

Panel members (21 experts from 11 EU MS)

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EFSA's scientific advice on scientific substantiation of health claims

European Food Saf

Function claims based on generally accepted scientific evidence (Art. 13)

• Disease risk reduction claims +claims for development & health of children (Art. 14)

• Function claims based on new science/proprietary data (Art. 13:5 and Art.18)

- **EFSA's scientific advice on nutrient profiles**
- **Dietary Reference Values for nutrients**

Criteria for evaluation of Art. 13.1. health claims by EFSA / NDA Panel

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

- the food/constituent is defined and characterised
- the claimed effect is defined and is a beneficial nutritional or physiological effect ("beneficial to human health")
- 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)
- and, if a cause and effect relationship is considered to be established, whether
- the quantity of food/pattern of consumption required to obtain the claimed effect can reasonably be consumed within a balanced diet
- the proposed wording reflects the scientific evidence
- the proposed wording complies with the criteria for the use of claims specified in the Regulation
- the proposed conditions/restrictions of use are appropriate.

Ref. EFSA Journal 2009; 7(11):1386

The outcome options of each assessment

The outcome of each assessment is one of three possible conclusions:

1. A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect.

This statement represents the best judgement of the NDA panel on whether a cause and effect relationship is established between consumption of the food/constituent and the claimed effect by the evidence provided (i.e. that the claim is substantiated by generally accepted scientific evidence).

2. The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect.

This statement represents the best judgement of the NDA panel that although there is scientific evidence supporting a cause and effect relationship, the evidence is not conclusive (i.e. that the claim is not substantiated by "generally accepted scientific evidence").

3. A cause and effect relationship is not established between the consumption of the food/constituent and the claimed effect.

The NDA panel considers that there is, at most, limited scientific evidence supporting a cause and effect relationship and the claim is not substantiated by "generally accepted scientific evidence".



Regulation (EC) No. 1924/2006: Article 13 Claims evaluation status

- Initially around 44 000 claims submitted by MS in 2007/2008
 After consolidation totally 4637 claims submitted by MS
 About 300 withdrawn later
- About 1000 claims now evaluated and published in opinions In two batches (July 2009 and February 2010)
- About 3300 claims still to be evaluated by end December 2011
- About 30 % of opinions positive, rest rejected for various reasons)

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Application submitted through Member State to EFSA EFSA validation of application

EFSA to inform other MS, EC, publish summary

EFSA evaluation - opinion (5 months) additional time (2 months) if supplementary information needed

EFSA Opinion published, sent to EC 30 days for comment to EC

Community authorisation (2 months) EC adopts decision through Regulatory Committee, EP scrutiny? Decision is notified to applicant and published in OJ



Regulation (EC) No. 1924/2006: Article 14 Claims evaluation status

Children: 219 received, 48 opinions adopted covering 55 applications

Disease risk reduction: 48 received, 15 adopted

New science /proprietary knowledge: 36 received, 15 adopted

 TOTAL: 303 received, 43 withdrawn, 78 opinions adopted covering 85 applications, 19 in progress



THE SETTING OF NUTRIENT PROFILES FOR FOODS BEARING NUTRITION AND HEALTH CLAIMS PURSUANT TO ARTICLE 4 OF THE REGULATION (EC) ° No 1924/2006

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies (Request N° EFSA-Q-2007-058)

Adopted on 31 January 2008

Published on 28 February 2008

The EFSA Journal (2008) 644, 1-44

EVIRAN Tiedote

28.02.2008

EFSAlta suositus ravintosisältöprofiileiden asettamisesta elintarvikkeille

Ravintosisältöprofiloinnilla tarkoitetaan elintarvikkeiden luokittelua niiden ravitsemuksellisen koostumuksen mukaan. Luokittelua tarvitaan, koska tulevaisuudessa vain sellaisille elintarvikkeille saa esittää ravitsemus- ja terveysväitteitä, jotka täyttävät ravintosisältöprofiileille asetetut kriteerit.

EFSAn mukaan ravintosisältöprofiiliin tulisi valita sellaiset keskeiset ravintoaineet, joilla on kansanterveydellistä merkitystä eurooppalaiselle väestölle. Tällaisia ravintoaineita ovat tyydyttynyt rasva, natrium, ravintokuitu ja tyydyttymätön rasva, joiden saanti ei yleensä vastaa ravitsemussuosituksia. Joidenkin elintarvikeryhmien osalta myös transrasvahapot, kokonaissokeripitoisuus, energiatiheys ja kokonaisrasvapitoisuus pitäisi huomioida.

Dietary Reference Values DRV

New opinions on Dietary Reference Values (DRV) are being established. DRVs are authoritative, quantitative estimates of human requirements for essential nutrients, usually set out with different amounts (in weight/day) considered to be adequate to meet the known nutrient needs. For some nutrients, instead of DRVs, Dietary Guidelines are given.

Dietary Guidelines differ from DRVs in that the advice is more

provisional, being based on a variety of information, including indirect evidence about the complex relationships of food components with health and disease (WHO, 1998).

DRV Dietary Reference Value

SCIENTIFIC REPORT OF EFSA

Outcome of the Public consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, *trans* fatty acids, and cholesterol [1]

[1] On request from EFSA, Question No EFSA-Q-2009-00784, issued on 04 December 2009.

EFSA Journal 2010; 8(3):1507

SCIENTIFIC OPINION

Scientific Opinion on Dietary Reference Values for carbohydrates and dietary fibre[1]

EFSA Panel on Dietetic products, Nutrition, and Allergies (NDA)[2], [3]

[1] On request from the European Commission, Question No EFSA-Q-2008-467, adopted on 04 December 2009.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen.

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[3] Acknowledgement: The Panel wishes to thank for the preparation of this opinion: Nils-Georg Asp, Wulf Becker, Henk van den Berg, Karin Hulshof, etc

DRV Dietary Reference Value

SCIENTIFIC OPINION

Scientific Opinion on Dietary reference values for water[1]

[1] On request from the European Commission, Question No EFSA-Q-2008-464, adopted on 04 December 2009.

EFSA Journal 2010; 8(2):xxxx

DRV Dietary Reference Value

SCIENTIFIC REPORT OF EFSA

Outcome of the Public Consultation on the Draft Opinion of the Scientific Panel on Dietetic Products, Nutrition, and Allergies (NDA) on establishing Food-Based Dietary Guidelines.

The European Commission requested the European Food Safety Authority (EFSA) to provide guidance on the translation of nutrient based dietary advice into guidance, intended for the European population as a whole, on the contribution of different foods or food groups to an overall diet that would help to maintain good health through optimal nutrition (food-based dietary guidelines).

FBDG constitute science-based policy recommendations in the form

guidelines for healthy eating.

EFSA Journal 2010; 8(3):1506