TECHNICAL REPORT

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Outcome of a public consultation on the draft scientific and technical guidance for the preparation and presentation of a health claim application

European Food Safety Authority

Abstract

The European Food Safety Authority (EFSA) carried out a public consultation to receive input from the scientific community and all interested parties on the draft scientific and technical guidance for the preparation and presentation of a health claim application, prepared by the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) and endorsed by the Panel for public consultation at its Plenary meeting on 29 June 2016. The written public consultation for this document was open from 18 July to 12 September 2016. EFSA received comments from ten interested parties. EFSA and its NDA Panel wish to thank all stakeholders for their contributions. The current report summarises the outcome of the public consultation, and includes a summary of the comments received and how the comments were addressed. The NDA Panel prepared an updated version of the scientific and technical guidance for the preparation and presentation of a health claim application taking into account the comments received. The guidance was discussed and adopted at the NDA Plenary meeting on 14 December 2016, and is published in the EFSA Journal.

Key words: health claims, application, scientific and technical guidance, public consultation

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1. Introduction

1.1. Background and Terms of Reference as provided by EFSA

Background

Regulation (EC) No 1924/2006[1] harmonises the provisions related to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. According to the Regulation, health claims should be only authorised for use in the Community after a scientific assessment of the highest possible standard to be carried out by EFSA.

Owing to the scientific and technical complexity of health claims, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA Panel) has placed considerable efforts on developing scientific criteria for the substantiation of health claims, and has published guidance on the scientific substantiation of health claims since 2007[2].

In the last years, the NDA Panel has gained considerable experience in the evaluation of health claim applications. Interactions and exchange of views with stakeholders have also increased considerably, both through a technical meeting[3] and through public consultations on guidance documents. The NDA Panel has translated the lessons learnt from these experiences into a revised General scientific guidance for stakeholders on health claim applications[4], which was recently published and represents a step forward in assisting applicants to compile their applications for health claims authorisation. In this context, it is noted the need to adapt the existing scientific and technical guidance for stakeholders[5] to the new scientific and technical developments in this area.

To this end, the NDA Panel is asked to update the scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim[6].

Terms of reference

The NDA Panel is requested by EFSA to update the scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim.

The guidance document shall clarify and address the scientific and technical developments in this area, taking into account the experience gained by the NDA Panel with the evaluation of health claims and the comments received from stakeholders in technical meetings and public consultations.

The draft guidance shall be released for public consultation prior to finalisation.

The draft guidance shall be revised taking into account the comments received during the public consultation before the adoption by the NDA Panel. A technical report on the outcome of the public consultation shall be published.

1.2. Consideration

Following a request from EFSA to the NDA Panel to update the scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim, which was published in 2007 and subsequently revised in 2011 (revision 1), the NDA Panel developed a Scientific and technical guidance for the preparation and presentation of a health claim application (hereafter 'scientific and technical guidance'). In line with EFSA's policy on openness and transparency, and in order for EFSA to receive comments on its work from the scientific community and stakeholders, EFSA engages in public consultations on key issues. Accordingly, the draft scientific and technical guidance was discussed and endorsed at the NDA Plenary meeting on 29 June 2016 for release for public consultation, and was published on EFSA's website for comments from 18 July to 12 September 2016 (see Appendix A). The NDA Panel prepared an updated version of the scientific and technical

[1] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.
[2] http://www.efsa.europa.eu/en/nda/ndaclaims.htm
[3] http://www.efsa.europa.eu/it/supporting/pub/569e
[4] http://www.efsa.europa.eu/it/efsajournal/pub/4367
[5] Scientific and technical guidance for the preparation and presentation of an application for authorisation of a health claim http://www.efsa.europa.eu/en/efsajournal/pub/2170
[6] http://www.efsa.europa.eu/en/efsajournal/pub/2170

guidance, taking into account the comments received. The updated scientific and technical guidance was discussed and adopted at the NDA Plenary meeting on 14 December 2016, and is published in the EFSA Journal (EFSA NDA Panel, 2017). EFSA is committed to publishing the comments received during the public consultation, as well as a short report on the outcome of the consultation.

2. Assessment of comments received

2.1. Comments received

EFSA received 63 comments submitted by means of the electronic form on the EFSA website (Appendix B) and two comments submitted by e-mail (Appendix C) from 10 interested parties, including the food industry and food industry associations, consultants, a research consortium and a non-governmental organisation.

Table 1: List of organisations submitting comments

Organisation	Country
Baby Milk Action - IBFAN	UK
Danone Nutricia Research	FR
Health Food Manufacturers Association (HFMA)	UK
International Probiotics Association (IPA) Europe	BE
Lallemand Health Solutions	ES
Mondelez Int. R&D	FR
Nutraveris	FR
REDICLAIM consortium (EU project contract number FP7-603036)	UK
Suntory Beverage & Food Europe	UK
Unilever R&D	NL

BE: Belgium; ES: Spain; FR: France; NL: Netherlands; UK: United Kingdom.

A summary of the comments received is given below. All written comments are listed in Appendices B and C. Several parties submitted identical comments.

2.2. General comments

EFSA wishes to highlight that the comments received referred to issues related to scientific substantiation that are common to all claims (e.g. principles applied for claims based on the essentiality of nutrients vs. claims other than those based on the essentiality of nutrients, aspects related to the characterisation of the food/constituent and to the characterisation of the claimed effect, examples of the evidence required for the substantiation of claims, criteria for the identification of pertinent human studies) or to administrative and procedural aspects governing the life cycle of a health claim application. Such aspects have already been addressed in the general scientific guidance for stakeholders on health claim applications[7] (EFSA NDA Panel, 2016), hereafter 'general guidance', and will not be reiterated in this scientific and technical guidance.

For clarity, the scientific and technical guidance has been revised by cross-referencing relevant sections of the 'general guidance', where applicable.

2.2.1. Comments related to the legal framework and to risk management

Many comments related to the legal framework for the authorisation of health claims and referred to risk management aspects, such as:

(a) Whether or not claims in foods targeted to infants, young children, pregnant women or "mothers", and claims in foods containing high levels of sugar, should be banned for safety reasons.

[7] http://www.efsa.europa.eu/en/efsajournal/pub/4367

(b) The level of evidence for health claim substantiation in the EU was regarded as being very high compared with other jurisdictions in the world (a barrier to small and medium-sized enterprises), and more appropriate for pharmaceutical products;

(c) Whether a "mutual recognition" agreement exists between EFSA and other Agencies in the world regarding the substantiation of health claims made on food;

Authorising, banning or restricting the use of health claims in specific foods or food categories in the EU (including foods for infants and young children) is outside EFSA's remit.

During the scientific evaluation of health claims, the NDA Panel may recommend restrictions of use based on safety considerations. When deciding on the authorisation of health claims, risk managers may also take into account factors other than EFSA's scientific opinion, such as nutrient goals or recommendations or safety aspects, on which EFSA could be consulted ad-hoc. The Claims Regulation does not foresee, however, a safety evaluation of the food/constituent for which the claim is made.

As already mentioned in previous guidance documents[8] and technical reports[9], the Claims regulation specifies that 'health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard'. Differences in the assessment of health claims in different jurisdictions are often driven by different legislative frameworks governing the authorisation of health claims made on food, and therefore no "mutual recognition" procedure is in place. However, regular exchanges of views on the scientific substantiation of health claims already take place between different risk assessors around the world (i.e. Heath Canada, FSANZ, NZ MPI, US FDA, and EFSA).

These comments are not discussed further in the present report and were not taken into account in updating the scientific and technical guidance.

2.2.2. Comments on procedural aspects, objectives and the scope of the guidance

Many of the comments received were beyond the objectives and scope of the draft scientific and technical guidance. Such comments referred to:

(a) The standards that should be applied for the safety evaluation of foods and food ingredients to be consumed by infants, young children, pregnant and lactating women;

(b) EFSA's criteria for the scientific evaluation of health claims;

(c) Lack of EFSA guidance concerning study design, definition/selection of (healthy) populations, selection of suitable biomarkers, etc.

(d) Requests for pre-submission meetings;

(e) Request for a summary document containing appropriate outcome variables for the claimed effects addressed in different EFSA guidance documents;

(f) Lack of reference in the guidance concerning the procedure laid down in Art 13(4) of Regulation (EC) No 1924/2006;

(g) The involvement of EU Member States in the scientific assessment of health claims.

EFSA would like to reiterate that pre-submission meetings with individual applicants, including open face-to-face discussions with EFSA staff or the NDA Panel, are not among the services that EFSA offers. Applicants are invited to consult 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products'[10] for more information about the various initiatives that EFSA has put in place in the area of regulated products to assist applicants.

Owing to the scientific and technical complexity of health claims, the NDA Panel has placed considerable effort into developing scientific criteria for the substantiation of health claims and updating guidance documents published since 2007. Interactions and exchange of views with

[8] http://www.efsa.europa.eu/en/applications/nutrition/regulationsandguidance
[9] http://www.efsa.europa.eu/en/supporting/pub/986e, http://www.efsa.europa.eu/en/supporting/pub/985e
[10] http://www.efsa.europa.eu/en/supporting/pub/1025e

stakeholders have also increased considerably, both through a technical meeting[11] and through public consultations on guidance documents. The NDA Panel has translated the lessons learnt from these experiences into the general scientific guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016)[12], in which practical examples have been used to illustrate the approach of the NDA Panel in the evaluation of health claim applications. Applicants are recommended to refer to the aforementioned guidance.

To further assist applicants, EFSA launched in 2014 a grant (GP/EFSA/NUTRI/2014/01)[13] which aims at gathering information in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims. The information collected will be published in a scientific report, which will help to inform the NDA Panel and serve as a basis for further guidance to applicants. The format(s) under which such guidance will be provided to applicants (e.g. guidance documents, searchable, interactive databases) will be carefully considered by EFSA.

Applicants are also invited to consult EFSA-published guidance[14] for health claims in specific areas for assistance in selecting appropriate outcome variables.

To date, EFSA has limited experience[15] with the evaluation of health claims pursuant to Article 13(4) that could be used by the NDA Panel to provide guidance in this specific area. Since the Article 13(4) procedure (for changes to the permitted list of Article 13(1) health claims) can only be triggered by the Commission's own initiative or following a request by a Member State, this aspect should therefore be addressed to the risk managers.

EU Member States are not involved in the scientific evaluation of health claims under the current legal framework.

Comments (a)–(g) are not discussed further in the present report and were not taken into account in updating the scientific and technical guidance.

2.3. Specific comments

2.3.1. General principles

Comments received

1. From lines 112-114 of the draft scientific and technical guidance released for public consultation it was understood that, for claims other than those based on the essentiality of nutrients, the studies submitted for substantiation should be published before the submission of the application.

Panel consideration of comments received

Ad1. EFSA wishes to clarify that publication of the studies submitted for the substantiation of health claims is highly recommended for transparency reasons[16]. For claims other than those based on the essentiality of nutrients, evidence on the relationship between the consumption of the food/constituent and the claimed effect could be obtained from both published and unpublished human studies. This is clearly reflected in several parts of the scientific and technical guidance i.e. summary, general principles 4 and 12, sections 4.2 and 4.2.2).

Comments received

2. It was asked to clarify the meaning of 'multiple formulations of a food/constituent'.

[11] http://www.efsa.europa.eu/it/supporting/pub/569e
[12] http://www.efsa.europa.eu/it/efsajournal/pub/4367
[13] http://www.efsa.europa.eu/en/art36grants/article36/gpefsanutri201401.htm
[14] http://www.efsa.europa.eu/en/nda/ndaguidelines.htm
[15] So far, EFSA has received one request from the Commission to provide a scientific opinion on the conditions of use for health claims related to meal replacements for weight control (EFSA-Q-2015-00579) http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4287/epdf
[16] http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2014.EN-569/pdf

Panel consideration of comments received

Ad2. An example to illustrate the meaning of 'multiple formulations of a food/constituent' is given in a footnote under general principle 5, which reads as follows: '*For example, a food product available in different flavours (e.g. vanilla, chocolate) or formats (e.g. tablets, powder, liquid)*'.

Comments received

3. It was considered that a re-analysis of data from peer-reviewed publications by EFSA contradicts general principle 4 (i.e. '*the Panel should not be required to […] process data in order to evaluate the application*'). It was also considered, however, that relying on applicants to gather all pertinent data constitutes a weakness in the process, and that the option of EFSA to consider pertinent data not provided in an application should be clarified in the guidance.

Panel consideration of comments received

Ad3. The publication of a scientific study in a peer-reviewed journal does not guarantee that the results of such a study are pertinent to a particular claim. The purpose of the peer-review process carried out by a scientific journal (i.e. publication of studies which are scientifically sound and of interest for the scientific community) is not the same as the purpose of the peer-review process carried out by the NDA Panel for the scientific evaluation of health claims (e.g. to establish a cause-effect relationship between the consumption of a specific food/constituent and the claimed effect), and thus both review processes serve different objectives and may reach different conclusions (i.e. on whether the scientific study is/is not appropriate for the particular purpose).

For the scientific substantiation of a claim, the NDA Panel considers the totality of the available scientific evidence. It is the responsibility of the applicant to provide these data. In its assessment, the NDA Panel may use data which are not included in the application if such data are considered pertinent to the claim.

General principle 4 of the scientific and technical guidance has been amended to clarify this aspect, as follows: '…*In its evaluation, the NDA Panel may use data which are not included in the application if they are considered pertinent to the claim. However, the NDA Panel should not be required to undertake any additional literature reviews, to assemble or process data in order to evaluate the application. As such, the application should be comprehensive and complete…*'.

Comments received

4. There was a request to explain the evidence needed to establish an effect of a fixed combination of constituents, and whether evidence should be provided for all single constituents in the fixed combination.

Panel consideration of comments received

Ad4. If the claim is for a fixed combination of constituents, then studies are needed on the fixed combination, whereas studies on the individual constituents or on combinations of constituents other than the fixed combination for which the claim is proposed are not required. However, if individual constituent(s) in the fixed combination have an established role on the claimed effect (e.g. evidence for their role on the claimed effect has already been evaluated by the Panel with a positive outcome), the NDA Panel also considers whether: i) the effect could be explained by the individual constituent(s), regardless of the source; ii) other constituent(s) in the fixed combination are required for/contribute to the claimed effect (i.e. whether the fixed combination has an effect beyond what could be expected from the presence of the individual constituent(s) with an established role on the claimed effect).

This aspect has already been addressed in section 7.1.1 of the 'general guidance' and in Ad15 of the technical report on the public consultation of the 'general guidance'[17].

[17] http://www.efsa.europa.eu/en/supporting/pub/986e

Comments received

5. It was requested not to publish the summary of applications to avoid an advantage for competitors.

Panel consideration of comments received

Ad5. For claims falling under the scope of Article 14, it is a requirement of Regulation (EC) No 1924/2006 (Article 15(2)(b)) that EFSA makes public the summary of the application as provided by the applicant upon its receipt. For claims falling under the scope of Article 13(5), the summary of the application is not published.

A note has been added to Appendix B to highlight that the summary of the application should not contain confidential data.

2.3.2. Part 1: Administrative and technical data

Comments received

6. Several comments related to the requirements to support claims regarding confidentiality and proprietary data, indicating a need for further explanation regarding these concepts. Clarification was requested on the meaning of 'verifiable justification', and on how EFSA makes decisions of whether data can be treated as confidential or not. It was suggested that confidentiality claims could be justified only by a declaration/certification from the applicant. There was also a question on the need to justify proprietary data in the application. A commenter understood that 'verifiable justification' (lines 418-419) was not requested before for Article 14 and 13.5 applications with requests for proprietary data protection.

Panel consideration of comments received

Ad6. The requirements for claims on confidentiality and how EFSA handles confidential and proprietary data have already been addressed in Annex A (section A.4) of the 'general guidance' and in Ad40 of the technical report on the public consultation of the 'general guidance'[18]. For reasons of clarity, cross-reference to Annex A (section A.4) of the 'general guidance' is now made in sections 1.4 and 1.5 of the scientific and technical guidance. In addition, a footnote has been added in section 1.4 to clarify the meaning of 'verifiable justification', as follows: '*Precise and factual information, ideally documents, proving that disclosure of the information requested by the applicant to be treated as confidential would result in concrete harm to the commercial or economic interest of the applicant/requestor, or would undermine the protection of privacy and/or integrity of concerned individual(s)*'.

2.3.3. Part 2: Characterisation of the food/constituent

Comments received

7. Several comments referred to the requirements for characterisation of the food/constituent. These comments requested the following:

(a) To indicate the reason for the distinction made between vitamins and minerals (section 2.1.1) and food/constituents other than vitamins and minerals (section 2.1.2), given that the manufacturing process and data on stability should be requested in both cases;

(b) To change the heading of section 2.1.2 into 'constituents other than vitamins and minerals', or 'food constituents other than vitamins and minerals', noting that foods are not addressed in that section;

(c) To specify the data needed for the characterisation of a food/constituent (e.g. on heavy metals, pesticides, mycotoxins or other contaminants; nutritional analysis);

(d) To specify the information needed for the characterisation of botanicals;

[18] http://www.efsa.europa.eu/en/supporting/pub/986e

(e) To indicate the level of certification needed for the measurements performed in a competent laboratory;

(f) For foods or category of foods, to clarify whether stability studies should focus on the active constituent of the food or food category, on stability of the food/food category *per se*, or on both. It was suggested to replace 'manufacturing process' with 'production process' to cover e.g. crop production, fish farming.

Panel consideration of comments received

Ad7. In relation to these comments, the NDA Panel wishes to clarify the following:

Comment (a) - The purpose of distinguishing between sections 2.1.1 and 2.1.2 is to simplify the type and amount of information to be provided for the characterisation of vitamins and minerals in the chemical form of the nutrient that is naturally present in foods and/or in chemical forms of the nutrient that are permitted for addition to foods, as these are already legislated in the European Union. Part 2 of the scientific and technical guidance has been updated to clarify that, where applicable, manufacturing process (section 2.3) and data on stability (section 2.4) should be provided.

Comment (b) - In the context of the scientific and technical guidance, 'food/constituent' means '*a food category, a food, or its constituents (including a nutrient or other substance, or a fixed combination of constituents)*' (general principle 1 and glossary). Instructions are given in section 2 to fill in only section 2.2 for the characterisation of a food or a food category.

Comments (c) – A safety assessment is not foreseen in the framework of Regulation (EC) No 1924/2006, and thus data related, for example, to heavy metals, pesticides, mycotoxins, or other contaminants are not required. The information to be provided for the characterisation of the food/constituent relates to those characteristics which may influence the specific physiological effect that is the basis of the claim. Such characteristics may depend on the nature of the food constituent, but also on the specific claimed effect. The NDA Panel consideration on the extent to which a food/constituent should be characterised is outlined in section 7.1 of the 'general guidance'.

Comments (d) - For plant products (EFSA Scientific Committee, 2009), the information required includes the scientific (latin) name (full systematic species, name including botanical family, genus, species, variety, subspecies, author's name and chemotype, where relevant; e.g. *Punica granatum* L, Lythraceae (Punicaceae)), the part used (e.g. fruit, root, leaf, seed), complete specifications of the manufacturing process (e.g. dried, hydroalcoholic extraction, plant extract ratio) and how the product is standardised (e.g. by its content of one or more specific constituents).

Comment (e) – With respect to the level of certification needed for the measurements performed in a competent laboratory, a footnote has been added under general principle 9 of the scientific and technical guidance to clarify that *'E.g. information on the accreditation of the involved facility should be provided*'.

Comment (f) – A footnote has been added in section 2.4 of the scientific and technical guidance to clarify that: *'Stability studies should focus on the food/constituent for which the claim is proposed (i.e. the food/constituent which is expected to exert the claimed effect). The information provided should ensure consistency and stability of the food/constituent in the final food product as consumed'*.

No health claim application has been evaluated by the NDA Panel on food/constituents which could be characterised by the production process (e.g. crop production and fish farming). No change was introduced in the guidance on the basis of this comment.

Comments received

8. It was noted that data on bioavailability have been moved to the section of 'supportive evidence' and thus it seems less important now than it was in the previous version of the scientific and technical guidance.

Panel consideration of comments received

Ad8. Bioavailability studies have been moved to section 5.2.3 as supportive evidence because, even if these may be important for the full characterisation of certain food/constituents, they could also be part of the totality of the evidence which could be taken into account for the scientific substantiation of the claim if pertinent human studies showing an effect of the food/constituent are available (see the definitions given under general principle 2).

2.3.4. Part 3: Characterisation of the claimed effect

Comments received

9. Several parties argued that EFSA overstepped Regulation (EC) No 1924/2006 with the requirement to identify the 'specific' function of the body that is the subject of the claim for function claims, as it was felt that claims such as 'could promote a favourable gut flora' could be possible.

Panel consideration of comments received

Ad9. According to Regulation (EC) No 1924/2006, '*reference to general, non-specific benefits of the nutrient or food for overall good health or health-related well-being may only be made if accompanied by a specific health claim*'. The scientific translation of 'specific' is 'measurable *in vivo* in humans by well-accepted methods', and only these types of claims can undergo a scientific evaluation by the NDA Panel. The claim 'could promote a favourable gut flora' is not specific enough for a scientific evaluation and does not identify a specific benefit. In addition, changes in outcome variable(s) (e.g. changes in the composition of the gut microbiota), which can be measured *in vivo* in humans by generally accepted methods, may not be considered beneficial physiological effects *per se*, and thus cannot be the claimed effect (i.e. constitute the only basis for the scientific substantiation of a health claim). Changes in such outcome variable(s) should be accompanied by evidence of a beneficial physiological effect or clinical outcome, and could be proposed as part of the mechanism(s) by which a food may exert the claimed effect, i.e. induce a beneficial change on a function.

The characterisation of the claimed effect has been addressed in section 7.2 of the 'general guidance'.

Comments received

10. It was suggested to include the explanation about the essentiality of nutrients in this guidance.

Panel consideration of comments received

Ad10. For clarity, footnotes cross-referencing to the relevant section of the 'general guidance' for the explanation on claims based on the essentiality of nutrients have been added throughout the scientific and technical guidance, where appropriate.

Comments received

11. There were several comments on reduction of disease risk claims, which requested to:

(a) reorder section 3.2.1, starting with the risk factor that is the subject of the health claim and how it can be measured *in vivo* in humans, and following with the disease to which the risk factor relates. It was felt that asking for the criteria used for the diagnosis of the disease was unnecessary;

(b) change the heading of section 3.2.2 to read 'characterisation of the relationship between the risk factor and the risk of the related disease';

(c) provide guidance in section 5.1 on the information needed for the substantiation of reduction of disease risk claims on essential nutrients;

(d) refer to Article 14.1(a) reduction of disease risk claims in section 5.2 which is equally appropriate for Article 13.5 and 14.1(b) children's claims, and clarify the focus of section 5.2 for Article 14.1 (a) claims, which should be on the effect of the food/constituent on the risk factor but not on evidence for the disease which is to be included in section 3.2.2;

Panel consideration of comments received

Ad11. *Comment (a)* - Section 3.2.1 of the scientific and technical guidance has been amended as follows: '*… a) the risk factor for the development of the human disease; b) how the specific risk factor can be assessed* in vivo *in humans. […]; c) the disease to which the risk factor relates; d) the criteria used for the diagnosis of the disease (i.e. the criteria used for diagnosis are widely accepted by the medical community and can be verified by a physician)'.*

Comments (b) - Section 3.2.2 of the scientific and technical guidance has been amended to read as '*Characterisation of the relationship between the risk factor and the risk of the related disease*'.

Comments (c) - The only example of a disease risk reduction claim evaluated by the NDA Panel for which the food/constituent was an essential nutrient relates to folate. The proposed risk factor was low maternal folate status and the proposed claimed effect was a reduction in the risk of neural tube defects (NTD). The substantiation of the claim was based on: i) the well-established association between low maternal folate status and increased risk of NTD (evidence obtained from human observational studies) and ii) human intervention studies showing an effect of maternal folic acid supplementation on the risk of NTD (EFSA-Q-2013-00265)[19]. Therefore, the scientific substantiation of the claim was not based on the essentiality of the nutrient for the function/disease risk (e.g. on deficiency symptoms), but on data from observational and human intervention studies and by weighing the evidence, as for other claims not based on the essentiality of nutrients. To date, the NDA Panel has no experience in the evaluation of disease risk reduction claims based on the essentiality of nutrients that could be used to provide guidance in this specific area. Disease risk reduction claims based on the essentiality of nutrients will have to be considered on a case-by-case basis in the context of specific applications.

Comment (d) - The general principles applied by the NDA Panel to decide whether there is a causal relationship between a beneficial modification of the risk factor and a reduction of the risk of the disease (i.e. whether the risk factor for disease is well established) are the same (i.e. hierarchy of studies, weighing of the evidence) as the principles applied by the NDA Panel to decide whether a causal relationship between the consumption of a food/constituent and the claimed effect is established (i.e. whether a health claim is substantiated). These principles apply to all claims other than those based on the essentiality of nutrients (Articles 14(1)(a), 14(1)(b) and 13(5)).

The general principles regarding disease risk reduction claims are explained in Section 7.2.2 of the 'general guidance', including the context in which evidence that the dietary intervention with the specific food/constituent induces a reduction (or beneficial alteration) of the risk factor would be sufficient for the scientific substantiation of the claim, as well as the context in which evidence that the dietary intervention with the specific food/constituent induces a reduction (or beneficial alteration) of the risk factor and also a reduction of the risk of disease needs to be provided.

The term 'the claimed effect' used throughout the scientific and technical guidance is self-explanatory to cover claims for Articles 14(1)(a), 14(1)(b) and 13(5). Thus, no specific reference to Article 14(1)(a) reduction of disease risk claims needs to be introduced in section 5.2 of the scientific and technical guidance.

[19] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3328/full

2.3.5. Part 4: Identification of pertinent scientific data

Comments received

12. A stakeholder considered that the requirement to specify, for each publication, the reason(s) for exclusion from the application was unnecessarily onerous, particularly if there is a long list of excluded references (section 4.2.1).

Panel consideration of comments received

Ad12. The NDA Panel notes that pertinent human studies have been excluded by applicants from health claim applications in the past without appropriate justifications and such actions may jeopardise the principle of providing the totality of the available scientific data. No change was introduced in the guidance on the basis of this comment.

Comments received

13. It was requested to provide guidance and examples of acceptable procedures for the identification of unpublished human studies (section 4.2.2), particularly, for example, a study conducted by other parties that was communicated as an abstract or oral communication and to which did not follow a full publication, or an historic study for which full details may not be available.

Panel consideration of comments received

Ad13. As outlined in Ad1 of this report, publication of studies is highly recommended for transparency reasons. It is at the discretion of the applicant to contact the authors or owners of studies (presented, for example, as abstracts or oral communications) to gain access to the unpublished human data. In this context, the procedure applied by the applicant to identify unpublished pertinent human data should be described. No change was introduced in the guidance on the basis of this comment.

Comments received

14. It was noted that the guidance on how to conduct a comprehensive review of the scientific literature is less detailed compared to other jurisdictions (e.g. New Zealand/Australia).

Panel consideration of comments received

Ad14. It is out of the scope of this scientific and technical guidance to provide detailed instructions on how to conduct a comprehensive review of the literature to identify pertinent human studies. To that end, applicants could consider the EFSA guidance on the application of systematic review methodology to food and feed safety assessments to support decision making (EFSA, 2010). A footnote referring to such guidance has been added to section 4.2.1 of the scientific and technical guidance.

2.3.6. Part 5: Overall summary of pertinent scientific data

Comments received

15. Clarification was sought about the level of information required to prove mechanisms of action of an ingredient(s). It was noted that, while in the past EFSA seemed to deem mechanisms of action as less important, many dossiers have been rejected due to insufficient data on the mechanism of action.

Panel consideration of comments received

Ad15. As already explained in Section 7.3 of the 'general guidance' and also in Ad9 of the technical report on the public consultation of the 'general guidance', there is no pre-established formula as to how many or which type(s) of studies are needed for substantiation. An understanding of the mechanism(s) by which a food/constituent exerts the claimed effect is an important

consideration in order to conclude on the biological plausibility of the association between the consumption of the food/constituent and the claimed effect, but it is not an absolute requirement for claim substantiation. In this context, please refer to the example of a claim being substantiated in the absence of a clear mechanism of action as illustrated in the 'general guidance' (i.e. Limicol® and reduction of blood LDL-cholesterol concentrations).

Whether evidence for a mechanism of action is/is not required for substantiation is considered by the Panel on a case-by-case basis in the context of specific applications.

2.3.7. Appendix C-Information to be presented in a full study report for unpublished studies or for proprietary studies

Comments received

16. There were several requests for clarification regarding the procedures for the approval and implementation of human intervention studies, in particular: (a) whether a contract research organisation must be tasked for every study, noting that industry-sponsored trials could also be conducted in an academic health centre; (b) whether EFSA would be in favour of multi-country clinical trials, considering differences in country-specific regulatory environments and procedures; (c) whether the approval of a study by an ethics committee also requires its approval by a government health agency. In this context, it was requested that EFSA organises/takes part in a workshop focused on the challenges to be faced by clinical research today, and especially by food-based clinical trials.

Panel consideration of comments received

Ad16. *Comment (a)* – It is important that the organisation tasked to conduct human intervention studies is familiar with the principles of good clinical practice and with the scientific principles governing the design, implementation and control of such studies, regardless of whether it is a contract research organisation or an academic health centre.

Comment (b) - The choice of conducting a single-centre or multicentre study involving different countries would depend on the objectives and hypotheses of the study, and thus EFSA cannot be 'in favour' or 'against' a particular type of study design. If multicentre studies involving studies in different countries are conducted, investigators should be aware of the regulatory environment and procedures governing the implementation of clinical trials in each country, and take the particular study design into consideration when planning the statistical analysis of the data.

Comment (c) - Applicants are invited to check with the national competent authority whether a study approval by an ethics committee also requires an approval by a government health agency.

Comment (d) - EFSA takes note of the proposal to organise/participate in a workshop to discuss the challenges of clinical research in nutrition in Europe, and invites stakeholders to consult 'EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products'[20].

No change was introduced in the scientific and technical guidance on the basis of these comments, being out of the scope of this guidance.

Comments received

17. There were several suggestions to clarify the requirements for the presentation of full study reports outlined in Appendix C. In particular:

(a) It was recommended to allow flexibility in the template of the study report provided that all the requested information is present; noting that not all reports currently comply with the template provided in Appendix C or ICH-E3, e.g. reports of efficacy studies in animals, study

[20] http://www.efsa.europa.eu/en/supporting/pub/1025e

reports compiled outside the EU, reports from universities/clinical research organisations worldwide which have their own template;

(b) It was suggested to add the following sentence: '*Whenever a quality control system has been used/reported in the conduct of the studies (e.g. GLP, GCP, as relevant), the particular system should be indicated*';

(c) There was a question on whether information on the study sponsor should be provided under 'general information about the study';

(d) It was suggested to include the hypothesis of the study under "study objectives", to define the meaning of 'objectives' and 'aims', and to clarify whether different terms used are synonyms, e.g. 'outcome variable', 'outcome' and 'endpoints';

(e) It was requested to clarify the required detailed description of the food/constituent under investigation;

(f) It was proposed to add 'colour and shape' among the characteristics of the food/constituent and the control food which could affect the blinding;

(g) It was suggested that any other specifications related to the concomitant medication allowed in the study should also be described, e.g. dosage, regimen/posology;

(h) It was suggested to add a section on biological samples that have been collected for analysis;

(i) Clarification was requested on whether the adverse effects assessment should involve both serious and non-serious adverse events, and whether there is a specific form for reporting adverse events.

Panel consideration of comments received

Ad17. In relation to these comments, the NDA Panel wishes to clarify the following:

Comment (a) - A study report compiled by universities or clinical research organisations either inside or outside the EU could be accepted by EFSA provided that all the requested information is present, i.e. that it contains <u>at least</u> the information outlined in Appendix C, but not necessarily in that format.

It should be noted that study reports not complying with the requirements outlined in Appendix C may not allow a scientific evaluation of the study by the NDA Panel. This will trigger requests for clarification/missing information/data by EFSA, which delay the evaluation of an application.

Appendix C has been primarily developed for human efficacy studies (unpublished and/or proprietary). For reporting of other type of studies, the same transparency standards should apply.

Comment (b) - Item 17 related to 'Data quality assurance" has been amended as follows: '*Any measures taken with respect to the quality assurance and quality control systems implemented for data collection should be addressed here. Whenever a quality control system has been used/reported in the conduct of the studies (e.g. GCP, as relevant), the particular system should be indicated*'.

Comment (c) – The name of the study sponsor including the name of the funding source should be given in the item 1-title page. The guidance has been amended accordingly.

Comment (d) – 'Hypothesis of the study' should be given together with the objective(s) and be considered when planning the statistical analyses of the study. It has thus been added under items 8 and 18. Appendix C has been amended using the following terms throughout: 'objective' instead of 'aim', 'outcome variable' instead of 'outcome' or 'endpoint'.

Comment (e) - 'A detailed description of the food/constituent' means *'sufficient information to establish that the study was performed with a food/constituent which complies with the specifications given for the food/constituent for which the claim is proposed (e.g. the*

microbial strain(s) used)'. A footnote has been added under item 11-study products to clarify this aspect.

Comment (f) - Item 13-Blinding has been amended as follows: '*Information on the strategy used to ensure blinding should be provided, e.g. measures taken to achieve that the study products were not distinguishable by smell, taste, colour, shape or packaging; […]*'.

Comment (g) - Item 14-Concomitant medication or interventions has been amended as follows: '*Any concomitant medication or non-pharmacological interventions, any rescue medication allowed by the study protocol should be described here (e.g. name of medication, dose and posology; type of non-pharmacological intervention, frequency, duration)*'.

Comment (h) – Information on the biological samples collected for analysis, if any, should be included in Item 16-outcome variables(s) measured, in which the methods of measurement used to assess the outcome variable(s) *in vivo* in humans should be specified. This includes the collection and analysis of biological samples.

Comment (i) - In case adverse events are assessed in the study, they should be clearly reported (possibly indicating those which may be related to the intervention and those which may be not related to the intervention), together with information on the (diagnostic) criteria used to ascertain them. For reporting of safety-related data, please see also ICH-E3-'Stucture and content of study reports'[21].

2.3.8. Editorial comments

Comments received

18. Several comments suggested purely editorial changes.

Panel consideration of comments received

Ad18. Editorial comments have been considered in order to update the scientific and technical guidance.

2.3.9. Appreciation comments

Comments received

19. Several comments support the changes introduced in the scientific and technical guidance, in particular:

(a) only information on regulatory status of health claims outside the EU is requested, which makes sense;

(b) addition of the indicators in Part 2 was considered helpful to ensure the correct section is completed;

(c) the new guidance provides more details about preparation of the "Overall summary of pertinent scientific data", clarifying preparation of critical and concise summary on the extent to which the relationship between the consumption of the food/constituent and the claimed effect is supported by the totality of the evidence identified as pertinent to the health claim;

(d) inclusion of Appendix C is a very useful addition to the guidance, which makes very clear the data requirement for non-published studies.

Panel consideration of comments received

Ad19. The NDA Panel takes note of these comments.

EFSA and its NDA Panel wish to thank all stakeholders for their comments and contributions.

[21] http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/structure-and-content-of-clinical-study-reports.html

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Appendix A – Explanatory text for the Public consultation on the draft scientific and technical guidance for the preparation and presentation of a health claim application

EFSA has launched an open consultation on its draft scientific and technical guidance for the preparation and presentation of a health claim application.

This document presents a common format for the organisation of information for the preparation of a well-structured application for authorisation of health claims which fall under Articles 13(5), 14, and 19 of Regulation (EC) No 1924/2006. This guidance outlines: the information and scientific data which must be included in the application, the hierarchy of different types of data and study designs (reflecting the relative strength of evidence which may be obtained from different types of studies) and the key issues which should be addressed in the application to substantiate the health claim.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft document developed by the NDA Panel of EFSA.

Interested parties are invited to submit written comments **by 12 September 2016**. Please use the electronic template provided to submit comments and refer to the line and page numbers. Please note that after 2 hours your working session will expire and comments submitted after that time will not be recorded and transmitted. If you would like to submit additional data to support your comments or files send an email to: NDA.PublicConsult.73@efsa.europa.eu. Please note that comments will not be considered if they:

- are submitted after the closing date of the public consultation;
- are not related to the contents of the document;
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- are related to policy or risk management aspects, which are out of the scope of EFSA's activity.

EFSA will assess all comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

All comments submitted will be published. Comments submitted by individuals in a personal capacity will be presented anonymously. Comments submitted formally on behalf of an organisation will appear with the name of the organisation.

Submit comments (deadline: 12 September 2016)

Appendix B – Full list of comments submitted by means of the electronic form on the EFSA website

Organisation	Chapter	Comment
Danone Nutricia Research	0.1. General principles	We welcome the good evolution on the possibilities of interactions with a broad range of stakeholders as applicants. But the introduction of the presubmission meetings for exemple between applicants and EFSA seems still not possible. We still highly recommend to introduce pre-submission meetings between applicants and EFSA instead of post-adoption meetings. The implementation of an interactive process for application and evaluation is possible. Just one-time one-way stop-the-clock procedure seems not enough. As part of improving the interactive process, we also want to reiterate the need for pre-assessment discussion or a "procedure" at EFSA that allows a sponsor to get scientific advice on a protocol draft before its finalization with the objectives to have a feedback from the agency on the acceptance and appropriateness of the outcome variables proposed for a claimed effect and to discuss the validity of study design that will be used in clinical studies for supporting the health claim – quote that pha rma agencies are offering such services to avoid launching inadequate clinical trials. This new possibility should improve the dialogue between applicants and EFSA. We are surprised that the guidance does not refer to scientific evaluations that follows procedure established in article 13.4 knowing that the list of article 13(3) now exists. This aspect is essential in terms of scientific evidence requirements for claims based on generally accepted scientific evidence well understood by the average consumers versus claims based on newly developed scientific evidence that follow procedure described in article 13.5. It would be very helpful for the Industry to understand how EFSA is considering opinions from other scientific authorities and claims approved within the EU and in other regions of the world. Is there any "mutual recognition" agreement existing between EFSA and other Agencies in the world? In negative case will EFSA motivate the reasons for not considering the same? Understanding EFSA's criterias could help Industry to provide additional data to help EFSA's conducting its assessments. Finally, will EFSA clarify how it envisage the cooperation with Member States of the EU so as to enable them to become more closely involved in scientific procedures?
IPA Europe	0.1. General principles	We are surprised that the guidance does not refer to scientific evaluations that follow procedure established in article 13.4, in view of the fact that the list of article 13(3) now exists. This aspect is essential in terms of scientific evidence requirements for claims based on generally accepted scientific evidence well understood by the average consumers versus claims based on newly developed scientific evidence that follow procedure described in article 13.5.
Lallemand Health Solutions	0.1. General principles	• Lines 361 and 362 – " For function claims, the (specific) function of the body that is the target of the claim should be specified" We agree that function claims should refer to a function of the body, however, we believe that EFSA has

Organisation	Chapter	Comment
		overstepped by adding the word "specific" before function of the body. According to Article 13 of Regulation 1924/2006, the concept of "specific" is not mentioned in relation to function of the body. According to Regulation 1924/2006, the reference to general, non-specific benefits of the nutrient or other substances for general well-being may only be made under certain conditions (Article 10 point 3.), but it does not specify that the benefit of the nutrient or other substance must refer to a specific function of the body (Article 13 point 1. a). In that respect, we believe that there should be a place for health claims related to the intestinal flora balance such as "could promote a favorable gut flora", already approved for probiotics by other governmental health agencies, as they refer to a body function that is the intestinal function.
Lallemand Health Solutions	0.1. General principles	• Lines 379-381 – " For claims other than those based on the essentiality of nutrients, a comprehensive review of published human studies…is required" We acknowledge that for claims other than those based on the essentiality of nutrients, human studies are required to substantiate the relationship between the food/constituent and the claimed effect. However, this sentence (line 112-114), the way it is written suggests somehow that the publication of the studies is mandatory prior to the application for a health claim, which is more restrictive to the former guidance where an application could be made based on available clinical studies although not necessarily published. We would like to see this clarified in the final guidance.
Lallemand Health Solutions	0.1. General principles	• Line 391: "…which the claim is proposed on appropriate outcome variables for the claimed effect…" We suggest that it would be helpful to have a summary document containing the different EFSA guidelines with their related outcomes. This would be a good tool for applicants to use before submitting a dossier or for investigators to consult before designing a clinical trial.
Lallemand Health Solutions	0.1. General principles	• Lines 361 and 362 – " For function claims, the (specific) function of the body that is the target of the claim should be specified" Same comment as above (line 96-97) We agree that function claims should refer to a function of the body, however, we believe that EFSA has overstepped by adding the word "specific" before function of the body. According to Article 13 of Regulation 1924/2006, the concept of "specific" is not mentioned in relation to function of the body. According to Regulation 1924/2006, the reference to general, non-specific benefits of the nutrient or other substances for general well-being may only be made under certain conditions (Article 10 point 3.), but it does not specify that the benefit of the nutrient or other substance must refer to a specific function of the body (Article 13 point 1. a). In that respect, we believe that there should be a place for health claims related to the intestinal flora balance

Organisation	Chapter	Comment
		such as "could promote a favorable gut flora", already approved for probiotics by other governmental health agencies, as they refer to a body function that is the intestinal function
Mondelez Int. R&D	0.1. General principles	L330 – 333: Could EFSA clarify what is a «multiple formulations of a food/constituent»? L416: Could EFSA clarify what is a "verifiable justification" for confidential data? Will the EFSA evaluate if data are confidential? We recommend that the confidentiality of data be justified only by a declaration/certification from the applicant. L418 - 419: This was not the case before for art 14 and 13.5 dossiers with a request for protection of proprietary data. This reveals a competitive advantage to competition. We ask the EFSA not to publish the summary.
Nutraveris	0.1. General principles	Line 321: EFSA indicates that experts "should not be required to process data in order to evaluate application". However, in several applications, EFSA has performed new statistical analyses on raw data from peer-reviewed publications, which surprisingly provided contradictory outcomes to those already published. Since data had been already reviewed, it is really surprising that EFSA re-analyze data. Information from such studies should be taken into account as published, without trying to minimize their significance.
REDICLAIM constortium (EU project contract number FP7-603036)	0.1. General principles	It is noted that a series of key definitions have been included on page 9, many of which were not directly included in previous version (i.e. disease/disorder, the totality of the evidence, efficacy study, pertinent study, supportive evidence, target population, study group, suitable study group). This change addresses issues raised by participants in a qualitative study conducted as part of the EU-funded FP7 REDICLAIM project that explored food manufacturers' willingness/capability to exploit new research findings in cardio-vascular health related innovation processes; and the role of health claim regulation as a facilitator or barrier to research-based innovation aimed at developing products based on new findings. Interviewees identified two main challenges linked with the EFSA requirements. First, the level of research and evidence needed for substantiation of the health claim was regarded as being very high. They had concerns what level of evidence would be sufficient in order to prove the link between the product, ingredient or the nutrient used and the claimed effect in a healthy population. The companies, which had completed the studies, required by EFSA, tended to be big multinational companies, not the small ones. The standards of the European Commission were thought to be so high that it has become a barrier for SMEs. Moreover, some companies compared the level of evidence for scientific substantiation in EU with other jurisdictions in the world. Some interviewees stated that regulations are harder in Europe and to get health claims approved is easier in North America (USA) and Asia (Japan).

Organisation	Chapter	Comment
		Secondly, EFSA's criteria for review and evaluation as well as the assessment of the health claim application were seen as unclear and not well documented. Applicants were seen as lacking guidance and advice concerning a study design, definition and selection of population, and selection of biomarkers that should be suitable to provide the evidence. This seemed to be a grey area for interviewees and regar ded as one of the main challenges. The major challenge was that the target group for health claims is typically healthy population and defining what is healthy population and then show the effect on this target group is very difficult to obtain in clinical studies. INTERVIEWEE QUOTE: "How do you measure a healthy person becoming healthier if he is already healthy? You need a large population to detect the differences when you make clinical trials. It costs a lot of money. So since the deviation is small, you need a really large cohort to be able to spot any differences. So, suddenly it becomes much more expensive to do such a clinical trial for the food industry". Some interviewees brought up the dilemma that food industry needs to prove in a healthy population that a specific nutrient or a specific ingredient works at a similar level of evidence that the pharmaceutical industry must comply with when testing medicines. The rules for evaluating health claims were seen as more applicable to the pharmaceutical sector and medical research than to food sector: they are assessed to be too strict at the moment. Furthermore, difference in the process of evaluating the evidence between the pharmaceutical and food sector was mentioned as a barrier. Pharmaceutical company can discuss with the evaluator about the clinical research and clinical trials which they plan to conduct. Once they agree that the study design is sound, the evaluation is based on the outcome of the study, not the design of that study. Such a process with a pre-submission consultation does not exist for food.
Unilever R&D	0.1. General principles	Concerning lines 281-285. We would welcome a further explanation whether evidence should be delivered for all ingredients specifically in order to prove that all ingredients are required.
Unilever R&D	0.1. General principles	Concerning lines 316-322. We believe it is (and was) a potentially serious weakness in the process that EFSA depends on the applicant alone as a source of documentation. Even though EFSA does specify details of the search (page 20), it is possible the applicant may fail to highlight some relevant information. We presume EFSA does have the option to consider pertinent evidence not cited by the applicant, which EFSA itself might discover or have brought to their attention during the evaluation. If so, this should be stated.
IPA Europe	1. Part 1: Administrative and technical data	The industry would like to understand how EFSA is considering opinions from other scientific authorities as well as claims approved in the EU and in other regions of the world. Is there any "mutual recognition" agreement between EFSA and other Agencies in the world? If not, will EFSA motivate the reasons for not considering these other opinions? Understanding EFSA's criteria could make clear to the industry how to provide additional

Organisation	Chapter	Comment
		data to help EFSA in its assessments. Finally, will EFSA clarify how it envisages the cooperation with the EU Member States so as to enable them to become more closely involved in scientific procedures?
Mondelez Int. R&D	1. Part 1: Administrative and technical data	L479: Do we have to justify in the EFSA dossier that we have the property of these data? There is a confusion regarding the confidentiality and the property the data. The property of data should represent the fact the data belong to the applicant. This can be justified by the study contract or any official document justifying this point. This property should imply that no other competitor could use these data for any claim proposal or commercial use. The data covered by the proprietary aspect should be able to be shown/discussed in congresses or in peer-reviewed journal to validate their scientific relevance. As the constitution of the scientific evidence for a claim can take several years (even 10 years), the applicant cannot keep secret all its research for such a long time. It would be deleterious for the research and collaboration with academic laboratories. It would be deleterious for the transparency of research of food industry. L488: The verification of the justification of the confidentiality of the data is not always possible for example confidential data could correspond to company know-how that must not be disclosed externally.
REDICLAIM consortium (EU project contract number FP7-603036)	1. Part 1: Administrative and technical data	It is noted that whilst in the previous version of the guidance applicants needed to provide the regulatory status of the claim both in EU and outside the EU, the new format only includes a chapter for providing of non-EU status. This makes sense, considering that EFSA evaluated all previous health claim applications.
Health Food Manufacturers Association (HFMA)	2. Part 2: Characterisation of the food/constituent	Line 551 Comment: Addition of the indicators in lines 552 and 553 and in 2.1 and in 2.2 are helpful to ensure the correct section is completed, particularly as the options have now been expanded.
Health Food Manufacturers Association (HFMA)	2. Part 2: Characterisation of the food/constituent	2.1.1 Vitamins and Minerals Line 560 Comment: The need to provide details of the manufacturing process and stability should be added to this section to be consistent with 2.1.2
Health Food Manufacturers Association (HFMA)	2. Part 2: Characterisation of the food/constituent	2.1.2 Food/constituents other than vitamins and minerals Line 569 Comment: Should this heading be 'Constituents other than vitamins and minerals', or 'Food constituents other than vitamins and minerals', i.e. without the backslash, as 'food' is not one of the options for discussion in this section.
Health Food Manufacturers	2. Part 2: Characterisation of	2.2.2 Manufacturing process Line 609

Organisation	Chapter	Comment
Association (HFMA)	the food/constituent	Comment: The title of this section could usefully be changed to Production process, to accommodate other methods of production that may not involve manufacturing as such e.g. crop production, fish farming etc.
Health Food Manufacturers Association (HFMA)	2. Part 2: Characterisation of the food/constituent	2.2.3 Stability information Line 614 Comment: It would be useful to clarify here if the stability studies only need to focus on stability of the active constituent of the food or food category, or on stability of the food/food category per se, or on both.
IPA Europe	2. Part 2: Characterisation of the food/constituent	(2. Part 2: Characterisation of the food/constituent, L550-590) (Distinction between "2.1.1. Vitamins and minerals" and "2.1.2. Food/constituents other than vitamins and minerals") Applicants should characterise the food/constituent on the basis of the conditions of use. In our opinion, it is inappropriate to separate vitamins and minerals from other food/constituents. The results and conclusions of the stability studies depend on the conditions of use and would be variable also in case of vitamins and minerals. Other components in the preparation may influence the stability and biological availability of the vitamins and minerals. We therefor ask EFSA to clarify why a distinction is made between "Vitamins and minerals" and "Food/constituents other than vitamins and minerals".
Lallemand Health Solutions	2. Part 2: Characterisation of the food/constituent	• Lines 579 and 605 – "Measurements should be performed in a competent laboratory that can certify the data" What level of certification is being requested? This point should be elaborated upon for increased clarification.
Nutraveris	2. Part 2: Characterisation of the food/constituent	Lines 570-581: EFSA should clarify which specific information is required for botanicals.
Nutraveris	2. Part 2: Characterisation of the food/constituent	Lines 571-573: EFSA indicates that characterisation of a food/constituent should include physical and chemical properties, composition, and microbiological constituents where applicable. EFSA should clarify whether further data is required, as for instance heavy metals, pesticides, mycotoxins, or other contaminants. Moreover, Is a nutritional analysis required or not?
REDICLAIM consortium (EU project contract number FP7-603036)	2. Part 2: Characterisation of the food/constituent	It is noted that whilst in previous guidance bioavailability data was specifically included as part of "Food/constituent characteristics" chapter, in the new guidance bioavailability data is deemed less important and moved to chapter "Supportive evidence".
Health Food	3. Part 3:	3.2 Disease risk reduction claims

Organisation	Chapter	Comment
Manufacturers Association (HFMA)	Characterisation of the claimed effect	3.2.1. Definition of the claimed effect Line 646 Comment: Part a) is not strictly correct as it is the risk factor that is the subject of the claim and not the disease, as in the definition of a reduction of disease risk claim in the Regulation (as stated in line 249). Hence this line should state 'The disease to which the risk factor that is the subject of the claim relates'. In view of this it would be preferable to reorder this list, with a) The risk factor for the development of a human disease, b) The disease to which the risk factor that is the subject of the claim relates, c) how the risk factor can be assessed etc.
Health Food Manufacturers Association (HFMA)	3. Part 3: Characterisation of the claimed effect	3.2 Disease risk reduction claims 3.2.1. Definition of the claimed effect Line 648 Comment: Part b) seems to be an unnecessary request for detail that is not strictly relevant to the claim
Health Food Manufacturers Association (HFMA)	3. Part 3: Characterisation of the claimed effect	3.2 Disease risk reduction claims 3.2.1. Definition of the claimed effect Line 651 Comment: Part c) should specify the risk factor that is the subject of the claim, since the definition of a reduction of disease risk claim is that the subject of the claim significantly reduces a risk factor in the development of a disease (as stated in line 249).
Health Food Manufacturers Association (HFMA)	3. Part 3: Characterisation of the claimed effect	3.2.2 Characterisation of the relationship between the factor and the risk of disease Line 657 Comment: This heading should specify 'risk factor' rather than just 'factor'. It could helpfully be reworded to 'Characterisation of the relationship between the risk factor and risk of the related disease'
Lallemand Health Solutions	3. Part 3: Characterisation of the claimed effect	• Lines 633 and 634 – "If not, please specify: a) the specific body function that is the subject of the claimed effect" Same comment as above (line 96-97). We agree that function claims should refer to a function of the body, however, we believe that EFSA has overstepped by adding the word "specific" before function of the body. According to Article 13 of Regulation 1924/2006, the concept of "specific" is not mentioned in relation to function of the body. According to Regulation 1924/2006, the reference to general, non-specific benefits of the nutrient or other substances for general well-being may only be made under certain conditions (Article 10 point 3.), but it does not specify that the benefit of the nutrient or other substance must refer to a specific function of the body (Article 13 point 1. a). In that respect, we believe that there should be a place for health claims related to the intestinal flora balance such as "could promote a favorable gut flora", already approved for probiotics by other governmental health

Organisation	Chapter	Comment
		agencies, as they refer to a body function that is the intestinal function
Health Food Manufacturers Association (HFMA)	4. Part 4: Identification of pertinent scientific data	4.2.1 Identification of published human studies etc. Line 752 Comment: Part b) now requests that the reason for exclusion is specified for each of the references that is not included as pertinent data. This is an unnecessary onerous requirement particularly if there is a long list of excluded references.
Health Food Manufacturers Association (HFMA)	4. Part 4: Identification of pertinent scientific data	4.2.2 Unpublished human studies etc. Line 761 Comment: Can EFSA please provide advice or examples of procedures that would be acceptable.
Health Food Manufacturers Association (HFMA)	4. Part 4: Identification of pertinent scientific data	4.2.2 Unpublished human studies etc. Line 779 Comment: The guidance assumes that details of unpublished studies will be available to the applicant. It does not cover situations where, for example, a study conducted by parties unrelated to the applicant may have been unpublished because a journal did not accept it perhaps because the results were negative or for other reasons. Guidance is also needed for these types of situations please.
Health Food Manufacturers Association (HFMA)	4. Part 4: Identification of pertinent scientific data	I WISH TO REPLACE MY PREVIOUS COMMENT ON: 4.2.2 Unpublished human studies etc. Line 779 WITH THE FOLLOWING REPLACEMENT COMMENT PLEASE: The guidance assumes that details of unpublished pertinent studies will be available to the applicant. It does not cover situations where, for example, a pertinent study was conducted by other parties that was perhaps previously communicated as an abstract or oral communication for example but was not then followed-up with full publication, or was an historic study for which full details may not be available.
REDICLAIM consortium (EU project contract number FP7-603036)	4. Part 4: Identification of pertinent scientific data	It is noted that a substantive change has been included, in that the new guidance introduces much more detail on the health claim based on the essentiality of nutrients. It is much clearer that for non-essential nutrients more information is needed, than for essential nutrients. It is noted that a substantive change has been included, in that that the application structure was changed in a way, which makes more sense. Previously a comprehensive review was at the end of the application, this has now been moved to just after the characterisation of the claimed effect. Somewhat more details about the preparation of the comprehensive literature review have been provided. We would like to note that in some other jurisdictions (e.g. New Zealand/Australia) guidance includes more detailed instructions on how to

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		conduct a literature review. The current document leaves the format of the review very free, thus less restrictive for applicants.
Danone Nutricia Research	5. Part 5: Overall summary of pertinent scientific data	We want to highlight that the definition of "Totality of evidence" is incorrect (L.922). The definition of "Target population" is given.
Health Food Manufacturers Association (HFMA)	5. Part 5: Overall summary of pertinent scientific data	5.1 Claims based on the essentiality of nutrients Line 815 Comment: Guidance is needed here specifically for Article 14.1(a) reduction of disease risk claims that are for essential nutrients – what information is needed in this situation?
Health Food Manufacturers Association (HFMA)	5. Part 5: Overall summary of pertinent scientific data	5.2 Claims other than those based on the essentiality of nutrients Line 832 Comment: Reference to Article 14.1(a) claims is needed in this section to underline that the guidance here is equally appropriate for reduction of disease risk claims as well as Article 13.5 claims and Article 14.1(b) claims. The guidance could usefully clarify that the focus in this section for Article 14.1 (a) claims should be on the effect on the food/constituent on the risk factor, i.e. that the 'claimed effect' is the effect on the risk factor, and not on evidence for the disease which is to be included in section 3.2.2. The guidance could also usefully clarify that this is not necessarily a 'reduction' in the risk as specified in the Regulation, but is a beneficial effect on the risk factor.
REDICLAIM consortium (EU project contract number FP7-603036)	5. Part 5: Overall summary of pertinent scientific data	It is noted that the new guidance provides quite a lot more detail about preparation of the "Overall summary of pertinent scientific data", clarifying preparation of critical and concise summary on the extent to which the relationship between the consumption of the food/constituent and the claimed effect is supported by the totality of the evidence identified as pertinent to the health claim (in previous parts of the application).
Suntory Beverage & Food Europe	5. Part 5: Overall summary of pertinent scientific data	874-879: Clarity over level of information required to prove mechanism of action of an ingredient(s). Previously, this was an area that EFSA deemed as less important in a health claims submission; however, many dossiers have since been rejected due to insufficient mechanism of action data. As such, it would be useful to have a more detailed mechanism of action section within the guidance document, specifically outlining the level of detail required.
Danone Nutricia Research	6. Appendix C - Information to be presented in a full study report for unpublished or	Because clinical trials are necessary to obtain regulatory approval in Europe, they are a high priority to companies. Cooperation among a diverse group of stakeholders—including research sponsors , clinical investigators, patients and regulators—is necessary in conducting a clinical trial today. Each stakeholder offers a different set of tools to support the essential components of a clinical trial, especially for food based clinicals trials. It would be very helpful for all to be included in workshop focused on the challenges facing clinical

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	proprietary studies	research today. Would EFSA considerer to organise such of meetings in Europe? Consider to be part of it? We welcome the fact that the part dedicated to the construction of the study report is well detailed but following point should be clarified: L 1000, "should also provide information about the study site and about the facilities which were used and whether a contract research organization has been tasked to carry out the work". Do you mean that for every study a contract research organisation must be tasked? Industry-sponsored trials can be conducted also in some academic health center for example. In the same section, L 1007, EFSA ask for information about the country setting. Is EFSA not in favor of conduction of multi-country clinical trials? If no, the regulatory environment in each collaborating country can have significant differences determined by various factors including the laws and the procedures used in each country. How EFSA is evaluating this approach? Significant effort to exchange expertise between stakeholders is required, to ensure that standards are similar and upheld, permitting exchange between the in-country regulators and EFSA. The need of workshop as mentioned above can be an efficient way to improve cooperation on food clinical research.
Health Food Manufacturers Association (HFMA)	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	Appendix C Line 965 Comment: Inclusion of this appendix is a very useful addition to the guidance document.
IPA Europe	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	(Glossary) (Presumed copy-paste error) The definition of "Totality of evidence" is incorrect (L.922). The definition of "Target population" is given.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	• Line 903 – this line should be amended to correctly reflect the title. This line should read "Full study protocols and reports of unpublished data identified in Part 4 (sections 4.2.2 and 4.2.3)".
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for	The Panel previously mentioned in lines 396-98 " Whenever a quality control system has been used/reported in the conduct of the studies (e.g. GLP, good clinical practice (GCP), as relevant), the particular system should be indicated."

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	unpublished or proprietary studies	We suggest that these lines should be included in the Appendix C as well.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	Line 984: Ethical considerations Could EFSA please provide clarification whether a study approval by an ethics committee also involves an approval of the study by a government health agency.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	Line 994: General information about the study In this section it is unclear if the study's sponsor information should also be included. We recommend that it should be.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	Line 1001: Study objectives$ • Hypothesis should be included in this section as well. In order to provide the rationale behind the study. • If there are multiple objectives, it should be the "study aim(s)". If objectives and aims are different (if they have a different meaning and are not synonyms), please define. Is "aim" the primary objective?
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	• Line 1020: Study products "A detailed description of the food/constituent…" The panel should give what they are expecting as a "detailed description" i.e. raw material, colors, shape, taste…
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	• Line 1029: Blinding In Line 1031, the panel mention " It should be described how it was achieved that products were not distinguishable by smell, taste or packaging and how products were labelled (e.g. by subject individual codes or other)." We suggest that color and shape should be included as well.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full	• Line 1041: The effects of concomitant medication should be discussed (if known). Any other specifications related to the concomitant medication should also be described e.g. Dosage

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	study report for unpublished or proprietary studies	regimen/posology of the concomitant medication should be described
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	Line 1063: Adverse events We would appreciate more clarification on whether the adverse effects assessment should involve both serious and non-serious adverse events.
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	• Line 1164: Is there a specific form for reporting adverse events?
Lallemand Health Solutions	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	General Comment on the Appendix C: • The panel uses different words to describe "outcomes": at times the panel uses "endpoints" (lines 1092 and 1148) , other times "outcome variables" (Lines 1048-51-53), and also line 1002: "The study objectives (i.e. the aim of the study) should be specified in this section" Could EFSA please provide clarification on these word synonyms and indicate if they can be used interchangeably? • In Appendix C, a section should be added on biological samples that have been collected for the results assessments.
Mondelez Int. R&D	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	L965-969: Not all type of study report could comply with the only 2 options mentioned here i.e. Appendix C or ICH E3. Indeed these types of report do not apply to animal studies which are considered in the efficacy study category (see L300-301). In addition, an applicant should be able to use a same study report in other region than the EU where different regulatory requirements may be applied. Several universities/ clinical research organizations worldwide have their own template for study reports which are different from the only two proposed. We recommend more flexibility in the template of the study report provided that all the requested information is present.

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REDICLAIM consortium (EU project contract number FP7-603036)	6. Appendix C - Information to be presented in a full study report for unpublished or proprietary studies	It is noted that a substantive change has been included in the form of a new, quite detailed section, namely "Appendix C – Information to be presented in a full study report for unpublished studies or for proprietary studies". This change makes very clear what kind of data applicants need to provide, when submitting non-published studies.
Danone Nutricia Research	GENERIC COMMENTS	At Danone, we appreciate EFSA's efforts in taking into account past experiences on health claim dossier submission and use of these experiences to revise the scientific and technical guidance for the preparation of an application for authorisation of a health claim and we welcome also the fact that EFSA opens for public consultation its document. This is a key step for us, as a stakeholder, to propose our comments in order to contribute to its development as we are really engage in this strategy for the last two years in where we use every EFSA public consultation to send our main comments. The document synthetizes the key elements for the construction of health claim application while clarifying some key points and identifying new adjustments. We would like to make the following comments and contribution to this EFSA's revised guidance.
Health Food Manufacturers Association (HFMA)	GENERIC COMMENTS	Line 422 Comment: The addition of the new part 3, and the order of the six parts is more logical than in the previous guidance.
IPA Europe	GENERIC COMMENTS	The International Probiotic Association Europe (IPA Europe) appreciates EFSA's efforts in taking into account past experiences on health claim dossier submission and use of these experiences to revise the scientific and technical guidance for the preparation of an application for authorisation of a health claim. IPA Europe also appreciates the opportunity provided by EFSA to comment on these revised draft guidelines. IPA Europe continues to request the possibility of having a dialogue between the applicant and EFSA prior to the submission of a dossier. It is our firm belief that such a process will improve the quality of submitted dossiers by promoting the submission of dossiers with sufficient scientific strength as expected by EFSA. We are also convinced that this, on the whole, will lighten the work load of EFSA as fewer weak dossiers will need to be evaluated.
Lallemand Health Solutions	GENERIC COMMENTS	• Lines 96 and 97-" For function claims, the (specific) function of the body that is the target of the claim should be specified" We agree that function claims should refer to a function of the body, however, we believe that EFSA has overstepped by adding the word "specific" before function of the body. According to Article 13 of Regulation 1924/2006, the concept of "specific" is not mentioned in relation to function of the body. According to Regulation 1924/2006, the reference to general, non-specific benefits of the nutrient or other

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		substances for general well-being may only be made under certain conditions (Article 10 point 3.), but it does not specify that the benefit of the nutrient or other substance must refer to a specific function of the body (Article 13 point 1. a). In that respect, we believe that there should be a place for health claims related to the intestinal flora balance such as "could promote a favorable gut flora", already approved for probiotics by other governmental health agencies, as they refer to a body function that is the intestinal function.
Lallemand Health Solutions	GENERIC COMMENTS	• Lines 112-114 – " For claims other than those based on the essentiality of nutrients, a comprehensive review of published human studies…is required" We acknowledge that for claims other than those based on the essentiality of nutrients, human studies are required to substantiate the relationship between the food/constituent and the claimed effect. However, this sentence (line 112-114), the way it is written suggests somehow that the publication of the studies is mandatory prior to the application for a health claim, which is more restrictive to the former guidance where an application could be made based on available clinical studies although not necessarily published. We would like to see this clarified in the final guidance.
Lallemand Health Solutions	GENERIC COMMENTS	General Comment on the Appendix C • The panel uses different words to describe "outcomes": at times the panel uses "endpoints" (lines 1092 and 1148) , other times "outcome variables" (Lines 1048-51-53), and also line 1002: "The study objectives (i.e. the aim of the study) should be specified in this section" Could EFSA please provide clarification on these word synonyms and indicate if they can be used interchangeably? • In Appendix C, a section should be added on biological samples that have been collected for the results assessments.
REDICLAIM consortium (EU project contract number FP7-603036)	GENERIC COMMENTS	Participants in a qualitative study conducted as part of the EU-funded FP7 REDICLAIM project that explored food manufacturers' willingness/capability to exploit new research findings in cardio-vascular health related innovation processes; and the role of health claim regulation as a facilitator or barrier to research-based innovation aimed at developing products based on new findings also raised the issue that they would like to have the opportunity to have pre-submission consultation. Those interviewed companies which received a positive opinion for their health claim application were very positive about the communication with EFSA and the European Commission.

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		INTERVIEWEE QUOTE: "So our cooperation with EFSA and the European Commission was very good in a very transparent way. No complaints from my side. Their comments, their reactions, their questions were very straightforward, very open and also from our side we responded very fast to them." However, most interviewees expressed a strong request f or a pre-submission consultation and open face-to-face discussions with the EFSA or the NDA Panel. The open dialogue would increase transparency about the process and enable companies to clarify specific requirements for the clinical research, and thereby reduce the uncertainty and associated risks. Having consultation beforehand was seen as an important step for the both parties – the applicant and the EFSA. On the one hand, the applicant would know in advance if pursuing an idea is worthwhile and whether anything is missing from the dossier. On the other hand, the EFSA would not have to go through the whole dossier if there is not enough data. That could be clarified in the pre-submission consultation. Some interviewees said that the industry is very willing to invest in scientific research but wanted more dialogue at different levels of process: both with individual companies and with food industry as a sector. This should result is better guidelines for setting up applications, performing research in the field of health and nutrition, and choosing the most appropriate methods in the scientific research. Currently, such a process does not exist and thus many companies having interest in new health claims feel challenged and perceive that they cannot effectively prepare the dossier. Few instances showed that companies succeeded in getting an authorised health claim but they also highlighted that preparation and communication were key elements for the successful application. INTERVIEWEE QUOTE: "If you want to get a health claim, you also need to think like a pharma company and make sure you do a study according to the golden standard and also do it perfectly. From the very beginning we made it clear what is our focus, what is our target, what do we want to obtain, what do we actually need to get there, which type of studies, which type of results, which type of relevant results. So based on this one, we had a very good project preparation. Preparation is the key to everything."
Unilever R&D	GENERIC COMMENTS	We agree that the guidance is more specific on the consideration whether the proposed health claim is based on the essentiality of nutrients. As the concept of essentiality is very well explained in the general scientific guidance, we are suggesting to also include explanation about essentiality in this guidance.

Appendix C – Full list of comments submitted by email

Comment 1

BabyMilk Action IBFAN response to Public consultation on the draft scientific and technical guidance for the preparation and presentation of a health claim application

IBFAN EFSA Health Claims Sept 2016 .pdf

Dear EFSA

I attach comments on behalf of IBFAN on the above consultation. I would be grateful if you could use this version rather than the one sent previously.

With best wishes

{signed}

Comment 2

NDA Public Consultation

Please may I introduce myself, I am the co-ordinator of the FP7 REDICLAIM project (http://www.rediclaim.eu/) that seeks to understand the way in which the European 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 and associated legislation, has had and continues to have an impact on the substantiation and use of "reduction of disease risk" claims on food and drinks.

As co-odinator of REDICLAIM I submitted a series responses to the Panel on Dietetic Products, Nutrition and Allergies (NDA) Consultation on the “Draft Scientific and technical guidance for the preparation and presentation of a health claim application” via the online form. In preparing our response we drew upon the findings detailed in of a number of our deliverable documents that that are not in the public domain, please see attached:

• REDICLAIM D3.2 Report in interest in using research findings as basis of innovation

• REDICLAIM D4.1 Report on comparison of health claims legislation of EU with legislation in other developed countries

• REDICLAIM D4.2 An overview of assessments of applications for reduction of disease risk health claims and reasons for rejections

I am also attaching two papers that summarize the project:

• Raats MM, Malcolm RN, Lähteenmäki L, Pravst I, Gage H, Cleary A, Karatzia A, Kušar A, Yang W, Jackson DL, Hodgkins CE, Klopčič M (2016) Understanding the impact of legislation on ‘reduction of

disease risk' claims on food and drinks: the REDICLAIM project. Teknoscienze Agro Food Industry Hi-Tech, 27(3), 30-32.

• Raats MM, Malcolm RN, Lähteenmäki L, Pravst I, Gage H, Cleary A, Klopčič M, REDICLAIM Consortium (2015) Understanding the impact of European Regulation on the substantiation and use of claims on food and drinks: Design of the REDICLAIM project and initial result. Nutrition Bulletin 40(4), 340-348.

We have a number of further deliverables reporting on our findings to date that are available upon request:

• REDICLAIM D2.2 Report on legislative frameworks across Member States for implementation of "reduction of risk claims"

• REDICLAIM D2.2 Report on legislative frameworks across Member States for implementation of "reduction of risk claims"

• REDICLAIM D3.1 Report on role of EU and national funded research in applying claim substantiation

•REDICLAIM D5.1 Report on the model (appraising the effectiveness and cost-effectiveness of consumption of plant sterol-enriched margarine-type spreads for the prevention of cardiovascular disease in people hypercholesterolemia)

• REDICLAIM D5.2 Report on the outcomes from applying the model (appraing the effectiveness and cost-effectiveness of consumption of plant sterol-enriched margarine-type spreads for the prevention of cardiovascular disease in people hypercholesterolemia)

We are currently finalizing our data collection and then will also be producing the following:

• REDICLAIM D2.3 Report on regulatory frameworks in operation for "reduction of risk claims" in three case studies

• REDICLAIM D3.2 Report on interest in using research findings as a basis of innovation

• REDICLAIM D3.3 Report on role of health claim legislation in simulating multidisciplinary innovation

• REDICLAIM D4.3 Report on experiences from health claim application process - case studies

With best wishes,

{Signed}

Note: Attachments received from the commenter are not enclosed since they are not in the public domain