1. Part 1: Administrative and technical data
	1. Comprehensive table of contents of the application

Table of contents

* 1. Applicant
		1. Company/organisation

Provide the name and address of the company or organisation.[[1]](#footnote-1)

Company

Address line 1

Address line 2

Country

* + 1. Contact person

Indicate the contact person authorised to communicate with EFSA on behalf of the applicant.[[2]](#footnote-2)

Name

Address, if different from the one in section 1.2.1

* 1. **Specifications**

Please select one of the options below:

[ ]  Application for a health claim pursuant to Article 13(5) of Regulation (EC) No 1924/2006

Please specify:

[ ]  Based on newly developed scientific evidence and/or

[ ]  Includes a request for the protection of proprietary data

[ ]  Application for a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

Please specify:

[ ]  Reduction of disease risk claim

[ ]  Claim referring to children’s development and health

[ ]  Application for a modification of an existing health claim authorisation in accordance with Article 19 of Regulation (EC) No 1924/2006

Please specify:

The health claim that has been authorised and for which the modification is requested:

Authorised health claim

The Commission Regulation under which the claim has been authorised:

EC regulation

The part of the authorisation which should be modified:

Part of the authorisation to be modified

* 1. Proprietary data[[3]](#footnote-3)

State whether the application includes a request for the protection of proprietary data according to Article 21 of Regulation (EC) No 1924/2006

[ ]  yes [ ]  no

If yes, please specify the Part(s) of the application which include proprietary data for which protection is requested, clearly stating section(s) and page number(s):

Parts of the application including proprietary data

Provide verifiable justification[[4]](#footnote-4)/declaration for the proprietary claim:

Justification for proprietary claim

* 1. Confidential data[[5]](#footnote-5)

State whether the application includes confidential data

[ ]  yes [ ]  no

If yes, please specify the Part(s) in the application (including unpublished studies) which contain confidential data, clearly stating section(s) or data sets, and page number(s), and verifiable justification(s)/reasons(s) why the afore-mentioned information needs to be kept confidential should be provided:

|  |  |  |
| --- | --- | --- |
| Elements of the application dossier for which a request for confidentiality treatment was filed by the applicant | Section(s) or data sets, and page number(s) | Verifiable justification(s)/reasons(s) |
| Element 1 | Section & page no. | Justification |
| Element 2 | Section & page no. | Justification |
| Element 3 | Section & page no. | Justification |

* 1. Regulatory status outside the European Union

If this health claim or a similar one has been submitted by the applicant to any regulatory body for authorisation outside the EU, please indicate the status of the evaluation of such health claim by each regulatory body (if more than one) and specify the requested information, as applicable:

[ ]  Under consideration

Specify the claimed effect, the wording of the claim, the food/constituent for which the claim has been submitted and the date of submission. Indicate the recipient regulatory body.

Click here to enter text.

[ ]  Withdrawn

Specify the claimed effect, the wording of the claim, the food/constituent for which the claim was withdrawn, the date of withdrawal and the reason for withdrawal. Indicate the regulatory body at the time of withdrawal.

Click here to enter text.

[ ]  Approved

Specify the approved claimed effect and the wording of the claim, the food/constituent for which the claim has been approved, and the date of approval. Indicate the authorising regulatory body, and if available, provide a copy of the scientific opinion of the authorising regulatory body (in Part 6, Section 6.2).

Click here to enter text.

[ ]  Rejected

Specify the rejected claimed effect and the wording of the claim, the food/constituent for which the claim has been rejected, the date of rejection and the reasons for rejection. Indicate the regulatory body which rejected the health claim, and if available, provide a copy of the scientific opinion of the regulatory body which rejected the health claim (in Part 6, Section 6.2).

Click here to enter text.

* 1. Health claim particulars
		1. Specify the food/constituent for which the health claim is made

Food/constituent

* + 1. Describe the relationship between the food/constituent and the claimed effect, including the outcome variable(s) used to assess the claimed effect *in vivo* in humans and the methods of measurement

Click here to enter text.

* + 1. Provide a proposal for the wording of the health claim

The proposed wording should be in English.

Click here to enter text.

* + 1. Conditions of use

Specify the target population for the health claim.

Click here to enter text.

Indicate the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect, and whether this quantity could reasonably be consumed as part of a balanced diet.[[6]](#footnote-6)

Click here to enter text.

Provide, where appropriate, a statement addressed to the category(ies) of the population who should avoid using the food/constituent for which the health claim is made, and include a rationale.

Click here to enter text.

Specify, where applicable, a warning for any food/constituent that is likely to present a health risk if consumed in excess, and provide a rationale.

Click here to enter text.

Specify, where applicable, other restrictions of use, and provide a rationale.

Click here to enter text.

Specify, where applicable, directions for preparation and/or use.

Click here to enter text.

* 1. Application form and summary of the application

Please use the application form provided in Appendix A.

For summary of the application, please use the form provided in Appendix B.

Information requested in Appendices A and B are mandatory.

Supporting documents cited (e.g. the scientific opinion of other regulatory bodies outside the EU) in Part 1 should be provided in Part 6 (Section 6.2).

1. Part 2: Characterisation of the food/constituent[[7]](#footnote-7)

Indicate if the food/constituent that is the subject of the health claim is:

[ ]  a single constituent or a fixed combination of constituents. If yes, please go to Section 2.1, and where applicable to Sections 2.3 and 2.4.

[ ]  a food or a food category. If yes, please go to Section 2.2, and where applicable to sections 2.3 and 2.4.

* 1. Single constituent or fixed combination of constituents

For single constituents or fixed combinations of constituents, which are exclusively vitamins and/or minerals, please go to Section 2.1.1.

For single constituents which are not vitamins or minerals as described in Section 2.1.1, and for fixed combinations of constituents in which at least one constituent is NOT a vitamin or a mineral (e.g. *a combination of EPA+DHA+GLA[[8]](#footnote-8) at a weight ratio of 9:3:1*), please go to Section 2.1.2.

* + 1. Vitamins and minerals

If the food constituent for which the claim is made is a vitamin or a mineral, or a fixed combination of vitamins and/or minerals, and its characterisation relates to the chemical form of the nutrient(s) naturally present in foods and forms that are permitted for addition to foods, please specify:

The name of the food/constituent:

Click here to enter text.

The chemical forms to which the health claim applies (one or more among those included in the Annexes to [Directive 2002/46/EC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002L0046)[[9]](#footnote-9) and to [Regulation (EC) No 1925/2006](http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32006R1925)[[10]](#footnote-10)):

Click here to enter text.

* + 1. Food/constituents other than vitamins and minerals falling under section 2.1.1

Name, the characteristic(s)[[11]](#footnote-11), the source and specifications (e.g. physical and chemical properties, composition, and where applicable, microbiological constituents) of the constituent(s), or fixed combination of constituents, for which the health claim is made should be provided.

Click here to enter text.

The variability from batch to batch should be addressed.

Click here to enter text.

Analytical methods applied should be scientifically sound and standardised to ensure quality and consistency of the data.

Measurements should be performed in a competent facility that can certify the data. Whenever a quality control system is in place for performance/control/documentation (e.g. GLP and applicable ISO standard) the particular system should be indicated.

Click here to enter text.

* 1. Food or category of food

A brief description of the food or food category, including characterisation of the food matrix and the overall composition (including the nutrient content of the food), should be provided.

Click here to enter text.

The source and specifications of the food or food category for which the health claim is made should be provided, and in particular the content of the food/constituent(s) which may contribute to exert the claimed effect, if known.

Click here to enter text.

The variability from batch to batch should be addressed.

Click here to enter text.

Analytical methods applied should be scientifically sound and standardised to ensure quality and consistency of the data.

Measurements should be performed in a competent facility that can certify the data. Whenever a quality system is in place for performance/control/documentation (e.g. GLP and applicable ISO standard) the particular system should be indicated.

Click here to enter text.

* 1. Manufacturing process

Where applicable, a brief overview of manufacturing process, including e.g. information that the food/constituent can be manufactured consistently to the stated specifications, should be provided. If the production follows a quality system (e.g. GMP), the particular system should be indicated.

Click here to enter text.

If the manufacturing process is claimed as confidential, a non-confidential summary of the manufacturing process should also be provided in the dossier for transparency reasons.

Click here to enter text.

* 1. Stability information

Where applicable, a brief summary of the studies undertaken[[12]](#footnote-12) (e.g. conditions, batches and analytical procedures), and of the results and conclusions of the stability studies, should be provided. Conclusions with respect to storage conditions and shelf-life should be given.

Click here to enter text.

* 1. References

Provide a complete list of the references quoted in Part 2 (alphabetical order of first authors).

Click here to enter text.

Supporting documents should be provided in Part 6 (Section 6.2).

1. Part 3: Characterisation of the claimed effect[[13]](#footnote-13)
	1. Function claims

The proposed health claim is based on the essentiality of a nutrient[[14]](#footnote-14)

[ ]  yes [ ]  no

**If yes**, please specify:

1. the function of the body that is the subject of the claimed effect.

Click here to enter text.

1. the rationale/reasons why the body function is a beneficial physiological effect for the target population for which the claim is intended.

Click here to enter text.

**If not**[[15]](#footnote-15), please specify:

1. the specific body function that is the subject of the claimed effect.

Click here to enter text.

1. the rationale/reasons why the specific body function is a beneficial physiological effect for the target population for which the claim is intended.

Click here to enter text.

1. how the specific body function can be assessed in vivo[[16]](#footnote-16) in humans by generally accepted methods. Please indicate the outcome variable(s) and the methods of measurement proposed to assess the claimed effect in human studies.

Click here to enter text.

* 1. Disease risk reduction claims[[17]](#footnote-17)
		1. Definition of the claimed effect

Please specify:

1. the risk factor for the development of the human disease:

Click here to enter text.

1. how the specific risk factor can be assessed *in vivo*16 in humans. Please indicate the outcome variable(s) and the methods of measurement proposed to assess the risk factor in human studies:

Click here to enter text.

1. the disease to which the risk factor relates:

Click here to enter text.

1. 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):

Click here to enter text.

* + 1. Characterisation of the relationship between the risk factor and the risk of the related disease

If available, provide evidence from observational studies for an independent association between the proposed risk factor and the incidence of the disease:

Click here to enter text.

Provide evidence that the relationship between the risk factor and the development of the disease is biologically plausible:

Click here to enter text.

If available, provide evidence from intervention (drug or dietary) studies that a reduction of the risk factor generally reduces the incidence of the disease:

Click here to enter text.

* 1. References

Provide a complete list of the references quoted in Part 3 (alphabetical order of first authors):

Click here to enter text.

Full reprints of the references quoted should be provided in Part 6 (Section 6.3).

1. Part 4: Identification of pertinent scientific data
	1. Claims based on the essentiality of nutrients[[18]](#footnote-18)

The procedure followed to identify the evidence on the essentiality of the nutrients should be depicted.

Click here to enter text.

Provide case reports of clinical signs and symptoms of deficiency, depletion–repletion studies in humans, animal studies, *in vitro* studies, and/or any other evidence (in favour and not in favour) to establish that:

1. the food/constituent is required for normal human body function(s), i.e. it has an essential mechanistic role in a metabolic function and/or it has the ability to reverse clinical signs and symptoms of its deficiency;
2. the food/constituent cannot be synthesised by the body, or cannot be synthesised in amounts which are adequate to maintain normal human body function(s);
3. the food/constituent must be obtained from a dietary source (i.e. a source which is appropriate for human oral consumption).

A complete list of the references (alphabetical order of first authors) should be provided and organised as follows:

1. depletion–repletion studies in humans

Click here to enter text.

1. case reports of clinical signs and symptoms of deficiency in humans

Click here to enter text.

1. animal studies

Click here to enter text.

1. *in vitro* studies

Click here to enter text.

1. review publications (e.g. narrative reviews, text-book chapters, etc.)

Click here to enter text.

Full reprints of references quoted should be provided in Part 6 (Section 6.4).

* 1. Claims other than those based on the essentiality of nutrients
		1. Identification of published human studies on the relationship between the consumption of the food/constituent and the claimed effect[[19]](#footnote-19)

Published human studies on the relationship between the consumption of the food/constituent and the claimed effect should be identified in a systematic and transparent manner through a comprehensive review of the scientific literature.[[20]](#footnote-20)

The following information on the comprehensive review should be provided, as appropriate:

Authorship

Name, affiliation, declaration of interests and signature of the reviewer(s) responsible for the comprehensive review should be indicated.

Click here to enter text.

Objectives

The questions that the comprehensive review aims to address should be clearly specified in relation to the study group(s), the food/constituent, the comparator (if applicable), the outcome variable(s) used to assess the claimed effect, the methods of measurement which are considered valid with respect to their analytical characteristics, and the study design(s).

Click here to enter text.

Eligibility criteria

Specify the inclusion (and exclusion) criteria applied in order to select publications that are considered pertinent to the health claim with respect to the study group(s), the food/constituent, the comparator (if applicable), the outcome variable(s) used to assess the claimed effect, the methods of measurement, the study design(s), and other characteristics, where appropriate.

Click here to enter text.

Literature search and other data sources

The databases that have been searched should be listed.

Click here to enter text.

Please provide the full search strategy, including the terms used, limits used (e.g. publication dates, publication types, languages, population subgroups or default tags), in order to allow replication. Other sources of data used to retrieve pertinent published human studies should be acknowledged (e.g. web sites, hand searching, expert knowledge).

Click here to enter text.

Published human studies on the relationship between the consumption of the food/constituent and the claimed effect identified as pertinent to the health claim

1. Provide a reference list of the publications that have been identified through the literature search (and/or other data sources) and which have been considered as pertinent to the health claim (i.e. which meet the eligibility criteria specified above). The reference list should be organised in accordance with the hierarchy of study design and publication type as follows:
	1. Publications reporting on human intervention (efficacy) studies (e.g. randomised controlled studies, randomised uncontrolled studies, non-randomised controlled studies, other intervention studies)

Click here to enter text.

* 1. Publications reporting on human observational studies (e.g. cohort studies, case–control studies, cross-sectional studies, other observational studies)

Click here to enter text.

* 1. Summary publications reporting on human intervention and/or human observational studies (e.g. systematic reviews, pooled analyses, meta-analyses, other review publications)

Click here to enter text.

Full reprints of the above-mentioned publications should also be provided in Part 6 (Section 6.4).

1. Please provide a reference list of the publications that have been identified through the literature search (and/or other data sources) on the relationship between the consumption of the food/constituent and the claimed effect, which have NOT been considered as pertinent to the health claim (i.e. which do NOT meet the eligibility criteria specified above). **For each publication, the** **reason(s)** **for exclusion** of the publication from the application should be clearly specified. The full text of these publications should NOT be provided in the application.

Click here to enter text.

* + 1. Unpublished human studies on the relationship between the consumption of the food/constituent and the claimed effect

The procedure followed to identify unpublished human studies that are considered as pertinent to the health claim should be depicted.

Click here to enter text.

**Reference list of unpublished human studies**

Provide a reference list of any unpublished human (intervention or observational) studies and of any summary publication (systematic reviews/meta-analyses/pooled analyses) reporting on human (intervention or observational) studies which the applicant considers as being pertinent to the health claim. The reference list should be organised in accordance with the hierarchy of study design and publication type, as follows:

1. Human intervention (efficacy) studies (e.g. randomised controlled studies, randomised uncontrolled studies, non-randomised controlled studies, other intervention studies)

Click here to enter text.

1. Human observational studies (e.g. cohort studies, case–control studies, cross-sectional studies, other observational studies)

Click here to enter text.

1. Summary reports of human intervention and/or human observational studies (e.g. systematic reviews, pooled analyses, meta-analyses, other reviews)

Click here to enter text.

The full protocol and the full study report of the above-mentioned studies **SHOULD** be provided in **Part 6** (Section 6.5).

For study reports of human efficacy studies (unpublished and/or proprietary), please see **Appendix C** for the content requirements.

* + 1. Published and unpublished supportive evidence

The procedure(s) followed to identify published and unpublished studies other than human studies on the relationship between the consumption of the food/constituent and the claimed effect (e.g. bioavailability studies, studies on the mechanism(s) by which a food could exert the claimed effect) should be depicted.

Click here to enter text.

Reference list of published/unpublished studies

Provide a reference list of the publications/unpublished studies other than human studies on the relationship between the consumption of the food/constituent and the claimed effect which have been considered as pertinent to the health claim. The reference list should be organised in accordance with the hierarchy of study design and publication type, as follows:

a) human studies

Click here to enter text.

b) animal efficacy studies

Click here to enter text.

c) other animal studies

Click here to enter text.

d) *in vitro* studies

Click here to enter text.

Full reprints of the above-mentioned publications, and the full protocol and study report for unpublished studies, should also be provided in Part 6 (Section 6.4 for published studies and Section 6.5 for unpublished studies).

1. Part 5: Overall summary of pertinent scientific data

The scope of this section is to critically and concisely summarise 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 **Part 4** of the application.

Note: No new/additional references should be cited in Part 5, except those identified in Part 4.

* 1. Claims based on the essentiality of nutrients[[21]](#footnote-21)

Provide a reasoned and concise summary on the extent to which:

1. the food/constituent is required for normal human body function(s), i.e. it has an essential mechanistic role in a metabolic function and/or it has the ability to reverse clinical signs and symptoms of its deficiency. Please provide a rationale for the relationship between the metabolic function and/or the specific clinical signs and symptoms of deficiency and the human body function that is the subject of the health claim.

1. the food/constituent cannot be synthesised by the body, or cannot be synthesised in amounts which are adequate to maintain the normal body function that is the subject of the health claim.

1. the food/constituent must be obtained from a dietary source (i.e. a source which is appropriate for human oral consumption).

Cross-references to the pertinent scientific data identified in Part 4 (Section 4.1) should be given, where appropriate.

* 1. Claims other than those based on the essentiality of nutrients

The scope of Sections 5.2.1 and 5.2.2 is to critically and concisely summarise the extent to which the relationship between the consumption of food/constituent and the claimed effect is supported by the totality of (published and unpublished) human studies identified as pertinent to the health claim in Part 4 (Sections 4.2.1 and 4.2.2) of the application. Cross-references to pertinent human studies (intervention or observational) should be given, as appropriate.

* + 1. Substantiation of a causal relationship between the consumption of the food/constituent and the claimed effect

The extent to which the data substantiate a causal relationship between the consumption of the food/constituent and the claimed effect should be addressed by considering:

1. the specificity of the effect;
2. the dose­­­­–response relationship;
3. the magnitude of the effect and its physiological relevance;
4. the consistency of the effect across studies (consistent results obtained from studies by different research groups and/or in different settings strengthen the evidence).

* + 1. Characterisation of the relationship between the consumption of the food/constituent and the claimed effect

The relationship between the consumption of the food/constituent and the claimed effect should be characterised by considering:

1. the study group(s) in which the effect has been demonstrated and whether study groups are representative of the target population;
2. the conditions under which the effect has been achieved (metabolic room, clinical setting, free-living subjects, etc.);
3. the sustainability of the effect over time with continuous consumption of the food/constituent, where applicable;
4. the lowest effective dose, when available;
5. the amount of the food/constituent used to achieve the effect, the usual intakes of the food/constituent in the target population, and whether these amounts could be reasonably consumed as part of a balanced diet.

* + 1. Supportive evidence

Bioavailability

Where applicable, concisely summarise the relevant data and rationale to support that the food/constituent for which the health claim is made is in a form that is available to be used by the human body.

If available, describe any factors (e.g. formulation and processing) that could affect the absorption or utilisation in the body of the food/constituent for which the health claim is made.

Note: If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres and lactic acid bacteria), concisely summarise the relevant data and rationale to support that the food/constituent reaches the target site.

**Mechanism(s) of action**

If known, concisely describe the mechanism(s) by which the food/constituent could exert the claimed effect. If the food/constituent is a fixed combination of constituents, please indicate how each constituent could contribute to the claimed effect.

Cross-references to published and unpublished supportive studies identified in Part 4 (Section 4.2.3) should be given, as appropriate.

Summary of supportive evidence

This section should critically and concisely summarise how, and the extent to which, the published and unpublished studies other than human studies on the relationship between the consumption of the food/constituent and the claimed effect identified in Part 4 (Section 4.2.3) may help to support the relationship between the food/constituent and the claimed effect in humans (e.g. by providing evidence on the biological plausibility of the specific claim, including bioavailability of the food/constituent, and the mechanisms by which the food/constituent could exert the claimed effect).

1. Annexes to the application
	1. Glossary and abbreviations

Used throughout the different Parts. To be presented alphabetically.

* 1. Supporting documents and copies/reprints of references cited in Parts 1 and 2

Supporting documents referred to in Part 1. If available, include here, e.g. scientific opinions of regulatory bodies outside the EU for health claim authorisation:

Supporting documents referred to in Part 2 related to characterisation of the food/constituent.

Copies/reprints should be provided by alphabetical order of first authors.

* 1. Copies/reprints of references related to characterisation of the claimed effect cited in Part 3

Copies/reprints should be provided by alphabetical order of first authors.

* 1. Copies/reprints of pertinent published data identified in Part 4

Copies/reprints of pertinent published data identified in Part 4 (Sections 4.1, 4.2.1 and 4.2.3) should be provided by alphabetical order of first authors.

* 1. Full study protocols and reports of pertinent unpublished data identified in Part 4

Copies/reprints of pertinent unpublished data identified in Part 4 (Sections 4.2.2 and 4.2.3) should be provided by alphabetical order of first authors.

1. In case more than one company or organisation submits an application, provide their names and addresses. Only one contact person is authorised to communicate with EFSA. [↑](#footnote-ref-1)
2. To facilitate communication, only one contact person should be indicated per application. [↑](#footnote-ref-2)
3. See also Annex A (Section A.4) of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-3)
4. 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). [↑](#footnote-ref-4)
5. See also Annex A (Section A.4) of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-5)
6. For claims based on the essentiality of nutrients, conditions of use are set on the basis that any significant amount of the essential nutrient in the diet will contribute to the claimed effect (e.g. conditions of use can be linked to nutrition claims). See also sections 6.2 and 7.9 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-6)
7. See also Section 7.1 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-7)
8. Eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA) + gamma-linolenic acid (GLA) [↑](#footnote-ref-8)
9. Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. OJ L 183, 12/07/2002 P. 0051 – 0057. [↑](#footnote-ref-9)
10. Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods. OJ L 404, 30.12.2006, p. 26–38. [↑](#footnote-ref-10)
11. Information relates to those characteristics which may influence the specific physiological effect that is the basis of the claim. [↑](#footnote-ref-11)
12. 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. [↑](#footnote-ref-12)
13. See also Section 7.2 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-13)
14. See also Section 6.1 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-14)
15. See Section 7.2.1 of the ‘general guidance’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-15)
16. It includes the measurement of functional outcome variables in vivo and the measurement (ex vivo) of outcome variables in biological samples following an intervention in vivo. [↑](#footnote-ref-16)
17. See also Section 7.2.2 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-17)
18. See also Section 6.1 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-18)
19. See also Section 7.4 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-19)
20. Applicants could consider the EFSA guidance on the application of systematic review methodology to food and feed safety assessments to support decision making for that purpose ([EFSA, 2010](#_ENREF_4)). [↑](#footnote-ref-20)
21. See also section 6.1 of the ‘[general guidance](http://www.efsa.europa.eu/en/efsajournal/pub/4367)’ (EFSA NDA Panel, 2016). [↑](#footnote-ref-21)