

# Assessing health claims for food stuffs

-  
*what and how?*

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# Outline

***1. Introduction***

***2. Definition and general principles***

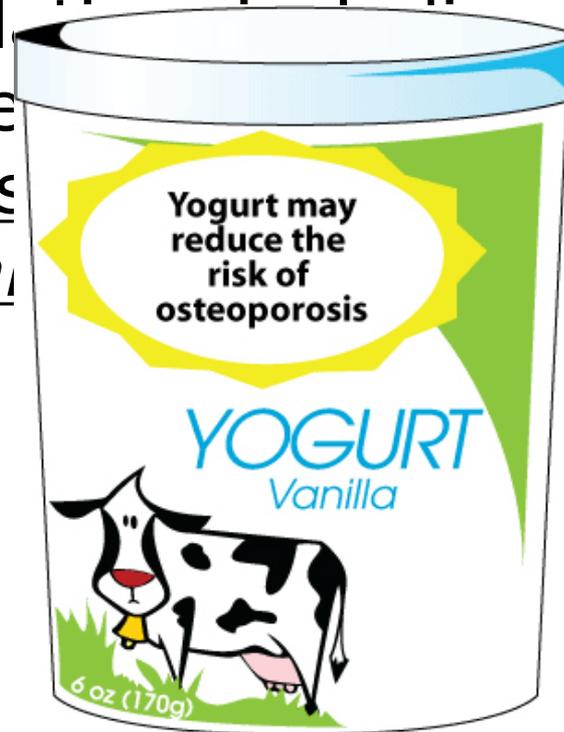
***3. Main issues addressed in the  
scientific assessment***

***4. Cases***

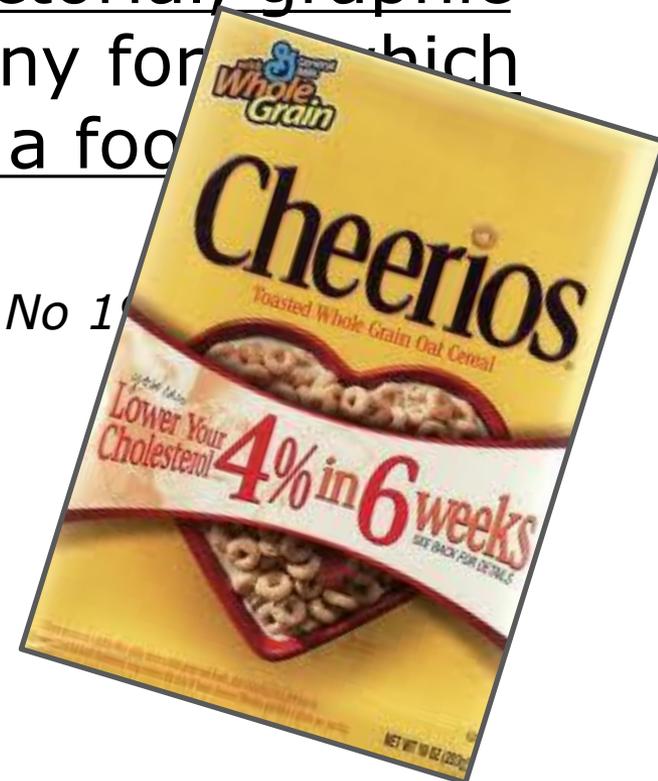
***5. Summary***

# What is a Claim?

“a claim means any message or statement, which is not mandatory under national legislation or symbolic regulation or national legislation, which is pictorial, graphic or any form which states, suggests or implies a particular characteristic of a food or food product.”



(C) No 1





**Health claims  
should be  
substantiated**

**consumers**

**scientists**

**authorities**

**industry**



# EU Regulation 1924/2006 on nutrition and health claim



18.1.2007

EN

Official Journal of the European Union

L 12/3

## CORRIGENDA

Corrigendum to 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

*(Official Journal of the European Union L 404 of 30 December 2006)*

**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**  
**of 20 December 2006**  
**on nutrition and health claims made on foods**

# Scientific criteria for the evaluation of health claims

*Regulation (EC) No 1924/2006:*

Health claims to be substantiated by:

- **“generally accepted scientific evidence”**
  - **“taking into account the totality of the available scientific data, and by weighing the evidence”**
- The NDA Panel makes a judgement on whether there is sufficient scientific evidence to support the claim



# General principles for health claims

## Claims must **not**:

- *be false, ambiguous or misleading!*
- *give rise to doubt about the safety and/or the nutritional adequacy of other foods!*
- *encourage excess consumption!*
- *state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general!*



# EU Regulation 1924/2006



## What it contains

### Nutrition claims

- Content claims
- Comparative claims

## What it does

### Health claims

Function claims

Based on generally accepted scientific data

Based on newly developed scientific data

Reduction of disease risk claims + claims growth and development of children

Art.13.1

Art.13.5

Article 14

# Main issues addressed by the NDA Panel in the scientific assessment

*The Panel considers the extent to which:*

- 1) The food/constituent is defined and characterised

## ***To what extent should a food/constituent be characterised?***

- Clearly defined and measurable
- Substantiation of the claim should be based on studies performed with the particular constituent
- For plant products, the scientific name, the part and the preparation used should be characterised
- For microorganisms (e.g. bacteria, yeast): species identification: genetic typing and internationally accepted molecular methods and naming of strains according to the International Code of Nomenclature
- For manufacturing processes, information should be provided to show consistency

# Main issues addressed by the NDA Panel in the scientific assessment

*The Panel considers the extent to which:*

- 1) The food/constituent is defined and characterised
- 2) The claimed effect is defined
- 3) The claimed effect is a beneficial physiological effect (“beneficial to human health”)

# ***How should the claimed effect be shown to be beneficial?***

- Scientific judgement
- For function claims, a beneficial effect may relate to maintenance or improvement of a function
- For reduction of disease risk claims, 'beneficial' refers to whether the claimed effect relates to the reduction of a risk factor for the development of a human disease

# Main issues addressed by the NDA Panel in the scientific assessment

*The Panel considers the extent to which:*

- 1) The food/constituent is defined and characterised
- 2) The claimed effect is defined
- 3) The claimed effect is a beneficial physiological effect (“beneficial to human health”)
- 4) 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*)

# Other issues addressed by the NDA Panel in the scientific assessment

## *Considerations on the substantiation*

- The totality of the available scientific data!
- Whether the studies are pertinent to the claim!
- How should the claimed effect be shown to be beneficial – considerations of target group?
- What are relevant risk factors for the development of a human disease?
- How to propose wordings of health claims?

# Outcomes of a scientific assessment?

- 1) A cause and effect relationship has been established between the consumption of the food/constituent and the claimed effect
- 2) The evidence provided is insufficient to establish a cause and effect relationship between the consumption of the food/constituent and the claimed effect
- 3) A cause and effect relationship has not been established between the consumption of the food/constituent and the claimed effect

# Cases



# Art. 14 claim - Plant sterols and effect on blood cholesterol



- Constituent well defined ⇒ sufficiently characterised
- Claimed effect: lower/reduce blood cholesterol and reduce the risk of (coronary) heart disease ⇒ considered beneficial to human health
- Studies (meta-analyses) with the constituent in several food matrices, in the target population, concerning the LDL-cholesterol lowering effect show consistent results, dose-response ⇒ cause-effect relationship established
- Wording reflecting the available scientific evidence: ‘Plant sterols have been shown to reduce blood cholesterol. Blood cholesterol lowering may reduce **the risk of coronary heart disease**’

# Art. 13(1) claim – Rye fibre and changes in bowel function, and others ....



- Constituent well defined ⇒ sufficiently characterised
- Claimed effects: 'gut health' ⇒ assumed that the claimed effect refers to changes in bowel function ⇒ considered beneficial to human health
- 4 human intervention studies showed consistently an effect on bowel function and the mechanism is known ⇒ cause-effect relationship established
- Wording reflecting the available scientific evidence: 'Rye fibre contributes to normal bowel function'. To bear the claim a food should be at least 'high in fibre'

# Art. 13(1) claim – Rye bread and carbohydrate metabolism and insulin sensitivity

- Rye bread comprises bread made exclusively from rye flour or from a mix of rye and other components. From the references provided, it is not possible to characterise the food ⇒ not sufficiently characterised
- The Panel concludes ⇒ cause-effect relationship not established



# Art. 14 claim – Kinder Chocolate® and growth

- Chocolate bar - ⇒ sufficiently characterised
- Claimed effect: chocolate product 'helps to grow' (target population is children) ⇒ normal growth is considered beneficial to children
- 39 publications considered by the applicant (abdominal symptoms in lactose intolerant subjects, calcium absorption, energy balance, interaction of some vitamins and minerals, studies in young adults) ⇒ studies not performed in target population, biomarkers/endpoints not related to growth, so cause-effect relationship not established



## SCIENTIFIC OPINION

### **Scientific Opinion on the substantiation of a health claim related to 3 g/day plant stanols as plant stanol esters and lowering blood LDL-cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006<sup>1</sup>**

**EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

#### **ABSTRACT**

Following an application from Raisio Nutrition Ltd, submitted pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of Finland, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver an opinion on the scientific substantiation of a health claim related to 3 g/day plant stanols as plant stanol esters per day and lowering blood LDL-cholesterol by 12 % and reduced risk of (coronary) heart disease. The applicant has further requested that the minimum duration to obtain the effect be stated to be one to two weeks, and that the claims be authorised for an extended range of foods, including yellow fat spreads, dairy products, cheese, rye bread, oatmeal,



# HEALTH AND CONSUMERS

## Food

EUROPA > European Commission > DGs > Health and Consumers > Food and Feed Safety

Food Law | Animal Nutrition | Labelling & Nutrition | Biotechnology | Novel Food | Chemical Safety | Biological Safety | Official Controls | Sustainability | Food Improvement Agents

Health & Nutrition Claims

### EU Register on nutrition and health claims

<http://ec.europa.eu/nuhclaims/>

Health claims  
Nutrition claims

Commissioner Dalli

Search the register

<b>Claim status:</b>	<b>Type of claim:</b>	<b>EFSA Opinion reference:</b>
<input type="text" value="All"/>	<input type="text" value="All"/>	<input type="text" value="All"/>

**Legislation:**

**Search:**



