GP/EFSA/NUTRI/2014/01 Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement

University of Parma, Italy

Daniela Martini, Daniele Del Rio
Department of Food and Drugs, University of Parma, Parma, Italy

Giorgio Bedogni
Clinical Epidemiology Unit, Liver Research Center, Basovizza, Trieste, Italy

Carlo Pruneti
Department of Medicine and Surgery, Clinical Psychology Unit, University of Parma, Medical School Building, Parma, Italy

Marco Ventura
Laboratory of Probiogenomics, Department of Chemistry, Life Sciences and Environmental Sustainability, University of Parma, Parma, Italy

Giovanni Passeri
Department of Medicine and Surgery, University of Parma, Building Clinica Medica Generale, Parma, Italy

Marco Vitale
Department of Medicine and Surgery, Sport and Exercise Medicine Centre (SEM), University of Parma, Parma, Italy

Alessandra Dei Cas, Ivana Zavaroni, Riccardo C. Bonadonna
Department of Medicine and Surgery, University of Parma, Parma, Italy, Division of Endocrinology; Azienda Ospedaliera Universitaria di Parma, Parma, Italy

Abstract

The present document refers to the project GP/EFSA/NUTRI/2014/01. This document aims at describing the methods used to retrieve and to critically analyse the scientific data pertinent to this project, besides giving information about the scheduled meetings and reports.

EFSA Scientific Opinions, guidance documents and comments received during public consultation were used to select the outcome variables and the methods of measurement that were evaluated by the Experts on the basis of an extensive research of the scientific literature. Purposely developed databases were used by the Experts to perform a critical analysis of the outcome variables and their methods of measurement.

The project was performed in 3 blocks, each including 2 categories of claims:
Block 1: 1a) Protection against oxidative damage and cardiovascular health and; 1b) Post-prandial blood glucose responses/blood glucose control, weight management;
Block 2: 2a) Bone, joints, oral and skin health and; 2b) Neurological and psychological functions;
Block 3: 3a) Gut and immune function and; 3b) Physical performance.
An additional Block ("Miscellaneous") was added and refers to all the claimed effects, outcome variables and methods of measurement that did not fall in any of the other blocks.

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**Key words:** health claims; outcome variables; methods of measurement; data collection; data collation; data analysis.

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**Correspondence:** nda@efsaeuropa.eu
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Summary

The present document refers to the project GP/EFSA/NUTRI/2014/01 “Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement”.

The project took into consideration the claimed effects proposed by Applicants in the context of:

1) applications for authorisation of health claims under Articles 13.5 and 14 for which a Scientific Opinion has been published;
2) guidance documents on the scientific requirements for health claims;
3) comments received during public consultations and related to the specific guidance documents on scientific requirements for health claims.

The project was performed in 3 blocks, each including 2 categories of claims:

Block 1: 1a) Protection against oxidative damage and cardiovascular health and; 1b) Post-prandial blood glucose responses/blood glucose control, weight management;
Block 2: 2a) Bone, joints, oral and skin health and; 2b) Neurological and psychological functions;
Block 3: 3a) Gut and immune function and; 3b) Physical performance.

An additional Block, “Miscellaneous”, was added and refers to all the claimed effects, outcome variables and methods of measurement that did not fall in any of the other blocks.

EFSA Scientific Opinions, guidance documents and comments received during public consultation were used to select the outcome variables and the methods of measurement that were evaluated by the Experts on the basis of an extensive research of the scientific literature. Purposely developed databases were used by the Experts to perform a critical analysis of the outcome variables and their methods of measurement. For each outcome and method, a detailed description of the literature with relevant references was provided. The analysis of methods also systematically applied the criteria proposed by Fitzpatrick et al. (1998), Atkinson et al. (2001) and Weir & Walley (2006).

During the 24 months of duration of the project, the drafts of 3 Interim Reports (1 for each block) and a Final Report were delivered. Six meetings were scheduled during this period.
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1. Introduction

1.1. Background

This grant was awarded by EFSA to:

Beneficiary: Università degli Studi di Parma
Grant title: Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement.
Grant number: GP/EFSA/NUTRI/2014/01-GA1

The present document (Final Protocol) refers to the project GP/EFSA/NUTRI/2014/01 “Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement”. The aim of this document is to describe the procedure and the methodology used to retrieve and analyse the outcome variables and their methods of measurement, besides giving information about the scheduled meetings and reports that were delivered.

2. Data and Methodologies

2.1. Data

The project refers to the claimed effects proposed by Applicants in the context of:

1) applications for authorisation of health claims under Articles 13.5 and 14 for which a Scientific Opinion has been published;
2) guidance documents on the scientific requirements for health claims;
3) comments received during public consultation and related to the specific guidance documents on scientific requirements for health claims.

2.2. Methodologies

The project work was performed in 3 blocks, each including 2 categories of claims (Figure 1):

Block 1: 1a) Protection against oxidative damage and cardiovascular health and; 1b) Post-prandial blood glucose responses/blood glucose control, weight management;
Block 2: 2a) Bone, joints, oral and skin health and; 2b) Neurological and psychological functions;
Block 3: 3a) Gut and immune function and; 3b) Physical performance.

An additional Block, called “Miscellaneous” was added and refers to all the claimed effects, outcome variables and methods of measurement that did not fall in any of the other blocks.
The outcome variables and their methods of measurements were evaluated only if the claimed effect has been sufficiently defined and has been considered beneficial by the NDA panel (Figure 2).

![Diagram](image.png)

**Figure 2** – Procedure to evaluate the outcome variables and their methods of measurement

If the outcome variable was considered appropriated by the NDA panel, a description of the available methods to measure the outcome variable was provided. If the outcome variable was not considered appropriate by the NDA panel because of the outcome variable itself, no evaluation of methods of measurement was performed. Lastly, if the outcome variable was not considered appropriated by the NDA panel because of the method(s) of measurement, a detailed description of the potentially available methods to measure the outcome variable was provided.

The collection, collation and critical analysis of the scientific literature relevant to the 3 blocks consisted of 3 main steps:

1) **Definition of the keywords**: Scientific Opinions, guidance documents and comments were obtained from the EFSA website ([http://www.efsa.europa.eu/en/publications.htm](http://www.efsa.europa.eu/en/publications.htm)). These documents were used to define lists of outcomes variables and methods of measurements, which were used for the search of the scientific literature.

2) **PubMed search and creation of databases of references for outcomes and methods**: the PubMed
database was used to identify the pertinent scientific references for each outcome variable and its methods of measurement. Only two pre-specified filters were used: MeSH = Humans and MeSH = English Abstract. Other filters were specifically defined after consulting the Experts. The PubMed search was converted into a FileMaker database, which runs on Microsoft Windows ≥ XP and Mac OS X ≥ 10.6 and was made available to the Experts.

The database included the following fields:

- Authors
- Title
- Journal
- Year
- Volume
- Pages
- Abstract
- Reference (implemented by the database as container field where PDF or other files can be collated)

3) Critical analysis of the outcome variables and their methods of measurements: Using the databases created during step 2, the experts performed the assessment of the outcome variables and their methods of measurements.

The outcome variables were described in detail under the following headings:

- Outcome – the name of the outcome variable
- Description – a short description of the outcome variable
- Data collection – a short description of the search strategy
- Review – a detailed review of the outcome variable, including references
- References – a container field where PDF or other files can be linked to
- Comments (if needed) – special comments on the outcome variable
- Link to the database of references – slight differences between the number of references reported in Data collection and the number retrieved through the link may be due to delay in paper uploading in the PubMed database.

The methods of measurements were described in detail considering the following headings:

- Method – the name of the method
- Description – a short description of the method
- Review – a detailed review of the method, including references
- References – a container field where PDF or other files can be linked to
- Comments – special comments on the method

- Appropriateness (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Reliability (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Validity (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Responsiveness (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Precision (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Interpretability (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Acceptability (yes/no/not applicable) (Fitzpatrick et al., 1998)
- Feasibility (yes/no/not applicable) (Fitzpatrick et al., 1998)
• Gold-standard (yes/no but related to gold-standard/no/not applicable) (Atkinson et al., 2001; Weir & Walley, 2006)
• Field acceptance (yes/no /under development) (Atkinson et al., 2001; Weir & Walley, 2006)

Data on outcome variables and methods of measurements were entered into a 1-to-many (outcome-to-methods) database from which all reports and analyses were generated.

3. Assessment/Results

3.1. Reporting

During the 24 months of the project the following documents were drafted:

1. Interim Report N.1: this Report described the results of the work related to the block 1.
2. Interim Report N.2: this Report described the results of the work related to the block 2.
3. Interim Report N.3: this Report must describe the results of the work related to the block 3.
4. Miscellaneous report
5. Final Report, consisting of the 7 final reports (1A, 1B, 2A, 2B, 3A, 3B and Miscellaneous) (see Supplemental Files from 1 to 7)

All reports were written in English (UK Standard) and included a narrative part (condensed description of methodologies and outcomes plus a detailed section justifying the flow chart) and worksheets (annexes) focusing on the different outcomes and outcome measures.

In order to guarantee excellence of reporting, an international group of external peer-reviewers was involved to scrutinize the reports. The database was also made available to the peer reviewers. Distance meetings for peer review of the scientific output were organised.

3.2. Meetings

During the 24 months, six meetings were scheduled:

1. Kick off meeting, held at EFSA on January 9th, during which the interim and final reports structure and timeframe have been clarified.
2. Interim face-to-face meeting, held two weeks after the submission of the protocol and aimed to discuss the proposed protocol together with the experts involved in the assessment of health claims at EFSA. Date: March 26th 2015.
3. Interim face-to-face meeting N.1, held two weeks after the submission of the Interim report 1 (Block 1), in order to discuss the proposed documents. Date: September 10th 2015.
4. Interim face-to-face meeting N.2, held two weeks after the submission of the Interim report 2 (Block 2), in order to discuss the proposed documents. Date: April 11th 2016.
5. Interim face-to-face meeting N.3, held two weeks after the submission of the Interim report 3 (Block 3), in order to discuss the proposed documents. Date: September 20th 2016.
6. Final physical meeting held at EFSA with the purpose to discuss the draft final report.

Minutes of the meetings were written in English (UK Standard) and provided to EFSA.

3.3. Publications

Part of this work has been published in the form of independent papers, after authorization from EFSA, in:


4. Conclusions

The present document refers to the project GP/EFSA/NUTRI/2014/01 Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement. This document clearly outlines the methodology used to retrieve the data and for their critical appraisal, besides giving information about the scheduled meetings and reporting.

The project has been formulated in such a way to assure the excellent science output on scientific substantiation of health claims made on food (collection, collation and critical analysis of information in relation to claimed effects, outcome measures and methods of measurement).

The multidisciplinary expertise provided by the members of the project, together with the excellent range of services and strategic elements, guarantees the excellent level of scientific outputs.
References

