Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim

(Request N° EFSA-Q-2007-066)

(Adopted on 6 July 2007)

SUMMARY

The European Commission has requested the European Food Safety Authority (EFSA) to issue an opinion on scientific and technical guidance for the applications for authorisations of health claims under Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

The Scientific Panel on Dietetic Products, Nutrition and Allergies has prepared a draft Opinion which was published for public consultation. After considering all comments received, the Panel has adopted this Opinion.

This guidance applies to health claims related to the consumption of a food category, a food, or its constituents (including a nutrient or other substance, or a combination of nutrients/other substances); hereafter referred to as food/constituent**.**

The purpose of this guidance is to assist applicants in preparing and presenting their applications for authorisation of health claims which fall under Article 14 of the Regulation, i.e. reduction of disease risk claims and claims referring to children's development and health. This guidance will be updated at a later stage to cover applications for authorisation of the health claims which fall under Article 18 of the Regulation, i.e. applications for inclusion of health claims in the Community list of permitted claims provided for in Article 13(3) which are based on newly developed scientific evidence and/or which include a request for the protection of proprietary data. It is intended that the guidance will be kept under review and will be amended and updated as appropriate in the light of experience gained from evaluation of health claim applications.

The guidance presents a common format to assist the applicant in the preparation of a well-structured application. This will also help EFSA to deliver its scientific advice in an effective and consistent way.

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In accordance with the requirements of the Regulation, the application must contain:

(a) information on the characteristics of the food/constituent for which a health claim is made. Where applicable, this information should contain aspects considered pertinent to the claim, such as the composition, physical and chemical characteristics, manufacturing process, stability, and bioavailability.

(b) a proposal for the wording of the health claim, including, as appropriate, the specific conditions of use. The following should be specified, with a rationale: the target population for the intended health claim; where appropriate, a statement addressed to persons who should avoid using the food/constituent for which the health claim is made; 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; a warning for a food/constituent that is likely to present a health risk if consumed to excess; any other restrictions of use; directions for preparation and/or use.

The application must also contain all pertinent scientific data (published and unpublished, data in favour and not in favour) identified that form the basis for substantiation of the health claim. Data from studies in humans addressing the relationship between the consumption of the food/constituent and the claimed effect will be required for substantiation of a health claim; because of the scientific uncertainties in extrapolating non-human data to humans, data from studies in animals or model systems may be included only as supporting evidence, e.g. to explain the mechanism underlying the claimed effect of the food/constituent.

A comprehensive review of the data from human studies addressing the specific relationship between the food/constituent and the claimed effect is required. This review, and the identification of data considered pertinent to the claim, should be performed in a systematic and transparent manner in order to demonstrate that the application reflects adequately the balance of all the evidence available.

In cases where any of the required data does not apply for a particular application, reasons/justification must be given for the absence of such data in the application.

Guidance is provided for the presentation of summaries of the data from intervention studies and non-interventional studies in humans according to a hierarchy of study designs, reflecting the relative strength of evidence that may be obtained from different types of studies. Instructions are provided for presenting summaries of data from individual studies in humans so as to highlight the relevant aspects related to the design, results and quality of the studies.

As specified in the Regulation, health claims should be substantiated by taking into account the totality of the available scientific data and by weighing the evidence, subject to the specific conditions of use. In particular, the evidence should demonstrate the extent to which:

(a) the claimed effect of the food/constituent is relevant for human health,

(b) a cause and effect relationship is established between the consumption of the

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food/constituent and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

KEY WORDS

Health claims, Regulation, food/constituent, substantiation, human data, comprehensive review

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