Reducing salt, fat and sugar in everyday foods
Results from TeRiFiQ EU project
and opportunities for food industry

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Health claim dossier: opportunities for SMEs and lessons learnt

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MAIN CRITERIA FOR HEALTH CLAIMS

Reg. (EC) No 1924/2006

"Health claims should only be authorised for use in the Community 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'S ROLE

Reg. (EC) No 1924/2006

- "In order to ensure a harmonised scientific assessment of these claims, **EFSA** should carry out such assessments"
  - ✓ NDA Panel applies a single standard of evidence for substantiation of all health claims
  - ✓ NDA Panel adopts scientific opinions

➢ **AUTHORISATION: by Commission/Member States, European Parliament scrutiny**

EU Register of Claims (http://ec.europa.eu/nuhclaims/)

HEALTH CLAIMS

Regulation (EC) 1924/2006

Art.13.1	Art.13.5	Art.14
Generally accepted scientific evidence	Newly developed scientific data / proprietary data	Reduction of disease Risk Children's development & health

List Claims — **Applications**

REGULATORY REQUIREMENTS

- subjects with a disease cannot be the target population for health claims made on food
- function claims cannot refer to a disease
- disease risk reduction claims cannot refer to the reduction of the risk of a disease, but should refer to the reduction of a risk factor for disease

➢ The NDA Panel considers that the target population for health claims made on food is **the general population or subgroups thereof** defined on the basis of age, gender, physiological conditions and/or lifestyle (e.g. children, men, post-menopausal women, adults performing endurance exercise)

SCIENTIFIC ASSESSMENT

3 main questions

- Claim definition
  1. Is the food/constituent **defined** and **characterised?**
  2. Is the claimed effect **defined** and is it a **beneficial physiological effect,** and can it **be measured *in vivo* in human?**
- Substantiation
  3. Is a **cause and effect relationship** established between the consumption of the food/constituent and the claimed effect?
     - ✓ for the **target group** and under the **proposed conditions of use**

Human data are central

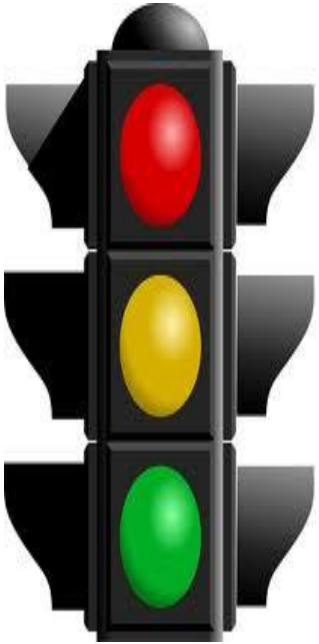
SCIENTIFIC ASSESSMENT

Steps

- Selection/review of **pertinent human studies:** central for substantiation
- Review of supportive studies on **biological plausibility** (e.g. mechanisms that explain the effect of the food)
- **Weighing the evidence** - combining the relevant human studies + other studies **to conclude on substantiation**

SCIENTIFIC ASSESSMENT

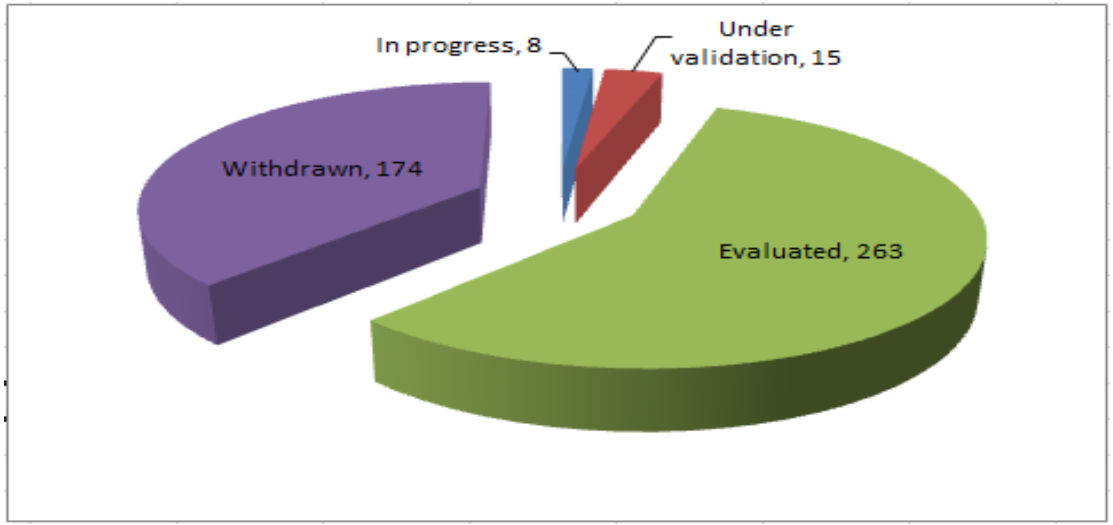
Possible conclusions



- a cause and effect **has not been** established
- **insufficient evidence** for cause and effect ….
- a cause and effect **has been** established

HEALTH CLAIMS (STATUS 22/09/2015)

- Applications on Article 13.5 and Article 14 health claims: 460 received



- Art 13.1 list: finalised except botanicals (1548 on hold)

HEALTH CLAIM APPLICATIONS

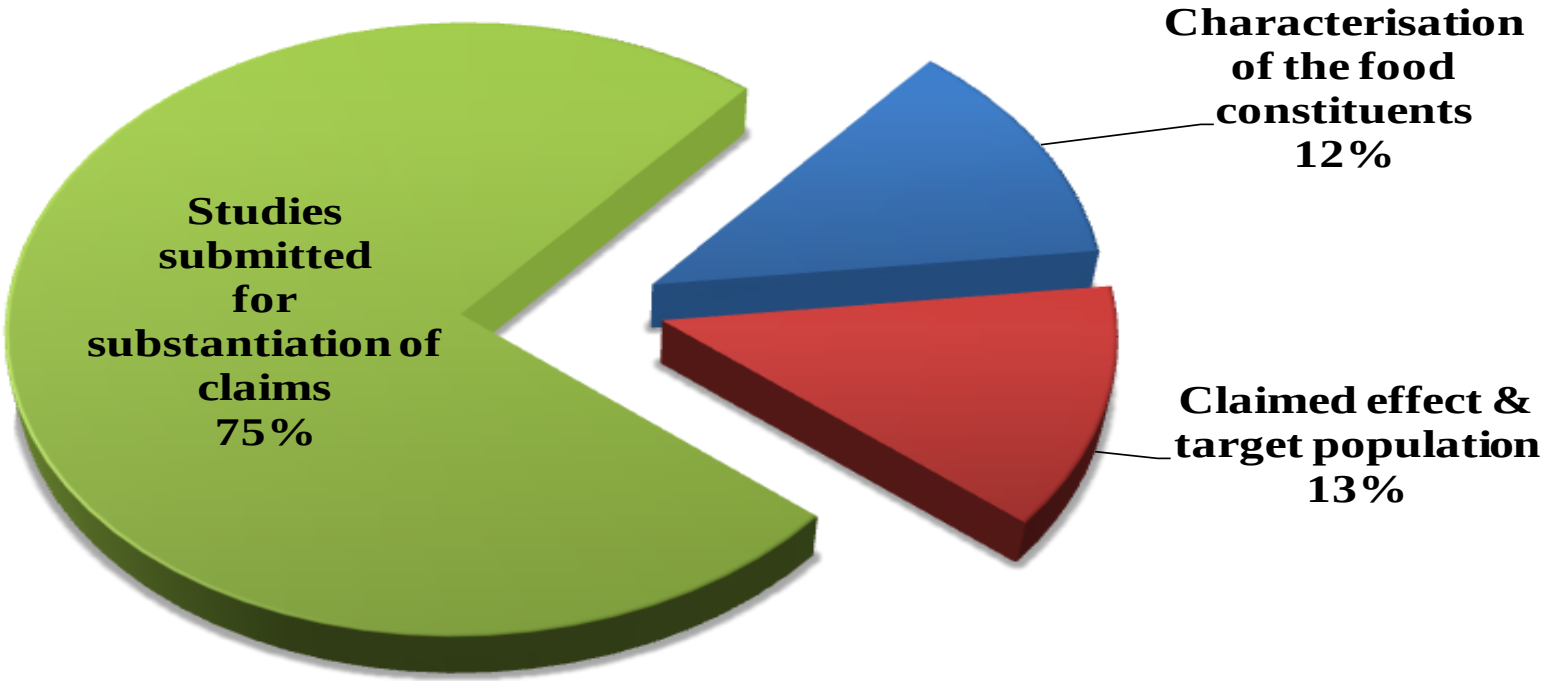
Issues arising while reviewing scientific evidence for health claims

Delays in evaluation process

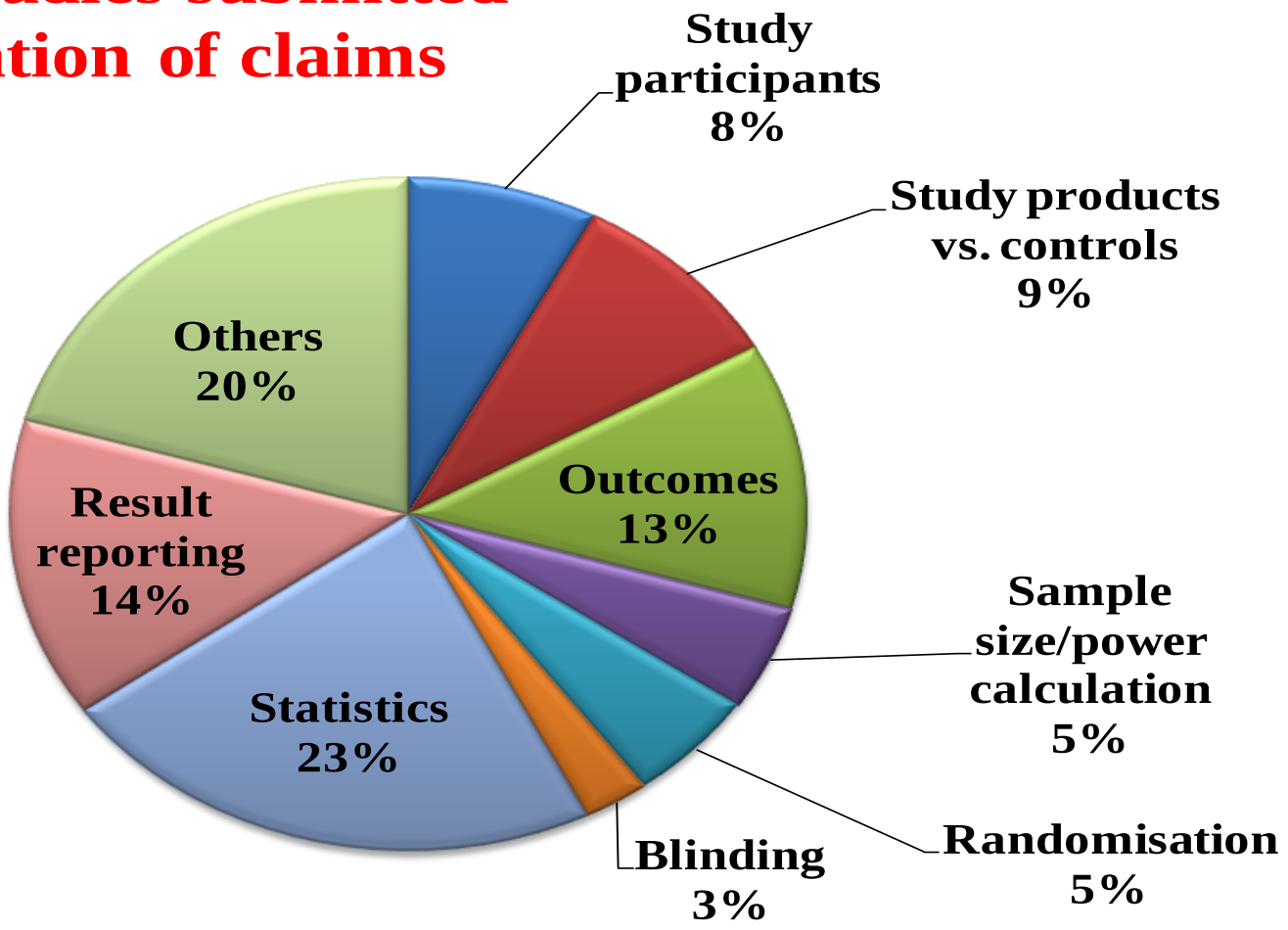
Reasons for **clock stops** requesting supplementary information

(***from 109 clock stop letters to applicants)***

Reasons for clock stops



Questions on studies submitted for substantiation of claims



MIS-REPORTING OF STUDIES

- **Published papers** may not accurately represent what was done and what was the outcome
  - incomplete reporting, e.g. subject selection, enrolment, randomisation, retention and drop outs; statistical analyses
  - selective reporting of outcomes, subgroup analyses – mainly favourable outcomes reported
- EFSA may request additional information from the applicant, including full study report for key studies

CLAIMS GUIDANCE

General

- ✓ Preparation and presentation of applications *(revised 2011)*
- ✓ General scientific guidance for stakeholders *(public consultation Jul-August; finalisation Dec 2015)*

Specific

- ✓ Gut, immune *(public consultations; finalisation Dec 2015)*
- ✓ Bone, joints, skin, oral
- ✓ Appetite, body weight, blood glucose
- ✓ Antioxidants, cardiovascular
- ✓ Physical performance
- ✓ Neurological, psychological function

SCIENTIFIC OPINION

EFSA Journal

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doi:10.2903/j.efsa.20YY.NNNN

Draft general scientific guidance for stakeholders on health claim applications

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

Thank you!

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