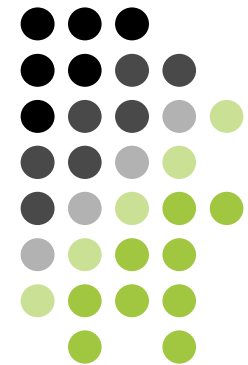


Training on Food Products with nutritional and health claims

BECICI, 12th October 2009

European regulation on nutrition and health claims: How it works?

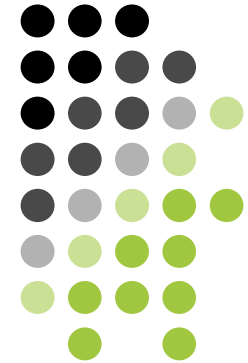


Julie Mardon

Enita Clermont, France



The Regulation N° 1924/2006



18.1.2007

EN

Official Journal of the European Union

L 12/3

CORRIGENDA

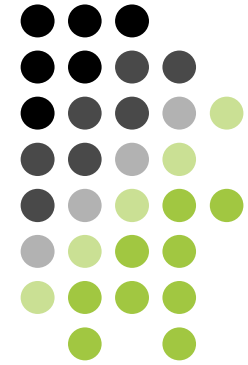
Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

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

Regulation (EC) No 1924/2006 should read as follows:

**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**

Why a regulation on claims in the EU?



- To achieve a high level of consumer protection
- To improve the free movement of goods within the internal market
- To increase legal security for economic operators
- To ensure fair competition in the area of foods
- To promote and protect innovation in the area of foods



EFSA's task under regulation



**Committed to ensuring
that Europe's food is safe**

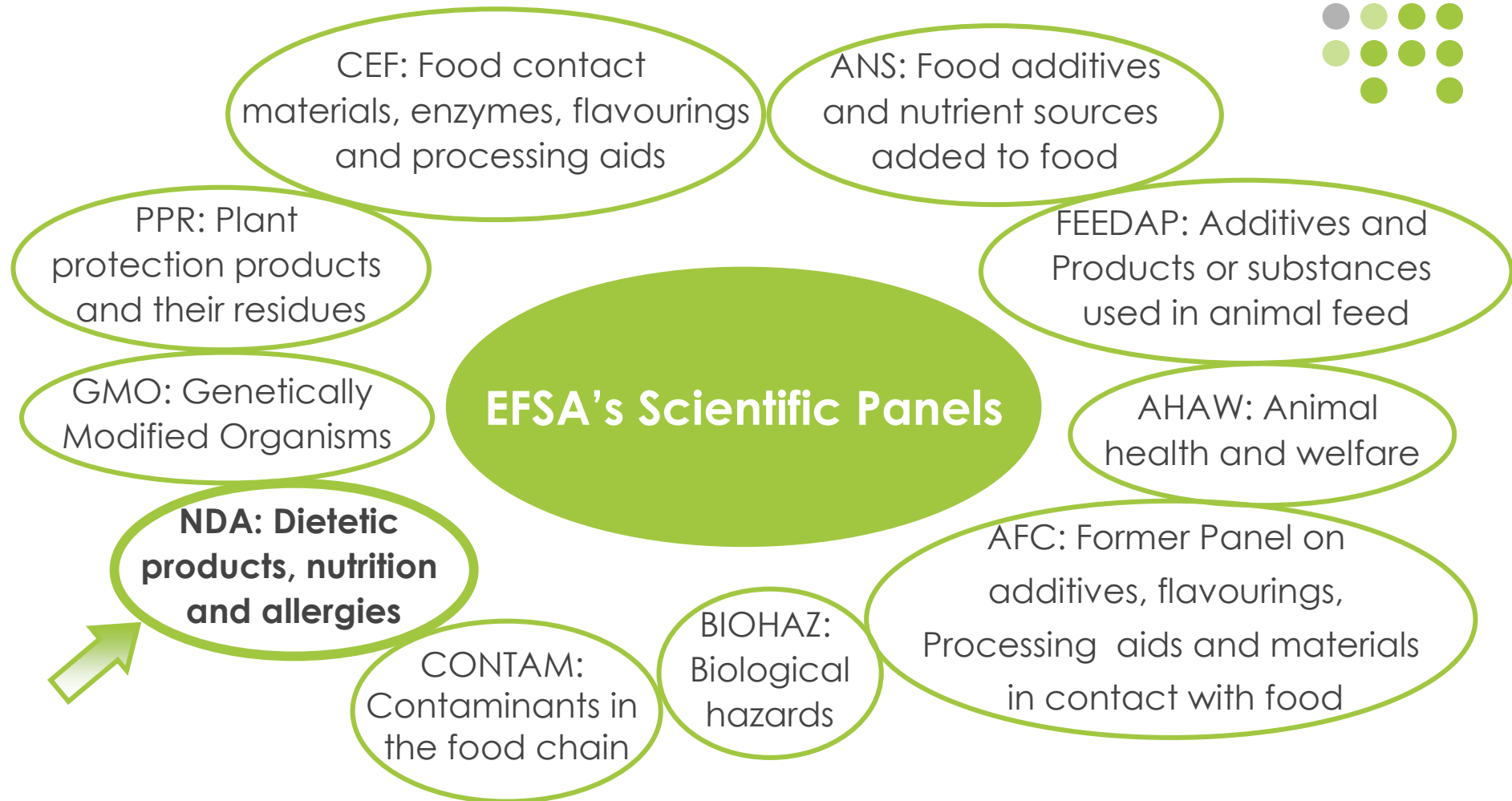
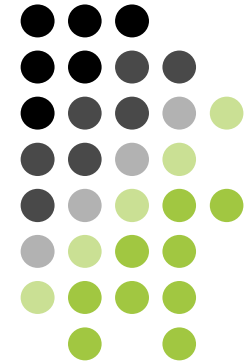
The European Food Safety Authority
is the keystone of European Union
risk assessment regarding food and
feed safety.

In close collaboration with national
authorities and in open consultation
with its stakeholders, EFSA provides
independent scientific advice and
clear communication on existing
and emerging risks.



The EFSA logo is located in the bottom left corner of the orange box. It features a white square containing a blue arc of stars, the word "efsa" in blue lowercase letters, and a small European Union flag icon. Below the square, the text "European Food Safety Authority" is written in blue.

EFSA's task under regulation

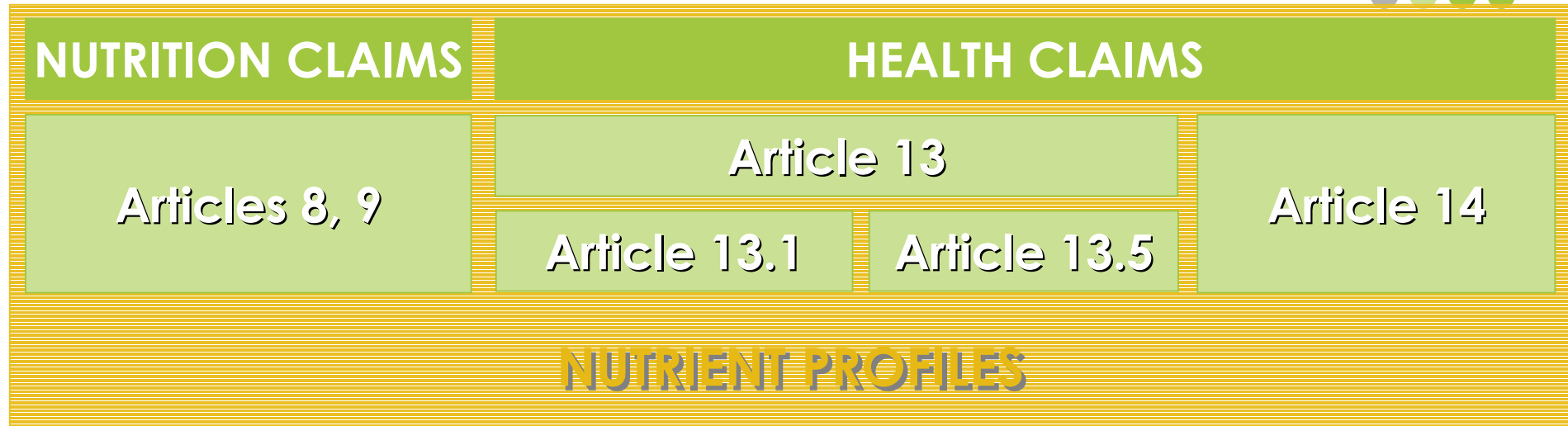




EFSA's task under regulation

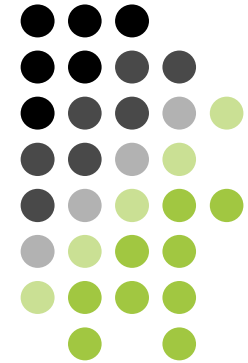
- 1. To give scientific advice on nutrient profiles
- 2. To give advice on establishing a positive list of permitted health claims
- 3. To give an opinion on individual applications for health claims
- 4. To provide guidance on the preparation of applications for the authorisation of health claims

1. Nutrient profiles



- What are nutrient profiles ?
 - » *Nutrient profiles will determine whether foods are eligible or not to bear claims, on the basis of their nutrient composition. Nutrient profiles will be based primarily on the levels of nutrients for which excessive intakes in the overall diet are not recommended (article 4).*

1. Nutrient profiles



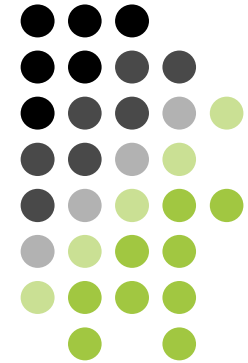
» *Main objective :*



» *The setting of nutrient profiles is a complex exercise that needs to take into account:*

- *dietary recommendations, public health considerations, and generally acceptable scientific evidence regarding the relationship between diet, nutrition and health.*
- *industrial/commercial considerations (innovation, cultural and dietary/culinary considerations).*

1. Nutrient profiles



■ Main outcomes :

- » A nutrient profile for food in general with exemptions from the general profile for a limited number of food groups.
- » Exemptions based on the use of different nutrients, thresholds or scores.
- » Choice of nutrients to be included in nutrient profiles:
 - saturated fatty acids
 - sodium
 - dietary fibre (for particular food groups)
 - unsaturated fatty acids,
 - total sugar content (for particular food groups)

1. Nutrient profiles



COMMUNIQUE DE PRESSE
PRESS RELEASE

Contact: Ruth Veale, Astrid Salcedo
Date: 17/03/2009
Reference: PR 011/2009

Nutrient profiles:
Commission puts industry interests before public health

EUROPEAN DAIRY ASSOCIATION
ASSOCIATION LAITIÈRE EUROPÉENNE
EUROPÄISCHER MILCHINDUSTRIEVERBAND

PRESS INFORMATION

Adoption of nutrient profiles delayed

high in fat, salt or
aggerated claims that
have positive impact

Nutrient Profiles Debate: EU dairy industry wants adequate criteria for setting nutrient profiles

European Dairy Association (EDA) supports EFSA's opinion to introduce separate categories for natural products, asks for adequate criteria for setting nutrient profiles and opposes firmly to the inclusion of imitation products in these categories.

Brussels, 9 March 2009

Within the context of the Commission's Regulation on Nutrient Profiles, the EDA calls for the application of adequate

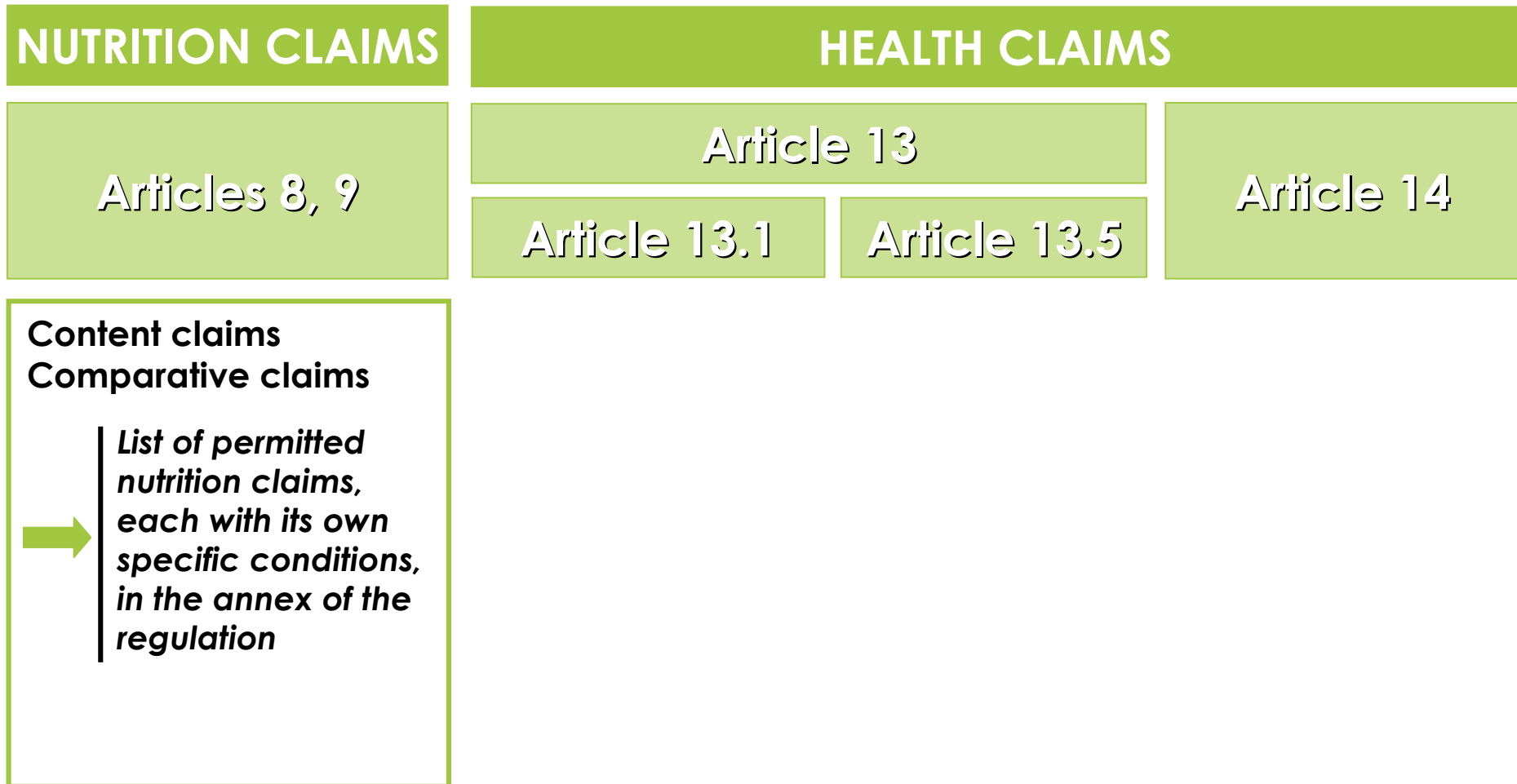
EUROPEAN BASIC
FOODS PLATFORM

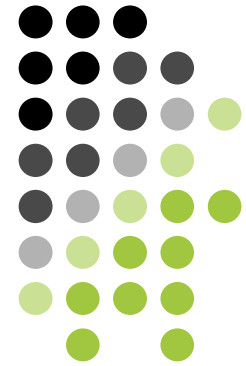
EBFP POSITION ON NUTRIENT PROFILES FOR THE CATEGORY "FATS AND OILS"

European Basic Foods Platform, representing the basic foods sector (e.g. vegetable oil, margarine, butter, cheese), would like to comment on the new threshold on saturated fatty acids for the category "fats and oils" suggested by the European Commission in its draft Regulation establishing nutrient profiles provided for in Article 4(1) of Regulation (EC) No 1924/2006, as submitted to inter-service consultation, namely 30kcal/100kcal.

As shown in the graph below resulting from the simulation on the Commission Food Basket, the threshold of 30 g saturated fatty acids/100 g product previously proposed by

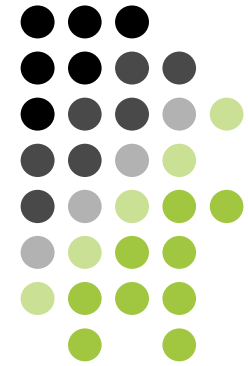
2. Nutrition claims





2. Nutrition claims

- What is a nutrition claim ?
 - » *Any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:*
 - *(a) the energy (calorific value) it*
 - (i) provides;*
 - (ii) provides at a reduced or increased rate; or*
 - (iii) does not provide; and/or*
 - *(b) the nutrients or other substances it*
 - (i) contains;*
 - (ii) contains in reduced or increased proportions; or*
 - (iii) does not contain;*



2. Nutrition claims

- » LOW ENERGY
- » ENERGY-REDUCED
- » ENERGY-FREE
- » LOW FAT
- » FAT-FREE
- » LOW SATURATED FAT
- » SATURATED FAT-FREE
- » LOW SUGARS
- » SUGARS-FREE
- » WITH NO ADDED SUGARS
- » LOW SODIUM/SALT
- » VERY LOW SODIUM/SALT
- » SODIUM-FREE or SALT-FREE
- » SOURCE OF FIBRE
- » HIGH FIBRE
- » SOURCE OF PROTEIN
- » HIGH PROTEIN
- » SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]
- » HIGH [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S]
- » CONTAINS [NAME OF THE NUTRIENT OR OTHER SUBSTANCE]
- » INCREASED [NAME OF THE NUTRIENT]
- » REDUCED [NAME OF THE NUTRIENT]
- » LIGHT/LITE
- » NATURALLY/NATURAL

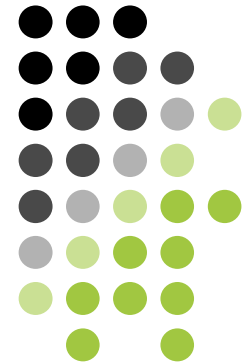
Condition of use :

« A claim that a food is high in fibre, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal. »

3. General function health claims



NUTRITION CLAIMS	HEALTH CLAIMS		
Articles 8, 9	Article 13		Article 14
<p>Content claims Comparative claims</p> <p>→ <i>List of permitted nutrition claims, each with its own specific conditions, in the annex of the regulation</i></p>	Article 13.1	Article 13.5	
	<p>Based on generally accepted scientific evidence</p> <p>→ <i>List of permitted claims, and all necessary conditions for their use provided by the Commission by 31 January 2010</i></p>	<p>Based on newly developed scientific evidence and/or requesting protection of proprietary data</p>	



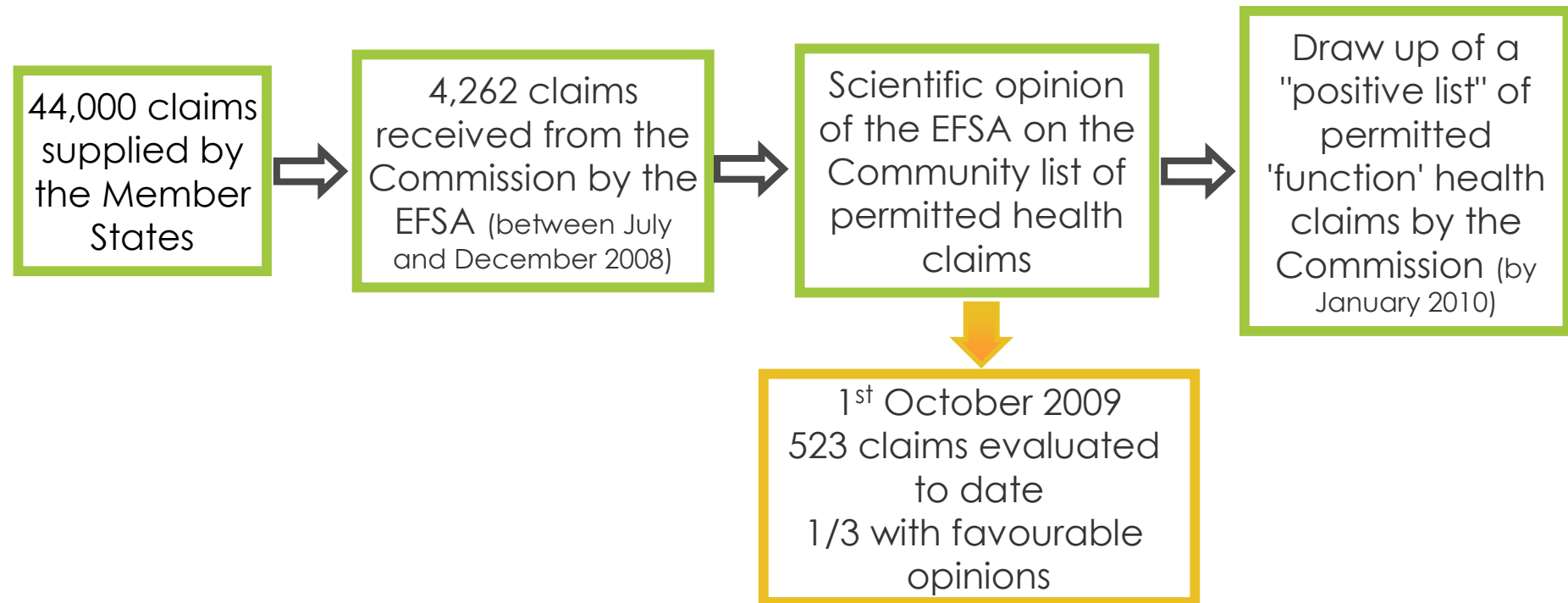
3. General function health claims

- What is a health claim ?
 - » *Any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.*
 - *Reduction of disease risk claims : any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.*
 - *Claims refering to children's development or health.*
 - *“General Function” health claims based on generally accepted scientific evidence.*



3. General function health claims

- A consolidated list of functional claims is currently being evaluated by EFSA . The European Commission will then draw up an EU-wide list of permitted function health claims by January 2010.





3. General function health claims

- Examples:

ID 2013: “Cinnamomum cassia, zeylanicum (Common Name : Cinnamon)” and “Glucose metabolism”

1 Anderson RA, Broadhurst CL, Polansky MM, Schmidt WF, Khan A, Flanagan VP, Schoene NW, Graves DJ, 2004. Isolation and characterization of polyphenol type-A polymers from cinnamon with insulin-like biological activity. *J Agric Food Chem*, 52, 65-70.

2 Anderson RA, *the Nutrition*

3 Bentley R and *plants employ products of m*

4 Berrio LF, Po *Brewer's yeast*

5 Broadhurst C

ID 2259: “Fucus vesiculosus” and “Thyroide function and production of hormone, energy metabolism”

1 BHMA (British Herbal Medicine Association), 1996. British Herbal Pharmacopoeia. British Herbal Medicine Association, Exeter.

2 Blaschek W, Ebel S, Hackenthal E, Holzgrabe U, Keller K, Reichling J, 2003. HagerROM 2003. Hagers Handbuch der Drogen und Arzneistoffe. Springer Verlag, Heidelberg.

3 Bra

4 Mon

5 Wic Ed.

ID 2892: “Conjugated Linoleic acid (cis-9, trans-11 and trans-10, cis-12)” and “weight management, fat metabolism enhancement”

1 Atkinson R, 1999. Clinical implications for conjugated linoleic acid (CLA) in the treatment of obesity. *Lipidforum*, the 21st Symposium, Kolding, Danmark.

2 Berven G, Bye A, Hals O, Blankson H, Fagertun H, Thom E, Wadstein J, Gudmundsen O, 2000. Safety of conjugated linoleic acid (CLA) in overweight or obese human volunteers. *Eur J Lipid Sci Technol*, 102, 455-462.

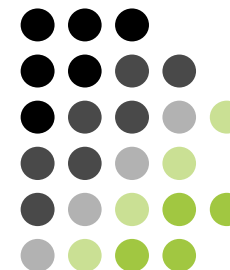
3 Blankson H, Stakkestad JA, Fagertun H, Thom E, Wadstein J, Gudmundsen O, 2000. Conjugated linoleic acid reduces body fat mass in overweight and obese humans. *J Nutr*, 130, 2943-2948.



3. General function health claims

<i>Food or nutrient</i>	<i>Health claim</i>	<i>Opinion of the panel</i>
Vitamin K	<ul style="list-style-type: none">▪ maintenance of bone▪ blood coagulation▪ function of the heart and blood vessels	YES YES NO
Taurine	<ul style="list-style-type: none">▪ protection of DNA, proteins and lipids from oxidative damage▪ energy-yielding metabolism▪ delay in the onset of fatigue and enhancement of physical performance	NO NO NO

4. Specific health claims



NUTRITION CLAIMS	HEALTH CLAIMS		
Articles 8, 9	Article 13		Article 14
<p>Content claims Comparative claims</p> <p>→ <i>List of permitted nutrition claims, each with its own specific conditions, in the annex of the regulation</i></p>	Article 13.1	Article 13.5	<p>Reduction of disease risk claims and claims referring to children's development and health</p>
	<p>Based on generally accepted scientific evidence</p> <p>→ <i>List of permitted claims, and all necessary conditions for their use provided by the Commission by 31 January 2010</i></p>	<p>Based on newly developed scientific evidence and/or requesting protection of proprietary data</p>	



4. Specific health claims



- Claims under article 14 (reduction of disease risk or to children's development or health).

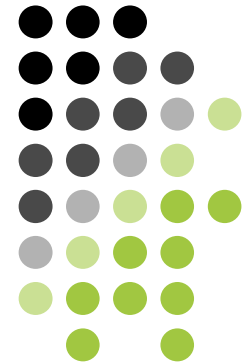




4. Specific health claims

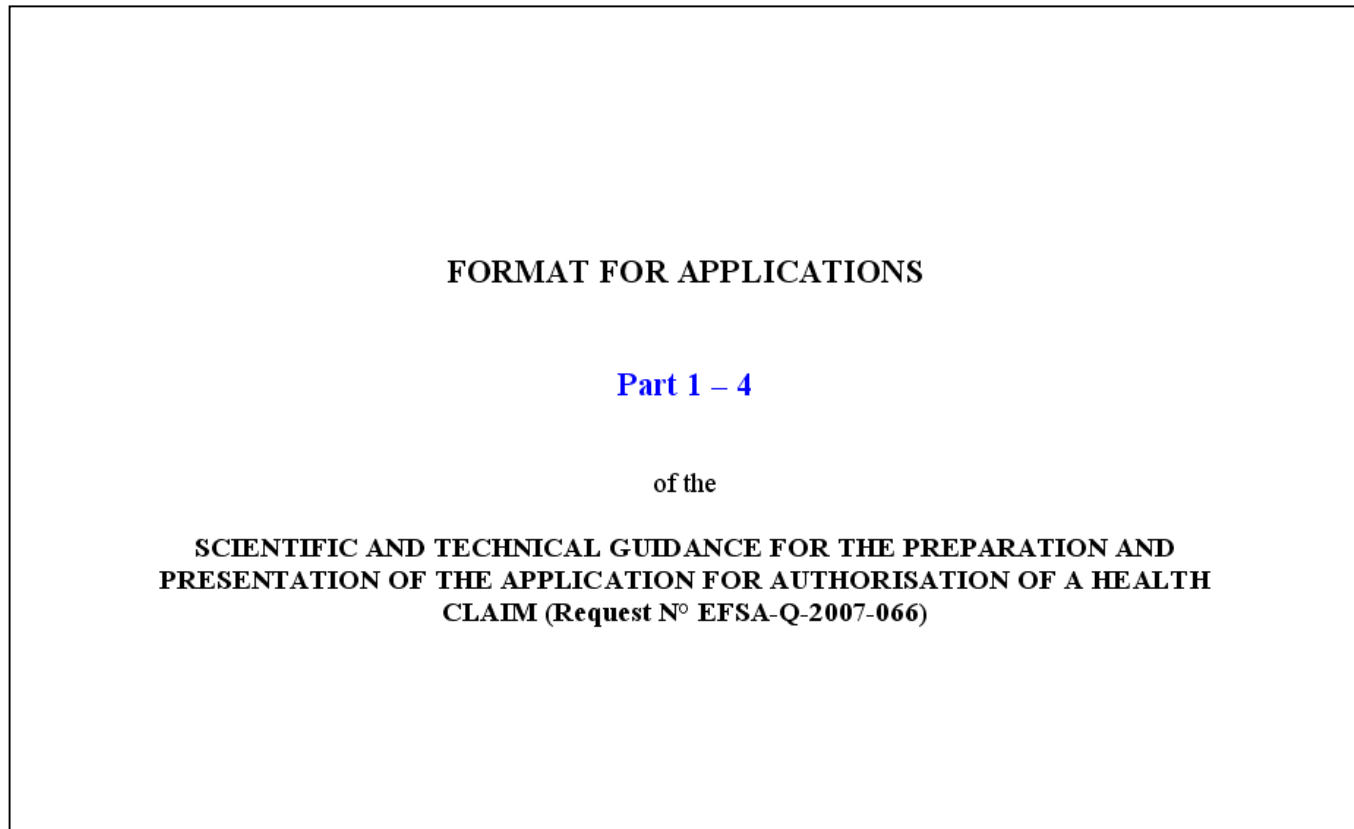
- Examples of favourable opinions:

	Proposed wording of the claim	Target population	Conditions of use	Wording approved by the EFSA
Unilever 	"Plant sterols and lowering/reducing blood cholesterol and reducing the risk of coronary heart disease"	people who need and want to lower their blood cholesterol	2 g of plant sterols added to fat-based food formats and low-fat foods	"Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease".
Abtei Pharma Vertriebs GmbH 	Calcium + Vitamin D3 chewing tablets improve bone density and reduce the risk of osteoporotic fracture.	women 50 years and older	1000 mg of Ca and 20 µg of vit D. Information provided was found insufficient to establish conditions of use for the claim.	"Calcium may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures" AND "Calcium and vitamin D may reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor in the development of osteoporotic bone fractures".



4. Specific health claims

- Guidelines

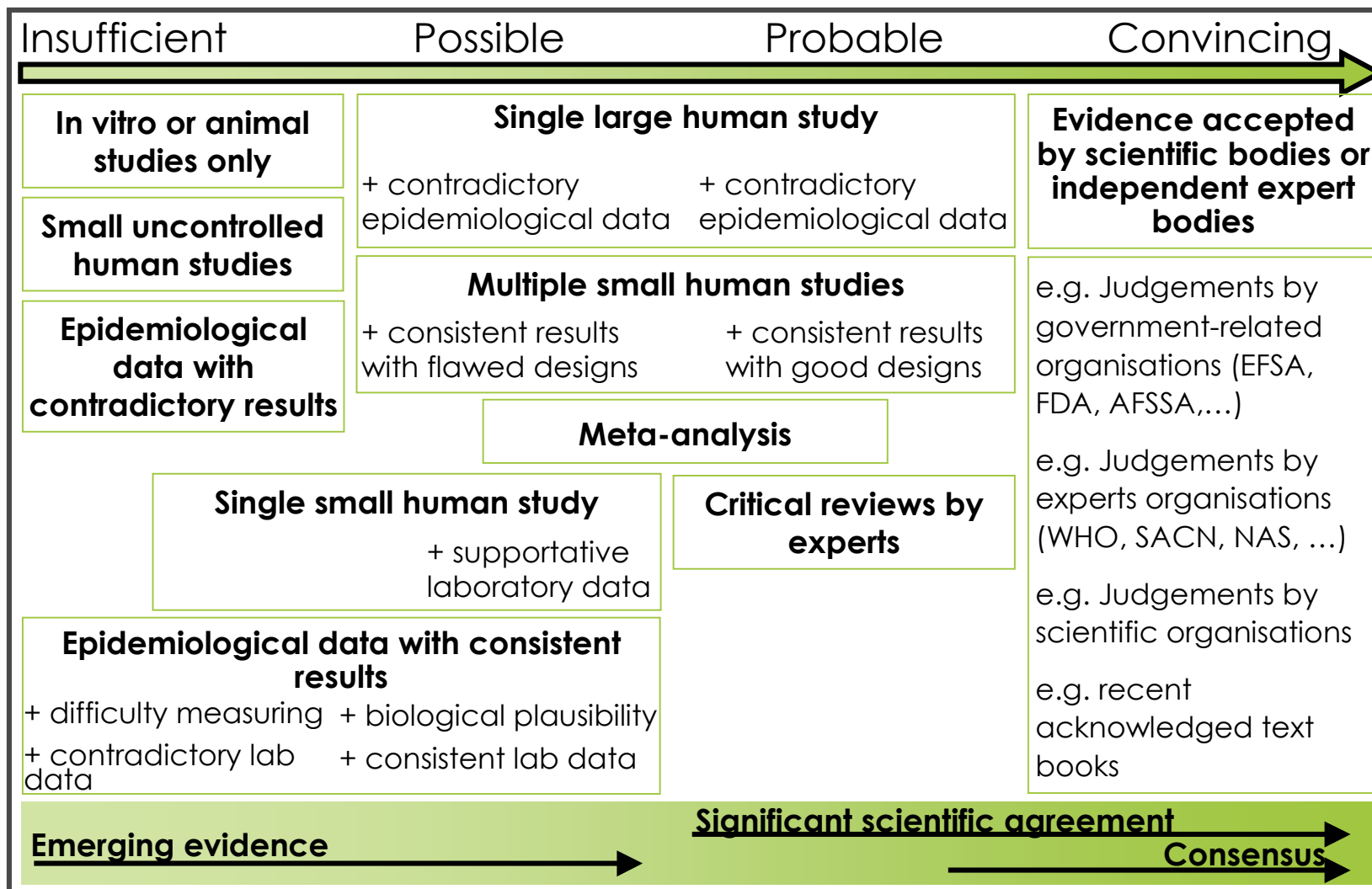




4. Specific health claims

- Main content of the dossier
 - » Food/constituent for which a health claim is made
 - » Relationship between the food/constituent and the claimed effect
 - » Proposal for the wording of the health claim for which autorisation is sought
 - » Specific conditions of use
 - Target population
 - Quantity of the food/constituent required
 - » Food/constituent characteristics
 - Manufacturing process
 - Stability information
 - Bioavailability data
 - » Body of pertinent scientific data identified
 - » Summary of pertinent scientific data

4. Specific health claims



(Richardson, 2003)



4. Specific health claims

- Main steps for pertinent scientific data identification

Search of scientific data
Example : database consultation (Medline) + available unpublished documents ?



Determination of suitable keywords combination
Example : (calcium OR vitamin D) AND supplementation AND bone AND post menopausal women) → 516 references



NCBI PubMed A service of the U.S. National Library of Medicine and the National Institutes of Health www.pubmed.gov

Search PubMed for (calcium OR vitamin D) AND supplementation AND bone AND post menopausal women

Display Summary Show 20 Sort By Send to

All: 516 Free Full Text: 98 Review: 149

Items 1 - 20 of 516 Page 1 of 26 Next

- 1: [Minimum Required Vitamin D Level for Optimal Increase in Bone Mineral Density with Alendronate Treatment in Osteoporotic Women](#)
Ishijima M, Sakamoto Y, Yamanaka M, Tokita A, Kitahara K, Kaneko H, Kurosawa H. *Calcif Tissue Int*. 2009 Oct 1. [Epub ahead of print] PMID: 19795092 [PubMed - as supplied by publisher] [Related Articles](#)
- 2: [Vitamin K in postmenopausal women with osteopenia](#)
Rennenberg RJ, Schurgers LJ, Vermeer C. *Ned Tijdschr Geneeskd*. 2009;153. pii: Ned Tijdschr geneesk. 2009;153:A340. Dutch. PMID: 19785816 [PubMed - in process] [Related Articles](#)
- 3: [Soy isoflavone supplementation and bone mineral density in menopausal women: a 2-y multicenter clinical trial](#)
Wong WW, Lewis RD, Steinberg FM, Murray MJ, Cramer MA, Amato P, Young RL, Barnes S, Ellis KJ, Shypailo RJ, Fraley JK, Konzelmann KL, Fischer JG, Smith EO.

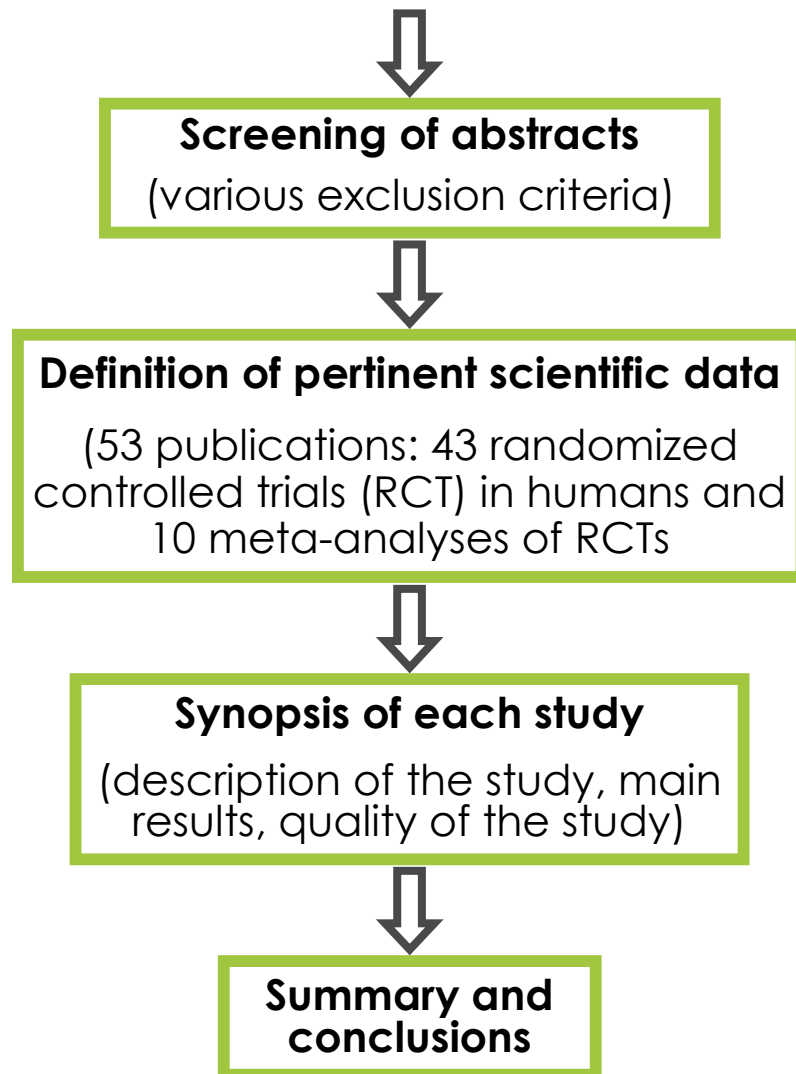
Titles with your search terms

- ▶ WITHDRAWN: Calcium supplementation on bone [Cochrane Database Syst Rev. 2007]
- ▶ Calcium supplementation on bone loss in postmenopausal women [Cochrane Database Syst Rev. 2004]
- ▶ A controlled trial of the effect of calcium supplementation on bone mineral density in postmenopausal women [N Engl J Med. 1990]

» See more...



4. Specific health claims



Points to consider in determining whether a study is pertinent to the claim:

Does the study address the food constituent that has been characterised in the application?

Does the study address endpoints that are relevant to the health relationship as defined in the application?

Is the study in the target population as indicated in the application or could it be extrapolated to the target population?

Is the dosage and/or food matrix relevant to the proposed condition of use as defined in the application?

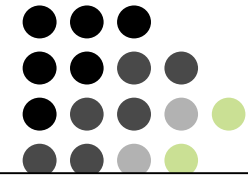


4. Specific health claims

- EFSA health claims evaluation status (11 June 2009)

Claim type	Received	Withdrawn	Adopted	In progress
New science / proprietary (Art. 13.5)	20	6	11	3
Disease risk reduction (Art. 14)	38	1	9	5
Children (Art. 14)	215	15	43 opinions covering 50 applications	4
TOTAL	273	22	63 opinions covering 70 applications	12

(Flynn, 2009)



4. Specific health claims

FOOD
navigator.com

Breaking News on Food & Beverage

GUEST ARTICLE

EFSA's harsh health claim regime

By Lorène Courrège, 30-Sep-2008

NUTRA
ingredients.com

Breaking News on Supplements & Nutrition - Europe

SPECIAL EDITION: MARKET INSIGHTS

F&S: The danger of overstepping health claim boundaries

By Deborah Cross, Frost & Sullivan, 17-Sep-2009

Breaking News on Supplements & Nutrition - Europe

EFSA says 'no' to probiotic health claims guidance

∴ Food Industry News

Categories: Product Innovations & Scientific Developments

Danone Temporarily Withdraws European Health Claim Applications

Source: FLEXNEWS
21/04/2009

April 21 - Danone has confirmed it has temporarily withdrawn its health claim applications for Activia.

FLEXNEWS

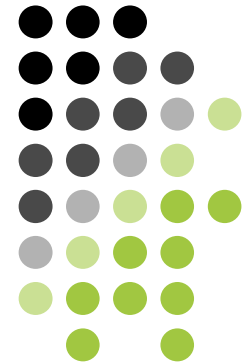
NUTRA
ingredients.com

Breaking News on Supplements & Nutrition - Europe

EFSA HEALTH CLAIM OPINIONS

EFSA health claim rejections 'shock' industry

By Shane Starling, 22-Aug-2008



Conclusions

- Achievable gold standard?
- Report on the technical meeting with applicants (15th june 2009)
 - » So far, it seems, EFSA's rejections have mostly been based on issues, which were avoidable by the company submitting the claim.
- Concerns
 - » What about the future of generic disease risk reduction claims on, for example, fibre, oats, fruits and vegetables is a huge issue (insufficiently characterised ?)