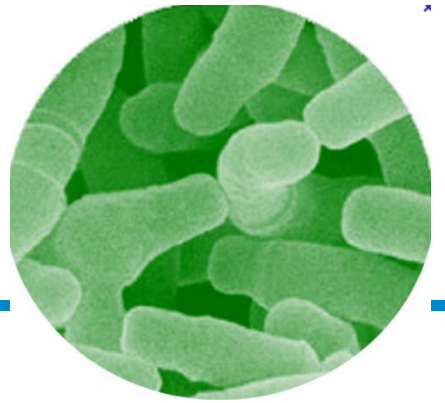
Establishing claims on foods: implications of recent legislation

Julian Stowell (DuPont)
Global Alliance for Probiotics
Ecole Polytechnique, 16 January 2013

INTRODUCTION TO PROBIOTICS

Probiotics are

- Safe and friendly live microorganisms that deliver beneficial effects
- Consumed as part of fermented foods and other food products and dietary supplements
- WHO/FAO definition: *"live microorganisms which when administered in adequate amounts confer a health benefit on the host"*, e.g. lactic acid bacteria, bifidobacteria
- In the last 20 years: > 7,500 papers published and listed on PubMed
- Science in constant development



BENEFITS OF PROBIOTICS

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GUT HEALTH

Contributes to reducing the presence of pathogenic micoorganisms or their toxins in the gut

Contributes to the defence against gastrointestinal pathogens

Contributes to reducing the risk factors of gastrointestinal infections

IMMUNITY

Modulation of immune function

Maintaining the normal skin immune function after UV-exposure

Defence against pathogens by stimulating immunologic responses

Reducing risk factors of e.g. allergic rhinitis

- Research into role of microbes in helping reduce the risk of certain metabolic disorders – e.g. diabetes, insulin resistance and obesity
- Key role in preventative health – economic savings, at a time when health budgets are squeezed

PROBIOTICS CLAIMS ON PRODUCTS

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"Defence against upper respiratory tract viruses"
Lactobacillus Rhamnosus GG

"Resistance to airborne allergens"
Lactobacillus Paracasei LP-33 ®

"Intestinal mobility"
Bifidobacterium breve BR03

"Improves intestinal transit"
combination of Bifidobacterium longum LA 101, Lactobacillus helveticus LA 102, Lactobacullus lactis LA 103, Streptococcus thermophillus LA 104

"Strengthens the body's natural defences"

""Balancing intestinal flora, improves skin, scalp and hair health"
Lactobacillus Rhamnosus LR04

PROBIOTICS IN EUROPE

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- The cutting edge of food sector innovation
- Sector is growing by around 6% each year
- 2008 retail value of EU probiotic supplements was €380m (26% of global total)
- For probiotic yoghurts, this figure was €5bn (32% of global total)
- The EU itself has invested more than €70m into research in this area
- 60% of consumers know that these “good bacteria” have a positive impact on their health

SEVENTH FRAMEWORK
PROGRAMME

NUTRITION & HEALTH CLAIMS REGULATION

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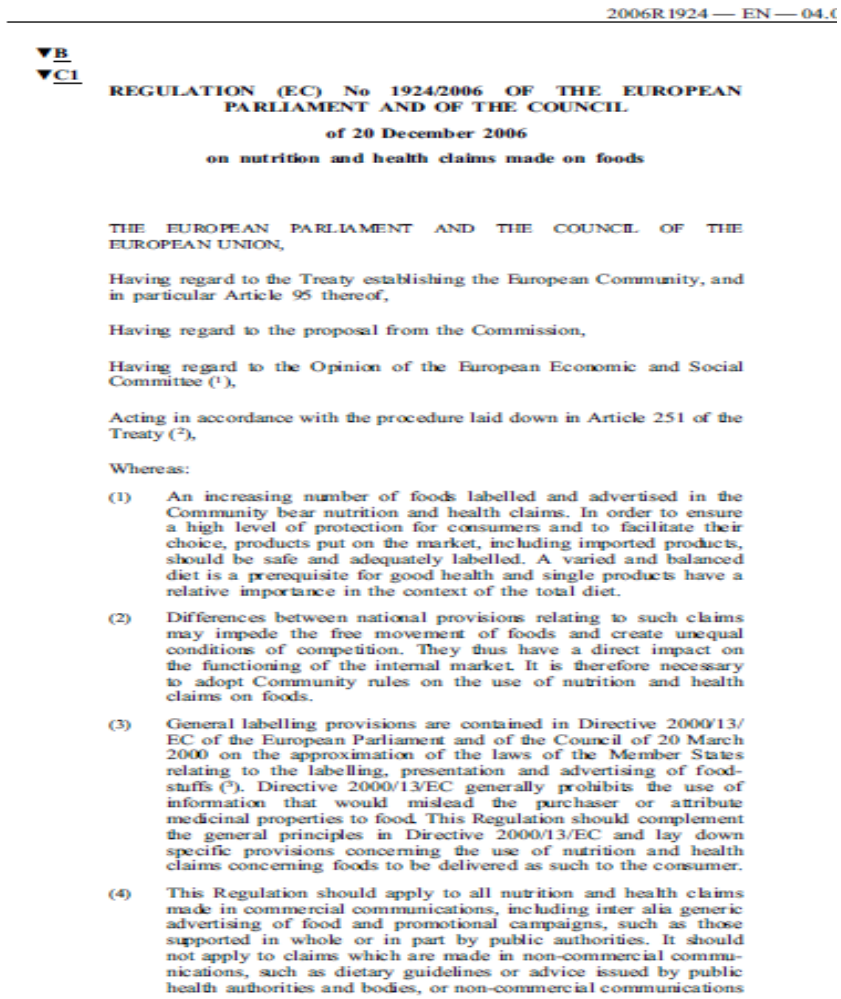
Adopted 20 December 2006



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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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Economic and Social Committee (1),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

(1) An increasing number of foods labelled and advertised in the Community bear nutrition and health claims. In order to ensure a high level of protection for consumers and to facilitate their choice, products put on the market, including imported products, should be safe and adequately labelled. A varied and balanced diet is a prerequisite for good health and single products have a relative importance in the context of the total diet.

(2) Differences between national provisions relating to such claims may impede the free movement of foods and create unequal conditions of competition. They thus have a direct impact on the functioning of the internal market. It is therefore necessary to adopt Community rules on the use of nutrition and health claims on foods.

(3) General labelling provisions are contained in Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (3). Directive 2000/13/EC generally prohibits the use of information that would mislead the purchaser or attribute medicinal properties to food. This Regulation should complement the general principles in Directive 2000/13/EC and lay down specific provisions concerning the use of nutrition and health claims concerning foods to be delivered as such to the consumer.

(4) This Regulation should apply to all nutrition and health claims made in commercial communications, including inter alia generic advertising of food and promotional campaigns, such as those supported in whole or in part by public authorities. It should not apply to claims which are made in non-commercial communications, such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications

Objectives

- Enhance consumer protection
- Ensure functioning of internal market
- Promote competition
- Encourage innovation

Nutrition and health claims may be used **only if authorised by** the European Commission (based on EFSA scientific opinion)

The **list** of authorised claims to be adopted through **implementing measures**
(final decision, based on EFSA opinion, belongs to the European Commission, EP/Council scrutiny)

STATUS OF HEALTH CLAIMS SUBMISSION

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Health Claims	Article 13.1	Article 13.5	Article 14 (incl. both DRR & children claims)
Submitted	4 637	48	268
Withdrawn	331	13	103
EFSA adopted opinions	- 222 positive - more than 1600 negative	27	75

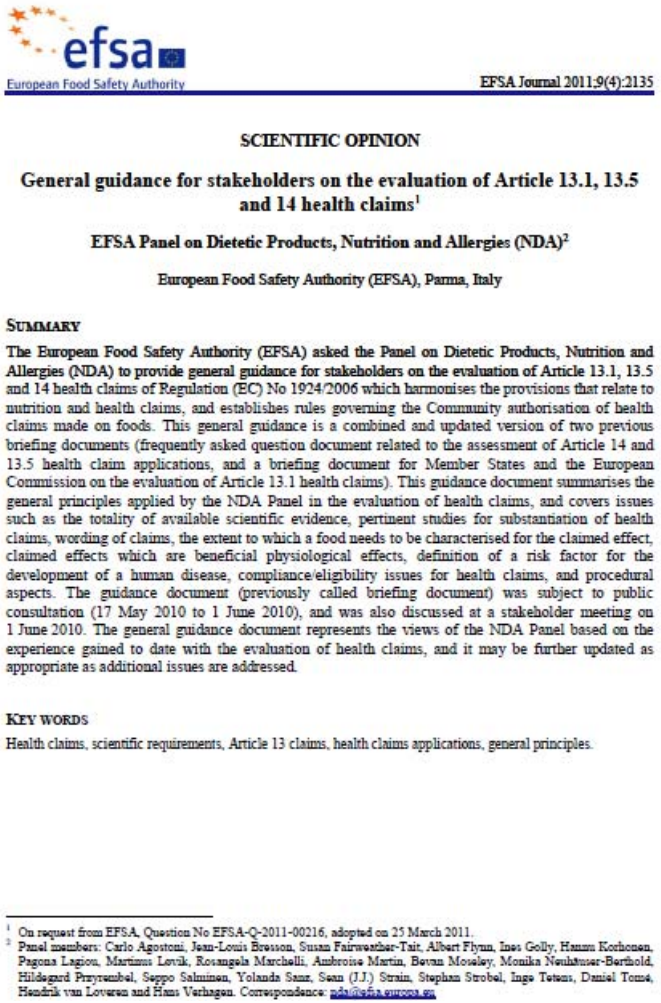
Source: EFSA website
http://www.efsa.europa.eu/en/topics/topic/article13.htm

efsa
European Food Safety Authority

EFSA GENERAL GUIDANCE

OBAL
IANCE FOR
OBIOTICS

Published 26 April 2011



efsa
European Food Safety Authority

EFSA Journal 2011;9(4):2135

SCIENTIFIC OPINION

General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Dietetic Products, Nutrition and Allergies (NDA) to provide general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims of Regulation (EC) No 1924/2006 which harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. This general guidance is a combined and updated version of two previous briefing documents (frequently asked question document related to the assessment of Article 14 and 13.5 health claim applications, and a briefing document for Member States and the European Commission on the evaluation of Article 13.1 health claims). This guidance document summarises the general principles applied by the NDA Panel in the evaluation of health claims, and covers issues such as the totality of available scientific evidence, pertinent studies for substantiation of health claims, wording of claims, the extent to which a food needs to be characterised for the claimed effect, claimed effects which are beneficial physiological effects, definition of a risk factor for the development of a human disease, compliance/eligibility issues for health claims, and procedural aspects. The guidance document (previously called briefing document) was subject to public consultation (17 May 2010 to 1 June 2010), and was also discussed at a stakeholder meeting on 1 June 2010. The general guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims, and it may be further updated as appropriate as additional issues are addressed.

KEY WORDS

Health claims, scientific requirements, Article 13 claims, health claims applications, general principles.

[1] On request from EFSA, Question No EFSA-Q-2011-00216, adopted on 25 March 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Marinos Lovik, Rosangela Marchelli, Ambrose 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. Correspondence: nda@efsa.europa.eu

Scope

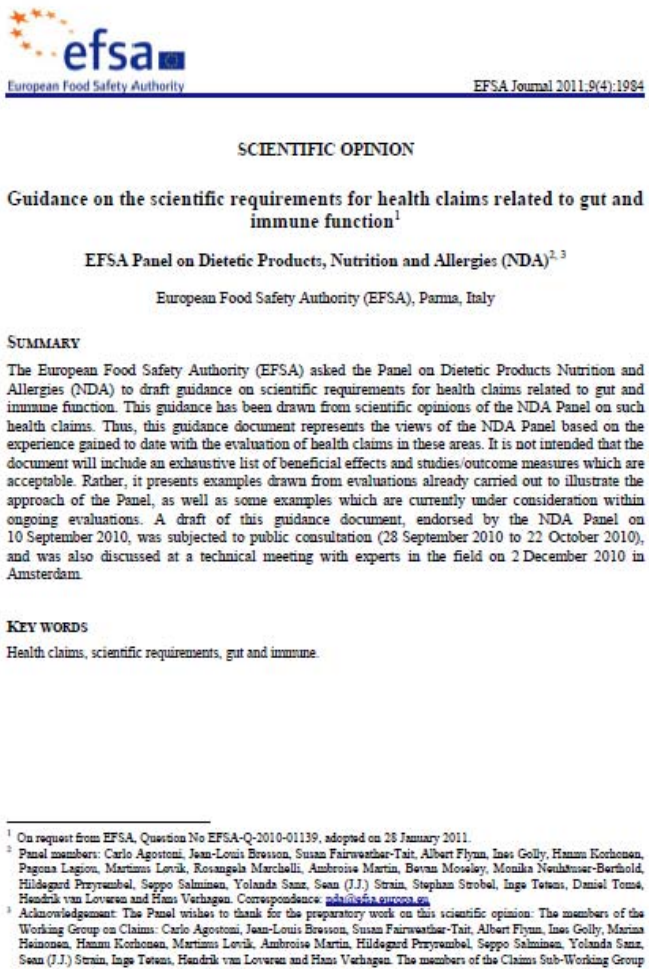
General principles applied by NDA Panel in evaluation of Article 13.1, 13.5, and 14 health claims

Main issues covered:

- totality of available scientific evidence
- pertinent studies for substantiation of health claims,
- wording of claims
- extent to which a food needs to be characterised for the claimed effect
- claimed effects which are beneficial physiological effects,
- definition of a risk factor for the development of a human disease
- compliance/eligibility issues for health claims
- procedural aspects

EFSA SPECIFIC GUIDANCE (GUT HEALTH & IMMUNE FUNCTION)

Published 26 April 2011



efsa
European Food Safety Authority

EFSA Journal 2011;9(4):1984

SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to gut and immune function[1]

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

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Dietetic Products Nutrition and Allergies (NDA) to draft guidance on scientific requirements for health claims related to gut and immune function. This guidance has been drawn from scientific opinions of the NDA Panel on such health claims. Thus, this guidance document represents the views of the NDA Panel based on the experience gained to date with the evaluation of health claims in these areas. It is not intended that the document will include an exhaustive list of beneficial effects and studies/outcome measures which are acceptable. Rather, it presents examples drawn from evaluations already carried out to illustrate the approach of the Panel, as well as some examples which are currently under consideration within ongoing evaluations. A draft of this guidance document, endorsed by the NDA Panel on 10 September 2010, was subjected to public consultation (28 September 2010 to 22 October 2010), and was also discussed at a technical meeting with experts in the field on 2 December 2010 in Amsterdam.

KEY WORDS

Health claims, scientific requirements, gut and immune.

[1] On request from EFSA, Question No EFSA-Q-2010-01139, adopted on 28 January 2011.

[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. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank for the preparatory work on this scientific opinion: The members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group

Scope

Presents examples from ongoing or evaluations already carried out on health claims related to the gastro-intestinal tract and immune system to illustrate NDA Panel's approach

Key elements

Which claimed effects are beneficial physiological effects?

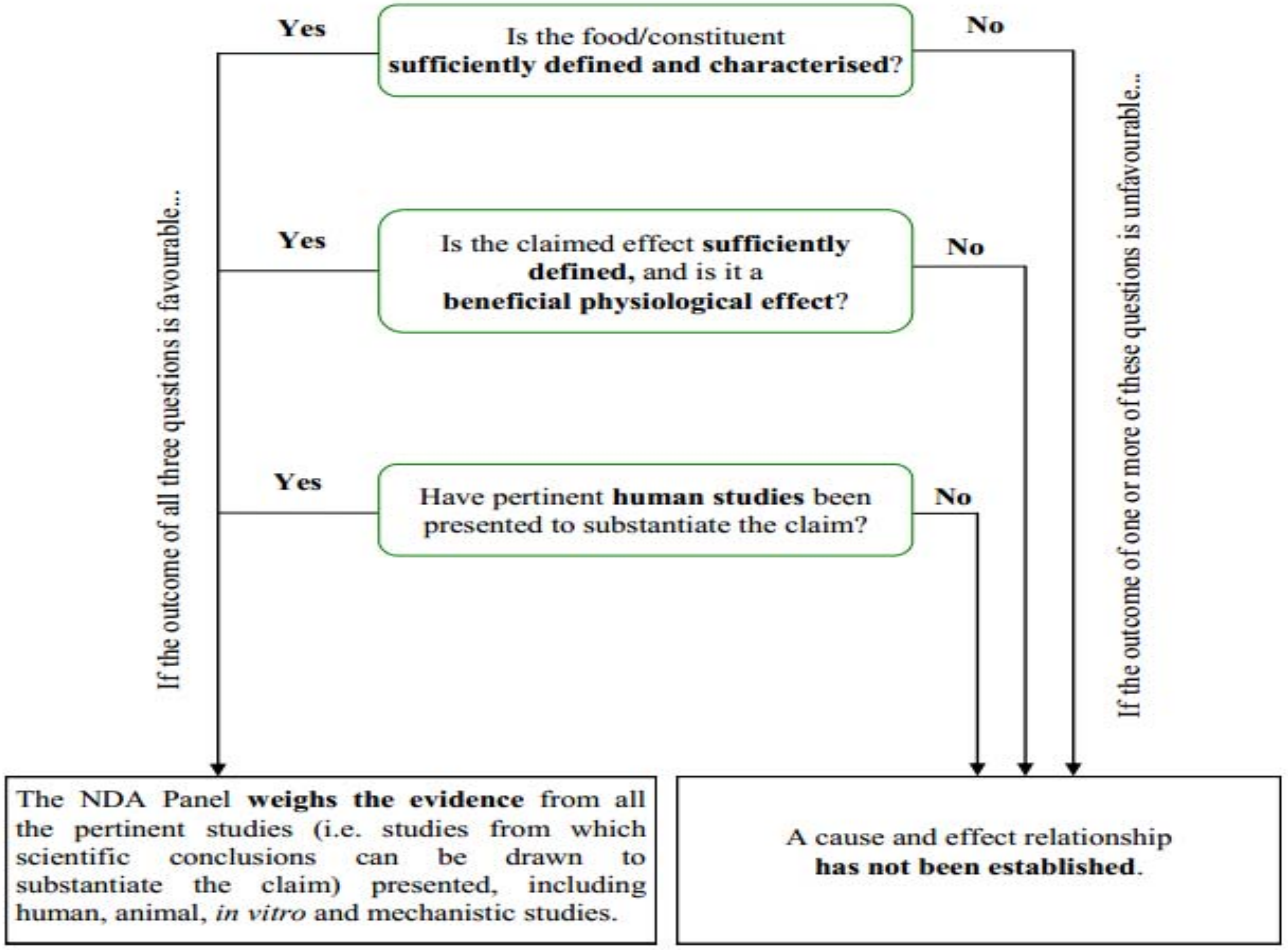
Which studies/outcome measures are appropriate for the substantiation of function claims and disease risk reduction claims?

Analysis of the guidance

- Inconsistent with EFSA's case by case approach;
- Published two years after the deadline for submission of Article 13.1 claims-dossiers;
- Biomarkers for probiotic validation are not recognised;
- Requirements for study protocol and clarification of "healthy subject" make it difficult to prepare a dossier.

EFSA GUIDANCE ON CLAIMS SUBMISSION

How the EFSA NDA Panel scientifically evaluates a claim



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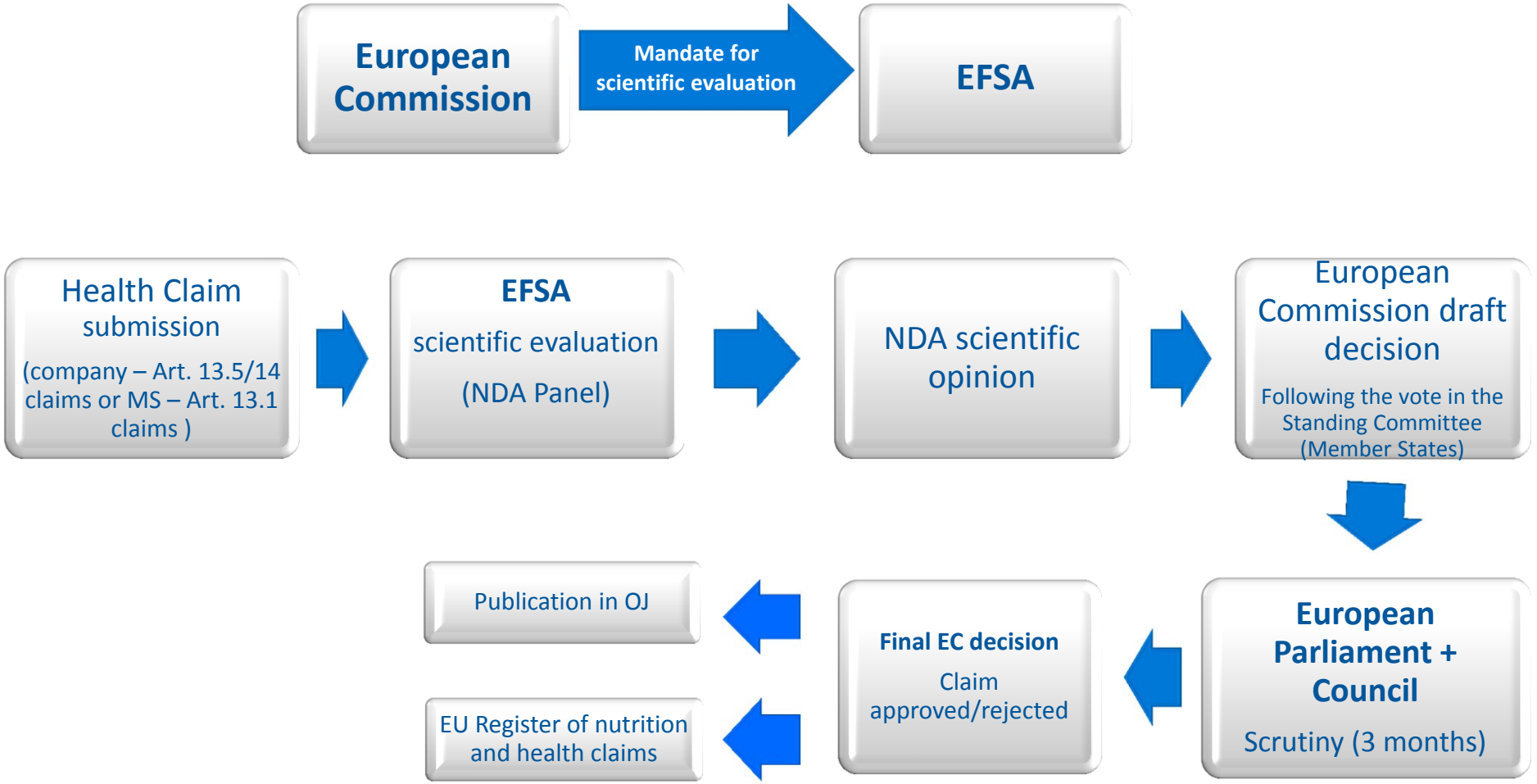
HEALTH CLAIMS REGULATION – PROCESS

EC REG 1924/2006



PROBIOTICS CLAIMS*

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Health Claims Status	ART 13.1	ART 13.5	ART 14 (incl. both DRR & children claims)
Submitted*	around 250	15	44
Withdrawn*		5	32
EFSA opinion provided*	150 evaluated 74 re-submitted	7 (negative)	11 (negative)
Ongoing*		3	1

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European Food Safety Authority

* Estimates based on the latest available data

SITUATION OF PROBIOTICS CLAIMS

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- 14 December 2012 → no probiotic claim approved
  → no longer able to use term 'probiotic'
  → difference in implementation by MSs

- Benefits of probiotics recognised globally and by individual EU member states
- Solid base of peer reviewed scientific publications on probiotics

- Uncertainty of EFSA expectations
- EFSA's first guidance published too late

=> Probiotics are one of most negatively affected foods

UNAPPROVED CLAIMS

"In weighing the evidence, the Panel took into account that there was no human study from which conclusions could be drawn for an effect of LcS consumption on upper respiratory tract infections, that one human study did not support an effect of LcS consumption on the immune response to influenza vaccination, and that there was a lack of evidence for an effect of LcS consumption on the immune system that could relate to the defence of the upper respiratory tract against pathogens" (Yakult, Lactobacillus casei strain Shirota, Article 13.5, NDA opinion June 2011)

"On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of Lactobacillus casei DG CNCM I-1572 and decreasing potentially pathogenic gastro-intestinal microorganisms." (Lactobacillus casei DG CNCM I 1572, Article 13.1, NDA opinion, June 2012)

"The Panel concludes that the evidence provided is insufficient to establish a cause and effect relationship between the consumption of Actimel and a reduction of the risk of C. difficile diarrhoea by reducing the presence of C. difficile toxins" (Danone, Lactobacillus casei DN-114 001, Article 14, NDA opinion, November 2010)

"The Panel concludes that a cause and effect relationship has not been established between the consumption of Synbio, a combination of Lactobacillus rhamnosus IMC 501 and Lactobacillus paracasei IMC 502, and contribution to maintaining and improving intestinal well-being by increasing intestinal regularity and faecal volume." (Synbio, Article 13.5, NDA opinion, September 2010)

MEDIA REPRESENTATIONS

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EFSA HEALTH CLAIM OPINIONS

EFSA slams door on probiotic health claims (again); Prunes pass

By Shane Starling, 06-Jun-2012

Related tags: probiotics, prunes, lutein,

Related topics: Health claims, Probiotics, health, Eye health, Gut health, Immune

Hopes that the resubmission of 74 | would win a sector-first claim in the after the European Food Safety Aut line and unanimously rejected them

News > Society > Health

Probiotic health claims ruled unproven

European Food Safety Authority says claims regarding immune system and digestive health lack sound scientific basis

Felicity Lawrence
guardian.co.uk, Tuesday 19 October 2010 16.27 BST

Health claim of probiotics not accepted

£220m-a-year 'dairy shots' industry in disarray following E ruling

BY MARTIN HICKMAN , CONSUMER AFFAIRS CORRESPONDENT | FRIDAY 02 OCT

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Life & Style blogs

Drink this yogurt for a healthier stomach. Thirty million shoppers have swallowed the claims for probiotics as enthusiastically as the sweet fermented milk in the belief that "good bacteria" will defeat "bad bacteria" in epic microscopic battles inside our bodies.

But claims that probiotic ingredients improve health can not be supported, according to an extensive review of scientific research by a team of experts from the European Union.

Of 180 claims for probiotic ingredients, the EU's

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Another probiotic claim gets the EFSA cold shoulder

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Yet another probiotic claim has been rejected by the European Food Safety Authority (EFSA).

To read the rest of this article please log in below.

EFSA beats off more Lactobacillus probiotic claims

By Shane Starling, 08-Aug-2012

Related tags: Lactobacillus, probiotic

Related topics: Health claims, Probiotics, Regulation, Probiotics and prebiotics, Gut health, Women's health

The most researched group of probiotic strains – *Lactobacillus* – has been delivered yet another blow by the EU's central science agency, which rejected digestive and vaginal health claims for nine individual strains.

IMPACT ON INDUSTRY

- Limited number of innovative product-specific claims vs. numerous generic claims
- Lack of approved claims - less investment into R&D
- Probiotics will continue to be added to products, consumers uninformed
- Risk that probiotics innovation moves away from Europe

GLOBAL RECOGNITION OF BENEFITS

- Recognition of category / authorisation of claims by:
  - WHO/FAO
  - Canada
  - Japan
  - Brazil
  - Russia
  - China
  - South Korea
  - Turkey

INDUSTRY'S APPROACH

- Companies continue to submit individual probiotics claims on their own individual strains

AND

- Industry working together to try to find a common approach to address the current impasse (→ GAP)

For both approaches, industry needs dialogue with EFSA to ensure dossier submissions are on right track, in particular for new and emerging science

GAP'S ACTIVITIES

The Global Alliance for Probiotics

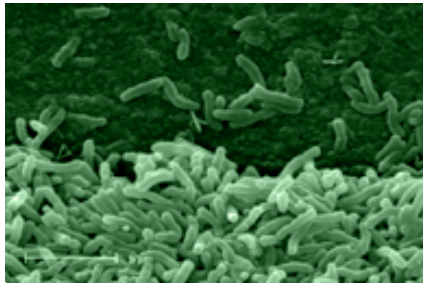
- Unincorporated association of 7companies representing probiotics industry
- Manufacturers of probiotics - Chr Hansen, DuPont, Lallemand and Probi
- Manufacturers of probiotic food products - Danone, Yakult and Valio

Objectives

- To promote understanding and awareness of probiotics and the recognition of health benefits associated to probiotics
- To get a priobiotic cluster claim (PCC) approved

Activities

- Advocacy and communication to stakeholders
- Scientific work - PCC



OUTREACH ACTIVITIES

- **Since end-2011, GAP has:**

POSITION PAPER ON EVALUATION OF PROBIOTIC CLAIMS

GAP GLOBAL ALLIANCE FOR PROBIOTICS

SUMMARY

The current evaluation and authorisation… been problematic. Despite the fact tha… authorities in EU member states ar… scientific evidence, more than 300 … Health Claims Regulation have rece…

GAP seeks to work constructively wi… relevant parties to find a viable solutio… outstanding questions and to agree on an … In the medium term, we wish to see the establis… …s in line with EFSA's case-by-case approach to assessment. … be available only when an applicant could not, without the consultation, reasonably be expected to understand all criteria that will be applied to evaluate a claim.

Probiotics are at the cutting edge of food sector innovation, and the sector is a European succes… story. The sector needs certainty regarding scientific assessment and the regulatory environmen… in order to maintain its growth and continue to be able to communicate the health benefits o… probiotics to consumers.

THE CURRENT FRAMEWORK FOR THE ASSESSMENT OF PROBIOTICS

It is clear that the evaluation and authorisation of health claims on individual probiotic strains has been problematic. More than 300 probiotic applications submitted under the EU Nutrition and Health Claims Regulation have received negative assessment by … Authority (EFSA) and …

GAP position on need for enhanced dialogue

Met European Commission:
- **DG Sanco**
- **DG RTD**
- **DG ENTR**

Met numerous MEPs

efsa
…ean Food Safety Authority
…suring that Europe's food is safe

Held meeting with EFSA Secretariat

OUTREACH ACTIVITIES II

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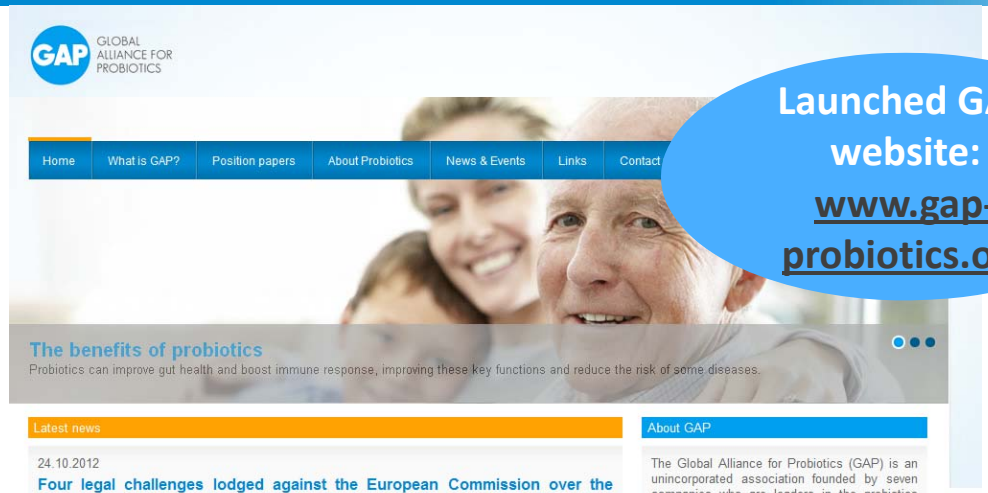


Launched GAP website: www.gap-probiotics.org

Organising Workshop in European Parliament – 02/2013

Commissioned Public Health study on Impact of Probiotics

GAP POSITION

GLOBAL ALLIANCE FOR PROBIOTICS

POSITION PAPER ON EVALUATION OF PROBIOTIC CLAIMS

SUMMARY

The current evaluation and authorisation of health claims for individual probiotic strains has been problematic. Despite the fact that the benefits of probiotics have been recognised by health authorities in EU member states and around the world and are supported by a solid base of scientific evidence, more than 300 probiotic applications submitted under the EU Nutrition and Health Claims Regulation have received negative assessment by EFSA.

GAP seeks to work constructively with EFSA, the European Commission, member states and all relevant parties to find a viable solution. GAP calls for an open dialogue with EFSA to clarify the outstanding questions and to agree on an approach to defining the health benefits of probiotics. In the medium term, we wish to see the establishment of a consultation for individual dossiers in line with EFSA´s case-by-case approach to assessment. Such consultations should be available only when an applicant could not, without the consultation, reasonably be expected to understand all criteria that will be applied to evaluate a claim.

Probiotics are at the cutting edge of food sector innovation, and the sector is a European success story. The sector needs certainty regarding scientific assessment and the regulatory environment in order to maintain its growth and continue to be able to communicate the health benefits of probiotics to consumers.

THE CURRENT FRAMEWORK FOR THE ASSESSMENT OF PROBIOTICS HEALTH CLAIMS IN THE EU HAS BEEN PROBLEMATIC

It is clear that the evaluation and authorisation of health claims on individual probiotic strains has been problematic. More than 300 probiotic applications submitted under the EU Nutrition and Health Claims Regulation have received negative assessment by the European Food Safety Authority (EFSA) and thereby no approvals from the European Commission. This makes probiotics one of the types of foods that have been most negatively affected by the Regulation. However, one generic claim on live yoghurt has received a positive opinion[1], but in this case it is due to the production of a single enzyme; lactase as the common factor for the whole category.

The benefits of probiotics have been recognised by health authorities in individual member states of the EU and around the world as there is a solid base of peer reviewed scientific publications on probiotics (in the last 20 years, more than 7,500 papers were published and listed on PubMed). Moreover, the European Commission has itself contributed more than €70 million of research funding to related topics. Clearly there is a problem that needs resolution, and GAP seeks to work constructively with EFSA, the European Commission, member states and all relevant parties to find a solution.

One of the reasons that applications for probiotic claims have not been accepted by EFSA is that companies involved had insufficient information about what EFSA would require when they were designing research studies. The companies submitting claims applications did so in good faith based on what they felt was a responsible approach taking into account established scientific standards and the best information available at the time. The industry welcomes the publication of EFSA's first guidance note on gut and immunity claims, but notes that it was only provided in April 2011, more than two years after the deadline for submission of Article 13.1 claims-dossiers, and also after several claims applications had already been negatively assessed by EFSA.

The guidance also leaves several important issues unaddressed such as the recognition of biomarkers for probiotic validation, the latest requirements for study protocols and clarification of the definition of "healthy subjects" that make it difficult to prepare a dossier meeting the standards required by EFSA.

[1] Scientific Opinion on the substantiation of health claims related to live yoghurt cultures and improved lactose digestion (ID 1143, 2976) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

GLOBAL ALLIANCE FOR PROBIOTICS

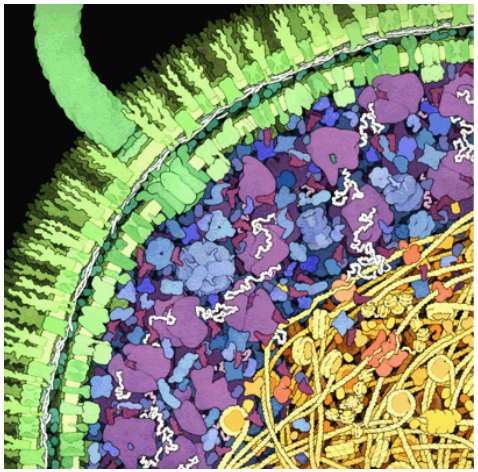
GAP seeks to **work constructively** with key stakeholders to find viable solution

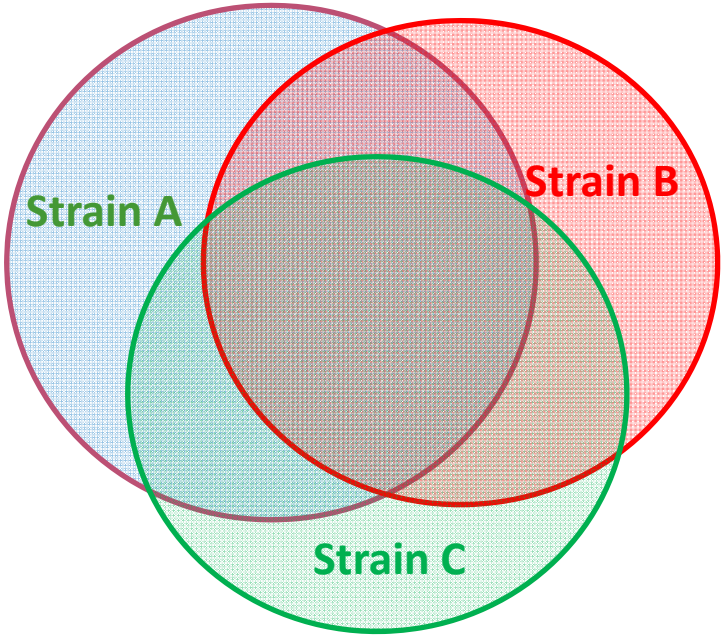
GAP calls for an **open dialogue** with respect to probiotic applications within existing framework

In the medium term, GAP wishes to see the establishment of a **consultation** for individual dossiers in line with EFSA's case-by-case approach to assessment.

The probiotics sector needs **certainty** regarding scientific assessment and the regulatory environment

PROBIOTICS CLUSTER CLAIM





- Living bacterial cells highly complex ingredients
- Contain a huge number of biological molecules
- Probiotics selected from narrow pool of bacterial genera: genomic commonalities
- Selected on the basis of common physiologies and functions
- Strain-specific effects possible
- Strain common effects also possible

FUTURE PROSPECTS

- GAP will continue call for enhanced dialogue between industry and EFSA (build on meetings with European Commission, MEPs…)
- GAP to continue scientific work on PCC claim-dossier

In future:

- Less investment into R&D?
  - short-term increase but possible long-term decline
- Risk that probiotics innovation moves away from Europe?
- Probiotics will continue to be added to products, consumers uninformed?

FUTURE PROSPECTS II

- Industry needs legal certainty in which to operate

- Open dialogue with EFSA is essential, and, in the medium term, a consultation for a dossier prior to submission would help to achieve alignment between EFSA and applicants, and therefore encourage further innovation in the sector

Establishing claims on foods: implications of recent legislation

Julian Stowell (DuPont)
Global Alliance for Probiotics
Ecole Polytechnique, 16 January 2013