EFSA assessment of health claims on probiotics

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IPA World Congress & Probiota Americas, 31 May - 2 June 2016, Chicago
RISK ASSESSMENT & RISK MANAGEMENT IN THE EU

- Scientific assessment
- Policy, legislation, authorisation, enforcement, control

European Commission
European Parliament
European Council
EU Member States
PROBIOTICS IN THE EU

- Food, including
  - food supplements
  - foods for special medical purposes
- Medicinal products
- Medical devices
- Cosmetics
- Feed additives

Products are regulated based on the category into which they fall
Regulation (EC) No 1924/2006

• protect consumers from misleading claims

Claim: any message or representation [...] which states, suggests or implies that a food has particular characteristics

- beneficial nutritional properties
- relationship between a food/constituent and health
- food/constituent significantly reduces a risk factor in the development of a human disease

nutrition claim

health claim

reduction of disease risk claim
Scientific assessment of the highest possible standard

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

**Scientific assessment**
EFSA

**Authorisation**
European Commission +
EU Member States
European Council
European Parliament scrutiny
EFSA SCIENTIFIC ASSESSMENT: 3 MAIN QUESTIONS

One food/constituent ↔ One claimed effect

- Characterisation of food/constituent
- Benefit of the claimed effect
- Established causality

- Target population = general (healthy) population or subgroups thereof
- Medicinal claims are not allowed on food
EVIDENCE ASSESSMENT: STEPS

Pertinent human efficacy studies
- central for substantiation
- studies designed for the treatment of diseases are generally not accepted

Supportive studies
- efficacy studies in animals
- non-efficacy studies in humans, animals and/or in vitro (mechanism)

Weighing the evidence
- combining the human efficacy studies + supportive studies
EFSA EXPERIENCE ON PROBIOTIC CLAIMS

>300 requests
>200 probiotic strains or combinations
>60 beneficial effects claimed

Why have no probiotic claims been approved in the EU?
MAIN REASONS FOR UNFAVOURABLE OPINIONS

- Insufficient characterisation
- Non defined claims
- Non beneficial claims
- Not all measurable outcomes reflect a direct benefit for humans
- Lack of pertinent human studies
- Quality of studies

Adapted from: NaturalMed Apothecary, Inc. 2006
NEW GUIDANCE ON CLAIMS

General scientific guidance for stakeholders on health claim applications

Panel on Dietetic Products, Nutrition and Allergies

**EFSA Journal:** EFSA Journal 2016;14(1):4367 [38 pp.].
**DOI:** 10.2903/j.efs2.2016.4367

Guidance on the scientific requirements for health claims related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms

Panel on Dietetic Products, Nutrition and Allergies

**EFSA Journal:** EFSA Journal 2016;14(1):4369 [23 pp.].
**DOI:** 10.2903/j.efs2.2016.4369
POSSIBLE REGULATORY SOLUTION

- **Use of the term “probiotics”**
  - “Contains probiotics/prebiotics” – considered as health claim in the Guidance on the implementation of Regulation 1924/2006

The European Commission and the EU Member States are reflecting on a possible European solution
CLOSING REMARKS

- Each claim is unique
- Scientific requirements have to be considered in the context of each application
- Guidance documents and past evaluations are a valuable source of information
- Important to understand the rationale of the principles applied
- No recipe for success can be provided
- Try, fail, learn, try again
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Thank you

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