A content analysis of the European food safety Authority's scientific opinion on authorised and rejected appetite-related health claim applications

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Journal of Functional Foods 102 (2023) 105471

Contents lists available at ScienceDirect

Journal of Functional Foods

journal homepage: www.elsevier.com/locate/jff

A content analysis of the European food safety Authority's scientific opinion on authorised and rejected appetite-related health claim applications

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ARTICLE INFO

Keywords:
Appetite
Health claim
UK Nutrition and Health Claims Committee (UKNHCC)
Satiety
Satiation
Content analysis

ABSTRACT

From 2006 to 2020, UK nutrition and health claims were assessed by the European Food Safety Authority (EFSA) under EU Nutrition and Health Claims Regulations (2006). Since Brexit, UK applications are considered by the UK Nutrition and Health Claims Committee (UKNHCC).

EFSA guidance documentation drawing together claims related to appetite ratings, weight management, and blood glucose concentrations was most recently published in 2012. 61 EFSA scientific opinions on appetite-related health claims applications from 2010 to 2020 were reviewed. Fifty-five related to hunger, fullness, energy intake, satiation and satiety were rejected, whereas three weight management claims and three blood glucose levels claims were authorised. 17 novel categories of reasons for claims application rejection were synthesised via Inductive Content Analysis (7 main-, 10 sub-categories). The resultant conceptual framework presented herein aims to support commercial pre-assessment of future appetite-related health claim applications and stimulate discussion regarding appetite-related health claims legislation in the new era of UKNHCC.

1. Introduction

Food innovation is a potent driver of the food industry. Food companies tend to strategically develop novel products in response to consumer demands, competitors, environmental factors, food safety and health benefits (Guiné, Florença, Barroca & Anjos, 2020). Functional food innovation infers a relationship between nutrition and the fortification of foods for the enhancement of the human physiological system (Bigliardi & Galati, 2013; Hardy, 2000).

In the EU, the use of a statement or a representation that implies the existence of a relationship between a food or one of its constituents and health, denoted as a 'health claim', is regulated. The Nutrition and Health Claim Regulation (NHCR) EC 1924/2006 (EU, 2006) enacted by the European Commission (EC) states that health claims shall only be authorised for use after a scientific evaluation of the highest possible standard has been carried out. The now discontinued Article 13(1) permitted applications for function claims based on well-accepted food/nutrient roles. Nutrition and health claims applications for specific foods or food components under the 2006 EU legislation (now adopted in the UK) can be made under Article 13(5) (function claims based on new science) or Article 14(1)(a) (reduction of disease risk claims focussed on mediation of disease risk factors, not the disease itself (Díaz, Fernández-Rui & Cámara, 2020)). Further applications relating specifically to children's development come under Article 14(1)(b).

Developing foods or food components with potential to enhance physiological functions can bolster commercial performance and encourage consumption when supported by an authorised nutrition or health claim. Nutrition and health claims can provide many benefits to the consumer and healthcare professionals alike, particularly providing them with food-based dietary information that is accurate and substantiated by scientific evidence (Ashwell et al., 2022; Stanner, Ashwell & Williams, 2023). It is also well established that consumers are willing to change their diets for health purposes (Hetherington et al. 2013), however, unless nutrition and health claims are regulated, they have the potential to be misrepresented by food manufacturers (Chimedtseren, Kelly, McMahon & Yeatman, 2020). These competing pressures in the

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https://doi.org/10.1016/j.jff.2023.105471
Received 12 November 2022; Received in revised form 11 February 2023; Accepted 16 February 2023
Available online 24 February 2023

fast-paced arena of voluntary foods and food ingredient labelling are wide-ranging, affected by commercial, political and individual drivers (de Boer, 2021).

1.1. UK health claims post-Brexit

Following the UK's exit from the EU, regulations related to nutrition and health claims have been adopted under the European Union (Withdrawal) Act 2018 as UK law. However, the adopted regulations are subject to amendment under 'The Nutrition (Amendment etc.) (EU Exit) Regulations 2019′, and 'The Nutrition (Amendment etc.) (EU Exit) Regulations 2020′. The UK Nutrition and Health Claims Committee (UKHNCC) is now responsible for the scientific assessment and risk assessment of all new UK health claim applications and the responsibilities for risk management falls to the Four Nations group (devolved to the Departments of Health; de Boer & Bast, 2021). It's important to note that though the processes adopted by UKHNCC currently broadly mirror those used previously by The Department of Dietetic Products, Nutrition and Allergies (NDA) of the European Food Safety Authority (EFSA), with this new dawn comes "potential for divergence in submitted and approved claims" going forward (Ashwell et al., 2022).

All health claims previously assessed by EFSA and authorised or rejected by the Commission as of 1 January 2021, have been transposed to the UK. These are listed on the Great Britain nutrition and health claims register.

1.2. The evaluation of health claims applications

EFSA guidance documents are available to support those compiling the dossier of evidence to support and application for the substantiation of a health claim (EFSA NDA Panel, 2011h, 2011i, 2012, 2016, 2017, 2018). De Boer et al. (2014) summarise how EFSA's evaluation protocol follows a sequential three criteria process: (1) food defined and characterised (2) claimed effect defined and beneficial, and (3) establishment of a cause-and-effect relationship, to guide the panel evaluating of the dossier of scientific evidence submitted in support of each claim application (de Boer et al., 2014; Lenssen, Bast & de Boer, 2018). The UKNHCC advises these documents are consulted by applicants before making related claims. Nevertheless, concerns have been expressed regarding the evaluation protocol for the regulation (Pravst et al., 2018), its verdict on health claims relative to antioxidants (de Boer, Vos & Bast, 2014), and pre- and probiotics (Salminen & van Loveren, 2012), amongst others.

1.3. Appetite-related health claim applications

In appetite studies, the manipulation of food and feeding interventions for nutritional composition (Chambers, McCrickerd & Yeomans, 2015); texture (Stribiţcaia, Evans, Gibbons, Blundell & Sarkar, 2020); and orosensory properties (Petit et al., 2016) have all been reported to influence motivation to eat under experimental conditions. Despite early enthusiasm to submit applications for health claims related to appetite sensations/ energy intake, weight management and blood glucose level concentration (referred to throughout this article as 'appetite-related claims') up to December 31st, 2020, no health claim suggesting a role for food to enhance or suppress appetitive sensations (such as perceived hunger or fullness), satiety or satiation had been authorised by EFSA.

Claims for both blood glucose modulation and weight management have had greater success (n = 3 authorised in each case) and in 2012 EFSA published the technical 'Guidance on the scientific requirement for health claims related to appetite ratings, weight management and blood glucose level concentration' summarising the evidence gathered by EFSA following assessments of applications related to these claims. It's worthy of note that most appetite-related claims applications were submitted under the now closed Article 13(1) (57 out of the 61 reviewed herein). The list of associated authorised claims (based on generally accepted scientific data and are understood by the average consumer) was published in 2012 (European Union (2012) Commission Regulation (EU) No 432/2012).

Published academic works on appetite-related claims prior to, and shortly after, the 2012 guidance called for enhanced knowledge and understanding as to how decisions were being made (Blundell, 2010; Griffioen-Roose, Wanders & Bánáti, 2013). Whilst the 2012 guidance (EFSA NDA, 2012) outlined the parameters to be applied in the decision-making process, to date, there has been no published overview of the collective *shortcomings* of submitted appetite-related applications that led to them not being authorised, nor has the tailored, appetite-related claims guidance from 2012 since been substantively updated (other than under Regulation (EU) No 6092/013 (foods for special groups) which required adjustment to the guidance for claims on meal replacers for weight management in 2016; de Boer, 2021).

Herein we present a systematic content analysis of the scientific opinion on appetite-related health claim applications made to EFSA, to clarify typical barriers to acceptance. Considering the ever increasing need to support the health benefits of appetite claims (whether in a short or long term), it is imperative we identify how effective product development, supported by adequate scientific evidence, with a focus on critical factors assessed by the panel, could enhance food innovation. Specifically the objectives of this work were to: (1) extract, categorise, and describe the justifications that have been provided in support or rejection of such claims, and (2) develop an evidence-based conceptual framework to guide/ pre-assess applications, now made to UKHNCC for appetite-related claims by retrieving and reflecting on EFSA's scientific opinion on precedent appetite-related health claim applications (up to 31st Dec 2020).

This novel framework of 17 evaluative categories and sub-categories, used alongside the extant 2012 technical guidance, has potential to assist future UK applicants in curating robust dossiers in support of their appetite-related health claims, now to be submitted to UKHNCC. We anticipate this will further add to the discourse over the future direction of UK health claims legislation post-Brexit, specifically the appetite-related work of UKHNCC.

2. Method

2.1. Search strategy

This research set out to analyse the scientific opinion provided on appetite-related health claim applications, following the scientific assessment by EFSA from 2010 to December 31st 2020. In 2010, EFSA published a guidance document for the scientific evaluation of all health claims for consultation with the public which harmonised and established the panel assessment criteria. This document has been adopted as the general guidance in the evaluation of Article 13(1), 13(5), 14(1)(a) and 14(1)(b) health claims (EFSA NDA Panel, 2011i). The UK exited the EU single market and customs union from 1st of January 2021.

The scientific opinion provided by EFSA following an appetite-related application according to regulation EC 1924/2006 was retrieved electronically from the EU register of health claims. The register provides free unrestricted access to all health claims submitted.

Available filters, including 'Claim status'; 'Type of claim'; 'EFSA opinion reference'; and 'Legislation' were set to 'All' to ensure maximal return across all appetite-related scientific opinions published. This ensured any claims submitted under articles 13(1), 13(5), 14(1)(a) and 14(1)(b) would be retrieved. Thereafter, the following key search terms were applied: 'appetite', 'satiety', 'satiation', 'hunger', 'fullness', 'weight gain', 'weight loss', and 'weight management'. Inclusion and exclusion criteria as summarised in Table 1 were used to identify the final scientific opinions for consideration.

Table 1
Inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
(i) Wording of the health claim in English. (ii) Health claim applications whose proposed physiological effects were appetite-related. This was limited to applications on satiation, satiety, food intake, energy balance, weight management, glycaemic control and peptides in response to feeding (Blundell et al., 2010; Hopkins, Blundell, Halford, King & Finlayson, 2016) (iii) Applications submitted from 2010 till 2021.	(i) Wording of the health claim not in English. (ii) Applications not substantiated by human scientific data at criterion 3 (i.e., cause-and-effect relationship established). This includes applications whose substantiating scientific evidence solely used animals or *in vitro* studies, but not those that used animals or *in vitro* studies to support a biological mechanism observed in the human evidence.

Table 2
Phases of Inductive Content Analysis as applied within this study.

Phase	Description of the process
1) Preparation	All qualified scientific opinions and data extracts were read in full. Each scientific opinion was broken into three segments for analysis as defined by EFSA, *viz* criterion 1 (food defined and characterised); criterion 2 (claimed effect defined and beneficial); and criterion 3 (cause-and-effect relationship established). The units of analysis were words, statements, or parts of statements (Juvani, Isola & Kyngäs, 2005) that inferred or presented a justification for the acceptance or rejection of a claim.
2) Content Analysis process	This phase involved three processes: (a) Coding; (b) Creating Categories; and (c) Abstraction. (a) Codes were generated from each unit of analysis. This was done manually with the use of pens, paper, highlighters, and colour-coded sticky notes. Segments of the unit of analysis that provided insights about the panel's ruling were isolated, marked, and coded. The codes were written on colour-coded sticky notes, each specific to a criterion. (b) Category creation remained criterion specific. Categories were generated by (i) sorting codes according to their colours (criterion); (ii) analysing codes for similarities, differences, and substantiation; and (iii) collating and grouping the codes into main categories and sub-categories where necessary. (c) The categories created were further refined and defined through a process of abstraction. Content-characteristic headings were given to these new categories, and the relationship between these categories was examined. Thereafter, they were arranged to form a conceptual structure of the main categories and sub-categories alongside EFSA's evaluation protocol (see Fig. 2).
3) Reporting	This phase is comprehensively presented in 3.0 Results and Discussion. A narrative of distinct categories, corresponding data excerpts, and explicit analysis are presented in these sections.

2.1.1. Scientific opinion

A total of 144 references were identified from the EU register of health claims using the keyword search. Fig. 1 summarises how the search strategy yielded the final 33 references hosting EFSA's scientific opinion for 61 entry identification numbers (EIDs).

The search strategy described in 2.1 yielded 144 references. Further screening and application of the inclusion and exclusion criteria refined the search result to 33 references (R), hosting scientific opinion for 61 entry identifications (EIDs) of appetite-related health claim applications that were then considered in the subsequent inductive content analysis.

2.2. Data analysis

2.2.1. Content analysis

Inductive Content Analysis as defined by Elo and Kyngäs (2008), was undertaken to examine the retrieved scientific opinions (see Table 2). Inductive Content Analysis (ICA) is a method of qualitative analysis indicated where little extant literature is available, and where there is no requirement for theory-based conclusions. The 'inductive' element of the process refers to the development of content categories during (and not in advance of) the data coding process, according to findings in the data (Elo & Kyngäs, 2008). ICA differs from Thematic Analysis in that it is not suitable for explicitly theoretical interpretation (Vears & Gillam, 2022), thus was judged appropriate for the subject matter of this study. The process of ICA includes open, or 'iterative' coding, creation of categories and abstraction (Elo & Kyngäs, 2008). ICA has been used previously to explore the overlap between health claims and drug claims (Skarupinski & Jakobs, 2014).

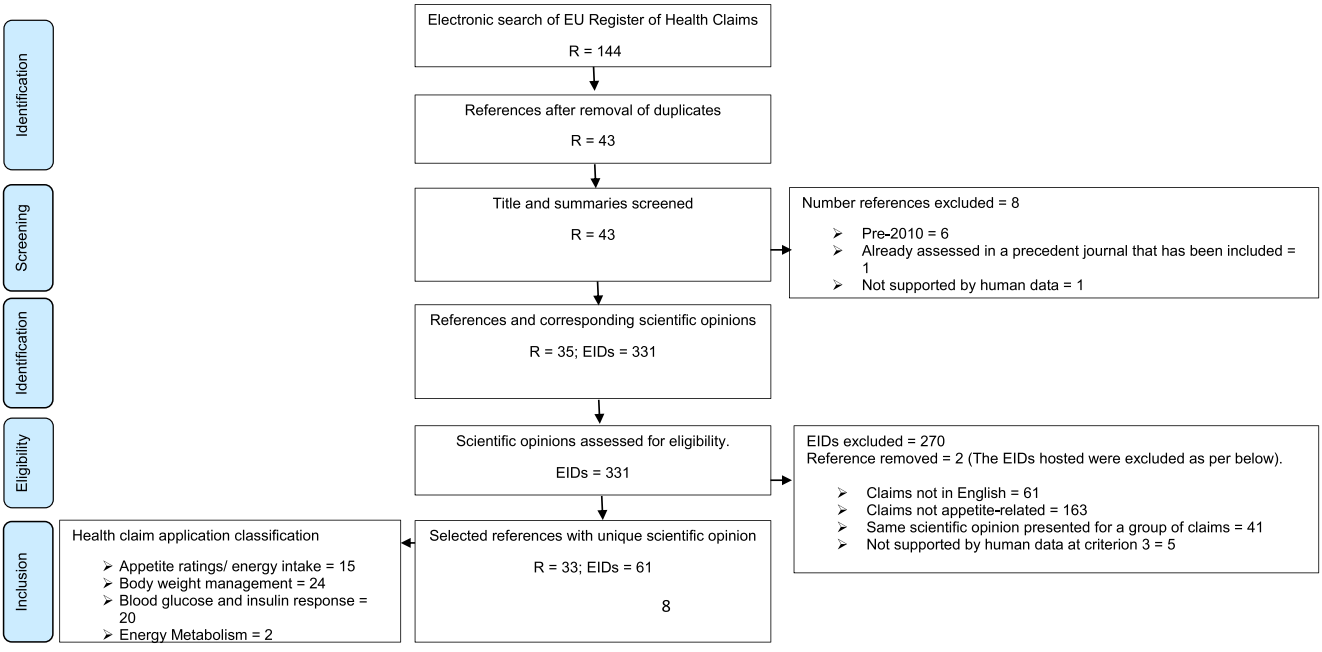

Fig. 1. The process of reference and scientific opinion identification and selection of relevant scientific opinions.

3. Results and discussion

3.1. Appetite-related health claim applications and criterion of rejection

The scientific opinions related to 61 appetite-related health claim EIDs were reviewed in this study; 55 were rejected, six were authorised. The stages of and reasons for rejection are summarised in Fig. 2 which shows most applications were rejected at criterion 3. Following the sequential process of EFSA's evaluation protocol, we found that 18 appetite-related health claim applications were rejected at criterion 1; none at criterion 2; but that 37 were rejected at criterion 3. The six authorised health claims (Table 3) related to weight management (three) and glycaemic control (three). Fig. 2 associates the number of authorised/rejected appetite-related health claim applications and the

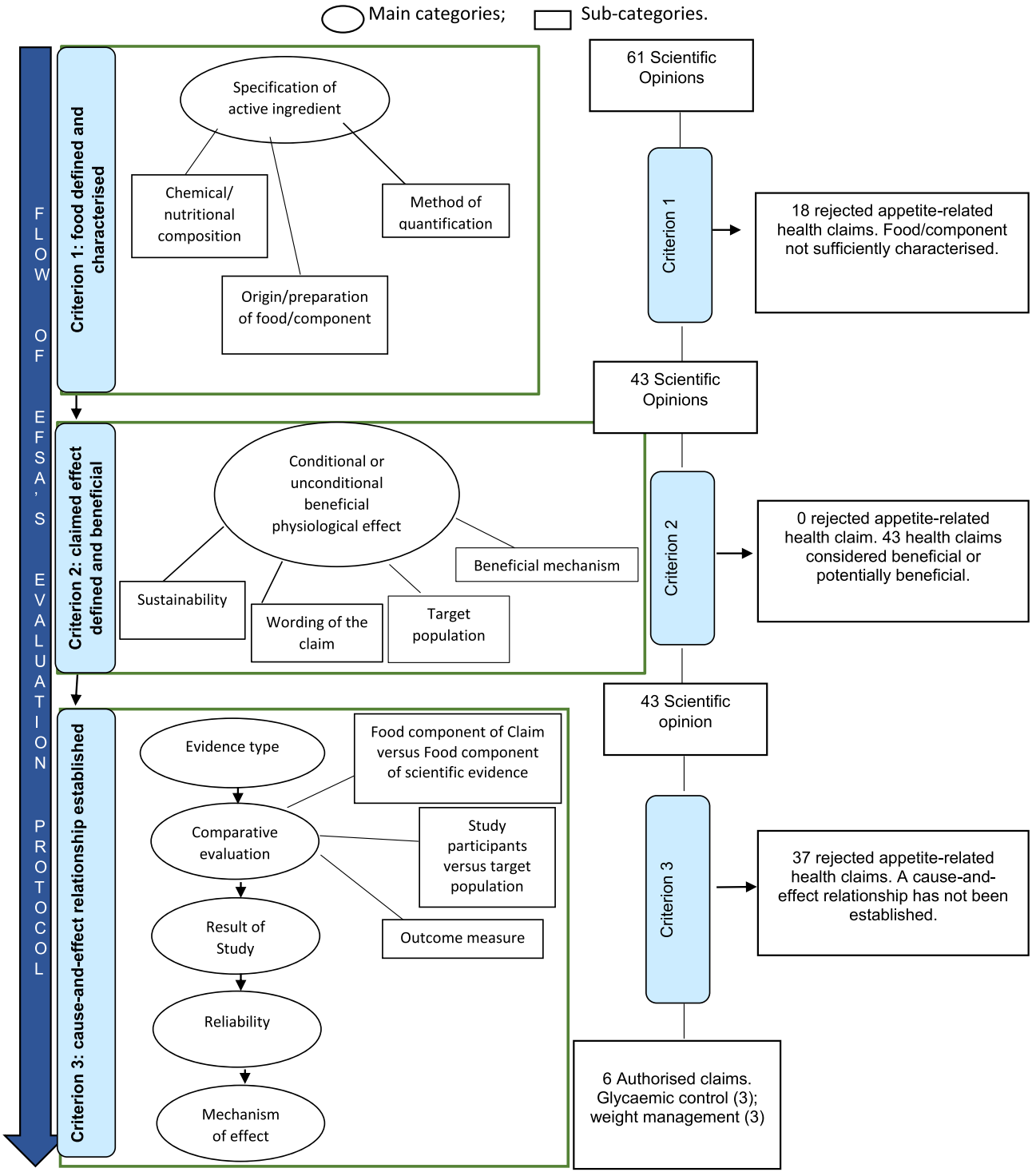

Fig. 2. Conceptual framework for appetite-related health claims, showing the relationship between novel categories derived from content analysis of published scientific opinion on submitted applications relative to the original EFSA evaluation criteria in the context of claims rejected/ authorised. Main categories; Sub-categories.

Table 3
The six authorised claims found in this research, including reference number, food/component, entry identification number, article applied under and health claim classification, proposed claim specifics and critical elements of the outcome of the evaluation protocol (see supplementary material).

AUTHORISED CLAIMS								
Journal reference number	Food/ component	Entry identification number (EID)	Article applied under	Health claim classification	Proposed claim	Criterion 1 - food defined and characterise	Criterion 2- claimed effect defined and beneficial	Criterion 3 – cause-and-effect relationship established
2011;9 (6):2207	Beta-glucans from oats and barley.	824	Article 13.1	Blood glucose and insulin response	Consumption of beta-glucans from oats or barley as part of a meal contributes to the reduction of the blood glucose rise after that meal.	Sufficiently characterised. Chemical composition of the component provided.	Reduction of post-prandial glycaemic responses as long as post-prandial insulinaemic response is not disproportionally increased may be a beneficial physiological effect.	Cause-and-effect relationship has been established. The panel notes that majority of the studies presented consistently showed an effect of the component in decreasing post-prandial glycaemia without disproportionally increasing insulinaemic responses. The panel notes that the mechanism by which the component exerts its effect is well established and relates to an increase in meal viscosity and bolus.
2010;8 (10):1739	Hydroxypropyl methylcellulose	814	Article 13.1	Blood glucose and insulin response	Consumption of hydroxypropyl methylcellulose with a meal contributes to a reduction in the blood glucose rise after that meal.	Sufficiently characterised. Analytical methods for the analysis of hydroxypropyl methylcellulose have been developed.	It may be beneficial to subjects with impaired glucose tolerance as long as post-prandial insulinaemic response is not disproportionally increased.	Cause-and-effect relationship has been established. The panel considers that the evidence submitted showed that in diabetic subjects, blood glucose concentration was significantly reduced at varying times compared to placebo. The panel considers that the mechanism by which hydroxypropyl methylcellulose exerts the claimed effect is via delayed glucose absorption in the intestinal tract.
2010;8 (10):1747	Pectins	786	Article 13.1	Blood glucose and insulin response	Consumption of pectins with a meal contributes to the reduction of the blood glucose rise after that meal.	Sufficiently characterised. Chemical composition of the component provided.	It may be beneficial to subjects with impaired glucose tolerance providing post-prandial insulinaemic response is not disproportionally increased.	Cause-and-effect relationship has been established. The panel notes that several studies reporting the effect of pectin in various doses report a significant reduction in post-prandial glucose and post-prandial insulin responses compared to the control. The mechanism by which pectin could exert its effect on post-prandial blood glucose concentration is partly due to delayed gastric emptying which decreases the rate of carbohydrate diffusion in the absorptive mucosal.
2010;8 (10):1798	Konjac glucomannan	854, 1556, 3725.	Article 13.1	Body weight management	Glucomannan in the context of an energy restricted diet contributes to weight loss.	Sufficiently characterised. Chemical structure of the component provided.	Reduction of body weight is a beneficial physiological effect for overweight individuals.	Cause-and-effect relationship has been established. Most of the intervention studies found a statistically significant effect of glucomannan on body weight. Weight loss during the intervention was significantly higher in the glucomannan group than in the placebo group. The panel notes that glucomannan is a soluble type of fibre which forms a viscous, gel-like mass and could delay gastric emptying leading to a decrease in subsequent energy intake.
2010;8 (2):1466	Meal replacement for weight control	1418	Article 13.1	Body weight management	Substituting one daily meal of an energy restricted diet with a meal replacement contributes to the	Sufficiently characterised. Meal replacement for weight loss is defined by Directive 96/8/EC.	Weight loss in overweight individuals is considered a beneficial physiological effect.	Cause-and-effect relationship has been established. The panel notes that the evidence provided reports a sustained weight loss that was

(*continued on next page*)

Table 3 (*continued*)

AUTHORISED CLAIMS								
Journal reference number	Food/ component	Entry identification number (EID)	Article applied under	Health claim classification	Proposed claim	Criterion 1 - food defined and characterise	Criterion 2- claimed effect defined and beneficial	Criterion 3 – cause-and-effect relationship established
					maintenance of weight after weight loss.			maintained after 4 years with one meal and one snack replacement compared to matched controls. Meal replacements tend to increase compliance with energy restricted diet programs for weight loss.
	Meal replacement for weight control	1417	Article 13.1	Body weight management	Substituting two daily meals of an energy restricted diet with meal replacements contributes to weight loss.	Sufficiently characterised. Meal replacement for weight loss is defined by Directive 96/8/EC.	Weight loss in overweight individuals is considered a beneficial physiological effect.	Cause-and-effect relationship has been established. The panel notes that weight loss was significantly greater in subjects receiving the meal replacement plan compared to subject receiving the energy-restricted diet. Meal replacements tend to increase compliance with energy restricted diet programs for weight loss.

criteria for rejection with our conceptual framework relative to the EFSA evaluation protocol criteria.

3.2. Creation of novel categories and sub-categories

Textual data of the scientific opinions were assigned codes and grouped into meaningful clusters with headings. The emerging clusters were organised relative to the entire data set to determine why each application had been accepted or rejected. This generated the seven main and 10 sub-categories presented in Fig. 2. This conceptual framework articulates the novel categories and sub-categories with EFSA's established evaluation protocol criteria (1. food defined and characterised; 2. claimed effect is both defined and beneficial; 3. cause-and-effect relationship is established).

3.3. Novel categories defined under criterion 1 – food defined and characterised

Four novel categories/sub-categories were defined under criterion 1 as follows.

3.3.1. Main category 'specification of active ingredient'

The main category 'specification of an active ingredient' represents the process by which the panel aim to identify the specific food/component to which the intended appetite-related claim is made. Eighteen appetite-related health claims were rejected based on this criterion (see Fig. 2). The panel scrutinises the unique properties of the food/component to ensure it is the same as that described and used in the associated scientific evidence provided in support of the claim. However, concerns have been raised about whether the characterisation of a functional ingredient can be done accurately by measuring one or a limited number of its active components, as is requested by EFSA (de Boer et al., 2014; Jacobs & Tapsell, 2007). Furthermore, unlike drugs, foods do not contain single active components (Jacobs & Tapsell, 2007), and as such this reductionist approach to specifying active ingredients may be questionable (Jacobs & Steffen, 2003, p. 1). This indicates that the evidence needs to demonstrate that the active ingredient is successful as a part of the food in which it will be sold and/ or consumed.

3.3.1.1. Sub-category 'chemical/nutritional composition'. Stating the chemical or nutritional composition of the food/component was a recurring phenomenon in the main category specification of active ingredient. In many cases, the chemical/biochemical compound (EFSA NDA Panel, 2010l, 2011b), percentage composition (EFSA NDA Panel, 2011e), chemical structure (EFSA NDA Panel, 2010b, 2010e), and molecular weight (EFSA NDA Panel, 2011b, 2011c) defined the components' characteristics; likewise, the nutritional information (EFSA NDA Panel, 2010a, 2011e).

For instance, in the characterisation of 'soups', the scientific evidence provided to substantiate the applicant's claim referenced soups with varying macronutrient composition and energy density. The panel thus concluded that a variety of factors could in fact be responsible for the proposed effect of the food/component on satiety (EFSA NDA Panel, 2011j). Two foods of differing macronutrient composition and equal energy density may have varying satiety effects (Chambers et al., 2015). According to the macronutrient satiety hierarchy, proteins are more satiating than carbohydrates, while carbohydrates are more satiating than fats (Blundell & MacDiarmid, 1997; Sánchez-Pimienta et al., 2021). Macronutrient composition is often overlooked in comparative food intake trials, an omission that contributes to confusion about the effect of macronutrient composition on food intake regulation (Bellissimo & Akhavan, 2015). For these reasons, the panel's expectation that the characterisation of a food/component must include all properties considered pertinent to a claim is unsurprising (EFSA NDA Panel, 2011i).

3.3.1.2. Sub-category 'origin/preparation of food/component'. Production processes and source of the food/component are factors considered in its identification (EFSA NDA Panel, 2016). To identify the active ingredient, information regarding the animal/plant origin (EFSA NDA Panel, 2010g, 2010h, 2011e); the production process (EFSA NDA Panel, 2011e); and biosynthesis (EFSA NDA Panel, 2010g, 2011d) were considered.

For example, in an evaluation regarding the characterisation of rye bread, the panel recognised that the chemical composition of rye flour may differ substantially depending on the extraction rate and extent of milling, which may influence the claimed effect (EFSA NDA Panel, 2011j). Similarly, in an evaluation regarding protein hydrolysate, the panel mentions that the composition of protein hydrolysate may vary according to the source of protein and manufacturing processes, therefore this component failed the evaluation at criterion 1 (EFSA NDA Panel, 2011j). This decision is perhaps bounded by EFSA NDA Panel (2016) which explains that information should be provided on manufacturing processes which influence properties relevant to the claimed effect, to demonstrate consistency in the final product.

3.3.1.3. Sub-category 'method of quantification'. In several references, the panel states whether or not the food/component can be measured by established methods (EFSA NDA Panel, 2010f, 2010g, 2010i, 2010j). Some have argued that the panel has been inconsistent in its evaluation (Lenssen et al., 2018). For example, it was noted in the current analysis that protein was considered to be sufficiently characterised although no specification was provided regarding the composition of the protein; the panel affirms that proteins can be measured by established methods (EFSA NDA Panel, 2010g). Nevertheless, proteins are known to vary in structure, peptide length, amino acid composition and physiological function (LaPelusa & Kaushik, 2020; Wu et al., 2014). Additionally, proteins vary in chemical characteristics and composition relative to the analytical method (Mæhre et al., 2018).

It seems the complexity of the food structures that illicit potentially beneficial physiological effects, are also likely factors in the rejection of associated claims. This is further compounded by the lack of consensus in the measurement of some components, and the utilisation of a variety of domestic and industrial processes that disturb such structures at a cellular or molecular level (Dagbasi et al., 2020), therefore making reliable characterisation of the food / component difficult.

3.4. Novel categories defined under criterion 2 - claimed effect defined and beneficial

Five novel categories/sub-categories were defined under criterion 2 as follows.

3.4.1. Main category 'conditional or unconditional beneficial physiological effect'

No appetite-related health claim was rejected at criterion 2. While some claims were considered beneficial without an attached condition (EFSA NDA Panel, 2010c, 2010g, 2010h); others attracted conditions, and upon fulfilment the panel considered them to be physiologically beneficial (EFSA NDA Panel, 2010j, 2010l, 2011c). Critical analysis of the panel's statement on a claim being beneficial, and the presence/absence of these conditions, underpinned this main category. For example:

a) EFSA (2011c, p.7) states "an increase in satiety leading to a reduction in energy intake if sustained, *might* be a beneficial physiological effect". For the purposes of this review, this statement is regarded as a conditional beneficial physiological effect.
b) EFSA (2010c, p.7) states "the panel considers that contribution to the maintenance or achievement of a normal body weight *is* a beneficial physiological effect". This statement is regarded as an unconditional beneficial physiological effect.

3.4.1.1. Sub-category 'sustainability'. Sustainability encompasses consistent and long-term benefits of appetite claims. For example, the statement in EFSA (2011c) above reveals two conditions attached to an increase in satiety claim for it to be a beneficial physiological effect: (i) the effect should lead to a reduction in energy intake; (ii) the combined effects should be sustainable.

Hetherington et al. (2013) argue however that the benefit of satiety should not only be limited to directly influencing food intake and suggest that dietary control or weight management goals such as enhanced adherence to healthy eating patterns, and healthy body weight maintenance are satiety benefits. A *meta*-analysis by Hansen et al. (2019) reports a positive association between interventions that target hunger and/or satiety, and weight management in people with obesity and overweight individuals, when sustained. Methodological variations between the reviewed studies however limit a conclusive inference of a causal link between appetite control and weight management (Hansen et al., 2019). Bellisle and Tremblay (2011) suggest that a proof-of-concept can be used to substantiate the effect of subjective sensations on weight control, provided each step of the concept is proven. Regardless, a claim should only be made on what has been demonstrated (Blundell et al., 2010).

3.4.1.2. Sub-category 'wording of the claim'. The wording of the claim is subject to interpretation by the panel to ascertain if a claim is beneficial. A proposed claim 'helps you to feel full for longer' was interpreted as appetite control by the panel and is not considered to be well defined (EFSA NDA Panel, 2010d). Therefore, appetite control is interpreted as an increase in satiety, which is often associated with changes in appetite ratings, a reduction in energy intake, and a reduction in body weight if sustained (EFSA NDA Panel, 2010d, 2010g, 2010n). There appeared to be a gap between appetite-related health claim applications and short-term physiological benefits. Nevertheless, one appetite-related health claim application "once you're in ketosis your physical hunger is suppressed" (EFSA NDA Panel, 2011g), was regarded as a reduction in the sense of hunger without being associated with a reduction in energy intake or bodyweight. Furthermore, an authorised health claim application "carbohydrate metabolism and insulin sensitivity" was interpreted to mean a reduction in post-prandial glycaemic response, and was considered beneficial, as long as insulinaemic responses were not disproportionately increased (EFSA NDA Panel, 2011c). EFSA interprets the wording of a claim to determine whether a claim is beneficial and to evaluate the substantiating scientific evidence with respect interpretation of the wording of the claim.

3.4.1.3. Sub-category 'target population'. The population at which the health claim is aimed is considered by the panel to ascertain if the claim is beneficial to the general population or a specific subgroup. However, individuals with diseases cannot be the target population of a health claim. For instance, in EFSA NDA Panel (2011c), though they recognise that a reduction in post-prandial glycaemic response is beneficial to individuals with impaired glucose tolerance, the stated target population was 'individuals who wish to reduce their post-prandial glycaemic responses'. In a claim directed at individuals with unintended weight loss, the panel considered the claim beneficial only for underweight individuals willing to increase their energy intake after unintentional weight loss (EFSA NDA Panel, 2010l).

3.4.1.4. Sub-category 'beneficial mechanism'. Here, the panel considers the mechanisms through which beneficial physiological effects may occur. In EFSA NDA Panel (2010m), the panel considered a reduction in waist circumference owing to a reduction in abdominal fat a beneficial

effect; whereas a reduction in waist circumference caused by a reduction in body water was not considered beneficial. Likewise, a reduction in post-prandial glycaemic response was only considered beneficial if insulinaemia was not disproportionately increased (EFSA, 2010j, 2011c).

3.5. Novel categories defined under criterion 3 – cause-and-effect relationship established

Criterion 3 is perhaps the most critical to understand since 37 health claim applications failed the evaluation at this criterion. Eight novel categories/sub-categories were defined under criterion 3 as follows.

3.5.1. Main category 'evidence type'

The quality of scientific evidence submitted to substantiate a claim is of critical importance because it indicates to the panel the depth and breadth of evaluation carried out by the applicant. Human studies are central in the demonstration of a relationship between the food/component and the beneficial physiological effect (EFSA NDA Panel, 2012). The type of studies used to substantiate appetite-related health claims include randomised control trials (EFSA NDA Panel, 2010c, 2010e); epidemiological studies (EFSA NDA Panel, 2010i); mechanistic studies (EFSA NDA Panel, 2010i, 2011e); narrative reviews (EFSA NDA Panel, 2010k, 2011g); technical reports (EFSA NDA Panel, 2010k); and meta-analyses (EFSA NDA Panel, 2010c).

EFSA NDA Panel (2021) reports the hierarchy of scientific evidence in substantiation of a claim, listed here (from highest to lowest) as:

(i) Human intervention studies (e.g., randomised controlled studies, randomised uncontrolled studies etc).
(ii) Human observational studies (e.g., cohort studies).
(iii) Summary reports of human intervention (e.g., systematic reviews).

Where controlled human intervention studies were submitted, in-depth evaluations regarding the study design, test meal, study duration, participants, outcome measures, results, and reliability were carried out (EFSA NDA Panel, 2010k, 2011c).

3.5.2. Main category 'comparative evaluation'

Once the food/component has been defined, and the claimed effect is deemed beneficial, 'comparative evaluation' is undertaken to support establishment of a cause-and-effect relationship between the defined food/component and the claimed effect.

3.5.2.1. Sub-category 'food component of claim vs food component in scientific evidence'. The panel ensures that the characteristics of the food/component are the same as the characteristic of the test/intervention in the substantiating scientific evidence via comparative evaluation, and reporting of this falls within the sub-category food component of claim vs food component in scientific evidence. In EFSA NDA Panel 2010b, the panel notes that the two pieces of evidence submitted reference 'modified' guar gum and that the extent of modification of the food/component could not be ascertained. In EFSA NDA Panel 2010d, the panel reports that the dosage of xanthan gum used in the supporting scientific evidence was lower than the proposed condition of use, thus was cited as one of the reasons the claim was rejected. Therefore, the claims were rejected by the panel due to discrepancies in the comparative evaluation (EFSA NDA Panel, 2010b, 2010d).

3.5.2.2. Sub-category 'study participant vs target population'. The panel considers whether the study participants are a representation of the target population of the appetite-related claim to ascertain if study findings can be extrapolated more widely (Aggett et al., 2005). For instance, in a claim related to increased appetite leading to an increase in energy intake in underweight individuals, the panel notes that the participants used in the study were patients with cancer-induced cachexia, thus rejected the claim (EFSA NDA Panel, 2010l). Similarly, in EFSA NDA Panel 2010j and 2011c, the panel notes that studies in diabetic patients treated with anti-diabetic medications cannot be extrapolated to the general population.

3.5.2.3. Sub-category 'outcome measure'. The outcome measure category represents evaluations assessing measures where changes in those measures have been investigated or presented to show efficacy or infer a relationship between the intervention and the health claim. In appetite claims, various outcome measures such as appetite sensations (EFSA NDA Panel, 2011a); energy intake (EFSA NDA Panel, 2010j); gastrointestinal peptides (EFSA NDA Panel, 2011a); bodyweight changes (EFSA NDA Panel, 2010c); blood glucose level (EFSA NDA Panel, 2010b, 2010c); and insulin levels (EFSA NDA Panel, 2010c, 2010k) were reported. It is important to consider whether the outcome measure reported is valid relative to the wording of the claim. For instance, in a health claim application related to guar gum and an increase in satiety, measures such as postprandial blood glucose and insulin concentration were reported in some of the evidence provided (EFSA, 2010b), however the panel considered these not to be measures of satiety. Although glycaemia, insulinaemia, and lipidaemia are known to rise postprandially, no consistent evidence suggests that an increase in blood glucose – whether acute or long term – is the major determinant of satiety (Anderson & Woodend, 2003). There is no universally accepted method for measuring appetite (Mattes, 2015). Common approaches include measurement of subjective ratings such as hunger, fullness, or desire to eat using a visual analogue scale (VAS) (Stubbs, Ferres & Horgan, 2000), measurement of gastrointestinal satiety peptides such as the orexigenic hormone ghrelin, and anorectic hormones cholecystokinin (CCK), glucagon-like peptide 1 (GLP-1) and peptide tyrosine tyrosine (PYY), and the direct measurement of food intake at an *ad libitum* feed/meal (Yeomans, 2018). In considering the development of an appetite-related health claim, consideration must be given to the outcome measures used in the substantiating evidence, and where no universally accepted measures are available, strong arguments must be in place for the use of proxy measures. Using inappropriate outcome measures as primary end point has been cited as a contributing factor to why appetite-related health claim applications have failed to be substantiated (Martini et al., 2018).

The difficulties of establishing, measuring and reporting appropriate outcome measures is not new in nutritional science. This has been elegantly reviewed elsewhere in relation to health claims specifically (Ashwell et al., 2002), particularly regarding function claims for non-nutrients and reduction of disease risk claims. Establishing gold-standard biomarkers of 'risk' relative to foods/ diets remains a priority for nutrition scientists and one that is increasingly challenging as we glean enhanced understanding of the individuality of response to particular patterns of consumption or ingestion of specific foods/ food components (so-called personalised nutrition). For appetite-related health claims in particular, the most absolute measure of appetite has oft been quoted as amount (energy) consumed when presented with food, however it is well established that social, environmental and psychological triggers for consumption and the cessation of feeding will commonly override the biological/ physiological drive to eat. Not least for this reason, "measuring" human appetite remains hugely challenging. Authorised claims to date are limited to those with body weight management and blood glucose/ insulin response end points. For claims relating to reduced sensations of hunger, increased satiety or the reduction of available energy from the diet to be authorised in future we anticipate further work to enhance the reliability and validity of such outcome measures would be needed.

3.5.3. Main category 'results of study'

After assessing the evidence type and comparative evaluation, the panel proceeds to examine the results of the submitted studies to determine whether the food/intervention influenced the stated claim. The result should show a sustained effect over time to negate the effect of any adaptative compensatory mechanisms (EFSA NDA Panel, 2012). Statistical analysis of the results of the treatment group compared with the control group is critically important in this part of the evaluation; however, the statistical analysis should be adequately powered to minimise errors (Blundell et al., 2010). For example, in EFSA 2010d, the panel reports that no statistically significant difference was observed between hunger, satiety or fullness between the xanthan gum group and the placebo group; therefore, there is insufficient evidence for efficacy. In contrast, in a health claim regarding glucomannan and a reduction in body weight claim, body weight loss was statistically significantly different between the test group and the placebo group ($p < 0.0017$) (EFSA NDA Panel, 2010h), leading to the authorisation of the claim. Whilst only the scientific opinions were subjected to content analysis in the present study we noted that all authorised appetite-related health claims were recognised for their extensive dossiers of evidence including relevant statistically significant findings.

3.5.4. Main category 'reliability'

Following positive evaluation of study results, further exploration by the panel establishes the reproducibility of an effect or the relationship between food/component and the proposed appetite-related health claim. In EFSA NDA Panel 2010c, the panel reports that two studies that used the same dosage of conjugated linoleic acid and a similar study design reported contradictory results, and therefore the finding cannot be deemed reliable.

3.5.5. Main category 'mechanism of effect'

Mechanism of effect considers how a physiological effect may occur and the biological plausibility of an observed effect. The availability of a defined mechanism of effect strengthens the substantiating evidence. In EFSA NDA Panel (2011f), the proposed mechanism of effect was considered weak and not convincing, therefore the claim was rejected. In all six health claims authorised, the panel takes note and reports the mechanism by which the effect may occur (EFSA NDA Panel, 2010a, 2010e, 2010h, 2010k, 2011c).

3.6. A new dawn

Appropriate and robust scientific evidence must be presented to substantiate an appetite-related claim, as for any other health claim. The evidence should be specific to the food/component of the claim, tested in a controlled environment, measure appropriate outcomes relative to the claim, show a sustainable effect, be reliable, and have an explainable biological mechanism. Appetite-related claims were predominantly submitted under the now discontinued Article 13(1) and mainly rejected. Rejection due to poor specification of the active ingredient highlighted the need to better characterise the chemical/ nutritional composition and origin/ preparation of the food or food component, with or without concerns over the method by which it was quantified. Most rejections occurred where cause-and-effect failed to be established across five main areas: evidence type, result of study, reliability, mechanism of effect or comparative evaluation (specifically due to the outcome measures used in supporting evidence, poor alignment between either the study vs target population, or the food component associated with the evidence vs the claim). Perhaps unsurprising, there were no appetite-related claims applications submitted beyond 2012 up to December 31st, 2020. Against a backdrop of ever rising obesity levels however, the debate has not gone away. Claims must now be made under Article 13(5), based on newly developed scientific evidence, or 14 (1)(a), focussed on disease risk factor reduction. Gleaning understanding of where claims have been rejected offers food manufacturers and researchers alike hope of re-igniting an interest in the submission of new claims, which in the UK, would now be to UKNHCC.

As of February 2022, only two health claim applications have been reviewed by UKNHCC. The first is unrelated to appetite ratings, weight management, or blood glucose concentrations however, the most recent was a health claim under Article 14(1)(a) for "assisting healthy blood glucose levels". The claim was classed 'unauthorised' in January 2023. The Committee concluded that *Morus alba* (white mulberry) leaf extract was insufficiently characterised relative to the claimed effect and that the requested wording of the claim did not meet the required criteria for a 14(1)(a) health claim. In addition, a cause-effect relationship could not be established with the claimed effect nor had the claimed effect been unequivocally linked to developing type 2 diabetes.

The lack of health claims applications to UKNHCC suggests a cautious approach is being taken by food manufacturers. The move to UKNHCC provides the opportunity to review the current guidance and evaluation protocol, and to stimulate research and innovation in the UK food sector. Consumers and health care professionals look to health claims for assurance that information is accurate and substantiated with rigorous high-quality scientific evidence. However often it is noted that the wording of health claims can be unclear (Stanner, Ashwell & Williams, 2023). Regardless, there are strengths in the transparent, rigorous scientific assessment by independent scientists underpinning the current claims process which cannot be undervalued, and any changes should be approached with care and attention.

Issues remain relating to satiety-modulation claims specifically. This is arguably and in part because of the difficulties associated with the subjective nature of related outcomes (compared to more objective / quantifiable end points in weight management or glucose control). Future discussion is warranted as to whether such functions as 'reduced sensations of hunger or feelings of fullness' are of any benefit, particularly for those following calorie restricting diets for weight management purposes. As it stands, future appetite-related claims to UKHNCC are only likely to succeed where energy intake and/or weight loss (short-term or a long-term) or glycaemic control are key outcome measures.

4. Conclusion

For the first time EFSA's scientific opinions on appetite-related health claim applications have been systematically reviewed and analysed to elucidate, then characterise, how and why applications have not been authorised. Overwhelmingly, appetite-related health claims have been rejected by EFSA. Though failure to properly characterise a food or component resulted in the rejection of 18 applications, the majority ($n = 37$) of applications were rejected for inadequacies in the substantiating scientific evidence. Our analysis presents seven novel main categories and 10 sub-categories, not previously published, grouping together the reasons for rejection. This systematic analysis provides a platform from which future UK appetite-related health claims, now to UKHNCC, can be assembled, bringing together the commonalities and disparities that cannot be observed elsewhere.

In total, 61 scientific opinions on appetite-related health claims were reviewed. Fifty-five claims relating to hunger, fullness, energy intake, satiation and satiety were rejected, whereas three claims relating to weight management and three relating to blood glucose levels were authorised. 464–88.

The evidence provided herein may be used in conjunction with EFSA's 2012 guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations to support food innovation in the field of appetite management, and guide industry in planning future health claim applications. Given the backdrop of continued high levels of obesity in the UK, we, the authors, hope the door remains open for further discussion with UKHNCC about the future of appetite-related health claims for the UK.

Data and code availability:

The data that support the findings of this study are available publicly

on the European Union register of health claims at https://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public. The data extract of the 61 appetite-related health claim applications reviewed is summarised in the supplementary file associated with this work.

Funding Sources:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. For the purpose of open access, the author has applied a Creative Commons Attribution (CC BY) licence to any Author Accepted Manuscript version arising from this submission.

Ethical Statement:

This work did not directly involve human participants but was, nonetheless, appropriately considered in line with the Sheffield Hallam University Research Ethics Policy.

CRediT authorship contribution statement

Adedamola H. Yakubu: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft. **Katharine Platts:** Conceptualization, Methodology, Formal analysis, Writing – review & editing. **Anna C. Sorsby:** Conceptualization, Writing – review & editing. **Miriam E. Clegg:** Methodology, Writing – review & editing. **Jenny R. Paxman:** Conceptualization, Methodology, Writing – review & editing, Supervision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

All EFSA applications are available in the public domain and the content analysis process and staged outcomes can be provided for review if requested.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jff.2023.105471.

References

Aggett, P. J., Antoine, J. M., Asp, N. G., Bellisle, F., Contor, L., Cummings, J. H., ... & Verhagen11, H. (2005). Process for the assessment of scientific support for claims on foods. *European Journal of Nutrition*, *44*, 1.

Anderson, G. H., & Woodend, D. (2003). Effect of glycemic carbohydrates on short-term satiety and food intake. *Nutrition Reviews, 61*(suppl_5), S17–S26.

Ashwell, M., Hickson, M., Stanner, S., Prentice, A., & Williams, C.M. (2022). On behalf of the Academic of Nutrition Sciences. 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, 1–18. doi:10.1017/S0007114522003300.

Bellisle, F., & Tremblay, A. (2011). Satiety and body weight control. Promise and compromise. Comment on 'Satiety. No way to slim'. *Appetite, 57*(3), 769–771.

Bellissimo, N., & Akhavan, T. (2015). Effect of macronutrient composition on short-term food intake and weight loss. *Advances in Nutrition, 6*(3), 302S 308S.

Bigliardi, B., & Galati, F. (2013). Innovation trends in the food industry: The case of functional foods. *Trends in Food Science and Technology, 31*, 118–129. https://doi.org/10.1016/j.tifs.2013.03.006

Blundell, J. (2010). Making claims: Functional foods for managing appetite and weight. *Nature Reviews Endocrinology, 6*(1), 53–56.

Blundell, J. E., & MacDiarmid, J. I. (1997). Fat as a risk factor for overconsumption: Satiation, satiety, and patterns of eating. *Journal of the American Dietetic Association, 97*(7). S63 S69.

Blundell, J., De Graaf, C., Hulshof, T., Jebb, S., Livingstone, B., Lluch, A., … Westerterp, M. (2010). Appetite control: Methodological aspects of the evaluation of foods. *Obesity Reviews, 11*(3), 251–270.

Chambers, L., McCrickerd, K., & Yeomans, M. R. (2015). Optimising foods for satiety. *Trends in Food Science & Technology, 41*(2), 149–160.

Chimedtseren, N., Kelly, B., McMahon, A. T., & Yeatman, H. (2020). Prevalence and credibility of nutrition and health claims: Policy implications from a case study of Mongolian food labels. *International Journal of Environmental Research and Public Health, 17*(20), 7456.

Dagbasi, A., Lett, A. M., Murphy, K., & Frost, G. (2020). Understanding the interplay between food structure, intestinal bacterial fermentation and appetite control. *Proceedings of the Nutrition Society, 79*(4), 514–530.

De Boer, A., Vos, E., & Bast, A. (2014). Implementation of the nutrition and health claim regulation–The case of antioxidants. *Regulatory Toxicology and Pharmacology, 68*(3), 475–487.

de Boer, A. (2021). Fifteen years of regulating nutrition and health claims in Europe: The past, the present and the future. *Nutrients, 13*(5), 1725.

De Boer, A., & Bast, A. (2021). *Nutrition and health claims: guidance to compliance with Regulation (EC) 1924/2006*. Retrieved from 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#section-4.

Díaz, L. D., Fernández-Ruiz, V., & Cámara, M. (2020). An international regulatory review of food health-related claims in functional food products labeling. *Journal of Functional Foods, 68*, Article 103896.

EFSA Nda Panel. (2010a). Scientific Opinion on the substantiation of health claims related to meal replacements for weight control (as defined in Directive 96/8/EC on energy restricted diets for weight loss) and reduction in body weight (ID 1417), and maintenance of body weight after weight loss (1418) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(2), 1466.

EFSA NDA Panel. (2010b). Scientific Opinion on the substantiation of health claims related to guar gum and maintenance of normal blood glucose concentrations (ID 794), increase in satiety (ID 795) and maintenance of normal blood cholesterol concentrations (ID 808) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(2), 1464.

EFSA NDA Panel. (2010c). Scientific Opinion on the substantiation of health claims related to conjugated linoleic acid (CLA) isomers and contribution to the maintenance or achievement of a normal body weight (ID 686, 726, 1516, 1518, 2892, 3165), increase in lean body mass (ID 498, 731), increase in insulin sensitivity (ID 1517), protection of DNA, proteins and lipids from oxidative damage (ID 564, 1937), and contribution to immune defences by stimulation of production of protective antibodies in response to vaccination (ID 687. *EFSA Journal, 8*(10), 1794.

EFSA NDA Panel. (2010d). Scientific Opinion on the substantiation of health claims related to xanthan gum and increased satiety (ID 838) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(2), 1481.

EFSA NDA Panel. (2010e). Scientific Opinion on the substantiation of health claims related to pectins and reduction of post-prandial glycaemic responses (ID 786), maintenance of normal blood cholesterol concentrations (ID 818) and increase in satiety leading to a reduction in energy intake (ID 4692) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(10), 1747.

EFSA NDA Panel. (2010f). Scientific Opinion on the substantiation of health claims related to gamma linolenic acid and maintenance of joints (ID 494, 637, 1774, 2098), weight maintenance following weight loss (ID 496), maintenance of peripheral blood flow (ID 638), maintenance of normal blood pressure (ID 1771), maintenance of normal blood cholesterol concentrations (ID 1771) and maintenance of bone (ID 1774) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(2), 1477.

EFSA NDA Panel. (2010g). Scientific Opinion on the substantiation of health claims related to protein and increase in satiety leading to a reduction in energy intake (ID 414, 616, 730), contribution to the maintenance or achievement of a normal body weight (ID 414, 616, 730), maintenance of normal bone (ID 416) and growth or maintenance of muscle mass (ID 415, 417, 593, 594, 595, 715) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(10), 1811.

EFSA NDA Panel. (2010h). Scientific Opinion on the substantiation of health claims related to konjac mannan (glucomannan) and reduction of body weight (ID 854, 1556, 3725), reduction of post-prandial glycaemic responses (ID 1559), maintenance of normal blood glucose concentrations (ID 835, 3724), maintenance of normal (fasting) blood concentrations of triglycerides (ID 3217), maintenance of normal blood cholesterol concentrations (ID 3100, 3217), maintenance of normal bowel function (ID 834, 1557, 3901) and decreasing. *EFSA Journal, 8*(10), 1798.

EFSA NDA Panel. (2010i). Scientific Opinion on the substantiation of health claims related to calcium and maintenance of normal bone and teeth (ID 2731, 3155, 4311, 4312, 4703), maintenance of normal hair and nails (ID 399, 3155), maintenance of normal blood LDL-cholesterol concentrations (ID 349, 1893), maintenance of normal blood HDL-cholesterol concentrations (ID 349, 1893), reduction in the severity of symptoms related to the premenstrual syndrome (ID 348, 1892), "cell membrane permeability"(ID 363), reduction of tiredness. *EFSA Journal, 8*(10), 1725.

EFSA NDA Panel. (2010j). Scientific Opinion on the substantiation of health claims related to partially hydrolysed guar gum and increase in satiety (ID 790), maintenance or achievement of a normal body weight (ID 790), maintenance of normal blood concentrations of triglycerides (ID 793, 816), maintenance of normal blood cholesterol concentrations (ID 793, 816), reduction of post-prandial glycaemic responses (ID 789, 2932) and maintenance of normal blood glucose concentrations (ID 792) pursuant to Article 13 (1) of Regulation. *EFSA Journal, 8*(2), 1465.

EFSA NDA Panel. (2010k). Scientific Opinion on the substantiation of health claims related to hydroxypropyl methylcellulose (HPMC) and maintenance of normal bowel function (ID 812), reduction of post-prandial glycaemic responses (ID 814), maintenance of normal blood cholesterol concentrations (ID 815) and increase in satiety leading to a reduction in energy intake (ID 2933) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(10), 1739.

EFSA NDA Panel. (2010l). Scientific Opinion on the substantiation of health claims related to eicosapentaenoic acid (EPA) and enhancement of mood (ID 633), calming (ID 634), increased attention (ID 634), increase in appetite after unintentional weight loss leading to an increase in energy intake (ID 635), and protection of blood lipids from oxidative damage (ID 636) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(10), 1736.
EFSA NDA Panel. (2010m). Scientific Opinion on the substantiation of a health claim related to ethanol-water extract of Caralluma fimbriata (Slimaluma®) and helps to reduce waist circumference pursuant to Article 13 (5) of Regulation (EC) No 1924/2006. *EFSA Journal, 8*(5), 1602.
EFSA NDA Panel. (2010n). Scientific Opinion on the substantiation of a health claim related to mycoprotein and maintenance of normal blood LDL-cholesterol concentrations (ID 1619) and increase in satiety leading to a reduction in energy intake (ID 1619) and increase in satiety leading to a reduction in energy intake (ID 1620) pursuant to Article 13(1)of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(4), 2042.
EFSA NDA Panel. (2011a). Scientific Opinion on the substantiation of a health claim related to "pine nut oil from Pinus koraiensis Siebold & Zucc" and an increase in satiety leading to a reduction in energy intake (ID 551) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(4), 2046.
EFSA NDA Panel. (2011b). Scientific Opinion on the substantiation of health claims related to chitosan and reduction in body weight (ID 679, 1499), maintenance of normal blood LDL-cholesterol concentrations (ID 4663), reduction of intestinal transit time (ID 4664) and reduction of inflammation (ID 1985) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(6), 2214.
EFSA NDA Panel. (2011c). Scientific Opinion on the substantiation of health claims related to beta-glucans from oats and barley and maintenance of normal blood LDL-cholesterol concentrations (ID 1236, 1299), increase in satiety leading to a reduction in energy intake (ID 851, 852), reduction of post-prandial glycaemic responses (ID 821, 824), and "digestive function"(ID 850) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA journal, 9*(6), 2207.
EFSA NDA Panel. (2011d). Scientific Opinion on the substantiation of health claims related to 5-hydroxytryptophan (5-HTP) and increase in satiety leading to a reduction in energy intake (ID 4223) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(6), 2198.
EFSA NDA Panel. (2011e). Scientific Opinion on the substantiation of a health claim related to diacylglycerol (DAG) oil and reduction of body weight pursuant to Article 13 (5) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(12), 2469.
EFSA Panel on Dietetic Products, & Nutrition and Allergies (NDA). (2011f). Scientific Opinion on the substantiation of health claims related to medium-chain triglycerides and reduction in body weight (ID 643, 677, 1614) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(6), 2240.
EFSA NDA Panel. (2011g). Scientific Opinion on the substantiation of health claims related to very low calorie diets (VLCDs) and reduction in body weight (ID 1410), reduction in the sense of hunger (ID 1411), reduction in body fat mass while maintaining lean body mass (ID 1412), reduction of post-prandial glycaemic responses (ID 1414), and maintenance of normal blood lipid profile (1421) pursuant to Article 13 (1) of Regulation (EC) No 1924/2006. *EFSA Journal, 9*(6), 2271.
EFSA NDA Panel. (2011h). Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim (revision 1). *EFSA Journal, 9*(5), 2170.
EFSA NDA Panel. (2011i). General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. *EFSA Journal, 9*(4), 2135.
EFSA NDA Panel (2011j). Scientific Opinion on the substantiation of health claims related to flavonoids and ascorbic acid in fruit juices, including berry juices (ID 1186); flavonoids from citrus (ID 1471); flavonoids from Citrus paradisi Macfad.(ID 3324, 3325); flavonoids (ID 1470, 1693, 1920); flavonoids in cranberry juice (ID 1804); carotenoids (ID 1496, 1621, 1622, 1796); polyphenols (ID 1636, 1637, 1640, 1641, 1642, 1643); rye bread (ID 1179); protein hydrolysate (ID 1646); carbohydrates with a low/reduced glycaemic load .... *EFSA Journal 9*(4), 2082.
EFSA NDA Panel. (2012). Guidance on the scientific requirements for health claims related to appetite ratings, weight management, and blood glucose concentrations. *EFSA Journal, 10*(3), 2604.
EFSA NDA Panel. (2016). General scientific guidance for stakeholders on health claim applications. *EFSA Journal, 14*(1), 4367.
EFSA NDA Panel. (2017). Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 2). *EFSA Journal, 15*(1), e04680.
EFSA NDA Panel. (2018). Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health: (Revision 1). *EFSA Journal, 16*(1), e05136.
EFSA NDA Panel. (2021). Scientific and technical guidance for the preparation and presentation of a health claim application (Revision 3) 1. *EFSA Journal, 19*(3), e06554.
European Union (EU) (2006). Regulation (EC) No 1924/2006 of the European parliament and of the council of 20 December 2006 on nutrition and health claims made on food. *Official Journal of the European Union* 404, 3.
European Union (EU) (2012). Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health. *Official Journal of the European Union* 136, 1–40.
Elo, S., & Kyngäs, H. (2008). The qualitative content analysis process. *Journal of advanced nursing, 62*(1), 107–115.
Griffioen-Roose, S., Wanders, A., & Bánáti, D. (2013). Satiety and appetite control claims: getting it right for consumers.
Guiné, R. P., Florença, S. G., Barroca, M. J., & Anjos, O. (2020). The link between the consumer and the innovations in food product development. *Foods, 9*(9), 1317.
Hardy, G. (2000). Nutraceuticals and functional foods: introduction and meaning. *Nutrition (Burbank, Los Angeles County, Calif.) 16*(7–8), 688–689.
Hansen, T. T., Andersen, S. V., Astrup, A., Blundell, J., & Sjödin, A. (2019). Is reducing appetite beneficial for body weight management in the context of overweight and obesity? A systematic review and meta-analysis from clinical trials assessing body weight management after exposure to satiety enhancing and/or hunger reducing products. *Obesity Reviews, 20*(7), 983–997.
Hetherington, M. M., Cunningham, K., Dye, L., Gibson, E. L., Gregersen, N. T., Halford, J. C. G., … Van Trijp, H. C. M. (2013). Potential benefits of satiety to the consumer: Scientific considerations. *Nutrition research reviews, 26*(1), 22–38.
Hopkins, M., Blundell, J., Halford, J., King, N., & Finlayson, G. (2016). The regulation of food intake in humans. *Endotext [Internet]*.
Jacobs, D. R., Jr, & Steffen, L. M. (2003). Nutrients, foods, and dietary patterns as exposures in research: A framework for food synergy. *The American Journal of Clinical Nutrition, 78*(3), 508S 513S.
Jacobs, D. R., & Tapsell, L. C. (2007). Food, not nutrients, is the fundamental unit in nutrition. *Nutrition Reviews, 65*(10), 439–450.
Juvani, S., Isola, A., & Kyngäs, H. (2005). The northern physical environment and the well-being of the elderly aged over 65 years. *International Journal of Circumpolar Health, 64*(3), 246–256.
LaPelusa, A., & Kaushik, R. (2020). *Physiology, Proteins*. StatPearls [Internet].
Lenssen, K. G., Bast, A., & de Boer, A. (2018). Clarifying the health claim assessment procedure of EFSA will benefit functional food innovation. *Journal of Functional Foods, 47*, 386–396.
Mæhre, H. K., Dalheim, L., Edvinsen, G. K., Elvevoll, E. O., & Jensen, I. J. (2018). Protein determination—method matters. *Foods, 7*(1), 5.
Martini, D., Biasini, B., Rossi, S., Zavaroni, I., Bedogni, G., Musci, M., … Del Rio, D. (2018). Claimed effects, outcome variables and methods of measurement for health claims on foods proposed under European Community Regulation 1924/2006 in the area of appetite ratings and weight management. *International Journal of Food Sciences and Nutrition, 69*(4), 389–409.
Mattes, R. D. (2015). Appetite: Measurement and management. In *Nutrition for the Primary Care Provider* (Vol. 111, pp. 19–23). Karger Publishers.
Petit, O., Basso, F., Merunka, D., Spence, C., Cheok, A. D., & Oullier, O. (2016). Pleasure and the control of food intake: An embodied cognition approach to consumer self-regulation. *Psychology & Marketing, 33*(8), 608–619.
Pravst, I., Kušar, A., Žmitek, K., Miklavec, K., Lavriša, Ž., Lähteenmäki, L., ... & REDICLAIM Consortium (2018). Recommendations for successful substantiation of new health claims in the European Union. *Trends in Food Science & Technology 71*, 259–263.
Salminen, S., & van Loveren, H. (2012). Probiotics and prebiotics: Health claim substantiation. *Microbial Ecology in Health and Disease, 23*(1), 18568.
Sánchez-Pimienta, T. G., Quezada-Sánchez, A. D., Rivera, J. A., Shamah, T., & Batis, C. (2021). Nutrient composition of mealtimes and its association with the energy intake of subsequent meals among Mexican adults. *Appetite, 164*, Article 105288.
Skarupinski, P., & Jakobs, S. (2014). Legal classification of borderline substances as melatonin, with particular regard to EFSA's assessment of article 13.1 health claims. *Aktuelle Ernährungsmedizin, 39*(05), 312–319.
Stanner, S., Ashwell, M., & Williams, C. M. (2023). Why do health professionals need to know about the nutrition and health claims regulation? Summary of an Academy of Nutrition Sciences' Position Paper. *Journal of Human Nutrition and Dietetics, 36*, 12–16.
Stribiţcaia, E., Evans, C. E., Gibbons, C., Blundell, J., & Sarkar, A. (2020). Food texture influences on satiety: Systematic review and meta-analysis. *Scientific reports, 10*(1), 1–18.
Stubbs, J., Ferres, S., & Horgan, G. (2000). Energy density of foods: Effects on energy intake. *Critical Reviews in Food Science and Nutrition, 40*(6), 481–515.
Vears, D. F., & Gillam, L. (2022). Inductive content analysis: A guide for beginning qualitative researchers. *Focus on Health Professional Education: A Multi-Professional Journal, 23*(1), 111–127.
Wu, G., Bazer, F. W., Dai, Z., Li, D., Wang, J., & Wu, Z. (2014). Amino acid nutrition in animals: protein synthesis and beyond. *Annu. Rev. Anim. Biosci., 2*(1), 387–417.
Yeomans, M. R. (2018). Measuring appetite and food intake. In *Methods in Consumer Research* (Volume 2, pp. 119–149). Woodhead Publishing.