EFSA remit & role: with focus on scientific substantiation of Health Claims made on foods

EFSA meeting with IPA Europe

Parma, 18 January 2019

efsa
European Food Safety Authority

OUTLINE

- EFSA legal framework & remit
- EFSA principles for scientific substantiation of claims
- Experience from health claim substantiation
- EFSA vs. non-EU jurisdictions
- EFSA guidance documents

RISK ASSESSMENT & RISK MANAGEMENT IN THE EU

European Food Safety Authority

Scientific assessment

Policy, legislation, authorisation…

European Commission

European Parliament

European Council

EU Member States

REMIT

EFSA Founding Regulation (EC) 178/2002

EFSA does not

- Develop or propose policies, legislation, norms and standards
- Enforce legislation
- Classification of products as food/food category
- Authorise products & nutrition/health claims made on foods
- Take charge of food safety/quality controls
- Setting labelling requirements
- Make recommendations to consumers
- Monitor or assess consumers' behaviour, societal/economical aspects

These are for Risk Managers

HEALTH CLAIMS MADE ON FOODS: LEGAL FRAMEWORK

Regulation (EC) No 1924/2006

Health claims should only be authorised in the EU after **a scientific assessment of the highest possible standard**

Claims substantiated by

- **generally accepted scientific evidence**
- **totality of the available scientific data**
- **weighing the evidence**

EFSA NDA Panel adopts scientific opinions

AUTHORISATION: by Commission/Member States, European Parliament scrutiny

HEALTH CLAIMS ON FOODS: REGULATORY REQUIREMENTS

Regulation (EC) No 1924/2006 and (EU) No 1169/2011

- Food category, a food or a food constituent (e.g. a nutrient or other substance, or a fixed combination of nutrients/other substances)
- Function claims **cannot** refer to a disease
- Disease risk reduction claims **cannot** refer to reduction of the risk of a disease, but to reduction of a risk factor for disease
- Subjects with a disease **cannot** be the target population for claims made on food
  - Target population for claims = **general (healthy) population or subgroups thereof**
- Efficacy assessment. No safety assessment

PRINCIPLES FOR SCIENTIFIC SUBSTANTIATION

General scientific guidance for stakeholders on health claim applications

A food/constituent  **A claimed effect**

1. Is the food/constituent **characterised?**
2. Is the claimed effect based on **the essentiality of a nutrient**? OR

   Is the claimed effect **defined** and is it a **beneficial physiological effect,** and can **be measured *in vivo* in humans?**
3. Is a **cause and effect relationship** established between the consumption of the food/constituent and the claimed effect?

   ✓ for the **target population** and under the **proposed conditions of use (CoU)**

Scientific substantiation (positive outcome) requires a favourable outcome to ALL three questions

PRINCIPLES FOR SCIENTIFIC SUBSTANTIATION (cont.)

General scientific guidance for stakeholders on health claim applications

Characterisation of the food/constituent

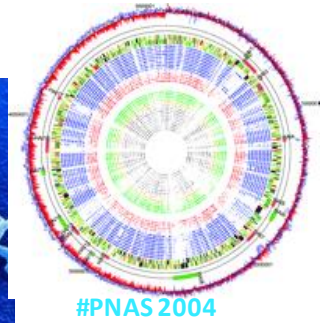
i. Composition/characteristics	**plant sterols/stanols** LDL-cholesterol **resistant starch** post-prandial blood glucose **sugar-free gum** tooth mineralisation
ii. Manufacturing process	**water-soluble tomato concentrate** standardised by the total of 37 constituents inhibiting platelet aggregation *in vitro*
iii. Known mechanism of action	**non-digestible carbohydrates** post-prandial blood glucose

For a food category: Whether the information provided sufficiently addresses the variability between individual foods regarding those characteristics which may influence the specific claimed effect?

PRINCIPLES FOR SCIENTIFIC SUBSTANTIATION (cont.)

General scientific guidance for stakeholders on health claim applications

Characterisation of microorganisms



- **Species identification + strain characterisation/typing** needed, since effects are strain specific unless the contrary is demonstrated
- New **molecular tools** (multilocus sequence typing, optical mapping, whole-genome sequencing, etc.). Open list to others.
- **Several methods** often needed in combination

PRINCIPLES FOR SCIENTIFIC SUBSTANTIATION (cont.)

General scientific guidance for stakeholders on health claim applications

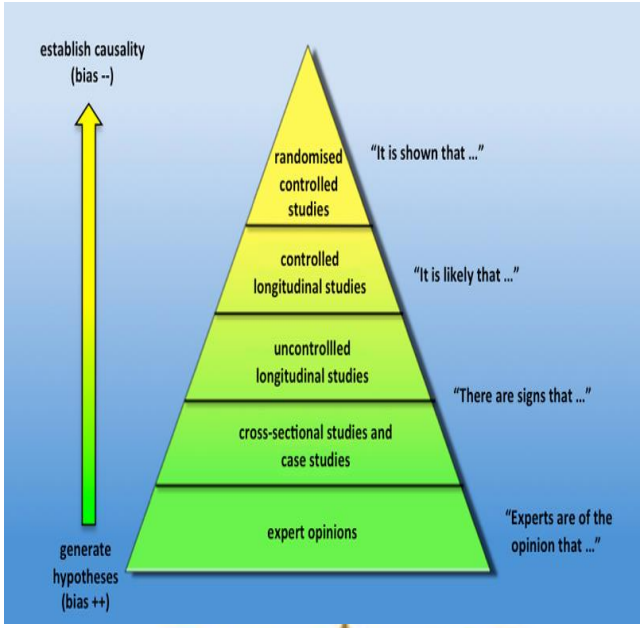
Characterisation of the claimed effect

- the human studies submitted
- Identify the health/disease **outcome(s)** in relation to the food/constituent and for which the available evidence may be strong
- Do outcome(s) describe **a beneficial physiological effect**?
- Are outcome variable(s) direct measures of the claimed effect?
- Are the **assessment methods** appropriate?

PRINCIPLES FOR SCIENTIFIC SUBSTANTIATION (cont.)

General scientific guidance for stakeholders on health claim applications

- **Pertinent human efficacy studies (central for substantiation) – hierarchy of evidence**
  - ✓ carried out with **the food/constituent for the claim**?
  - ✓ **appropriate outcome measure(s)** for the claimed effect?
  - ✓ **study group** is representative of the target population?
  - ✓ **the design and quality of the study** in relation to the risk of bias?
  - ✓ **conditions for human studies** vs. conditions of use for the claim?
- **Supportive studies:** Efficacy studies in animals, non-efficacy studies in humans, animals/*in vitro* (e.g. mechanisms that explain the effect of the food)
- **Weighing the evidence:** combining human efficacy studies +supportive studies +biological plausibility of the effect to conclude on substantiation



EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION

Insufficient characterisation of the food/constituent

a major reason for unfavourable opinions related to microorganisms in 2009/2010

- Non-characterised microorganisms (87%)
- Characterised microorganisms (13%)

EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION (cont.)

Insufficient characterisation of the claimed effect
other major reason for unfavourable opinions

- **Non defined claims**:

'gut health', 'digestive health', 'healthy microbiota', 'natural defences' etc.

specific and measurable ?

- **Non beneficial claims**:

' reduction of gastric acid levels',
' reduction of inflammation'

is a beneficial physiological effect for the target population ?

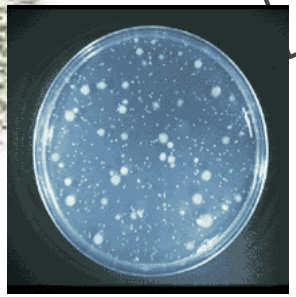
EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION (cont.)

Insufficient characterisation of the claimed effect

Not all outcomes, which can be measured *in vivo* in humans by generally accepted methods, reflect a direct benefit on human physiology

Adapted from NaturalMed Apothecary, Inc. 2006

E.g. Changes in the composition of the gut microbiota / immune markers *per se* / SCFA



EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION (cont.)

Lack of pertinent human studies

Altern Ther Health Med. 2011 Jan-Feb;17(1):72-9.

Clinical utility of probiotics in inflammatory bowel disease.

Cain AM, Karpa KD.

York Hospital, Pennsylvania, USA.

Curr Opin Pediatr. 2010 Oct;22(5):626-34.

Probiotics and pre… …ects in allergic disease.

Tang ML, La…

…**munology**, Royal Children's Hospital, Parkville, VIC, Australia. mimi.tang@rch.org.au

… 2010 Aug 25;10:253.

Probiotics in the treatment of acute rotavirus diarrhoea. A randomized, double-blind, controlled trial using two different probiotic preparations in Bolivian children.

Grandy G, Medina M, Soria R, Terán CG, Araya M.

Paediatric Centre Albina Patiño, Department of Gastroenterology and Nutrition, Cochabamba, Bolivia. ggrandy@inta.cl

Studies designed for the treatment of diseases

EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION (cont.)

Peer-reviewed publications

may not provide the evidence needed for scientific substantiation of health claims

- **Aim of the publication** (human intervention/observational studies, meta-analysis of RCTs) **may not fit the purpose and conditions of the claim** (e.g. insufficient characterisation of the food/constituent, study group not representative of the target population, inappropriate outcome measures of the claimed effect)
- **Statistical analyses may be inappropriate in relation to the outcome measure of interest for the claim** (e.g. PP and/or ITT analyses based on a different outcome)
- **Relevance of findings may depend on the context** (e.g. hypothesis-generating, exploratory studies vs. confirmatory studies

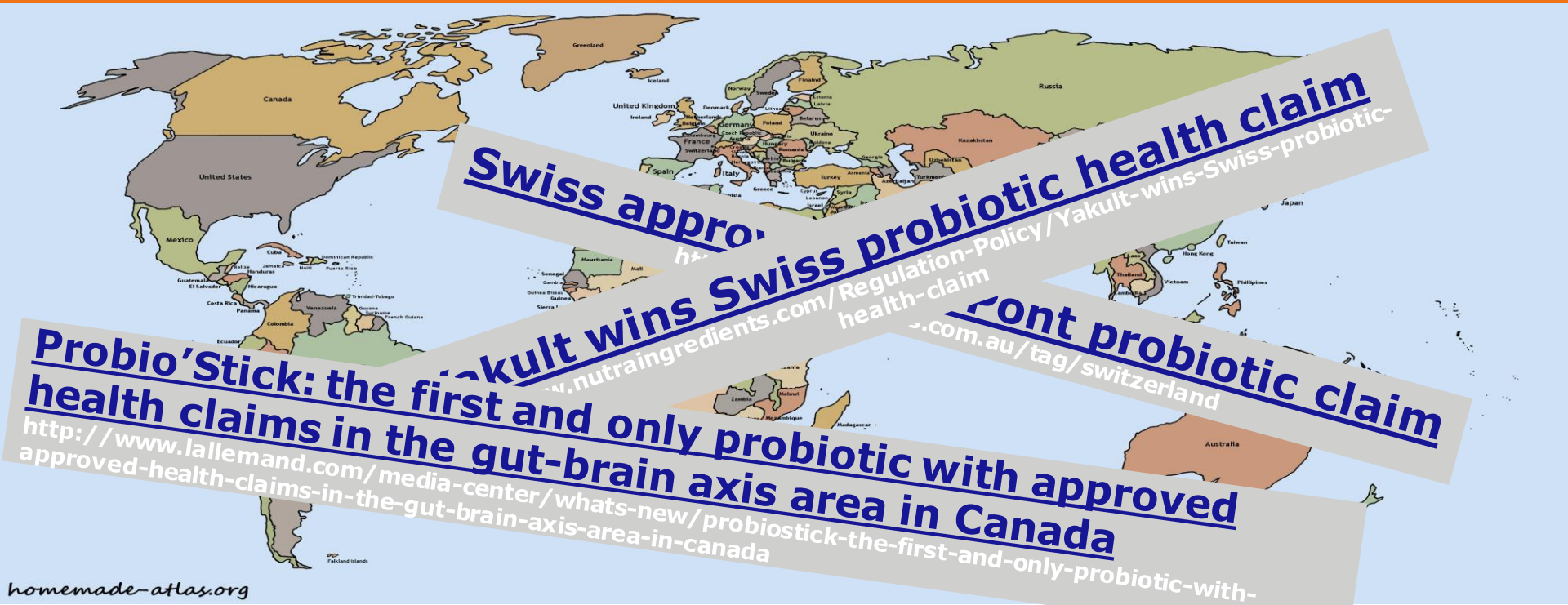
The use and value of peer-reviewed publications depend on their purpose

EXPERIENCE FROM HEALTH CLAIM SUBSTANTIATION (cont.)

Examples of authorised/non-authorised health claims (Art. 13.1)

Food/constituent	Health relationship	Reasons/outcomes
Dietary fibre	• Maintain a healthy immune system; • Maintain normal blood lipid levels/a healthy cardiovascular system • Maintain healthy cholesterol levels • Maintain normal blood sugar levels • Low glycaemic response • Reduce fat absorption • Maintain your body weight • Maintain normal bowel/colonic function	**Unfavourable evaluation: Not sufficiently characterised** **Non-authorised**
Arabinoxylan from wheat endosperm	Reduction of post-prandial glycaemic responses	**Favourable evaluation Authorised**
Rye fibre	Changes in bowel function	**Favourable evaluation Authorised**
Wheat bran fibre	↑ intestinal transit	**Favourable evaluation Authorised**

EFSA vs NON-EU JURISDICTIONS



Health claim assessments in different jurisdictions are often driven by different legislative frameworks governing the authorisation of health claims made on food!

ALTERNATIVES to HEALTH CLAIMS?

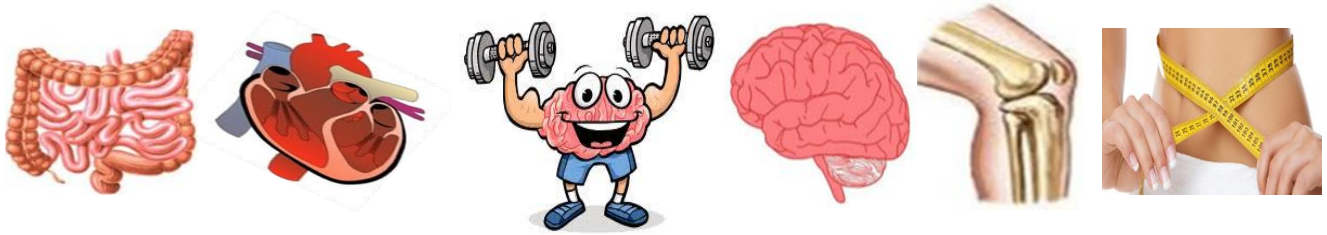
- "Probiotics" as generic descriptor
- Nutrition claim "contains probiotics"
- "Probiotics" as recognised food category (comparable to "dietary fibre")
- "Probiotics" in "positive list" (as Canada)

For consideration by EU Risk Managers

(i.e. Member States and the European Commission)

EFSA GUIDANCE DOCUMENTS

- General scientific guidance for stakeholders on health claim applications
- Preparation and presentation of health claim application
- 6 guidance on specific health claims areas



- Scientific Committee Guidance on the assessment of the biological relevance of data in scientific assessments
  - generic issues/criteria to consider biological relevance, particularly when deciding on whether an observed effect is of biological relevance

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