide the power for the UK secretary of state to legislate for the whole of Great Britain where devolved administrations in Scotland and Wales agree.

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32 Decree of the Italian Minister of Health of August 10th 2018

33 Description of the BELFRIT Project www.salute.gov.it/imgs/C_17_EventiStampa_163_intervisteRelatori_itemInterviste_7_fileAllegatoIntervista.pdf

34 Coppens P, Pettman S. The Regulatory Situation in Europe and Other Continents in P. Restani, Food Supplements Containing Botanicals: Benefits, Side Effects and Regulatory Aspects. The Scientific Inheritance of the EU Project PlantLIBRA. Springer, 2018, pp. 28-45.

35 The food and feed hygiene and safety (EU exit) regulations no. 1504

In amending Regulation (EC) No. 1924/2006, the Nutrition EU Exit Regulations 2020 has made a few changes to adapt it to the national legislation, mainly regarding:

- the application procedure;
- the scientific framework for evaluation of applications/dossiers/files, carried out by the UK Nutrition and Health Claims Committee (UKNHCC); and
- the risk management guidelines.[36]

The Great Britain Nutrition and Health Claims Register sets out all authorised and rejected nutrition and health claims.[37]

Northern Ireland / Ireland Protocol (NIP) has introduced some exceptions in the legislation of nutrition and health claims in Northern Ireland:

- the claims authorised by the EC can be still used of food marketed in Northern Ireland along with those claims authorised by Great Britain, in order to facilitate the trade between Northern Ireland and the EU MSs;
- Northern Ireland's competent Authority is not entitled participate in the decision process of the authorisation of health claims.[38]

The UK Nutrition and Health Claims Committee

The UK Nutrition and Health Claims Committee **(**UKNHCC) is a committee of independent experts responsible for providing scientific advice to the UK government on the authorisation of nutrition and health claim applications.[39] This committee follows a framework for the evaluation of evidence to ensure consistency in all its decisions. The current version of this framework (March 2023) is mainly based on the EFSA's guidance.[40] All of the UKNHCC's opinions are available online, and a yearly report on its activities is published.

With the EU exit and the approval of the Retained EU Law (Revocation and Reform) Act 2023, the statuary supremacy of EU laws and regulations is no longer enforced in the UK, and national laws will replace the EU legal framework.[41] The UK government is proposing to reform nutrition labeling, including the nutrition and health claims law, and to revoke certain Commission Regulations related to Regulation (EU) No 432/2012. A consultation on the proposed changes in Reg. (EC) No 1924/2006 has been launched:

- introducing an improvement notice regime and
- revoking 60 Commission Regulations) regarding decisions either to reject claims or modify the list of approved health claims recorded in Regulation (EU) No 432/2012.

The consultation period for these two proposals will end 31 October 2023.

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36 UK Department of Health and Social Service Nutrition and health claims: guidance to compliance with Regulation (EC) 1924/2006

37 UK Department of Health and Social Service Great Britain nutrition and health claims register

38 UK Department of Health and Social Service, Northern Ireland / Ireland Protocol

39 UK Department of Health and Social Service UK nutrition and health claims committee

40 UK nutrition and health claims committee Framework for evaluation of evidence

41 UK Office for Health Improvement & Disparities, Open consultation, Nutrition and health claims on food: proposed legislative reforms

1.3.2. The normative framework for botanicals as food

The UK's EU exit has not affected the regulatory framework for botanicals as ingredients in food supplements in the UK due to the lack of harmonisation of EU legislation on this matter. Regulatory and industry bodies have compiled a non-exhaustive and non-legally binding list of herbal ingredients, which includes herbals for all uses (food supplements, medicines and cosmetics); the competent authorities authorise herbal products on a case-by-case basis.[42]

1.4. The normative framework in the United States

1.4.1. The normative framework on nutritional and health claims

In US official documents, the terms 'dietary supplements' are preferentially used in place of 'food supplements'. For consistency, in this brief, the term 'dietary supplements' is used when describing the US legislation on this topic.

In the US, the FDA is the regulatory authority in charge of the authorisation of nutrition and health claims. The US regulation established three categories of claims: nutrient content claims, structure/function claims and health claims.[43]

Nutrient content claims

Nutrient content claims characterise, implicitly or explicitly, the level of a nutrient in a food (e.g., 'rich in Vitamin A'). Beside terms such as *free, high and low* and the comparative *more, reduced and light/lite*, the exact contents of a nutrient could be reported in the labeling provided that the nutrients overall content is low compared to the average content of similar products or it is accompanied by a statement that the food does not qualify for the claim. Dietary supplements might report on the labeling the percentage of the nutrient that a serving of a product provides compared to the recommended daily values.[44]

In the US, use of the claim '*healthy*' is allowed on labeling as an implied nutrient content claim. This voluntary claim can be used if the nutrient composition falls within the set limits for saturated fats, added sugars and sodium according to the relevant scientific evidence in the field. At the moment, the limits applying for the claim 'healthy' for the above-mentioned nutrients fall within a range from 0 % to 20 % of the daily value, depending on the food groups. For example, the limits for saturated fats is 5 % for grain products and 20 % for oils.[45]

Health claims

According to US legislation, a health claim is a statement, symbol, or vignette that describes a relationship between a food substance and a disease or health-related condition. In the US, a health claim might be used according to three different procedures:

- **Authorised health claims**
  - the 1990 **Nutrition Labeling and Education Act (NLEA),** allows the FDA to issue regulation authorising health claim for foods and food supplements after reviewing and

[42] UK Medicine and Healthcare products regulatory agency Guidance banned and restricted herbal ingredients

[43] Kietz M. Nutrition and Health Related Claims in the US and EU - A Legal Comparison of the Regulations. Vol. 1, *European. Food & Feed Law*, HeienOnLine, 2022, pp. 39

[44] U.S. Department of Health and Human Services Dietary Guidelines for America

[45] FDA Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy',

evaluating the scientific evidence, either in response to a health claim petition or on its initiative;[46]

- the 1997 **Food and Drug Administration Modernization Act (FDAMA)** provides for health claim based on an authoritative statement of the National Academy of Sciences or a scientific body of the U.S. government that is responsible for public health protection or nutrition research.[47] These types of claims may be used 120 days after their notification to the FDA. They are not allowed to be used on dietary supplements.

- **Qualified health claims** are those, for which the quality and strength of scientific evidence, falls below the scientific standard the FDA requires for authorisation.[48] In the case the FDA finds the evidence supporting the claim credible, it issues a letter of enforcement discretion, specifying the wording and the circumstances under which the claim is authorised to be used.

Statements that address the role of overall dietary patterns or general categories of foods in maintaining good health are considered dietary guidance rather than health claims and they do not require a premarket authorisation.

Structure/function claims

The structure/function claims have those claims traditionally used in the labeling of foods and food supplements. There is no FDA regulation for this type of claim. Unlike health claims, structured/function claims are not subject to premarket review and authorisation by the FDA. Structure/function claims describe the role of a nutrient or ingredient intended to affect the normal structure or function of the human body, provided that the claim does not imply that the food product can cure, mitigate, treat, or prevents disease, which then confers medicinal status. An example of these claims is 'calcium builds strong bones.' This type of claim might also refer to the consumers' general well-being. To use a structure/function claim, the manufacturer must substantiate the claim is truthful and not misleading and he must submit a notification to the FDA with the claim no later than 30 days after marketing the food with the claim. Suppose a dietary supplement label includes such a claim. In that case, it must state in a disclaimer that: '*FDA has not evaluated the claim and that the food/food supplement is not intended to diagnose, treat, cure or prevent any disease.*' [49]

Evaluation of scientific substantiation of health claims in the US

For FDA approval as an authorised health claim according to the NLEA, there must be a **significant scientific agreement (SSA)** among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. The SSA standard provides a high level of confidence in the validity of the substance/disease relationship. In 2009, FDA issued guidance for the industry on the evidence-based review system for the scientific evaluation of health claims.[50] This document describes the methodology:

- evaluate the human study according to the experimental design;
- identify surrogate endpoints of disease risk;
- assess the methodological quality of investigations;
- consider the totality of scientific evidence;
- consider significant scientific agreement;

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46 US Congress Nutrition Labeling and Education Act

47 US Congress The Food and Drug Modernization Act, 1997

48 FDA Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, 2003

49 FDA Notifications for structure function and related claims in dietary supplement labeling

50 FDA Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims,

- define the specificity of the claim language for qualified health claims.
- re-evaluate the existing SSA or eligible health claims.

In particular, according to the FDA guidance: '*FDA's determination of SSA represents the agency's best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship. SSA means that new and evolving science will not likely reverse the relationship's validity. However, the exact nature of the relationship may need to be refined. SSA does not require a consensus based on unanimous and incontrovertible scientific opinion. SSA occurs well after the stage of emerging science, where data and information permit an inference, but before the point of unanimous agreement within the relevant scientific community that the inference is valid.* '

A list of approved claims in the US is available online.[51] Currently, the FDA has authorised 12 claims according to the NLEA and 6 claims according to FDAMA.

1.4.2. The normative framework on botanicals as food

According to the Dietary Supplement Health and Education Act (DSHEA) of 1994, FDA does not need dietary supplements to be approved for safety and efficacy before they are marketed. In many cases, producers can lawfully introduce dietary supplements to the market without notifying the FDA.[52] FDA authorisation is requested if the dietary supplements contain a 'new' ingredient, that is a substance not marketed as food before 1994 in any state of the US.

The DSHEA regulates dietary supplements as a separate category of foods and establishes the requirements for safety and labelling. The manufacturer is responsible for the safety and the claims made on labelling of a dietary supplement.

In July 2011, FDA published draft guidelines on complying with the regulatory requirements to provide a pre-market safety notification for dietary supplements containing new ingredients. This draft contains criteria for determining the identity of plant-based ingredients and how to use 'history of use' or other evidence to demonstrate the safety of plant-based ingredients.[53]

1.5. The similarities and differences of the EU legislative framework on nutritional health claims with the UK and US framework

The EU, the UK, and the US have robust legislative frameworks to regulate nutrition and health claims on foods and food/dietary supplements. The US developed its framework earlier than the EU did (1990 vs 2006, respectively). UK legislation has been changing because of the UK's exit from EU, and currently it differs slightly from EU legislation. However, more significant changes to Regulation (EC) No 1924/2006 have been proposed by the UK competent authority and they are now under consultation by stakeholders.

In Europe (and in the UK), a marked separation between the risk assessment (scientific assessment of the claim) and the risk management (authorisation of the claim) has been set.[54] EFSA (UKNHCC in UK) expresses an opinion on the scientific substantiation of the new claims based on the evidence.

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51 FDA Significant scientific agreement

52 Dietary Supplement Health and Education Act

53 FDA Draft Guidance for Industry: Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-market

54 Regulation (EC) No 178/2002

Then, EC (the Department of Health in the UK) gives the final authorisation for a health claim. In the US, FDA is the agency in charge of both assessing the scientific substation of the new claims and issuing the authorisation for most of the claims.

In the US, a health claim is defined as 'a statement that characterises the relationship of any substance to a disease or health-related condition'. On the contrary, in the EU, all claims directly linked to disease are excluded. A health claim in the EU must only refer to an existing relationship between food and health, and the disease risk reduction claims are permitted within the very narrow limits of Article 14 of the Reg. (EC) No 1924/2006.

The structure/function claims in the US are the equivalent of the health claims based on the art. 13 and 14.1b of Reg. (EC) No 1924/2006. Structure/function claims in the US do not require to be pre-authorised, whereas health claims in the EU need prior approval.[55]

The nutrient content claim in the US can be considered equivalent to the EU nutrition claim, but the rules underlying the US nutrient content claims are more complex and extensive than those of EU nutrient claims. Both in the US and in the EU, comparative claims are permitted.

In the EU, foods that are naturally *(nutrient)-free* cannot carry nutrient claims, even if they meet the conditions for such a claim, e.g. olive oil is not allowed to bear the claim cholesterol-free. Conversely, in the US, nutrient claims are allowed on unprocessed foods that meet the requirements for nutrient content claims based on their natural composition.

Both US and EU normative frameworks require scientific assessment of new health claims before authorisation, although with some differences in approach. In the US, the FDA requires an SSA to determine whether a substance/disease relationship is proven. As stated above, SSA is a rigorous standard used among qualified experts that ensures that the claim is supported by the totality of available scientific evidence and the food/disease link is not likely to be controverted by future evidence.[56]

Finally, the claim 'healthy' is allowed on foods both in the US and in the EU. In the EU it is considered a general health claim on non-specific benefits of the nutrient or food for overall good health or health-related well-being, which can be use only if accompanied by an authorised specific claim.[57] In the US it is allowed on foods that have a content of salt, sugars and satured fats below thresholds set in the rules.

[55] Kietz M. Nutrition and Health Related Claims in the US and EU - A Legal Comparison of the Regulations. Vol. 1, *European. Food & Feed Law*, HeienOnLine, 2022, pp. 39

[56] Domínguez Díaz L, Fernández-Ruiz V, Cámara M, An international regulatory review of food health-related claims in functional food products labelling. *Journal of Functional Foods*. Vol. 68, Elsevier, 2020, pp. 103896

[57] Article 10(3) of Regulation (EC) No 1924/2006

Table 3: Comparison of the claim authorisation procedure and categories in the EU and US

	EU	UK	US
Competent Authority for claims authorisation	European Commission - Directorate General SANTE'	Department of Health and Social Care will forward the request to: the Secretary of State (England) the Scottish ministers the Welsh ministers Food Standard Agency (Northern Ireland)	Food and Drug Administration
Authority for evaluation of the scientific evidence to support the authorisation	European Food Safety Authority	UK Nutrition and Health Claims Committee (UKNHCC)	National Academy of Sciences or a scientific body of the US government with responsibility for public health protection or nutrition research or Food and Drug Administration
Evidence required	Generally accepted scientific evidence of beneficial physiological effects in humans	Consistent with the EFSA approach	Significant scientific agreement
Pre-authorisation is required for health claims	YES	YES	NOT in all the cases
Protection of the proprietary data and window of exclusivity of marketing	YES	YES	NO
Claims categories	Nutrition claim	Similar to EU *)	Nutrient content claim.
	Generic descriptors General nonspecific health claims: reference to general, nonspecific benefits of the nutrient/food for overall good health or health-related well-being (for example, 'healthy' (Art. 10.4) which can be used if accompanied by a specific authorised claim)	Similar to EU *)	Healthy is a nutrient content claim that might be used if the nutrient composition falls into the set limits for total fat, saturated fat, cholesterol, and sodium.

	EU	UK	US
	Function claim (art. 13) Claims referring to children's health and development (Art. 14.1.b)	Similar to EU *)	Structure/function claims

*) Ongoing legislative review in the UK

1.6. Conclusions

Regulation (EC) 1924/2006 has been in force for more than 15 years and the rigorous and evidence-based scientific framework for authorising nutrition and health claims is now well established. This procedure is based on a marked separation between the scientific evaluation of the claims and the final authorisation, robust scientific evidence on the claimed effect of the food, often consisting of *ad hoc* clinical trials on healthy individuals, and the fact that the health claims on food cannot refer to a preventive or curative effect. At the moment, 269 health claims have been authorised in the EU. Health claims authorised on the basis of Art. 13 (1) total 229 whereas 13 claims have been authorised on the basis of Art.13(5) and 15 on the basis of Art. 14.1(b) and, finally,12 claims on the basis of Art. 14.1(a) (reduction of the disease risk factor).

Two aspects envisaged in the NCHR have still to be implemented: the definition of nutrient profiles, and the scientific and regulatory framework for the claims on botanicals and their preparation in food. Both these elements have been highlighted in the Commission's evaluation report and the academic literature as important tools to achieve two objectives of Regulation (EC) No 1924/2006: a high level of consumer protection and a smooth functioning of the internal market.

The EFSA has suspended opinions on claims on botanicals because of:

- the absence of a harmonised and shared list of permitted plants in food and food products among MS;
- difficulty characterising the overall composition of botanicals;
- a lack of RCTs investigating the effects of botanicals on humans.

In the meantime, consumers are being exposed to unsubstantiated claims from the 'on-hold' list of botanicals.

Since the adoption on the NHCR in the EU, nutrient profiles remain a concept envisaged by the regulation but not implemented in practice. Nutrient profiles were introduced by the legislator to avoid claims on foods high in energy, fats, sugars and salt. The EFSA provided a first opinion on the setting of nutrient profiles for foods bearing nutrition and health claims back in 2008.

The planned revision of the EU regulation on food information to consumers (FIC) in the context of the farm to fork strategy has brought attention back to the question of establishing nutrient profiles. In the meantime, both the EFSA and the WHO have presented definitions of nutrient profile models. In 2022, the updated EFSA scientific advice on nutrient profiling provided a model in relation to front-of-pack labelling and nutrition and health claims in the EU. The nutrient profile model published by the WHO Regional Office in Europe also underpins this pertinent discussion.

In the US, not all health claims require a rigid scientific assessment for authorisation. The scientific assessment, when required, is routinely carried out by the same agency in charge of final authorisation, the FDA. The standard for this scientific assessment is based on the experts' opinion

on the scientific evidence available. Some claims in the US might be authorised by FDA even if the available evidence is below the standard required for full authorisation. No FDA regulation is needed for structure/function claims. In the EU, all claims are reviewed by the EFSA for their scientific substantiation on a case-by-case basis. The applicant must provide evidence to support the claim scientifically and in most cases, ad hoc RCTs on humans are carried out.

2. The impact of health claims on foods to consumer behavior and marketing practices using health claims on botanicals

2.1. Introduction/Methodology

This section describes the impact of nutritional and health claims on consumers' food choices and preferences. In addition, the role of health claims, presented as marketing, is discussed.

Desk research has been carried out with the following inclusion criteria:
Keywords: nutritional OR health AND claims AND impact AND consumers [behavior] OR marketing OR advertising;
Databases: PubMed, Embase, Scopus, Cochrane database and Google.
Research limit: years 2010-2023;
Country of study: An EU Member State or UK or US;
Intervention: authorised nutrition and health claims (front-of-pack labeling and nutrient profiles are excluded from the analysis);
Target population: healthy adults;
Exclusions: Papers not reporting original results (i.e.: review, meta-analysis, commentary) were excluded from the analysis.
The selection of articles was conducted by using two different methodologies: SPIDER[58] (Sample, Phenomenon of Interest, Design, Evaluation, Research type) and PICO[59] (Population, Intervention, Comparison, Outcome). These tools have been used for the definition of the research questions mentioned above. As a result, a set of quantitative studies (RCTs, observational studies on health outcomes) and qualitative and mixed research (attitude or experience) have been selected for further analysis.

2.2. Results

Out of 3 086 papers retrieved in the search, 59 were selected after reviewing the abstract. After retrieving the full text, 25 papers were included in the analysis (Tables 4 and 5).
Table 4 presents an overview of the main attributes of the qualitative studies selected whose data are extracted through the SPIDER methodology. The column 'Ref' includes information on the authors, 'Sample' column describes the population enrolled in the study, 'Phenomenon of Interest' column describes the topic of the research, 'Design' column describes the technique used to collect the data; typically, these are focus groups, interviews, and observation study. 'Evaluation' column is the outcome of the study and 'Research type' describes whether the study is qualitative or mixed qualitative–quantitative.

Table 5 contains the attributes of the two quantitative studies selected, whose data are extracted according to the PICO methodology. The Authors of the studies are presented in the first column and the second column provides information on the target group population. The type of intervention, possible comparison group and a summary of the outcome of the study are listed in

[58] https://researchguides.gonzaga.edu/qualitative/spider

[59] https://guides.mclibrary.duke.edu/ebm/pico

the following columns. The final column on the 'Grade score' provides information on the strength of the evidence on GRADE scale, that ranges from 1 (=very low) to 4 (=high).[60]

[60] GRADE score

Table 4: Data from the selected papers extracted according to the SPIDER methodology

ref	Sample	Phenomenon	Design	Evaluation	Research type
Hong X et al. (2022)	330 panelists	Influence on consumers' sensory preferences and willingness to pay (WTP)	Observational	Labeling an omega-3 nutrition claim increased consumers' sensory liking for omega-3-enriched sausages in appearance and texture. This labeling did not improve participants' WTP for omega-3-enriched sausages.	Mixed Choice-based conjoint
Lin H et al. (2021)	80 + 121 university students	Consumers response to statistical and narrative health claims when they evaluate food products	Observational	Statistical health claims are more attractive than narrative health claims. Health and nutritional individual knowledge affect the evaluation of health claims.	Mixed Two variables, each with two levels
Prada et al. (2021)	200 participants from Portugal	Perceived healthfulness, taste, and caloric content	Web-questionnaire	Products containing claims related to sugar content were rated as more healthful and less caloric than their regular alternatives but less tasty.	Mixed
Franco-Arellano et al. (2020)	1997 on-line panelist	Consumers' implicit and explicit recall, understanding, and perceptions of products with a nutrition claim and a symbol depicting 'health.'	Interview	75% of participants could recall the presence of a claim where present, while 12% incorrectly mentioned the presence when there was none. Claims likely attracted consumers' attention and increased perceived nutritional quality, with limited influence among NFt users (23%).	Mixed

ref	Sample	Phenomenon	Design	Evaluation	Research type
Pichierri M et al. (2020)	200 consumers	Consumers' different reactions, in terms of word-of-mouth and purchase intentions, to functional claims and risk-related claims on extra-virgin olive oil	Interview	Risk-related claims significantly increase the perceived healthiness of extra-virgin olive oil concerning functional claims.	Qualitative moderated mediation analyses
Menozzi D et al. (2020)	2509 consumers in five European countries: France, Germany, Italy, Spain, and the UK	Consumer choices (WTP) were investigated for fresh fish in a retail market under omega-3 claim for seven fish species	Observational	Health claims increased WPT, with high heterogeneity across species and countries	Mixed Choice experiments
Theben A et al. (2020)	300 participants	Effects of health claims of a fruit yogurt on attitude towards the product and, subsequently, consumer's buying intention	On-line questionnaire	The health claims are effective in influencing consumer attitudes toward the product	Mixed between-subjects
Viscecchia et al. (2019)	601 respondents	Effect of nutritional claims (high in omega-3 reduced saturated fatty acids, high in omega-3, and reduced saturated fatty acids) and health claims (contributes to maintaining normal blood cholesterol levels, reduces	Questionnaire	'Rich in omega-3' claim is more effective in attracting consumers than 'reduced fat.' Health claims influence consumers' preferences more than nutrition claims. More than one claim is more attractive.	Mixed Choice experiment

ref	Sample	Phenomenon	Design	Evaluation	Research type
		cardiovascular disease risk) on consumers' preferences.			
Ballco P et al. (2019)	218 Spanish consumers	Relationship between choice behavior, attitudes, and socio-demographic characteristics and consumers' choice of products with nutritional and health claims	Observational	Consumers are health-claims oriented', 'nutritional- and health-claim oriented' and 'indifferent.' Women are more attracted by health claims, whereas man by nutritional claims. Claims more attract older consumers (> 55 years old).	Mixed choice experiment
Benson T et al. (2019)	78 participants	Relationships and pathways between NHCs and consumers' attitudes and behaviours and understand how and why NHCs influence perceptions and consumption behavior	Focus group	Certain individuals or groups were most likely to benefit from using products with claims. Participants recognised that claims could sometimes influence their purchasing behaviours, such that claims encouraged them to buy a product. A nutrition or health claim on a product affects consumer perceptions of the product. Participants also recognised that NHCs could sometimes influence their consumption, with many stating that claims had or would increase their consumption	Qualitative

ref	Sample	Phenomenon	Design	Evaluation	Research type
Benson T et al. (2018)	1039 adults in Ireland	Assess whether health claims help healthy food choices. A nutrition claim = 'Low in fat'; a health claim = 'With plant sterols. Proven to lower cholesterol'; and a satiety claim = 'Fuller for longer' were tested on four food	Cross-sectional survey	Claims influenced willingness perceptions of some of the foods. Claims had little influence on tastiness or healthiness perceptions or the portion size selected.	Mixed
Jurado F et al. (2017)	121 Spanish consumers	Assess consumers' valuation of claims: 'high in fiber' and 'reduced saturated fat.'	Observational and questionnaire	Three consumer segments were detected. Two positively valued both nutritional claims, while the third segment's valuation was negative.	Mixed an artefactual non-hypothetical experiment carried out in a realistic setting (supermarket)
Masson E et al. (2016)	1000 participants (quantitative study) + 89 participants (qualitative study) in France	Consumers' perception of health claims	Multiapproach: questionnaire, interview and observation	Some claims are more accepted and credible than others. The health claims resulted are more credible are those in line with the non-expert knowledge of the consumers.	Mixed
De Magistris et al. (2016)	219 Spanish cheese consumers	Willingness To Pay (WTP) for reduced-fat and low-salt claims	Observational	Consumers were willing to pay a positive premium for cheese packages with reduced-fat claims and cheese with reduced-fat and low-salt claims. Consumers valued low-salt content claims negatively. Normal-weighted, young people and highly educated people showed a higher WTP for normal cheese.	Mixed Choice experiments

ref	Sample	Phenomenon	Design	Evaluation	Research type
Cadario R (2016)	414 American adults	Effect of health claims on the health risk perceptions of real brands fast-food restaurants	Interview	Risk perceptions for obesity, diabetes and cardiac illnesses are lower (higher) for the restaurant with stronger (lower) health claims; food deprivation levels moderate this effect	Mixed within-subjects
Hung Y et al. (2014)	5337 participants in 10 European countries: United Kingdom, Germany, The Netherlands, Czech Republic, France, Denmark, Greece and Lithuania	Consumers' views and use of health claims	Questionnaire	Interest in health claims significantly varies among Countries and types of claims. Higher educational level and/or presence of children in the household are positively associated with health claim use.	Qualitative
Annunziata A et al. (2014)	650 Italian consumers	Factors influencing consumer understanding and use of food health claims on FFs	Interview	Consumer use and understanding of health claims depend on intrinsic variables. socio-demographic characteristics, knowledge and confidence with nutrition information and extrinsic variables: wording and related to the product.	Qualitative
Vadiveloo M et al. (2013)	37 university students	Effect of healthy' or 'hearty' labeling of a pasta salad on self-reported satiety, consumption volume, and subsequent	Interview	Individuals who report low taste importance were more satiated-when a salad is labeled 'hearty' rather than 'healthy'. In contrast, for individuals with higher taste importance, consumption and self-reported satiety were correlated and are both higher	Qualitative

ref	Sample	Phenomenon	Design	Evaluation	Research type
		consumption of another food.		when a salad is labeled as 'hearty' versus 'healthy'.	
Wong CL (2013)	506 Canadian consumers	Consumer attitudes and understanding of different types of sodium claims and the effect: disease risk reduction, function, and nutrient-content claims) and a tastes-great claim (control)	On-line questionnaire	Food packages with any sodium claim resulted in more positive attitudes toward the claim and the product healthfulness than did packages with the taste control claim,	Mixed
Byrne S (2013)	1504 respondents in the U.K., France, Italy and Germany	(a) Consumers (over-) interpretation of satiety claims, and (b) consumers recognition that personal efforts are required to realise possible satiety-related.	Interview	Most respondents correctly interpret satiety-related claims and understand that personal efforts are required to translate product attributes into potential weight control.	Mixed
Patterson NJ et al. (2012)	367 on-line respondents	Consumers' associations with sugar and awareness of reduced sugars and no added sugars claims; the perceived calorie content of different dietary components and the perceived link between reduced	Focus group, questionnaire	Consumers expect reduced sugar claims to be associated with a similar and meaningful level of calorie reduction and feel misled if this is not the case. The research has also highlighted a high level of consumer confusion regarding the calorie content of different macronutrients.	Qualitative

ref	Sample	Phenomenon	Design	Evaluation	Research type
		sugars claims and calorie content.			
Krunert KG et al. (2011)	720 respondents from a German web panel	Consumers' claims understanding of a yogurt	Observational	67% of respondents were classified as *safe* in their interpretation of the health claim, 21% were classified as *risky*, and 12% as *other*.	Qualitative
Svederberg et al. (2011)	30 Swedish consumers	Consumers' thoughts about these claims and food products are affected by various types of food-related experiences.	Observational	Participants who have concern for their own and their family's health were eager to find out the meaning of concepts and statements made	Qualitative

Table 5: Data from the selected papers extracted according to the PICO methodology

Refs	Population	Intervention	Comparison	Outcome	GRADE Score
Presseau T et al. (2020)	US and Canada population by OECD Health Statistic Database	Health claim approval	Population	Life – expectancy (female +0.3 male + 0.6 years)	Very low
Annunziata A et al. (2019)	504 Italian consumers	Consumer knowledge and use of nutrition and health claims	None	40% of the responders often pay attention to nutritional claims, and 29% to health claims. 36% of respondents buy products with a nutritional claim 26% with health claims	Very low

2.3. Discussion of the results

This section provides an overview of the results of the papers cited in Tables 4 and 5. Further details on each of the papers are presented in Tables 4 and 5 and in the full text of the papers, which are indicated as references at the end of this chapter.

For over fifteen years, the NHCR has been an important policy tool to protect consumers from misleading messages on food products. The evidence about the impact of nutrition and health claims on the consumers' attitudes and food choices is listed in Tables 4 and 5 and summarised below.

- Willingness to pay for the food products

From the analysis of the studies investigating this issue, it is unclear whether the presence of an authorised nutrition/health claim positively affects consumers' willingness to pay more for a food compared to the same product without such a claim. The available evidence is contradictory, and this issue requires further studies.

- Correct understanding of the claim

Consumers' correct understanding of nutrition and health claims seems to be one of the main challenges in terms of the effects of Regulation (EC) No 1924/2006 in practice. Consumers' understanding of nutrition and health claims made on foods depends on the wording (scientific vs. lay terms) and the length of the claim.[61]

Individual nutrition knowledge and attention towards self-care are two fundamental factors that influence the processing of information contained in a nutrition and health claim.[62, 63] Consumers with high nutritional knowledge are more prone to read claims on the label and to understand and use them correctly. As confirmed in several studies, socioeconomic status and education level relate positively to understanding a claim. Personal motivation plays a pivotal role in the understanding and use of claims. Often, a high level of understanding of the nutrition and health claims is underpinned by a habit of paying attention to food labelling in general and to an acquired knowledge on dietary issues. In addition, consumers show a positive attitude and a higher level of comprehension concerning claims relating to nutrients they are familiar with or believe they know about.[64]

- Food choices and attraction toward the food product

The presence of nutrition or health claims on the food labeling affects consumers' food choices, along with other characteristics that do not relate to its nutritional values or health effects, such as price, brand, color and packaging shape. It is noteworthy that taste has been found to be the main determinant of consumers' choices and often consumers are not willing to sacrifice the pleasure of

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61 Tan KY, van der Beek EM, Kuznesof SA, Seal CJ. Perception and understanding of health claims on milk powder for children: A focus group study among mothers in Indonesia, Singapore and Thailand. *Appetite.* Vol. 105 Elsevier 2016, pp. 747-57.

62 Franco-Arellano B, Vanderlee L, Ahmed M, Oh A, L'Abbé MR. Consumers' Implicit and Explicit Recall, Understanding and Perceptions of Products with Nutrition-Related Messages: An Online Survey. *International Journal of Environmental Research Public Health.* Vol17(21) MDPI 2020 pp. 8213.

63 Masson E, Debucquet G, Fischler C, Merdji M. French consumers' perceptions of nutrition and health claims: A psychosocial-anthropological approach. *Appetite.* Vol. 105, Elsevier, 2016, pp.618-29.

64 Ballco P, Gracia A Tackling nutritional and health claims to disentangle their effects on consumer food choices and behaviour: A systematic review *Food and Quality Preference Vol.101, Elsevier,* 2022 pp. 104634

sensory function for health benefits.[65] It is also a common belief that tastier foods are unhealthier and that the less healthy a food product is, the better it tastes. Consumers are most attracted by positive nutrition claims (high in….) and risk reduction claims.[66]

- Perception on the food healthiness and portion/size (halo effect)

Perception of the healthiness of foods relates to consumers' correct understanding of the nutrition and health claim. Consumers know that a 'magic bullet' does not exist in nutrition and that personal responsibility is central for controlling weight, beyond weight-control claims. In this regard, some individuals may incorrectly perceive that a product with a nutrition or a health claim has some positive health attributes unrelated to the claim on it (positivity bias) (the 'health halo' effect) and they over-consume them. Foods carrying reduction claims, might be interpreted by consumers as having a beneficial effect and this compensatory belief might result in a larger portion size consumed. For example, nutrition claim 'low-fat' is reported to increase the intake of foods bearing this claim.[67]

- Effect on consumers' health

The only paper investigating the correlation between health status, measured as longevity, and health claims, found that the average life span of the US and Canadian population has become longer in the 20-year period since the implementation of the US legislation on health claims. However, this finding describes just a temporal correlation and cannot be considered as a proof of a cause-effect link between longevity and the adoption of nutrition and health claims legislation.

In conclusion, major challenges to consumer protection at the present status of knowledge are as follows:

- There is a significant heterogeneity in consumers' attitudes to nutrition and health claims owing to individual attributes: socio-economic status, education, attention towards health and nutrition knowledge.
- Disadvantaged people (low education level and/or low socio-economic status) are likely: 1) not to receive useful information about their food choices from nutrition and health claims; and 2) to be more exposed to an incorrect understanding of the claims and to the halo health effect and over-portioning.
- Health claims, especially risk reduction claims, are more effective than nutrition claims in impacting consumers' attitudes.[68]
- The taste of the food, more than the nutrient composition or claims on the food, drives consumers' choices.

2.3.1. Advertising and/or marketing of food to circumvent Regulation (EC) No 1924/2006

To circumvent the provisions of the Nutrient and Health Claims Regulation, FBOs and marketers sometimes use short-cuts in advertising and commercial communications conveyed through

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65 Ballco P, Gracia A Tackling nutritional and health claims to disentangle their effects on consumer food choices and behaviour: A systematic review *Food and Quality Preference Vol.101, Elsevier,* 2022 pp. 104634

66 Suzuki, S., Park, J. Consumer evaluation of healthy, unpleasant-tasting food and the post-taste effect of positive information. *Food Quality and Preference.* Vol. 66, Elsevier, 2018, pp. 107–110.

67 Wansink, B., Chandon, P. Can 'low-fat' nutrition labels lead to obesity? *Journal of Marketing Research,* Vol. 43(4), SAGE, 2006 pp. 605–617.

68 Pichierri M, Pino G, Peluso AM, Guido G. The interplay between health claim type and individual regulatory focus in determining consumers' intentions toward extra-virgin olive oil. *Food Research International*. Vol136, Elsevier 2020 pp. 109467.

newspapers, magazines, TV broadcasts, websites and social media. They can deliver misleading messages on the health benefits of foods and foodstuffs.

Some practices used to circumvent provision of health claims are:

- featuring the claim in the name of the product (this occurs especially for the claims of weight-control food products);
- using a non-authorised claim;
- using images from medical textbooks, and doctors;
- using images that recall the body's fitness or wellness;
- using wording that implies a broader or different meaning with respect to the authorised claim;
- selling food products from non-EU countries, via the web;
- abusing the negative claim '...-free'.[69]

Comprehensive statistics regarding violations of the NCHR are not available at EU level, as official control of the correct use of claims is the responsibility of the individual Member States and often involves various national authorities.

Nevertheless, the scale of these phenomena is well described in a study conducted in Spain, that analysed 437 advertisements on food broadcasted in 2017 by a local commercial radio station. This study investigated the presence of misleading, false and non-authorised claims on foods in the advertising and how often the advertising breached the regulatory principles of Regulation (EC) No 1924/2006. Radio was chosen as setting for the research because 49 % of Spanish citizens and 59 % of Europeans identify this media as the news source they trust the most.[70]

The results this study revealed the presence of function claims in all the 437 advertisements analysed. Out those, 80.3 % (n=351) were non-authorised. Irregular claims relating to a direct benefit for human health of the foods were recorded in 89 advertisements. Out of the 38 claims on the reduction of disease risk included in the 437 advertising analysed, none were authorised.

2.4. Recommendations

- Understanding of nutrition and health claims is underpinned by various factors, such as, education level and nutrition knowledge. Thus, it might be recommended to inform consumers by means of education campaigns and programmes, about the correct use and understanding of nutrition and health claims, and about the effect of a healthy dietary pattern for the prevention of obesity and related non-communicable diseases.
- Nutrient profiles are an aspect envisaged by Regulation (EC) No 1924/2006, but not yet implemented. The setting of a nutrient profile model to limit the use of nutrition and health claims for foods with a high content, sugars, fats and salt is a tool to prevent wrong and misleading belief in the consumers that a food with a claim has an overall healthy composition. It would therefore be advisable to develop a nutrient profile model, that limits the content of at least the following nutrients: saturated fats, added sugars and salt.
- The scientific evidence also shows that consumers tend to overconsume a food bearing a nutrition and health claim, because they mistakenly believe that a food

[69] Carreno I, Vergano P. Uses and Potential Abuses of 'Negative Claims' in the EU: The Urgent Need for Better Regulation European Journal of Risk Regulation, Vol. 4, Cambridge University Press, 2014, pp. 469-490.

[70] European Commission (2018) Flash Eurobarometer 464 Report. Fake news and disinformation online.

with a claim is healthy (the so-called 'halo effect'). In order to avoid the halo effect, it might be useful that the portion size (the quantity of that food recommended to be consumed in a single occasion for a balanced diet) be reported on the label of the food with a claim.

3. Health implications of botanicals: overview of (medical) scientific literature

3.1. Introduction and methodology

This chapter aims to give an overview of the positive and negative health effects of botanicals. Botanicals and their parts are widely used ad food supplements and medicines for their claimed beneficial effects on human health.

Desk research has been performed with the following methodology:

Keywords:

health effect AND consumers AND botanicals
health risk [OR] side effects AND botanicals
Databases: PubMed, Embase, Scopus, Cochrane database and Google (for grey literature)
Research limit: years 2010-2023

3.2. Beneficial health effects of botanicals on human health

There is no common definition of the term 'botanical.' According to EFSA[71], *botanicals* are whole, fragmented, or cut plants, plant parts, fungi and lichens. The term botanical includes whole, fragmented or cut plants, plant parts, fungi and lichens and the terms *botanical preparations* include all preparations obtained from botanicals by various processes, such as pressing, squeezing, extraction, fractionation, distillation, concentration, drying up and fermentation.

The main use of plants and their parts is as foods for human nutrition. Vegetables are sources of healthy macro-nutrients (proteins, unsaturated fats, complex carbohydrates and fibers) and micro-nutrients (minerals and vitamins). Consuming vegetables and fruits is associated with a favorable health outcome, including a reduction in the prevalence of chronic non-communicable diseases, such as cardiovascular events and cancers.[72] A secondary use of vegetables is as food additives: some widely used flavorings, colorants, and gelling agents are extracted by botanical species, i.e.: yellow colorant E100 is curcumin, a component of turmeric, the pectin used in jam and marmalade is extracted from apple).

Some botanical extracts, components, or parts affect the human body's functions and health status. Thus, many botanicals have been used as food supplements and/or traditional medicines. The health effects of botanicals are due to bioactive molecules naturally present in the plants. Food supplements' most frequently used ingredients are polyphenols, essential oils, carotenoids and phytosterols, glucosinolates and saponins.[73]

Botanical food supplements have very little nutritional value. They do not contribute to the daily recommended intake of protein, fats and carbohydrates and they cover very little of the required

[71] EFSA Scientific Committee Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. EFSA Journal. Vol. 7(9), Wiley, 2009, pp. 1249

[72] Woodside JV, Nugent AP, Moore RE, McKinley MC. Fruit and vegetable consumption as a preventative strategy for non-communicable diseases. *Proceedings of the Nutrition Society*. Vol. 82(2), Cambridge Press, 2023, pp. 186-199.

[73] Franz C, Chizzola R, Novak J, Sponza S. Botanical species being used for manufacturing plant food supplements (PFS) and related products in the EU member states and selected third countries. *Food Function*. Vol. 2(12), RSC, 2011, pp. :720-30.

intake of vitamins and minerals. The scientific literature reveals that the main reason consumers buy botanical food supplements is the possible health effect, which is mainly claimed based on a tradition or for advertising purposes and is not supported by scientific evidence (see below the case of the Serenoa repens)[74].

Food supplements containing botanicals represent a significant market share. The global market size was valued at USD 27.47 billion in 2020 and is expected to expand at a compound annual growth rate of 9.1% from 2020 to 2028.[75] Within the EU, the food supplement market size was valued at USD 38.1 billion in 2020 and it is expected to grow at a compound annual growth rate of 7.0% from 2023 to 2030. Of this volume, vitamins have a 29% share and botanicals have a rough 10% share.[76] The COVID-19 pandemic has boosted this market, especially for those food supplements with a claimed effect on the immune system.[77] Consumers purchase food supplements because of the claimed health effects and the belief that their consumption has no side effects, since they are natural and not artificially processed.[78]

A survey has reported that the ten most used botanicals as food supplements are in descending order: Ginkgo biloba L. (ginkgo), Oenothera biennis L. (evening primrose), Cynara scolymus L. (artichoke), Panax ginseng C.A. Meyer (ginseng), Aloe vera L. (aloe), Foeniculum vulgare Mill. (fennel), Valeriana officinalis L. (valerian), Glycine max (L.) Merr. (soybean), Melissa officinalis L. (lemon balm), and Echinacea purpurea Moench (echinacea).[79]

The scientific assessment of the health effect of botanicals presents several obstacles, consisting of:

- Complete characterisation of the herbal ingredient;
- The limited usefulness of the *in vitro* cellular models to screen the botanical and their parts concerning their potential health effects. Scientific studies carried out in laboratory on cells have showed that several botanicals have a protective action on the molecular mechanisms pathogenic of diseases. However, those results are seldom confirmed, when the same botanicals are studied with RCTs on healthy individuals;
- lack of shared standard experimental protocols to ensure the repeatability of the results;
- the set-up and the cost of randomised placebo-controlled trials on sufficiently large healthy populations to have statistically valid results (see also Chapter 1);
- the identification of the outcomes regarding a physiological effect or a normal function (in case of botanicals to be authorised as food supplements);
- the demonstration of the traditional use that can be used only for botanicals to be authorised as medicine.[80]

3.2.1. Traditional use

Botanicals can be registered as traditional herbal medicinal products in the EU if bibliographical or expert evidence is available that the product has been in medicinal use throughout at least 30 years, including at least 15 years in an EU Member State. In this case, the product might be registered under

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74 Franco JV, Trivisonno L, Sgarbossa NJ, Alvez GA, Fieiras C, Escobar Liquitay CM, Jung JH. Serenoa repens for the treatment of lower urinary tract symptoms due to benign prostatic enlargement. Cochrane Database Systemic Review.Vol 6(6):CD001423.

75 grandviewresearch.com/industry-analysis/botanical-supplements-market

76 www.grandviewresearch.com/industry-analysis/europe-dietary-supplements-market-report

77 Netherlands Ministry of Foreign Affairs, CBI The European market potential for immune-boosting botanicals

78 Dickinson A, MacKay D. Health habits and other characteristics of dietary supplement users: a review. *Nutrition Journal*. Vol. 13(14). BMC 2014

79 Franz C, Chizzola R, Novak J, Sponza S. Botanical species being used for manufacturing plant food supplements (PFS) and related products in the EU member states and selected third countries. *Food Function*. Vol. 2(12), RSC, 2011, pp. :720-30.

80 Restani P, Food Supplements Containing Botanicals: Benefits, Side Effects and Regulatory Aspects. The Scientific Inheritance of the EU Project PlantLIBRA. Springer, 2018, pp. 117-141.

a simplified registration procedure without proving its efficacy with clinical trials.[81] The provision of traditional use does not apply for authorising botanicals as food supplements. EU MSs allow the use of botanicals under various national legislations, based on different cultural approaches, traditions, and availability of plants via a discretionary procedure that is not harmonised at EU level. Under current EU rules, it is possible that a MS classifies a botanical product as food or as medicine on a case-by-case basis. In other words, as EU law states, the same product may be classified as a foodstuff in one MS and a medicinal product in another.

Some stakeholders have proposed the use of a 'traditional use' procedure to substantiate health claims. It is questionable whether this approach could work in the 'food' setting. The assessment procedures for foods and medicinal products differ from each other. Firstly, a benefit/risk assessment is required for medicine, whereas a mere benefit assessment is requested for food claims. Secondly, while traditional use might represent helpful information on the therapeutic effect of a botanical, it does not provide any evidence on the effect of a botanical in reducing a disease risk factor and/or helping a physiological function. The high number of claims rejected by the EFSA demonstrates how challenging and resource-demanding it is to prove those effects. Even though the traditional use stance is currently not considered sufficient to support a health claim authorisation request in the EU, it does play a role in various European legal frameworks that deal with the authorisation of chemical products, including THMPs and novel foods.[82]

There are about 1 900 botanical species inventoried overall in the EU MSs. At the moment, there is no definitive and complete list of all health effects of botanicals, because the EFSA has suspended the systematic revision of botanical species that might be authorised as food with the possible claims that each of these can bear.

On the health effect of botanicals, there are some limited and partial databases:

- The EFSA Compendium (see Chapter 1), a database of botanicals that are reported to contain naturally occurring substances of possible concern for human health;[83]
- The US National Institute of Health – National Center for Complementary and Integrative Health has summarised the evidence available on the health effect, an indication of use, and side effects of the most widely used botanicals in a database called 'Herbs at a glance'.[84]
- The EuroFIR (European Food Information Resource) hosts ePlantLIBRA, a database containing plant information- and plant-food supplements, specifically bioactive compounds in botanicals and herbal extracts with putative health benefits and adverse effects.[85]
- The Committee on Herbal Medicinal Products (HMPC) has compiled a series of monograph on herbal medicines that contains a scientific opinion on safety and efficacy data about the herbal substance and its preparations intended for medicinal use. The HMPC evaluates all available information, including non-clinical and clinical data, and documented long-standing use and experience in the EU. The EU monographs provide all information necessary to use a medicinal product containing

[81] Directive 2004/24/EC

[82] Lenssen KGM, Bast A, de Boer A. The complexity of proving health effects with data on 'traditional use': A critical perspective on supporting botanical health claims. *Trends in Food Science & Technology*, Vol 120, Elsevier, 2022, pp 338-343.

[83] EFSA botanical compendium

[84] NIH Herbs at Glance

[85] Eurofir EPlantLibra

a specific herbal substance or preparation. At the moment, 167 monographs are available.[86]

- In the absence of a harmonised legislative and scientific framework on botanicals permitted as food supplements, some EU MSs, such as Italy and Belgium, have adopted legally binding positive lists of botanicals. These lists also report for some botanicals the health effect that could be claimed.

Box 1: The case of Serenoa Repens

The case of products containing Serenoa Repens is an example of the complex and sometimes confusing aspects of the current regulatory and scientific frameworks concerning botanicals in the EU.

Among the botanical species used in human nutrition, the Fructus extract of Serenoa Repens (hexane or ethanolic) is one with the most robust body of evidence, used both as a food supplement for the normal function of the urinary system and traditional herbal medical product for the treatment of the benign prostate hypertrophy.

Several papers have demonstrated the in vitro anti-inflammatory and spasmolytic properties of the fatty acids extracted from the Fructus of Serenoa Repens by the inhibition of androgenic receptors and eicosanoids synthesis, respectively. However, when the analysis of the evidence was addressed to randomised, blind, placebo-controlled trials (the gold standard to study the effect of a molecule on human health) in the cumulative group of 4 656 men over 50 with moderate symptoms of benign prostate hypertrophy, it revealed that a treatment up to 17 months with Serenoa Repens extract alone or in combination with other phytochemicals with the same supposed properties did not result in any clinical improvement.

In conclusion, Serenoa repens extract is the main ingredient of a food supplement, claiming an effect on prostate function and the active principles of traditional herbal medicine with the indication of reduction of symptoms related to prostatic hyperplasia. The clinical trials on human patients on its active molecules have not found evidence supporting these effects.

Source: Franco JV, Trivisonno L, Sgarbossa NJ, Alvez GA, Fieiras C, Escobar Liquitay CM, Jung JH. Serenoa repens for the treatment of lower urinary tract symptoms due to benign prostatic enlargement. Cochrane Database Systemic Review. Vol 6(6):CD001423.

3.3. Health risk of botanicals

On the safety side of using botanicals as food, scientific literature recognises certain side and toxic effects. The most prominent factors endangering the safety of botanicals as food can be divided into intrinsic and extrinsic factors and are summarised below[87]:

Intrinsic factors:

- quality of the raw botanical material, contamination of the botanical species with a toxic herbal;
- misrecognition of the botanical species;
- presence of environmental contaminants;
- technological process for the extraction and concentration of the active molecules;
- misidentifications of the plant ingredients;
- adulterations;
- counterfeits.

[86] EMA Committee On Herbal Medical Products Monographs on traditional herbal medicine product

[87] Colombo, F.; Restani, P.; Biella, S.; Di Lorenzo, C. Botanicals in Functional Foods and Food Supplements: Tradition, Efficacy and Regulatory Aspects. *Applied Sciences* Vol. 10, MDPI, 2020, pp 2387.

Extrinsic factors:

- consumer's age and gender;
- unsuitable use of botanical food supplements;
- genetic factors and specific pathological or physiological conditions (allergy, intolerance, idiosyncrasy);
- overdosage;
- simultaneous consumption of two or more food supplements and/or drugs.

A summary of risks for human health has been collected into EFSA's chemical hazards database, denominated Open Food Tox for individual substances in the botanicals.[88] This database provides open-source data for substance characterisation, links to EFSA's related output and European legislation, and a summary of the critical toxicological endpoints and reference values for many food ingredients and contaminants.

Among the other information, The Open Food Tox & EFSA content includes:

- **Toxicological information:**
  - genotoxicity;
  - reference points;
- **reference values for**
  - contaminants: i.e., TDI for acrylamide
  - regulated products, i.e., ADI for pesticides;
  - nutrients: i.e., DRV for vitamins and minerals.

Besides the small populations studied in the scientific papers, the dimension and the types of health risks of botanical food supplements are difficult to estimate in the general population since a mandatory post-marketing surveillance system does not exist for foods. There are some voluntary web-based programs to report the side-effect of using herbals (Italy,[89] France[90], US[91]). Still, they are incomplete, not specific for food supplements, and heavily affected by sampling bias. The sampling bias occurs when the individuals from the target population of the study are more likely to be included in the study than the others. In the case of a surveillance systems, a sampling bias occurs because these programs are designed to enroll only the cases adverse reactions and are not linked with information about the sale or consumption volumes. In addition, consumers often consider the botanical food supplement completely safe because they are natural. Therefore, they tend not to refer the eventual symptoms or clinical signs showed up in concomitance of the consumption of a botanical food supplement.

A review of the available scientific literature has highlighted that the human systems most frequently affected by herbal toxicity are hepatic, cardiovascular, central nervous system and digestive systems.[92]

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88 OpenFoodTox: EFSA's chemical hazards database

89 ISS, Italian surveillance system on herbals

90 ANSES, French system of nutrivigilance

91 FDA, US CAEN CFSAN Adverse Event Reporting System

92 Hudson A, Lopez E, Almalki AJ, Roe AL, Calderón AI. A Review of the Toxicity of Compounds Found in Herbal Dietary Supplements. Planta Med. Vol. 84(9-10), Thieme, 2018 pp. 613-626.

The following two case studies explain the narrow safety margin of some botanicals widely used as ingredients in food supplements.

Box 1: Two case examples illustrating the use of botanicals as ingredients in food supplements

Although rice is not botanical, the case of red yeast rice (RYR) illustrates the scientific substantiation of the claimed health effect and the regulatory challenges relating to botanicals.

In 2011, a claim of 'reduction of LDL-cholesterol plasma level, if the daily intake of monacolin K was 10 mg' was authorised by the Commission for RYR. The hypocholesterolemic effect of RYR has been attributed to its content of monacolin K, an active compound naturally present in the RYR that has a structure similar to lovastatin, a hypocholesterolemic drug. A few years later, the EFSA was asked for a second opinion about the safety of RYR following the report of several cases of adverse reactions involving the muscle apparatus and liver in individuals taking RYR. EFSA concluded that the 3-10 mg dose of monacolin K falls into the therapeutic range for this molecule and is not acceptable for a food supplement. Secondly, EEFSA noted that it was not possible to identify a safe dose of monacolin K for all consumers, especially those more susceptible.

According to the EFSA opinion, the EC decided that food supplements containing RYR must be labelled with a statement warning consumers not to consume more than 3 mg of monacolin K, not to consume RYR if the consumer was aged under 18 or over 70 years old and to refer to their doctor if any symptoms showed up during the period of consumption of the RYR-based food supplement.

Sources: EFSA Panel on Food Additives and Nutrient Sources added to Food. Scientific opinion on the safety of monacolins in red yeast rice. *EFSA Journal*. Vol. 16(8), Wiley, 2018, pp. 5368

EC website 'Food safety – restrictions on the use of monacolins from red yeast rice in foods'

The case of turmeric-containing food supplements

In Italy, in March-June 2019, a cluster of 28 cases of acute hepatitis with cholestasis following the consumption of turmeric products was reported in the web-based Italian Phyto vigilance system. In 27 of these cases, the cause-effect link with turmeric food supplements could be assessed. The batches of food supplements that potentially triggered the adverse reactions were collected and analysed for the presence of drugs, heavy metals, aflatoxins, pesticides, synthetic dyes, and pyrrolizidine alkaloids. All those analyses indicated a negative result. After reviewing the medical literature and collecting experts' opinions, it was concluded that the cause of those adverse reactions was an idiosyncratic reaction triggered by the peculiar composition of these supplements, that in 27 cases out of 28 contained a molecule able to increase the adsorption of the turmeric up to 9-fold.

Source: Menniti-Ippolito F, Ippoliti I, Pastorelli AA, Altieri I, Scalise F, De Santis B, Debegnach F, Brera C, Pacifici R, Pichini S, Pellegrini M, Rotolo MC, Graziano S, Palazzino G, Multari G, Gallo FR, Neri B, Giannetti L, Russo K, Fedrizzi G, Bonan S, Mazzanti G, Moro PA, Salvi E, Firenzuoli F, Valeri A, Moretti U, Traversa G, Silano M, Stacchini P, Boniglia C. Turmeric (Curcuma longa L.) food supplements and hepatotoxicity: an integrated evaluation approach. Ann Ist Super Sanita. Vol. 56(4), ISS, 2020, pp.462-469.

In conclusion, there is no 'official' comprehensive list on the health effects of botanicals. Several limited lists (see above) are available for national and EU regulatory purposes, for information to consumers, or as results of research projects. In some of these lists, a health effect is described for some botanicals based on the tradition of use and old recipes. Those effects are not confirmed for most plants when rigorous studies on humans, such as RCTs, are carried out.

3.4. Recommendations

- At the moment, because of the lack of harmonisation at EU level and the situation of the 'on-hold' the list, every MS has a different legislative and scientific framework on botanicals as foods and the claims that the botanicals can carry. Consequently, consumers are exposed to claims on botanicals that might not be scientifically substantiated and to botanicals products whose effect on health is not well

established. The fact that that a herbal might be marketed as a food supplement in one MS and as a traditional medicinal herbal product another Member State can create confusion among consumers. Setting a harmonised and shared positive list of permitted plants across the EU Member States, with a marked separation between botanicals authorised as ingredients of foods and herbals authorised as medicines might ensure European consumers receive correct information and increased safety of use of these products.

- Establishing an EU surveillance system for adverse reactions to botanical food supplements, linked to sales volume and consumption patterns, might be an important tool for early identification of products with 'safety concerns'. This proposed surveillance system should be linked to the analytical capacity for the characterisation of active biomolecules and contaminants in botanical species.

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This European implementation assessment has been drawn up to support the work of the European Parliament's Subcommittee on Public Health (SANT) on its implementation report on Regulation (EC) No 1924/2006. Building on the Commission evaluation report published in 2020, the study assesses the implementation and application of the Regulation on nutrition and health claims made on foods. Health claims and use of health claims on foods containing botanicals are at the heart of this study, while nutrition claims and food safety are excluded from its scope.

The study is composed of three independent parts: an overview of the Nutrition and Health Claims Regulation and its evaluation report, plus two research papers. One of the papers analyses the application of the regulation through the case law of the Court of Justice of the European Union, presenting findings on the main legal issues and the European Food Safety Agency's risk assessment procedure. The other research paper examines the available literature on health implications of botanicals. It also delves into marketing practices on health claims and their impact on consumer behaviour. It then describes similarities and differences between the legal framework for health claims in the EU, the UK and the US. Both research papers provide policy recommendations on how to future-proof the rules on health claims made on foods in the EU.

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