TECHNICAL REPORT

Discussion paper on the revision of the guidance on the scientific requirements for health claims related to gut and immune function[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) has asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to revise the guidance on the scientific requirements for health claims related to gut and immune function, which was published in 2011. The present document is a discussion paper released with the aim of collecting comments and suggestions from interested parties before drafting the guidance document. It proposes a plan for the revision, outlines the scope and issues to be covered in the revised guidance document, and proposes a timetable for finalising the guidance. The outcome of the public consultation together with new scientific evidence available to the NDA Panel and the experience gained with the evaluation of health claims will serve as a basis for revising the guidance document. The draft guidance document on the scientific requirements for health claims related to gut and immune function will also be subject to a public consultation.

KEY WORDS

health claims, scientific requirements, gut and immune, consultation

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BACKGROUND AS PROVIDED BY EFSA

Regulation (EC) No 1924/2006[3] 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 focus on developing scientific criteria for substantiation of health claims and has published guidance on scientific substantiation of health claims since 2007[4].

To date, over 570 scientific opinions related to health claims have been published and the Panel notes that additional health relationships and outcome measures for specific claimed effects have been considered in the context of specific applications.

Based on experiences gained with the evaluation of health claims, and to further assist applicants in preparing and submitting their applications for the scientific evaluation of health claims, the NDA Panel deems it necessary to update existing guidance documents, and/or to develop new guidance documents, on the scientific requirements for the substantiation of health claims, if considered appropriate.

The NDA Panel also emphasises the importance of engaging in consultation with experts/stakeholders in the process of updating existing guidance documents and/or developing new guidance documents.

It is proposed to undertake this task in a stepwise manner, taking into account the experience gained and new scientific evidence available to the NDA Panel, including outcomes of public consultations with experts/stakeholders.

Owing to high demand from stakeholders and questions received from applicants requesting clarifications related to gut and immune function claims, it is proposed to start first with updating the existing Guidance document on the scientific requirements for health claims related to gut and immune function[5].

TERMS OF REFERENCE AS PROVIDED BY EFSA

The NDA Panel is requested by EFSA to update the existing Guidance document on scientific requirements for health claims related to gut and immune function.

In this context, as an initial step, the Panel is requested to issue a statement to be released for public consultation to gather views from experts/stakeholders in the field before proceeding with the updating of the guidance document. The statement shall point out the issues to be covered in the guidance document, propose recommendations for the updating of the guidance document, and propose a timetable for the release of draft and final guidance.

As a second step, taking into account the experience gained and new scientific evidence available to the NDA Panel, including the outcome of the public consultation on the statement, the Panel is requested to update and draft the Guidance document to be released for public consultation before finalisation.

Before the adoption of the guidance document by the NDA Panel, the draft guidance needs to be revised taking into account the comments received during the public consultation.

A technical report on the outcome of the public consultation on the guidance document shall be published, in which comments received on the statement shall be included.

[3] 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.
[4] http://www.efsa.europa.eu/en/nda/ndaclaims.htm
[5] http://www.efsa.europa.eu/en/efsajournal/pub/1984.htm

CONSIDERATION

1. Introduction

The Guidance on the scientific requirements for health claims related to gut and immune function (EFSA-Q-2010-01139)[6] laid down recommendations on specific issues that need to be addressed in the applications submitted for substantiation of health claims related to the gastro-intestinal tract and the immune system. These issues included claimed effects which are considered to be beneficial physiological effects, and studies/outcome measures which are considered to be appropriate for the scientific substantiation of health claims. The guidance, which was based on the experience gained by the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA Panel) with the earlier evaluation of health claims in these areas, was published in April 2011. Since then, the NDA Panel has evaluated additional health claim applications related to gut and immune function.

2. Problem statement

Regulation (EC) No 1924/2006[7] 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 is carried out by EFSA.

Owing to the scientific and technical complexity of health claims, the NDA Panel has put considerable effort into developing scientific criteria for the substantiation of health claims and has published guidance since 2007[8].

To date, over 570 scientific opinions related to health claims have been published. The NDA Panel notes that new health relationships and outcome measures have been considered in the context of specific applications related to gut and immune function since April 2011. The Panel also notes that a considerable number of requests for clarification have been received from applicants related to gut and immune function claims, and therefore deems it necessary to revise and update the Guidance document on scientific requirements for health claims related to gut and immune function[9].

The NDA Panel also emphasises the importance of engaging in consultation with experts from academia and with stakeholders in the process of updating existing guidance documents and/or developing new guidance documents. It is proposed to undertake this task in a stepwise manner, taking into account new scientific evidence available to the NDA Panel and based on the experience gained with the evaluation of health claims, and on the outcome of public consultations.

It is anticipated that the revision would benefit both industry (by providing clearer requirements) and evaluators of health claims (through receiving better applications).

3. Scope and plan for the revision

The aim is to clarify the claimed effects already submitted and the scientific requirements for the scientific substantiation of those claims. The revision will be based on experiences gained in the evaluation of health claims in the context of specific applications. The revision is not aimed at addressing and proposing new possible beneficial effects and/or studies/outcome measures which may be acceptable beyond those evaluated so far.

[6] http://www.efsa.europa.eu/en/efsajournal/pub/1984.htm
[7] 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.
[8] http://www.efsa.europa.eu/en/nda/ndaclaims.htm
[9] http://www.efsa.europa.eu/en/efsajournal/pub/1984.htm

The Panel plans to revise the Guidance document by addressing the following issues:

General considerations:

- **Suitability of the study population**
- **Evaluation of claims related to essential nutrients compared to non-essential nutrients**
- **Considerations on the validity of tools used to measure outcomes (e.g. questionnaire)**
- **Appropriate reporting of human studies**
- **Handling of data which are claimed as confidential**

Characterisation of microorganisms and other food constituents in relation to claims on gut and immune function:

- **Characterisation of microorganisms at the strain level**
- **Characterisation of microorganisms and other food constituents in relation to the claimed effect**

Function claims:

- **Claims that are insufficiently defined for a scientific evaluation** (e.g. "gut health", "natural defences", "strengthen the immune system", "maintenance of a normal immune function")
- **Claims which are not considered beneficial physiological effects *per se*** (e.g. "increasing the number of lactobacilli/bifidobacteria", "stimulation of marker(s) of the immune system", "changes in marker(s) of inflammation", claims referring to mechanisms by which the food/constituent may exert the claimed effect-e.g. bacterial adhesion inhibition)
- **Claims on bowel function.** Scientific requirements for substantiation in relation to study design, appropriate/non-appropriate outcome measures, and whether/in which circumstances changes in only one outcome may be beneficial; study population vs. target population.
- **Claims on gastro-intestinal discomfort.** Scientific requirements for substantiation in relation to study design, appropriate/non-appropriate outcome measures; study population vs. target population.
- **Claims on defence against pathogens.** Scientific requirements for substantiation in relation to study duration, appropriate/non-appropriate outcome measures and study population vs. target population will be addressed separately to cover the following sites of pathogen colonisation/infection: **gastrointestinal tract; respiratory tract; urinary tract; genital tract,** etc.
- **Claims on immune defence against pathogens.** In addition to the requirements for Claims on defence against pathogens, relevant immune markers need to be measured. Appropriate outcome measures related to vaccination will be clarified.
- **Claims on a beneficial change in response to allergens.** Characterisation of the study population and of the target population, and scientific requirements for substantiation.
- **Claims on improvement in digestion and/or absorption of nutrients.** Clarification, with examples, of the context in which such a claim is considered to have a beneficial physiological effect.

Disease risk reduction claims:

- **Beneficial change in a risk factor for infections.** The scientific requirements for substantiation in relation to study duration, appropriate/non-appropriate outcome measures, study population vs. target population, and differences depending on the target organ system will be addressed.
- **Beneficial change in a risk factor for allergy.** Appropriate/non-appropriate outcome measures and study population vs. target population will be addressed.

4. Proposed timetable

Release of the discussion paper for public consultation: 18 June 2014.

Deadline for external comments: 10 September 2014.

Draft revised guidance will be endorsed for release for public consultation: December 2014/February 2015 (depending on the number of comments to be addressed after the public consultation on the discussion paper).

Possible finalisation: June 2015.

CONCLUSIONS

The outcome of the public consultation together with new scientific evidence available to the NDA Panel and the experience gained with the evaluation of health claims will serve as a basis for revising the guidance on the scientific requirements for health claims related to gut and immune function.