EFSA PRE-SUBMISSION GUIDANCE FOR APPLICANTS INTENDING TO SUBMIT APPLICATIONS FOR AUTHORISATION OF HEALTH CLAIMS MADE ON FOODS

Last updated (Rev.): 21 December 2007
Publication Date: 14 March 2007

NOTES to users:

The information provided in this guidance document should be cross-read in conjunction with the *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*[*] (hereafter "the Regulation").

This guidance document addresses a number of administrative and procedural questions which applicants intending to submit applications for health claims authorisation may have. It provides an overview of issues related to the afore-mentioned procedure and aims to assist applicants in the submission of applications.

Questions and Answers will be updated progressively, and will be marked by "*New*" or "*Rev.*" upon publication. EFSA advises applicants to check the most recent version before submitting an application.

For questions related to the format and content of the application for authorisation of a health claim, please refer to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim": http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html

[*] 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. Official Journal of the European Union OJ L 404, 30.12.2006. Corrigendum OJ L 12, 18.1.2007, p. 3–18.
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_012/l_01220070118en00030018.pdf

LIST OF QUESTIONS

RESPONSES

1. Is my application for authorisation of a health claim eligible for scientific evaluation by EFSA? *Rev.*

The 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 lays down the following provisions:

- For **health claims which fall under Article 14** of the Regulation, i.e.
  - Health claim referring to reduction of disease risk (meaning any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of human disease).
  - Health claim referring to children's development and health.

  an application is needed. Applications for authorisation **are subject to scientific evaluation (i.e. scientific Opinion) by EFSA** according to the procedure laid down in Articles 15, 16, 17 and 19 of the Regulation, prior to their inclusion in a Community list of permitted claims.

- **Health claims (other than those referring to the reduction of disease risk and to children's development and health) which fall under Article 13(1)** of the Regulation, i.e. health claims describing or referring to:
  - the role of a nutrient or other substance in growth, development and the functions of the body, or
  - psychological and behavioural functions; or
  - slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

  have to be included in the Community list of permitted claims provided for under Article 13(3) of the Regulation. For inclusion in the afore-mentioned Community list of permitted claims, **PLEASE CONTACT:**

  - **the National Competent Authority of a Member State in the EU** where the health claim applies;
  - or alternatively the **European Commission, Unit E4 of Directorate General Health and Consumer Protection**, Rue de la Loi 200, B-1049 Bruxelles, Belgium (http://ec.europa.eu/comm/food/index_en.htm; http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm).

- For **health claims (other than those referring to the reduction of disease risk and to children's development and health) which fall under Article 13(5)** of the Regulation, i.e. health claims which **have not been included** in the Community list of permitted claims, which are:
  - based on **newly developed scientific evidence** and/or which
  - include a **request for the protection of proprietary data**

an application is needed. Applications for authorisation **are subject to scientific evaluation (i.e. scientific Opinion) by EFSA** according to the procedure laid down in Article 18 of the Regulation, prior to their addition to the list of permitted health claims referred to in Article 13(3) of the Regulation.

As regards the classification of claims under one of the categories identified above, applicants are kindly invited to refer to the **European Commission "Guidance on the implementation of Regulation 1924/2006 on nutrition & health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health dated 14 December 07"** (*the link to the webpage will be given once the afore-mentioned guidance is published by the Commission*)**.**

2. Is my application for authorisation of a health claim eligible for scientific evaluation by EFSA under the scope of Article 14 procedure?

Article 14 procedure:

Art 14 of the Regulation applies only to **health claims** referring to:

- reduction of disease risk (meaning any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of human disease).
- children's development and health.

For such health claims an application is needed. Applications for authorisation **are therefore subject to scientific evaluation (i.e. scientific Opinion) by EFSA** according to the procedure laid down in Articles 15, 16, 17 and 19 of the Regulation, prior to their inclusion in a Community list of permitted claims.

3. Is my application for authorisation of a health claim eligible for scientific evaluation by EFSA under the scope of Article 18 procedure? *Rev.*

Article 18 procedure:

Article 18 of the Regulation applies **only** to health claims (other than those referring to the reduction of disease risk and to children's development and health) referred to in Article 13(5), **i.e. which have not been included in the Community list of permitted health claims** under the provision of Article 13(3), which are:

- based on **newly developed scientific evidence** and/or which
- include a **request for the protection of proprietary data.**

For such health claims an application is needed. Applications for authorisation **are subject to scientific evaluation (i.e. scientific Opinion) by EFSA** according to the procedure laid down in Article 18 of the Regulation, prior to their addition to the list of permitted health claims referred to in Article 13(3) of the Regulation.

4. How should I organise my application for health claim authorisation and under which format?

Format

According to Article 15(4) of the Regulation*, '*The Commission, having first consulted EFSA, shall establish in accordance with the procedure referred to in Article 25(2) (comitology procedure) implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application.*'

Upon the request from the European Commission, EFSA Scientific Panel on Dietetic products, Nutrition and Allergies (NDA Panel) has adopted an Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" (hereafter referred to as "**the Guidance**") after having released it for public consultation and taking into consideration all comments received.

The Guidance presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application. Adherence to this format will also facilitate easy access to information and scientific data in applications to help the NDA Panel with its evaluation in an effective and consistent way.

To streamline and optimise the authorisation process of the health claim applied for, **EFSA strongly advises the applicant to adhere to the Guidance** for preparing their application for authorisation of a health claim before submitting it for scientific evaluation by EFSA (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

To facilitate the preparation of the application for health claim authorisation, a ready-to-use word-format of the application including Templates is also provided: http://www.efsa.europa.eu/en/science/nda/Pre_submission_guidance/nda_technical_guidance.html.

5. How should my "Summary of the Application" look like? *Rev.*

Summary of the Application:

According to Articles 15(2b) and 15(3g) of the Regulation, the application shall be accompanied by a Summary of the Application, and EFSA shall make the Summary of the Application available to the public.

The Summary of the Application should be presented in a standardised form. Therefore it is **mandatory** to use the form provided in the **Appendix B** of **the Guidance** (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html). To facilitate the preparation of the Summary of the Application, a ready-to-use word-format of the application including Templates is also provided:

http://www.efsa.europa.eu/en/science/nda/Pre_submission_guidance/nda_technical_guidance.html.

The Summary of the Application shall be preferably presented in English in an easily comprehensible and legible form. It should be brief and concise, and reflect the information in the application.

The Summary of the Application shall not contain parts which are considered to be confidential as it will be published on the EFSA website following receipt of the application from a National Competent Authority of a Member State.

Acknowledging the above, applicants are encouraged for transparency purpose to make publicly available a maximum of information submitted in the Summary of Application.

For publication purposes, an electronic file containing exclusively the Summary of the Application should be provided (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592471.htm).

6. Can I submit multiple health claims in the same application?

An application should be prepared for each individual health claim; this means that only one relationship between a food/constituent (Notes: *"food/constituent" refers to the food category, a food, or constituents (including a nutrient or other substance, or a combination of nutrients/other substances) for which the health claim is made*) and **a single claimed effect can be the object of each application.** If multiple claimed effects are proposed for a food/constituent, a separate application should be submitted for each claimed effect.

For the presentation and format of the application for health claim authorisation, please refer to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

The Guidance presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application. Adherence to this format will also facilitate easy access to information and scientific data in applications to help the NDA Panel with its evaluation in an effective and consistent way.

To streamline and optimise the authorisation process of the health claim applied for, **EFSA strongly advises the applicant to adhere to the Guidance** when preparing their application for authorisation of a health claim to be evaluated by EFSA.

7. What is the procedure for the submission of applications for authorisation of health claims? *Rev.*

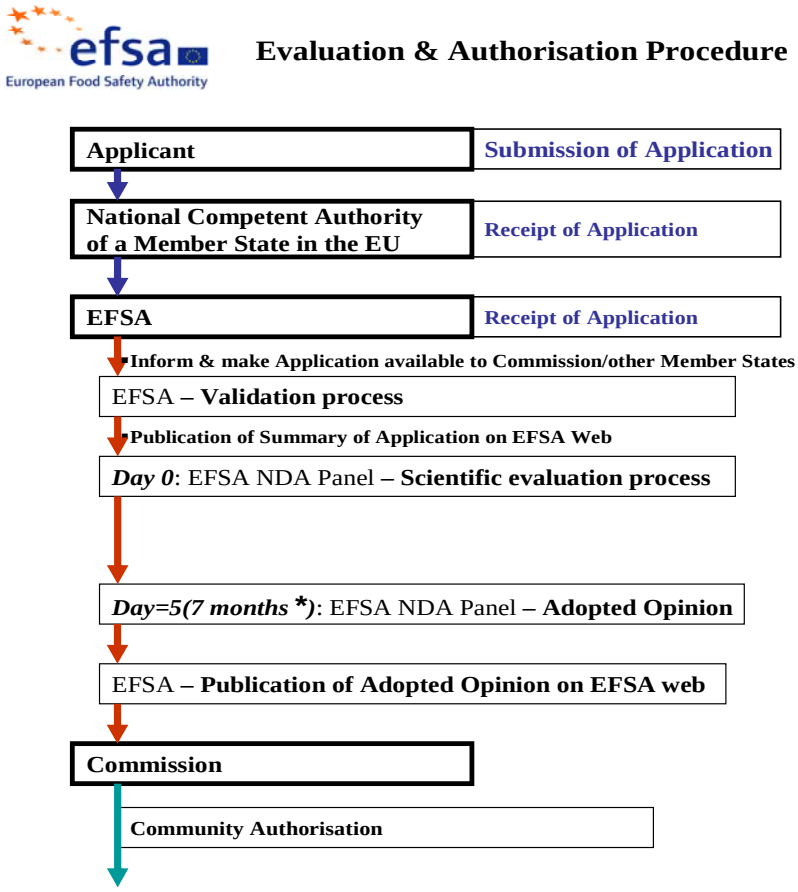
Procedure:

Applications for authorisation of health claims pursuant to Articles 14 and 13(5) of the Regulation (EC) No 1924/2006 shall be submitted to the National Competent Authority of a Member State in the European Union in accordance with Articles 15 and 18, respectively.

The National Competent Authority of the Member State shall then make the application and any supplementary information supplied by the applicant available to EFSA at the following mailing address:

European Food Safety Authority
Scientific Coordinator NDA Panel
Quoting the reference Ref: **"efsa-NDA-claims"**
Address:
Largo N. Palli 5/A,
I-43100 Parma, Italy
Email: **efsa-NDA-claims@efsa.europa.eu**
Fax: +39 0521 036 175

Subsequently, EFSA will follow the procedure as laid down in the **CHART** below.



* ***Evaluation procedure including clock stop mechanism for request of supplementary information if needed***

Please be advised that it is not for the EFSA to authorise the use of a health claim. The authorisation of claims is under the remit of the European Commission. After scientific evaluation (i.e. scientific Opinion) by EFSA of the application received from the National Competent Authority of a Member State, the Commission will take the decision concerning the authorisation of the health claim applied for.

8. How shall I submit an application based on proprietary data?

Proprietary data:

Article 21 of the Regulation gives provision for the handling of proprietary data in the application required under Article 15(3).

The application for authorisation of a health claim shall clearly state which parts or sections of the application are considered to be proprietary data, together with a verifiable justification/declaration by the applicant.

For presentation and submission of applications based on proprietary data, please refer to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

The Guidance presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application. Adherence to this format will also facilitate easy access to information and scientific data in applications to help the NDA Panel with its evaluation in an effective and consistent way.

To streamline and optimise the authorisation process of the health claim applied for, **EFSA strongly advises the applicant to adhere to the Guidance** when preparing their application for authorisation of a health claim to be evaluated by EFSA.

9. How shall I submit an application containing confidential data?

Confidential data:

The whole application in itself cannot be confidential. Sections considered as confidential by the applicant should be kept to a minimum. The application for authorisation of a health claim shall clearly state which parts or sections of the application are considered to be confidential, together with a verifiable justification/declaration by the applicant for each part or section considered to be confidential.

When dealing with confidential data, EFSA will apply Articles 8 and 9 of the decision of its management board concerning implementing measures of transparency and confidentiality requirements (link to website:

http://www.efsa.europa.eu/etc/medialib/efsa/mboard/statutory_texts/internal_rules/409.Par.0011.File.dat/mb_transparency_confidentiality_requirements1.pdf).

For presentation and submission of applications including confidential data, please refer to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

The Guidance presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application. Adherence to this format will also facilitate easy access to information and scientific data in applications to help the NDA Panel with its evaluation in an effective and consistent way.

To streamline and optimise the authorisation process of the health claim applied for, **EFSA strongly advises the applicant to adhere to the Guidance** when preparing their application for authorisation of a health claim to be evaluated by EFSA.

10. If my application cites references, and encloses copies/reprints of published or unpublished data, how shall I address their Intellectual Property Rights?

Applicants are responsible of all references cited, published or unpublished, and for obtaining permission to reproduce, distribute or communicate such material from the concerned holder of an Intellectual Property Rights.

11. In which language shall I submit my application?

Languages to be used:

In order to facilitate the processing of the application and make the assessment more efficient, applications should preferably be submitted in **English**. Should the applicant not provide the English translation, the EFSA will translate those parts of the application in English. However, it should be noted that the responsibility for validating the English translation of the application provided by the EFSA rests with the applicant.

12. How and to whom shall I submit my application?

Dossier requirements:

The paper copy remains the formal submission. In case of discrepancies between the paper copy and the electronic one, EFSA will consider the paper one as the correct version and will ask the applicant an updated electronic version of the application. It is strongly recommended that both paper and electronic submissions fully be in compliance with the EFSA adopted Opinion on "scientific and technical guidance for

the preparation and presentation of the application for authorisation of a health claim" (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

Applicants must submit applications for health claim authorisation and written responses to questions from EFSA as follows:

Number of copies:

For EFSA = one paper copy + one electronic copy.

Additional copies may be required either by EFSA or the National Competent Authority of the Member State. Applicants are advised to contact the National Competent Authority of the Member State for specific requirements prior to submission of applications for health claim authorisation to Member States. Please refer to the "**List of National Competent Authorities within the framework of the Regulation" as prepared by the European Commission**.

- In the event that **EFSA asks the applicant for additional data or information in the process of validation of the application**, the applicant should send that information to EFSA as requested.

- **After validation of the application by EFSA**, the applicant will be requested to send to EFSA within a notified period:

  3 paper copies + 5 electronic copies of the complete application (including any additional data or information supplied during the validation phase), unless otherwise specified.

  In case additional copies are requested, EFSA will inform applicants of the exact number of copies required.

- **Written responses to questions from EFSA**:

  3 paper copies + 5 electronic copies, unless otherwise specified.

If in individual situations there is any divergence from the standard requirement, EFSA will inform the applicant accordingly.

Each box containing the application should weigh less than 15 kg. All boxes should be numbered and labelled, indicating which part of the application is contained inside. Boxes containing the cover letter and diskettes/CD-ROMs should be clearly identified.

For information about submission of **electronic copies** of the application, please see **electronic submissions**.

a. How many paper copies?

Number of copies:

For EFSA = one paper copy + one electronic copy.

For the National Competent Authorities requirement, applicants are advised to contact the National Competent Authority of the Member State for specific requirements. Please refer to the "**List of National Competent Authorities within the framework of the Regulation" as prepared by the European Commission**.

- In the event that **EFSA asks the applicant for additional data or information in the process of validation of the application**, the applicant should send that information to EFSA as requested.

- **After validation of the application by EFSA**, the applicant is requested to send to EFSA within a notified period:

  3 paper copies + 5 electronic copies of the completed application (including any additional data or information supplied during the validation phase), unless otherwise specified.

  In case additional copies are requested, EFSA will inform applicants of the exact number of copies required.

- **Written responses to questions from EFSA**:

  3 paper copies + 5 electronic copies, unless otherwise specified.

If in individual situations there is any divergence from the standard requirement, EFSA will inform the applicant accordingly.

Each box containing the application should weigh less than 15 kg. All boxes should be numbered and labelled, indicating which part of the application is contained inside. Boxes containing the cover letter and diskettes/CD-ROMs should be clearly identified.

13. Can I submit electronic copies of my dossier? *Rev.*

Electronic submissions

Besides the submission of hard copies (i.e. paper copies) of the dossier, the submission of complete copies using an electronic storage media is required.

Common electronic formats should be used, such as MS Office type documents or Adobe Acrobat Reader. The files should be searchable using the search facilities of standard software packages.

Applicants must sign a letter in which they confirm that the electronic data supplied **are identical** to those in any written submission.

The paper copy remains the formal submission. In case of discrepancies between the paper copy and the electronic one, EFSA will consider the paper one as the correct version and will ask the applicant an updated electronic version of the application. It is strongly recommended that both paper and electronic submissions fully be in compliance with the EFSA adopted Opinion on "scientific and technical guidance for

the preparation and presentation of the application for authorisation of a health claim" (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

For publication purposes, an electronic file containing exclusively the Summary of the Application should be provided (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592471.htm).

For the National Competent Authorities requirements, applicants are advised to contact the National Competent Authority of the Member State.

14. Where can I find the list of National Competent Authorities within the framework of the Regulation? *Rev.*

List of National Competent Authorities within the framework of the Regulation:

The List is prepared by the European Commission. The List indicates the addresses for submission points including the contact persons in charge in the National Competent Authorities in the European Union Member-States.

Please be advised that applications for authorisation of health claims pursuant to Articles 14 and 13(5) of the Regulation (EC) No 1924/2006 shall be submitted to the National Competent Authority of a Member State in the European Union in accordance with Articles 15 and 18, respectively.

Applicants are advised to contact the National Competent Authority of the Member State for specific requirements prior to submission of applications for health claim authorisation to Member States.

15. When shall I submit my application? *Rev.*

- **Application for authorisation of a health claim as referred to in Article 14** of the Regulation can be submitted to the National Competent Authority of a Member State in the EU for scientific evaluation by EFSA as from 1 July 2007.

  To streamline and optimise the authorisation process of the health claim applied for, EFSA strongly advises the applicant to adhere to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" for preparing their application for authorisation of a health claim before submitting it for scientific evaluation by EFSA (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

- For addition of health claims referred to in Article 13(5), **i.e. which have not been included in the Community list of permitted claims** under the

provision of Article 13(3), which are **based on newly developed scientific evidence** and/or **which include a request for the protection of proprietary data**, application for authorisation in accordance with the procedure laid down in **Article 18** of the Regulation can be submitted to the National Competent Authority of a Member State in the European Union for scientific evaluation by EFSA as from 1 February 2008.

To streamline and optimise the authorisation process of the health claim applied for, EFSA strongly advises the applicant to adhere to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" when preparing their application for authorisation of a health claim to be evaluated by EFSA (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

Please be advised that it is not for the EFSA to authorise the use of a health claim. The authorisation of claims is under the remit of the European Commission. After scientific evaluation (i.e. scientific Opinion) by EFSA of the application received from the National Competent Authority of a Member State, the Commission will take the decision concerning the authorisation of the health claim applied for.

16. How shall my application be validated? *Rev.*

Validation by EFSA – Upon receipt of the application from the National Competent Authority of a Member State, EFSA will proceed with its **administrative checking**. EFSA will start the scientific evaluation procedure of the submission when it will have completed its validation; the timetable for each application will be published on the EFSA website (http://www.efsa.europa.eu/en/science/nda.html).

During validation EFSA may consult the NDA Panel on the need for action relating to matters such as completeness of data. If relevant, the Commission Services will be consulted on points of interpretation of EU legislation particularly in relation to the scope.

In the event that EFSA requires additional data, information or clarification in order to consider an application valid, the applicant will be asked to supply these data, information or clarification within a notified time limit.

When supplying EFSA with this information, the applicant should send the requested number of paper copies of this information to EFSA together with the electronic version, as indicated by EFSA.

In this case, the validation can only be completed after receipt and verification by EFSA of the information submitted.

To streamline and optimise the validation process of the health claim applied for, EFSA strongly advises the applicant:

- To check that the application applied for is under the right scope, by referring to the **European Commission "Guidance on the implementation of Regulation 1924/2006 on nutrition & health claims made on foods – Conclusions of the Standing Committee on the Food Chain and Animal Health dated 14 December 07"** (*the link to the webpage will be given once the afore-mentioned guidance is published by the Commission*)**.**
- To adhere to the EFSA adopted Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" when preparing their application for authorisation of a health claim to be evaluated by EFSA (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

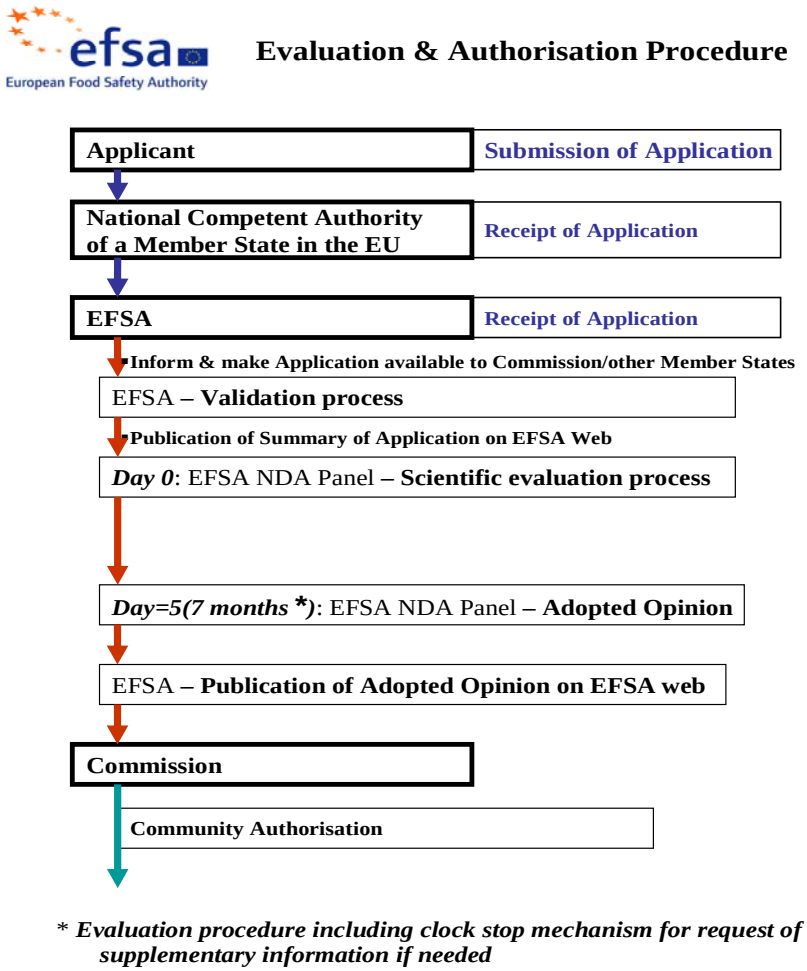
17. How shall my application be evaluated (timetable)?

Timetable for the evaluation of the application for authorisation:

Once the application is validated, EFSA starts the scientific evaluation procedure.

A timetable for each application is prepared by EFSA; the starting date and evaluation timetable are published on the EFSA website (http://www.efsa.europa.eu/en/science/nda.html).

EFSA shall ensure that the Opinion of the Scientific Panel on Dietetic products, Nutrition and Allergies (NDA Panel) is given **within 5 months** (plus clock-stops for the applicant to provide answers to questions from EFSA, if needed) in accordance with the following timetable as referred to in the **CHART** below.



* *Evaluation procedure including clock stop mechanism for request of supplementary information if needed*

18. How and when is an EFSA application Number attributed?

Management of applications:

Upon receipt of an application, details of the application are entered into an EFSA database and tracking system.

An application Number will be attributed to the application for authorisation of the health claim received. This number, which is given after the submission of the application and published on the EFSA website at the start of the scientific evaluation procedure, is retained throughout the life cycle of the application.

These numbers are used as a reference by EFSA and should be used by the Applicant in all correspondence with EFSA throughout the life cycle of the application.

19. Is there Guidance available to help me to prepare my application for authorisation of a health claim?

Guidance available:

According to Article 15(4) of the Regulation*, '*The Commission, having first consulted EFSA, shall establish in accordance with the procedure referred to in Article 25(2) (comitology procedure) implementing rules for the application of this Article, including rules concerning the preparation and presentation of the application.*'

Upon the request from the European Commission, EFSA Scientific Panel on Dietetic products, Nutrition and Allergies (NDA Panel) has adopted an Opinion on "scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim" (hereafter referred to as "**the Guidance**") after having released it for public consultation and taking into consideration all comments received.

The Guidance presents a common format for the organisation of the information to assist the applicant in the preparation of a well-structured application. Adherence to this format will also facilitate easy access to information and scientific data in applications to help the NDA Panel with its evaluation in an effective and consistent way.

To streamline and optimise the authorisation process of the health claim applied for, **EFSA strongly advises the applicant to adhere to the Guidance** when preparing their application for authorisation of a health claim to be evaluated by EFSA (http://www.efsa.europa.eu/en/science/nda/nda_opinions/claims/ej530_guidance_health_claims.html).

Working-format of the application:

To facilitate the preparation of the application for health claim authorisation, a ready-to-use word-format of the application including Templates is also provided: http://www.efsa.europa.eu/en/science/nda/Pre_submission_guidance/nda_technical_guidance.html.

20. How can I communicate with EFSA or the Panel during the evaluation process of my application and who is the EFSA contact person for my application?

Communication with EFSA or its scientific Panel on Dietetic products, Nutrition and Allergies:

In accordance with the Rules of Procedure of the EFSA Scientific Committee and Panels[1], please be advised that any question from an applicant or a third party to any of the members of the EFSA Panels should be addressed through the EFSA scientific Secretariat. The contact details of the NDA Secretariat are available on the EFSA web site[2].

For questions related to the procedural and administrative aspects of applications for authorisation of health claims, the applicants could contact:

- Dr. Pilar Rodríguez Iglesias / Dr. Leng Heng
  Email: **efsa-NDA-claims@efsa.europa.eu**
  Fax: +39 0521 036 175

References:

http://www.efsa.europa.eu/mboard/statutory_texts/internal_rules/409/decision_panels_mb_04_en11.pdf

[2] http://www.efsa.europa.eu/en/about_efsa/contact_us.html

21. If I have questions related to the interpretation of the regulation or on the authorisation procedure, who shall I contact?

Contact point:

Please be advised that for questions related to such as interpretation of the Regulation (e.g. the scope) or concerning the authorisation procedure of a health claim, they are under the remit of the European Commission.

Therefore, you may wish also to contact: European Commission, Unit E4 of Directorate General Health and Consumer Protection, Rue de la Loi 200, B-1049 Bruxelles, Belgium (http://ec.europa.eu/comm/food/index_en.htm; http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm).

22. What is the role of EFSA & the NDA Panel under the context of the Regulation? *New*

Role of EFSA:

In the context of the authorisation procedures foreseen in the Health and Nutrition Claims Regulation, the role of the EFSA is to evaluate the scientific substantiation of individual applications (adopting a scientific Opinion). The EFSA has allocated this task to its Scientific Panel on Dietetic Products, Nutrition and Allergies ("the NDA Panel").

Please note that in the context of the authorisation procedures foreseen in the Nutrition and Health Claims Regulation, the EFSA is not supposed to undertake a safety evaluation of products or substances in respect of which a claim is to be made. In that regard, it is for the applicants to comply with the relevant legislation applicable to those products or substances.

Once available, EFSA scientific Opinion is published on its website.

Please be advised that it is not for the EFSA to authorise the use of a health claim. The authorisation of claims is under the remit of the European Commission. After scientific evaluation (i.e. scientific Opinion) by EFSA of the application received from the National Competent Authority of a Member State, the Commission will take the decision concerning the authorisation of the health claim applied for.

