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Organic foods and contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage: evaluation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006

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Abstract

Following an application from Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology, submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Cyprus, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to organic foods and contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage. The scope of the application was proposed to fall under a health claim referring to children's development and health. The food proposed by the applicant as the subject of the health claim is 'organic foods'. The applicant claimed that organic foods are characterised by their lower level of pesticides residues compared with foods not labelled as organic. The Panel notes, however, that in the application and the human studies submitted the nutritional composition and the pesticide concentration in 'organic food' are not reported. The Panel considers that organic foods which are the subject of the health claim, and the foods that they are intended to replace are not sufficiently characterised. Therefore, the Panel concludes that a cause and effect relationship cannot be established between the consumption of organic foods and contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage.

Keywords: organic foods, oxidative damage, pesticides, health claim

Requestor: Competent Authority of Cyprus following an application by Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology

Question number: EFSA-Q-2021-00055

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1924/2006 harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 14–17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to this Regulation, an application shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

1.2. Interpretation of the Terms of Reference

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: organic foods and contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage.

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of organic foods, a positive assessment of their safety, nor a decision on whether organic foods are, or are not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

2. Data and methodologies

2.1. Data

Information provided by the applicant

Food/constituent as stated by the applicant

According to the applicant, *'the food for which the health claim is made is organic foods. The product 'organic food' is defined and characterised by any food with at least 95% of their agricultural ingredients to be organic (Regulation No 834/2007; Regulation No 889/2008). Crops grown under an organic agricultural scheme do not use chemical pesticides by default, and thus, on average, produced organic foods have significantly lower pesticide residues levels than conventionally grown foods. Organic food is typically characterized by substantially lower pesticide residues levels when compared against conventional food items (non-organic)'.*

Health relationship as claimed by the applicant

According to the applicant, the health effect is related to *'contributes to the protection of body cell constituents from oxidative damage due to lipid-based oxidative damage and oxidative DNA damage'.*

Mechanism by which the food/constituent could exert the claimed effect as proposed by the applicant

The applicant claims that *'the direct prospective association between organic food consumption and the claimed beneficial effect on oxidative damage to lipids and DNA is coupled with evidence from a biologically intermediate layer, which is the body burden of pesticides (risk factor) that is temporally and biologically acting between organic food and the claimed effect'.*

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: *'Organic food (lower levels of pesticide residues than those in conventional food) contributes to the protection of body cells and molecules (lipids and DNA) from oxidative damage'.*

Specific conditions of use as proposed by the applicant

According to the applicant, the target population for the intended health claim are healthy children 3–15 years old. It is proposed that organic foods should be consumed in amounts that cover the total energy requirement of children for the particular age and sex group.

Data provided by the applicant

The health claim application on 'organic foods and contribute to the protection of body cells and molecules (lipids and DNA) from oxidative damage' pursuant to Article 14 of Regulation (EC) No 1924/2006, was presented in a common and structured format as outlined in the Scientific and technical guidance for the preparation and presentation of applications for authorisation of health claims (EFSA NDA Panel, 2017).

As outlined in the General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016), it is the responsibility of the applicant to provide the totality of the available evidence.

2.2. Methodologies

The general approach of the NDA Panel for the evaluation of health claim applications is outlined in EFSA's General guidance for stakeholders on health claim applications (EFSA NDA Panel, 2016). The scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health are outlined in a specific EFSA guidance (EFSA NDA Panel, 2018).

The application does not contain data claimed as proprietary and confidential.

3. Assessment

In assessing each specific food/health relationship, which forms the basis of a health claim the NDA Panel considers the following key criteria:

i) the food/constituent is defined and characterised;
ii) the claimed effect is based on the essentiality of a nutrient; OR the claimed effect is defined and is a beneficial physiological effect for the target population and can be measured in vivo in humans;
iii) a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Each of these three criteria needs to be assessed by the NDA Panel with a favourable outcome for a claim to be substantiated. In addition, an unfavourable outcome of the assessment of criterion (i) and/or (ii) precludes the scientific assessment of criterion (iii).

3.1. Characterisation of the food/constituent

The food/constituent proposed by the applicant as the subject of the health claim is 'organic food'.

The applicant refers to the definition of 'organic food' as specified in the EC Regulations No 834/2007[1] and 889/2008[2], which define organic food as 'any food with at least 95% of their agricultural ingredients to be organic'.[3] In response to EFSA's view that this definition does not provide any nutritional information on organic foods that could be used to characterise them for the purpose of the health claim substantiation, the applicant claimed that organic foods are characterised by their lower level of pesticide residues compared with foods not labelled as organic. The Panel notes, however, that the level of pesticide residues required to characterise foods as 'organic' has not been specified neither in the application nor in the human studies submitted for the substantiation of the health claim.

[1] Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32007R0834

[2] Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R0889

[3] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 that entered into force on 1 January 2021 does not contain a definition of 'organic foods' anymore, but a definition of 'organic product'. According to this Regulation, an 'organic product' means a product resulting from organic production, other than a product produced during the conversion period referred to in Article 10. The products of hunting or fishing of wild animals are not considered as organic products.

The Panel notes that the applicant proposes to distinguish the food/food category for which the claim is made from the food/food category that is intended to be replaced solely based on the consideration that organic foods would generally show not-further-specified lower concentrations of pesticide residues than foods that are not labelled as organic. The Panel also notes that, for example, some vitamins and essential minerals present in foods have a role in the function of enzymes belonging to the human antioxidant network which protects cells and molecules from oxidative damage (EFSA NDA Panel, 2018).[4] Therefore, the Panel considers that the foods/food category for which the claim is made and the foods/food category that intends to replace have not been characterised with respect to the levels of pesticide residues, and that the characterisation of such foods/food categories in relation to the claimed effect (i.e. protection of cells and molecules from oxidative damage) would require nutritional information that has not been provided in the application.

The Panel considers that organic foods, which are the subject of the health claim, and the foods that they are intended to replace, are not sufficiently characterised.

Therefore, the Panel concludes that a cause and effect relationship cannot be established between the consumption of organic foods and protection of body cells and molecules (lipids and DNA) from oxidative damage.

4. Conclusions

On the basis of the data presented, the Panel concludes that:

- the food/constituent, organic foods, which are the subject of the health claim, is not sufficiently characterised.
- a cause and effect relationship cannot be established between the consumption of organic foods and contribution to protection of body cells and molecules (lipids and DNA) from oxidative damage.

5. Documentation as provided to EFSA

Health claim application on 'organic foods' and 'contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage' pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0502_CY). Submitted by Cyprus Ministry of Health/Cyprus International Institute for Environmental and Public Health, Cyprus University of Technology 95, Irinis, Limassol, 3041, Cyprus.

Steps taken by EFSA

1) This application was received by EFSA on 23/12/2020.
2) The scope of the application was proposed to fall under a reduction of disease risk claims and claims referring to children's development and health.
3) The scientific evaluation procedure started on 7/4/2021.
4) On 15/4/2021, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The scientific evaluation was suspended on 5/5/2021 and was restarted on 5/6/2021, in compliance with Article 18(3) of Regulation (EC) No 1924/2006.
5) On 16/07/2021, Applicant's hearing was held via Web.
6) During its meeting on 14/9/2021, the NDA Panel, having evaluated the data, adopted an opinion on the scientific substantiation of a health claim related to the consumption of organic foods and contribution to the protection of body cells and molecules (lipids and DNA) from oxidative damage.

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[4] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2018.5136

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Abbreviations

DNA deoxyribonucleic acid
NDA Nutrition, Novel Foods and Food Allergens