



Good Food, Good Life

***Substantiate  
what one claims;  
claim only  
what has been  
substantiated***



Nestlé Research™

# ***Scientific Substantiation Nutrition & Health Claims European Union***

**National Conference on Processed Foods &  
Beverages for Health: Beyond Basic Nutrition  
*New Dehli, 30 April 2011***

**Dr Loek Pijls, Group Leader *Claim Development & Assessment***



- **Who are we / am I**
- **EU Regulation**
- **Types of claims**
- **Authorisation**
- **Terminology**
- **Scientific Substantiation: Principles**
  - **Food (constituent) characterisation**
  - **Health relevance**
  - **Effect exists**
- **EFSA Opinions so far**

- **Who are we / am I**
- EU Regulation
- Types of claims
- Authorisation process
- Terminology
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***Support development  
of health claims,  
from start early  
research,  
to claims on products***

- Who are we / am I
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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**

Official Journal of the European Union L12/3–L12/18. Available at: [http://eur-lex.europa.eu/LexUriServ/  
LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF).

## SHOULD

1. Fit in healthy diet & public health messages
2. Be understandable for consumers
3. Scientifically substantiated

## CANNOT

1. Be false, ambiguous or misleading
2. Raise doubts about competitors' products
3. Encourage or support excessive consumption of any food
4. Suggest varied diet is not adequate
5. Exploit fear



# EU Regulation

- Largely similar to Codex
- Harmonisation across EU
- Non-EU (Switzerland, Norway) follow
- Maximise & protect R&D investment (our company: 1.3 US \$)
- 500 million consumers



# 27 Member States of the EU



- Who are we / am I
- EU Regulation
- **Types of claims**
- Authorisation
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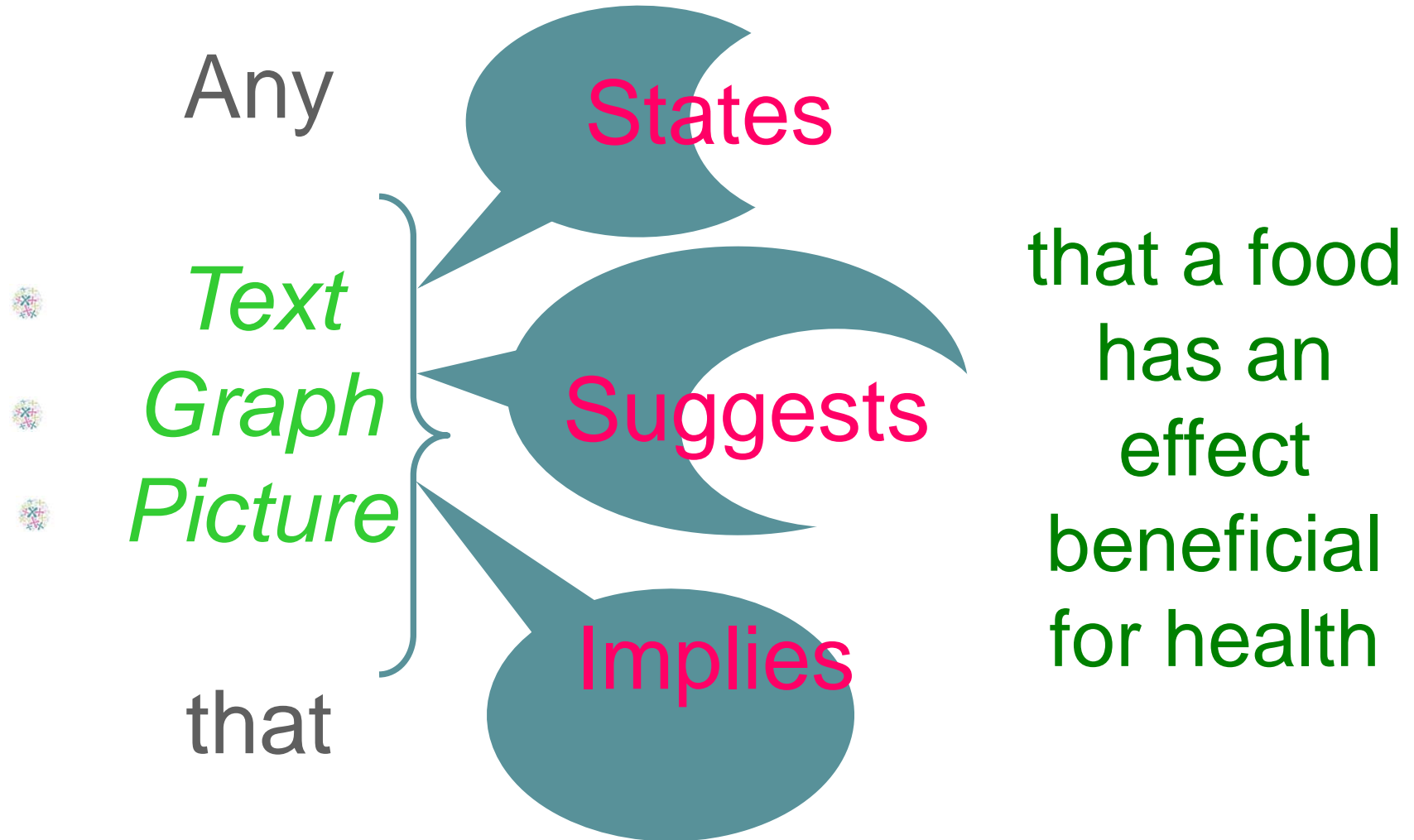
## Nutrient (Content) & Comparative Claims

What is *in* the  
food?

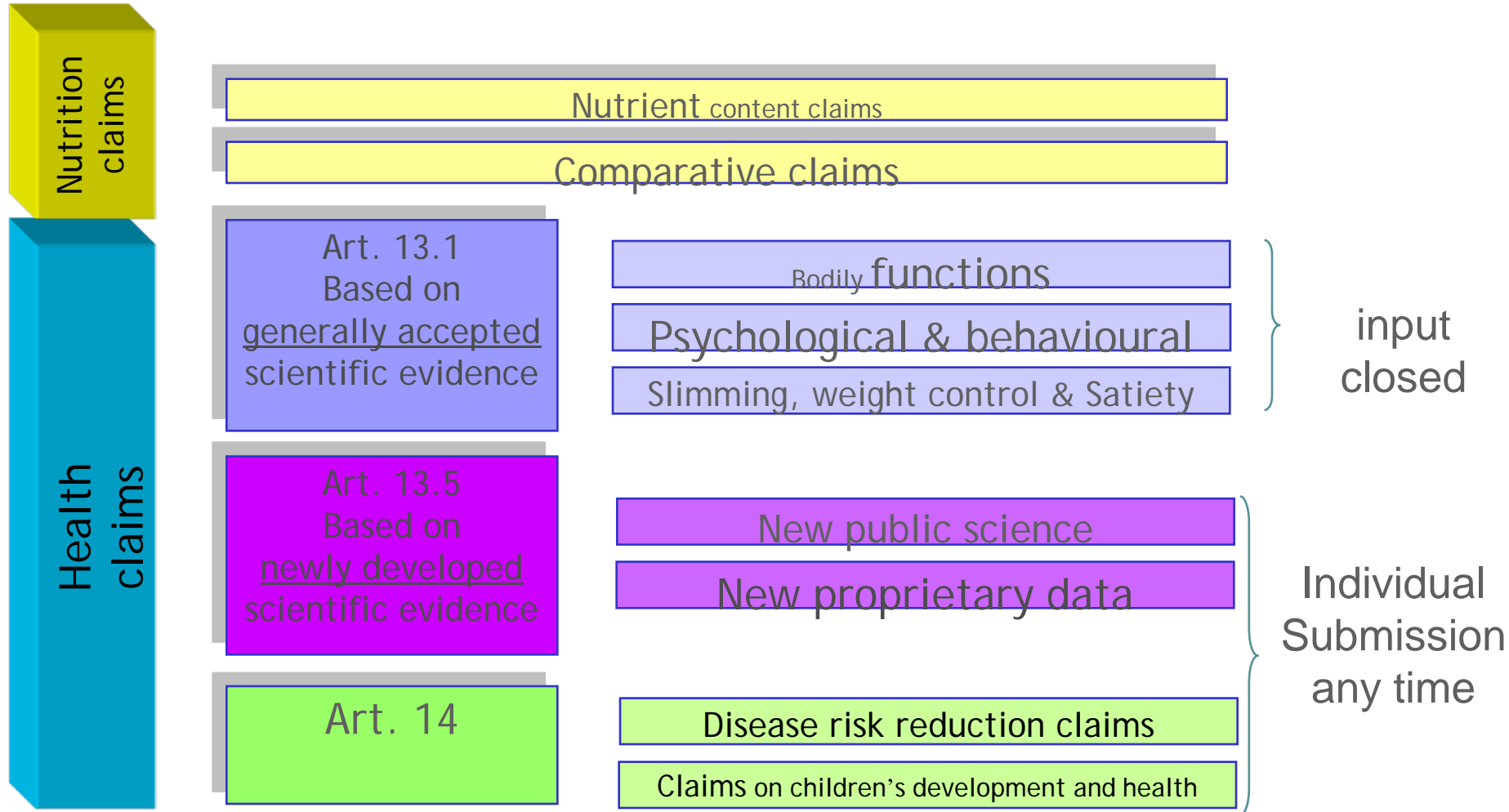


## Health (or functional) Claims

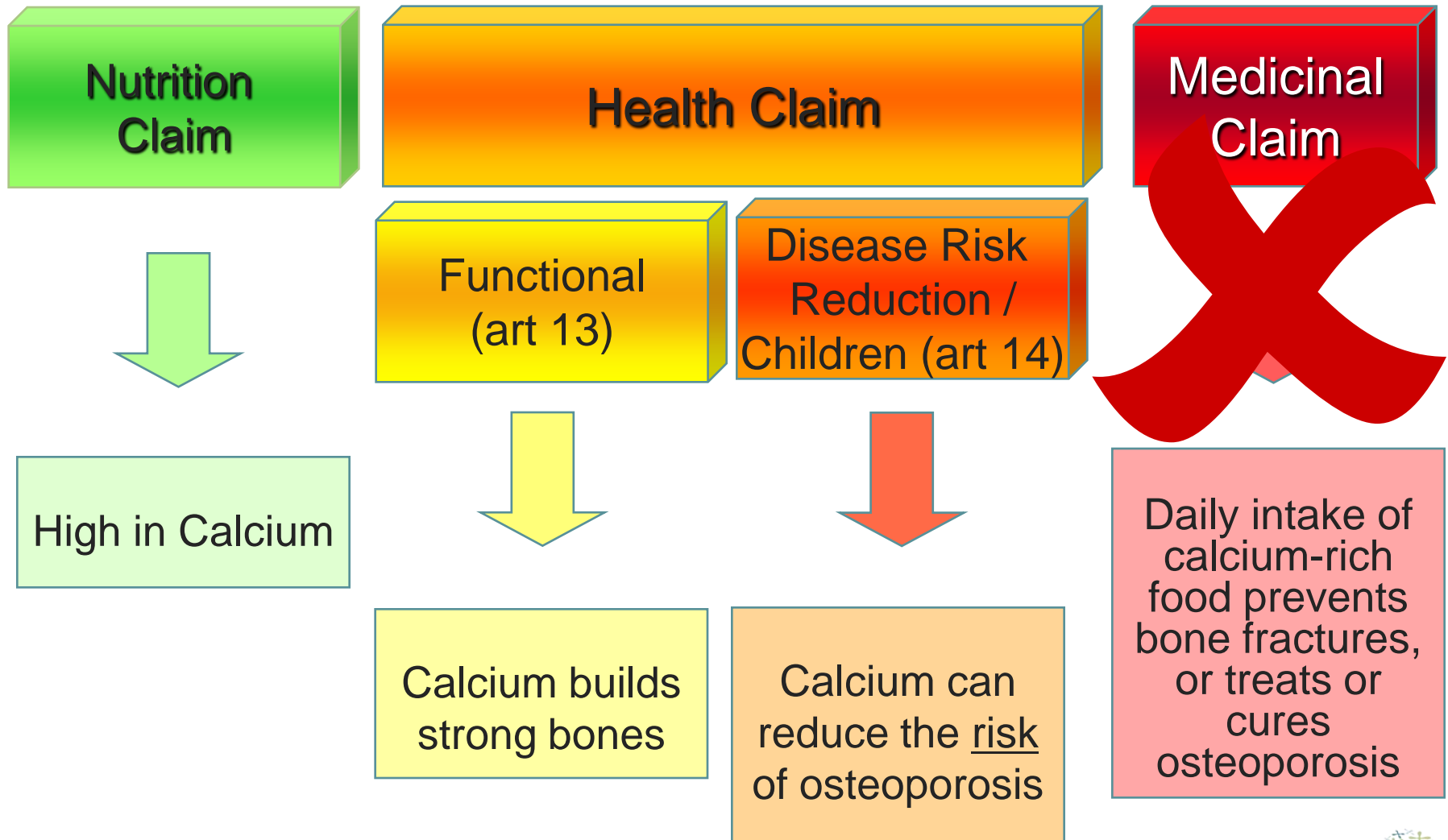
What does the  
food *do*?



# Types of Claims



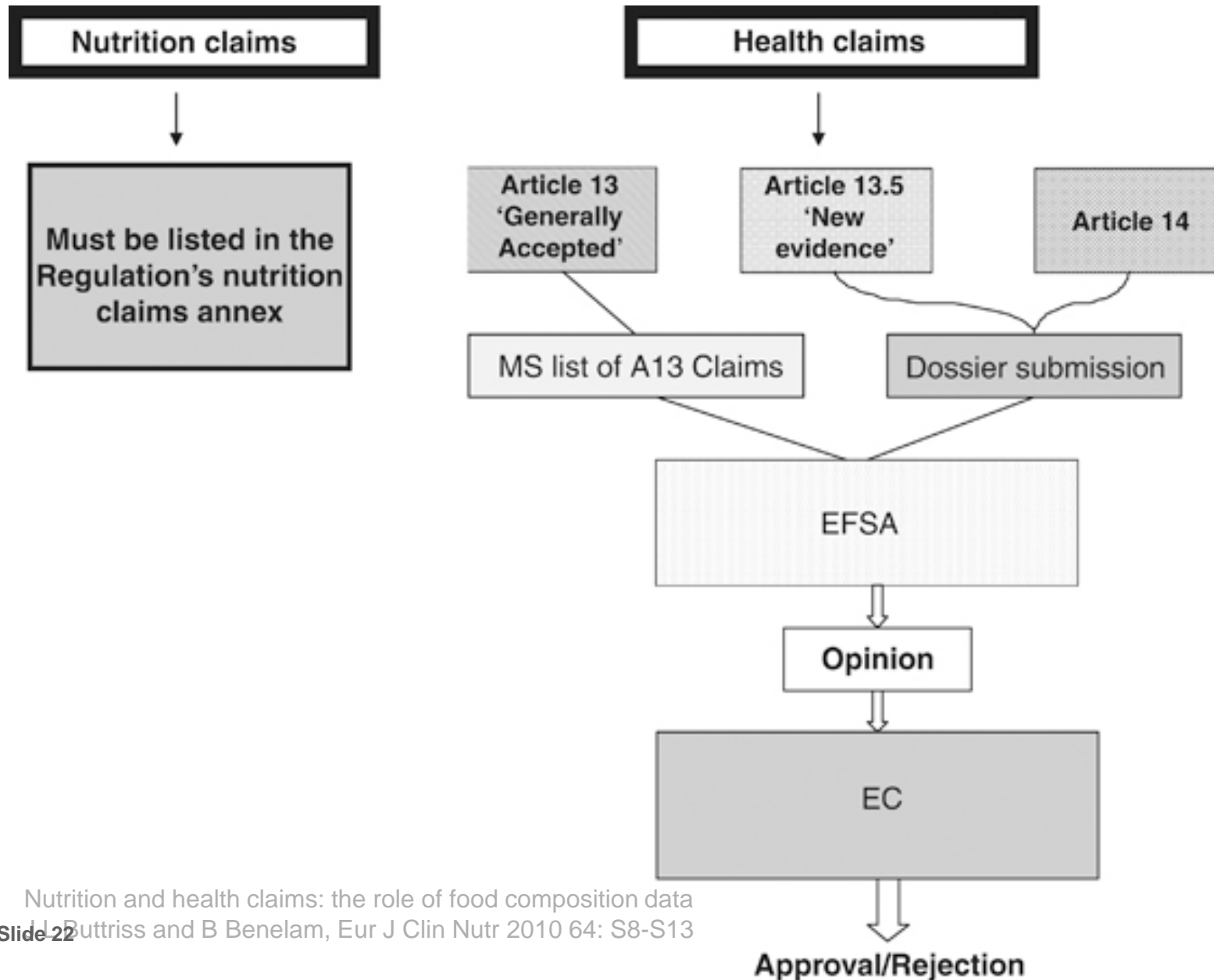
# EU terminology



- Who are we / am I
- EU Regulation
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# Procedure claim approval





**European Food Safety Authority**  
Committed to ensuring that Europe's food is safe

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AHAW

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NDA

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Nutrition & health claims

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Article 13

▶ Article 13/5

Article 14

### "New function" health claims under Article 13.5

Claims under article 13/5 [EC Regulation on nutrition and health claims](#) are those based on newly developed scientific evidence and/or for which protection of proprietary data is requested. For these health claims authorisation is required on a case-by-case basis, following the submission of a scientific dossier to EFSA for assessment.

Valid applications are transmitted to EFSA by competent authorities in Member States. EFSA is then required to deliver its opinions within five months. If supplementary information is needed, EFSA has an additional month for the evaluation.

Article 13.5 applications submitted to EFSA are included in the [Register of Questions](#), with indication of the food substance and claimed effect. The panel has received to date 12 applications, 9 have been withdrawn and so far 25 scientific opinions have been adopted.

For confidentiality reasons, and in accordance with the claim regulation, summaries of these Article 13.5 claims applications are not published.

[NDA opinions on Article 13/5](#)





## Food Safety - From the Farm to the Fork

EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety

Site Map |

[General Food Law](#) [Animal Nutrition](#) [Labelling & Nutrition](#) [Biotechnology](#) [Novel Food](#) [Chemical Safety](#) [Biological Safety](#) [Official controls](#)

### European Union Register of nutrition and health claims made on food - Introduction

Health claims means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its components and health.

> [Authorised health claims](#)

> [Rejected health claims](#)

#### Topics

[Introduction](#)

[Nutrition claims](#)

[Health Claims](#)

Available at [http://ec.europa.eu/food/food/labellingnutrition/claims/community\\_register/health\\_claims\\_en.htm](http://ec.europa.eu/food/food/labellingnutrition/claims/community_register/health_claims_en.htm)

# Authorisation Process

**EFSA evaluates the science, publishes Opinion**

**EU Commission authorises or rejects the claim**

**EC Decision applies once published in the Official Journal EU**

EFSA opinion



3-6 months

EC draft decision



Min 3 months

EU authorisation



Permitted claim

Unlikely but possible

Slide 25



3-6 months



Min 3 months



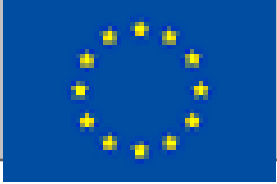
6 months



NON authorised claim

Removal, if on existing product





The use of nutrition and health claims shall only be permitted if...a nutrient or other substance...has been shown to have a **beneficial nutritional or physiological effect**, as established by generally accepted scientific evidence.

***Assessment*** of highest possible standard

[EC 1924/2006, Article 5 (1)(a)]

- Who are we / am I
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# **Not *functional* foods, but *foods with health claims***



Good Food, Good Life

- 1. All foods are *functional***
- 2. When we say FF, we mean *Foods with Health Claims***
- 3. No FF in EC, EFSA, EU HC Reg or PASSCLAIM**
- 4. No *health effects of diet* beyond *nutrition effects***
- 5. Who wants *adequate* if *optimal* is better?**

**1. maintain health = prevent disease =  
reduce risk of disease**

**2. Disease risk reduction = maintaining  
health**

***1. If disease risk reduction is not  
maintaining health, then what is it?***

***2. If maintaining health is not reducing  
disease risk, then what is it?***

**3. Prevention = risk reduction,  
sometimes to 0, but usually not**



**The best vitamin to be a  
happy person is B1**

*Unknown*

**It is so Simple to be Happy,  
but so Difficult to  
be Simple**

*Mohandas Karamchand (Mahatma) Gandhi*

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# British Journal of Nutrition

## Scientific Concepts of Functional Foods in Europe: Consensus Document

Supplement Authors

A. T. Diplock

P. J. Aggett

M. Ashwell

F. Bornet

E. B. Fern

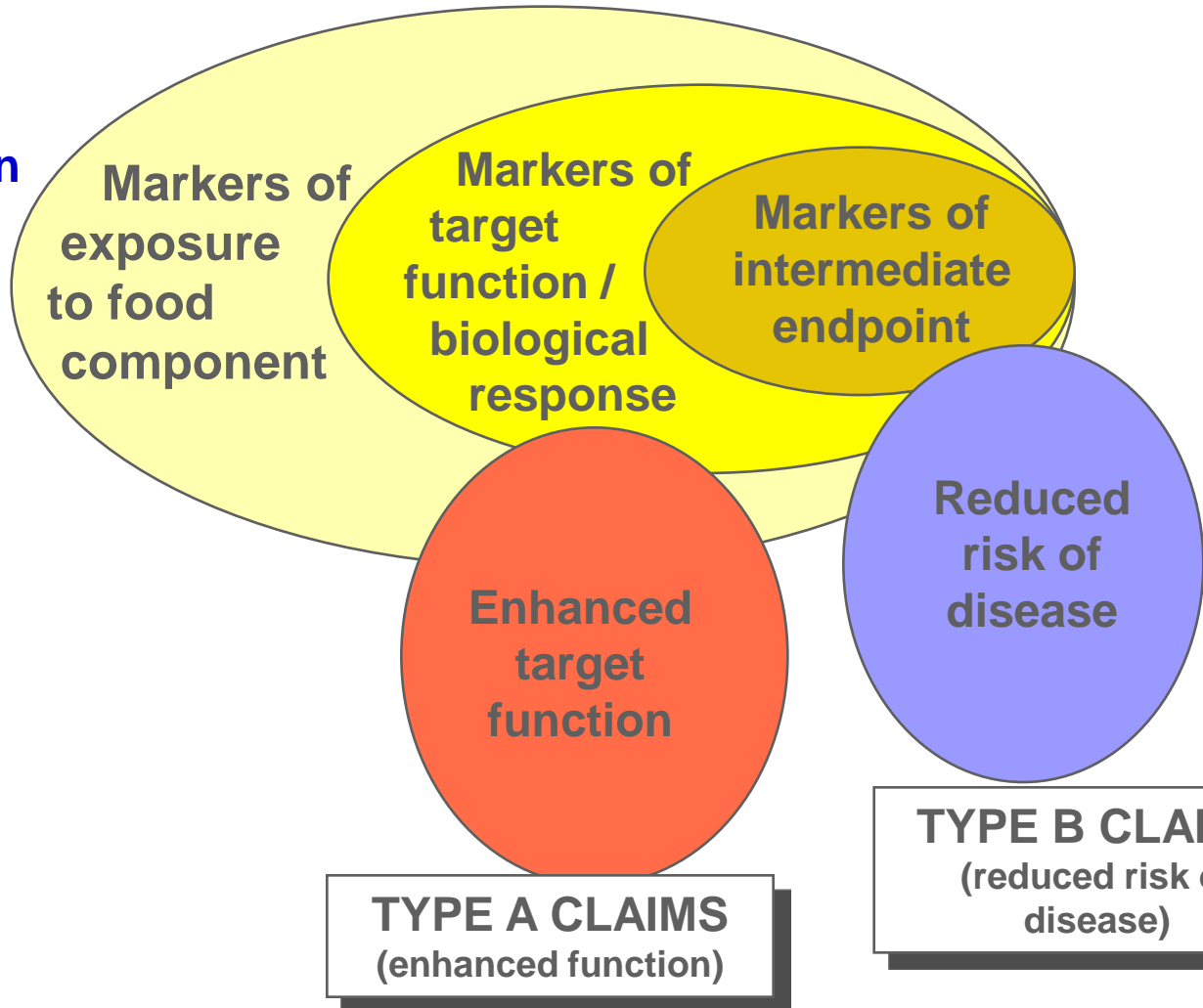
M. B. Roberfroid



Published on behalf of The Nutrition Society by  
CABI Publishing

# FUFOSE: Evidence-based markers for functional foods, to types of claims relevant to them

Consumption  
of  
functional  
food  
component



# PASSCLAIM

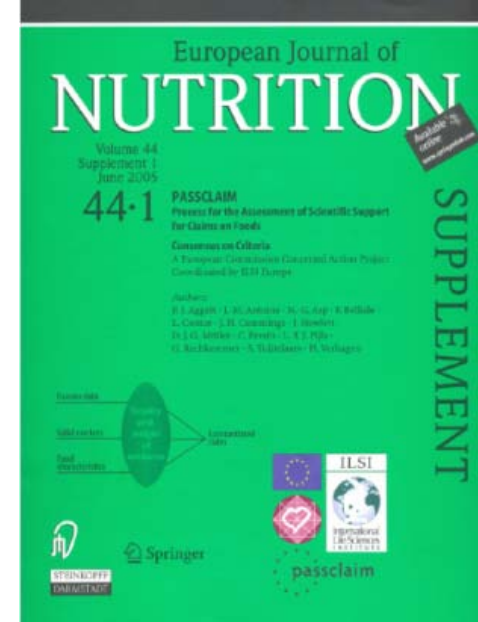
Human data

Valid markers

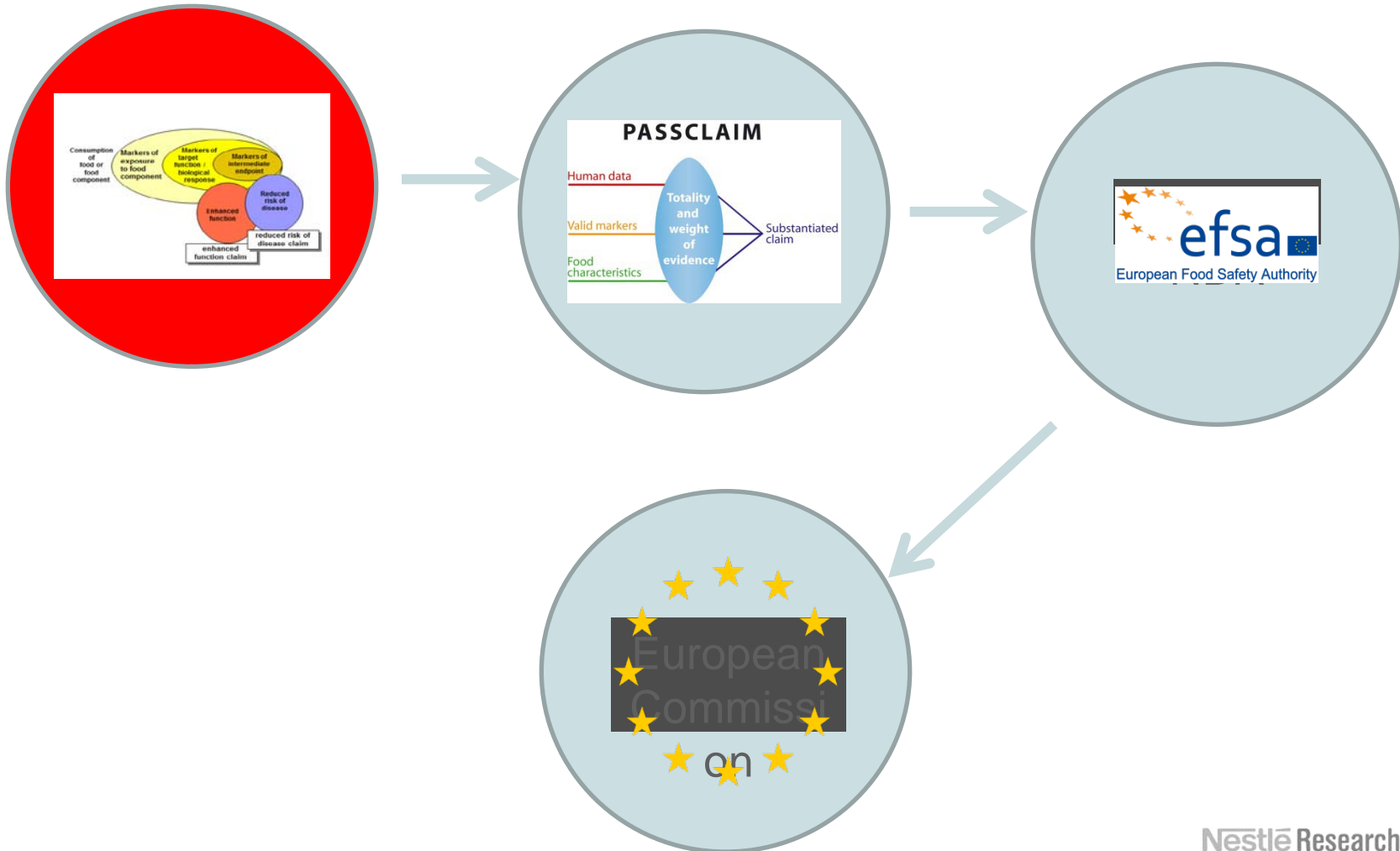
Food characteristics

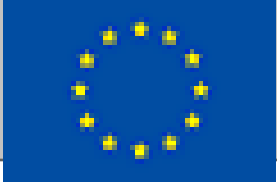
Totality  
and  
weight  
of  
evidence

Substantiated  
claim



# PASSCLAIM to Health Claim





# Regulation

The use of nutrition and health claims shall only be permitted if...a nutrient or other substance...has been shown to have a **beneficial nutritional or physiological effect**, as established by generally accepted scientific evidence.

***Assessment*** of highest possible standard

[EC 1924/2006, Article 5 (1)(a)]

**In God we trust;  
everyone else,  
*please bring data.***



# Cause and effect relationship



➤ Established



➤ Evidence insufficient to establish ..



➤ Not established

# Demonstrate what one claims; claim only what has been demonstrated

Characterised  
Constituent

Health effect

Causal relationship

Human studies

Study design (randomised, double-blind, placebo-controlled)  
Quality (data collection, statistics, outcomes, subjects)

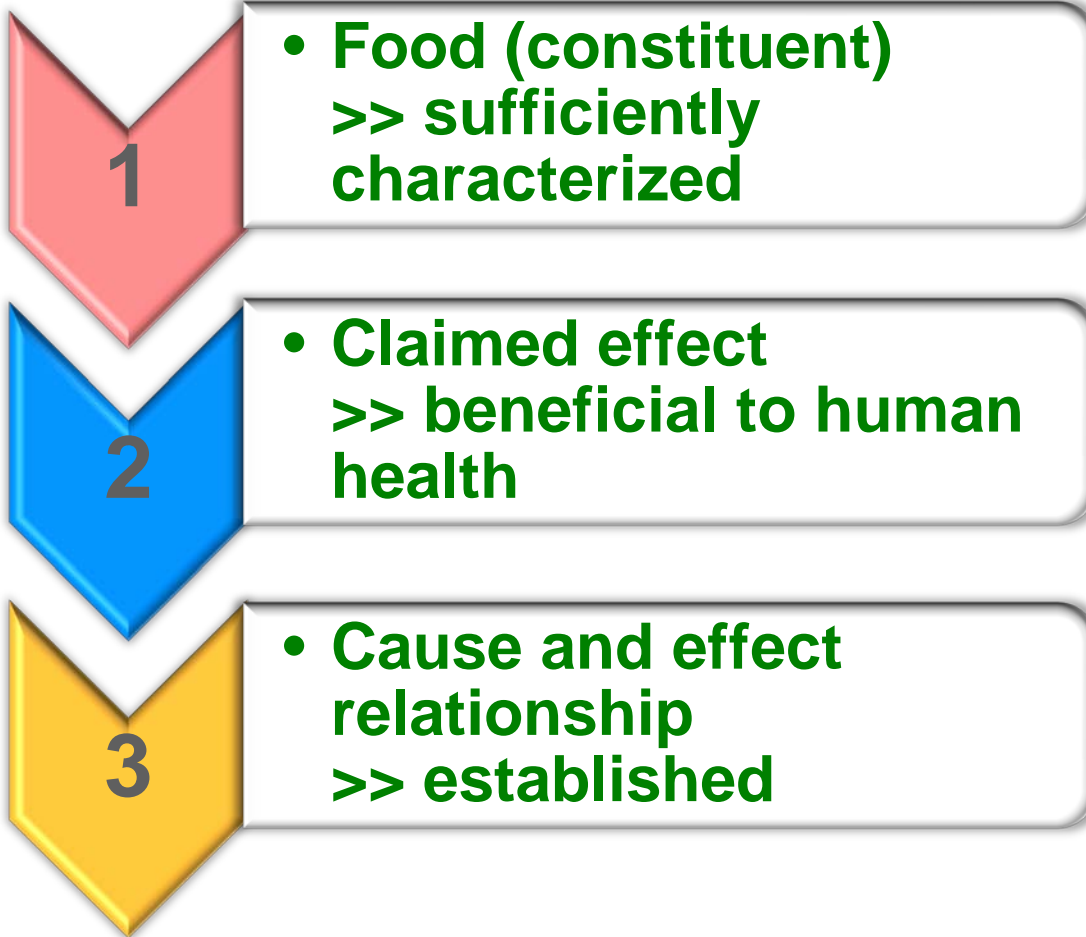
Interpret results

(Sufficiently)  
substantiated

Conclusion

Not (sufficiently)  
substantiated

# EFSA assessment



IF



CLAIM  
SUBSTANTIATED

1. Characterise food  
(constituent)
2. Relevance human health
3. Causal relationship
4. ***Matching population & dose***

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1

Ensure that the **scientific evidence** that substantiates the claim also applies **to the product** that with the health claim

1

1. Source
2. Specifications: physical, chemical, microbiological
3. Variability batch-to-batch
4. Analytical methods
5. Quality assurance
6. Manufacturing process
7. Stability: storage, shelf-life
8. Bioavailability

1

- Simple for a single constituent, e.g. vitamin, mineral
- Complex for plants or (other) whole foods e.g. dairy
- Probiotic, prebiotic, antioxidant = health claim!



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# Changes in “normal” ranges “biologically relevant”?



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- Yes, according to EFSA; also in US and Canada
- E.g.: *decrease blood cholesterol* to a lower end of normal range is biologically relevant

- ***Maintain normal blood glucose concentration: beneficial physiological effect***
- **But, studies in type 2 diabetes under therapy do not predict effect general population**

- **No list of “accepted” risk factors**
- **EFSA**
  - **Risk factor is independent predictor of human disease**
  - **Relationship of the risk factor to development of the disease is biologically plausible**
- **Evaluated “case by case”**

2

## *Function claim*

Maintenance or improvement of a function, e.g.

*gut health is **too general**, it is unclear how to characterize this, but transit time is specific and measurable by generally accepted methods.*

## *Reduction of disease risk*

Reduce risk **factor**, e.g.  
*Arterial stiffness is **not** a risk factor of cardiovascular disease but LDL cholesterol **is** a risk factor of coronary heart disease*

# All different? All the same? Some, some not?



Good Food, Good Life

	<b>Marker</b>	<b>Factor</b>	<b>Predictor</b>	<b>Endpoint</b>	<b>Outcome</b>
<b>Bio-</b>	Biomarker	Biological factor	Biological predictor	Biological Endpoint	Biological outcome
<b>Risk</b>	Risk marker	Risk factor	Risk predictor	Risk endpoint	Risk outcome
<b>Intermediate</b>	Intermediate marker	Intermediate factor	Intermediate predictor	Intermediate endpoint	Intermediate outcome
<b>Independent</b>	Independent marker	Independent factor	Independent predictor	Independent endpoint	Independent outcome
<b>Surrogate</b>	Surrogate marker	Surrogate factor	Surrogate predictor	Surrogate endpoint	Surrogate outcome
<b>Predictive</b>	Predictive marker	Predictive factor	Predictive predictor	Predictive endpoint	Predictive outcome
<b>Clinical</b>	Clinical marker	Clinical factor	Clinical predictor	Clinical endpoint	Clinical outcome

*Say what we mean,  
mean what we say*



Good Food, Good Life

**Marker: something that  
marks (something else)**

**It is not about the marker,  
but about the marked**

- **When is extrapolation valid?**
- **When is effect *beneficial to health*?**
- **True risk factors?**
- **Relevant for health, but not *preventing, treating or curing disease***



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***Does intake of the  
food (constituent)  
actually cause  
the claimed effect?***

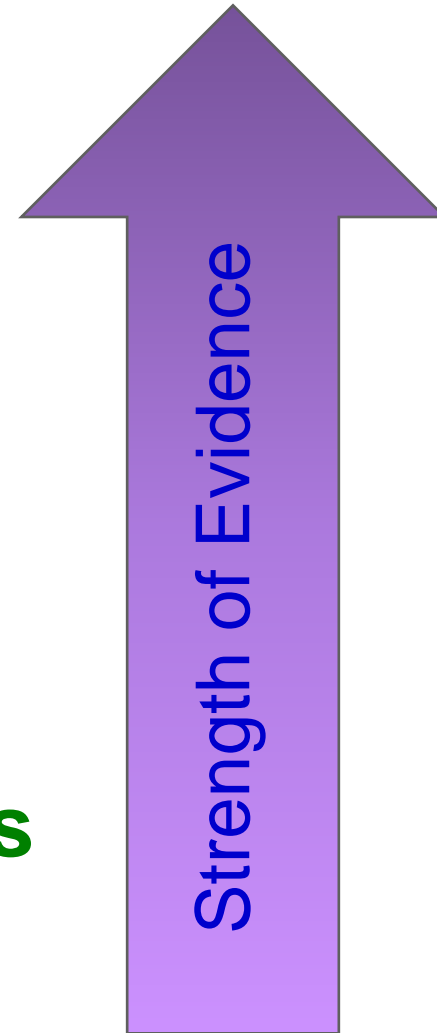
# Does intake of the food (constituent) actually cause the beneficial health effect?

**Core: studies in humans, primarily intervention:**

- 1. Subjects representative target group**
- 2. Appropriate control group**
- 3. Long enough**
- 4. Intake realistic**
- 5. Outcomes reflect directly the claimed effect, or are biologically and methodologically valid markers**
- 6. Effect statistically significant**
- 7. Size of the effect biologically meaningful**
- 8. Claimed effect plausible**
- 9. Consistency; no rule for # studies, but > 1**
- 10. TOTALITY of evidence**

- **Both** observe and compare aspects of health across groups with different intakes of a food (constituent)
- **Only difference:**
  - **intervention:** researcher allocates intake
  - **Observational:** researcher does **not**

- **Human Intervention Studies**
  - Randomized controlled
  - Controlled
  - No control
- **Human Observational Studies**
  - Cohort
  - Case-control
  - Cross-sectional
- **Human Studies on Mechanisms**
- **Case studies**
- **Non-human Data**



- **Single active constituent**
- **Mix**
- **Humans**
- **Children**
- **Healthy people**
- **Certain dose**

***If no such match, then data, at best, supportive***

# Everything depends on how you look at it

- Good data, *and* good assessment
- Next 47 sec: creative example of assessment / interpretation...



01\_speak french.mpg

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European Food Safety Authority

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 Print

- Scientific output definitions
- Printed science publications
- Requests & mandates

## Opinion of the Panel on dietetic products, nutrition and allergies (NDA) on a request from the Commission related to scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim

Question number: EFSA-Q-2007-066

Adopted: 6 July 2007

[See Also](#)

Available at <http://www.efsa.europa.eu/en/scdocs/scdoc/530.htm>

## SCIENTIFIC OPINION

**Scientific Opinion on the substantiation of health claims related to wheat bran fibre and increase in faecal bulk (ID 3066), reduction in intestinal transit time (ID 828, 839, 3067, 4699) and contribution to the maintenance or achievement of a normal body weight (ID 829) pursuant to Article 13(1) 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

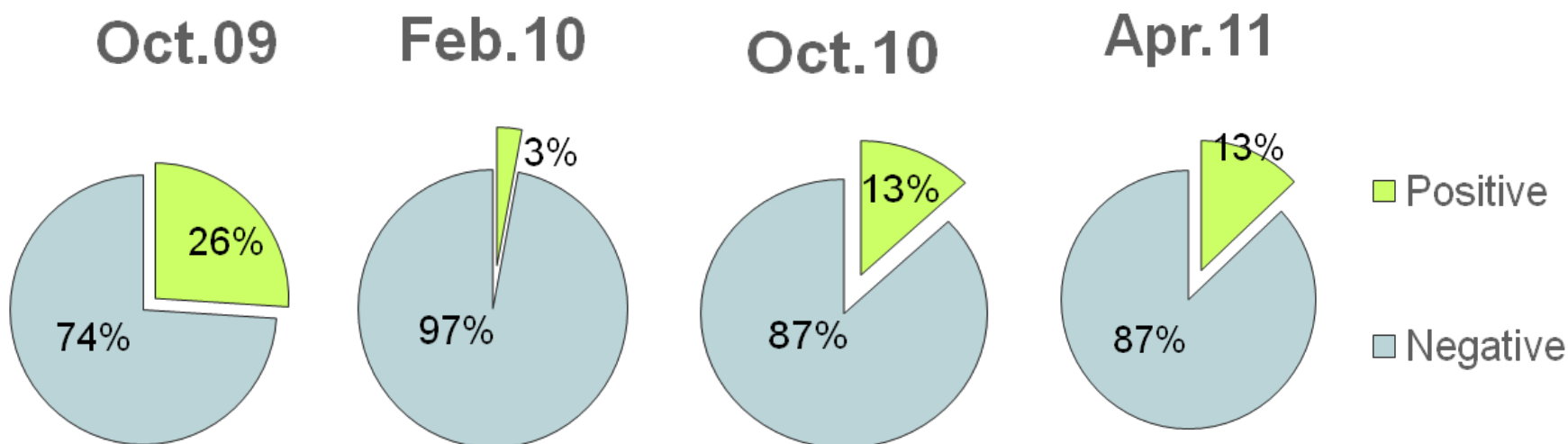
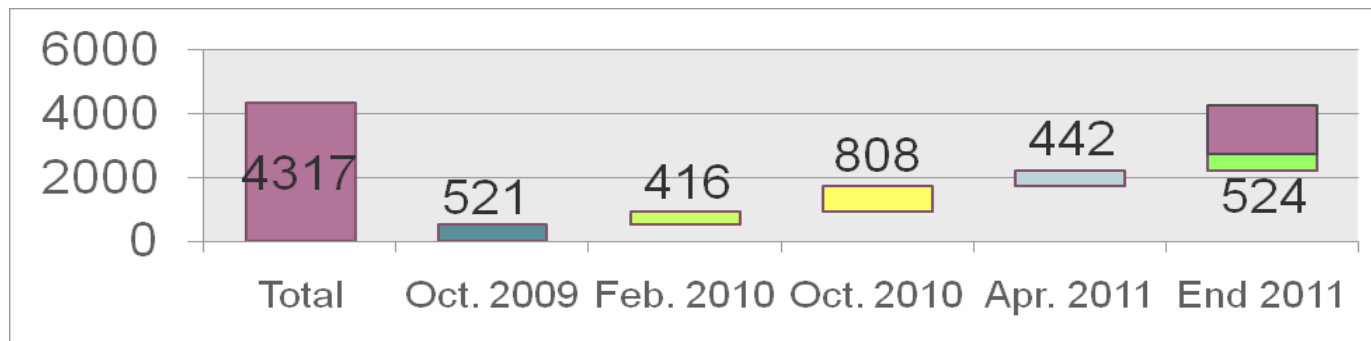
# An EFSA Opinion

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# EFSA Opinions Art. 13.1

## Oct 09, Feb & Oct 10, Apr 11

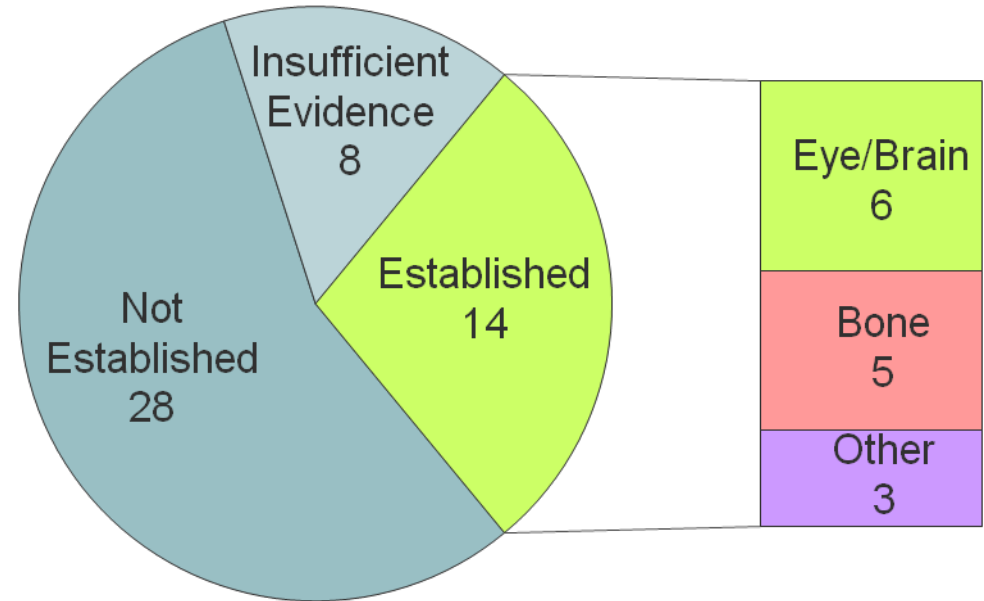


- EFSA provides scientific opinion
- EC and member states authorise or reject

### 14 Positive:

- **DHA: visual**
- **ALA, Fe, Vit B1: brain, cognitive, neurological**
- **Ca, Vit D, P, protein: for bone**
- **Essential fatty acids (ALA, LA): growth & development**
- **I: growth**
- **Vit B1: energy-yielding metabolism**

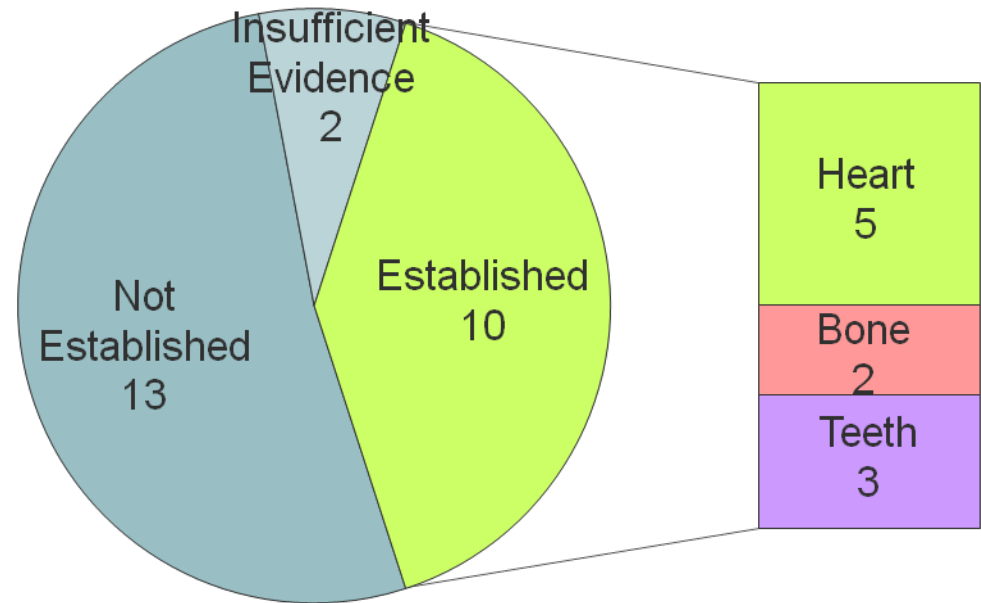
### Art. 14 Children



## 10 Positive:

- **Plant sterols, stanols, oat beta-glucan: reduced blood cholesterol**
- **Ca + Vit D: reduced loss of bone**
- **Sugar-free chewing gum: reduced tooth demineralization, neutralization plaque acids**

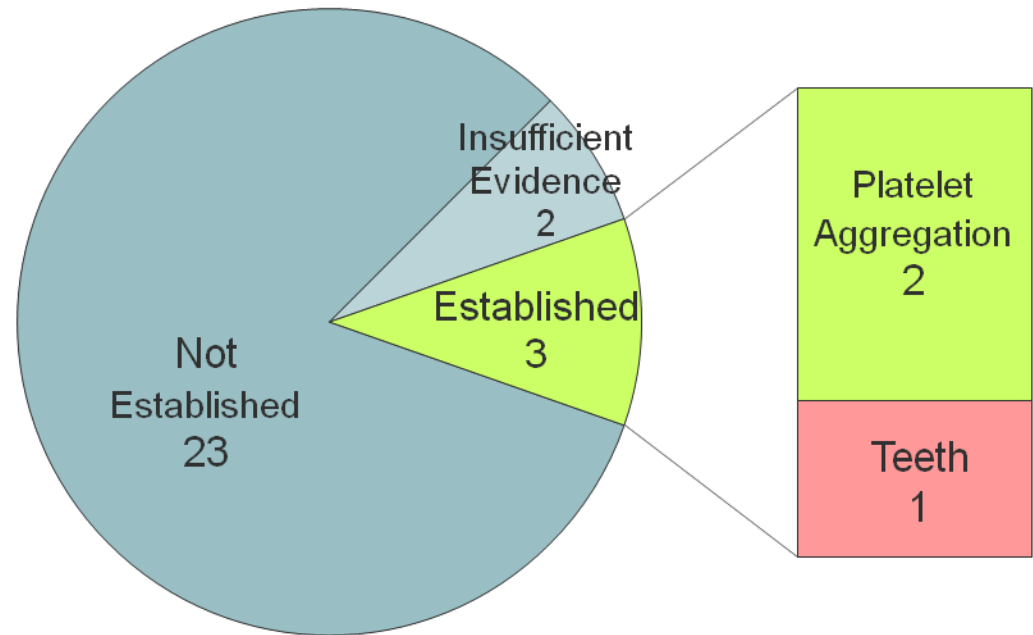
## Art. 14 Disease Risk Reduction



## 3 Positive:

- **Tomato extract concentrate: platelet aggregation**
- **Toothkind drinks: reduce tooth demineralization**

Art.13.5 Claims



**NO**



Good Food, Good Life

**Prunes/plums**

**Maintenance normal bowel function**

**Lutein**

**Maintenance of vision**

**170 substances for antioxidant effect**

**142 substances for joint, bone & muscle health**



# YES

Mainly well-established nutrient functions:

**Vitamin A** Normal function of immune system;  
maintenance of normal vision

**Vits B<sub>1</sub>, B<sub>12</sub>, niacin, pantothenic acid**

Normal energy-yielding metabolism

**Vitamin C** Protection of DNA, proteins and lipids  
from oxidative damage

**Calcium & vitamin D** Maintenance of normal bones  
at all ages


**Folate** Normal blood function; normal maternal  
tissue growth during pregnancy

**Iron** Normal formation of red blood cells and  
haemoglobin; oxygen transport

# YES

- Plant sterols lower blood cholesterol; blood cholesterol lowering may reduce the risk of coronary heart disease
- Meal replacements and weight control; reduction in body weight

*Make things as  
simple as possible,  
but not  
simpler than that*



***Substantiate  
what one claims;  
claim only  
what has been  
substantiated***



***The art  
of asking questions  
is the source  
of every progress***