European Food Safety Authority

EFSA's Role in Nutrition & Health Claims

Joint PVD/EFSA Seminar
17 October 2012

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Outline

- EU Regulation on nutrition and health claims
- EFSA review of the evidence for scientific substantiation of health claims
- Status of applications, ongoing and near future

REGULATION (EC) No 1924/2006

efsa
European Food Safety Authority

of 20 December 2006

on nutrition and health claims made on foods

EU Regulation - Features

- **Types of health claims:**
  - function claims
  - disease risk reduction claims
  - claims on development and health of children
- Applies equally to supplements, ingredients, other foods
- No provision for qualified health claims or different standards for different foods

  ⇒ A single standard of evidence for substantiation

- **Nutrition claims**

EU Regulation - Features

- All claims must be authorised and all must be assessed by EFSA (*"on the highest possible standard"*, recital 23) before authorisation

- All claims must be substantiated by generally accepted scientific evidence

  = generally accepted by scientific experts

- Taking into account totality of available scientific data, and weighing the evidence

Types of Health Claims

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‘Function claims‘

Art.13.1

Generally accepted scientific evidence

Art.13.5

Newly developed scientific data/ proprietary data

Reduction of disease risk Art. 14.1(a)

Risk factor
e.g. LDL cholesterol

Children’s development and health Art. 14.1(b)

e.g. Calcium – needed for bones

Process for "General Function Claims" Art 13.1

4185
Claims submitted by EC to EFSA (Jul/Nov/Dec 2008)

EFSA Screening (Jan, June 2009)

2466
Claims sent back to EC/MS for clarification

331
Claims withdrawn (including product specific claims)

620
Claims no clarification received

1515
Claims clarification received

1719
Claims directly accepted for assessment

4306
Claims in

2758
Claims to be published in 6 batches

1st batch Oct 09
94 Opinions
521 Claims

2nd batch Feb 10
31 Opinions
416 Claims

3rd batch Oct 10
75 Opinions
808 Claims

4th batch April 11
63 Opinions
442 Claims

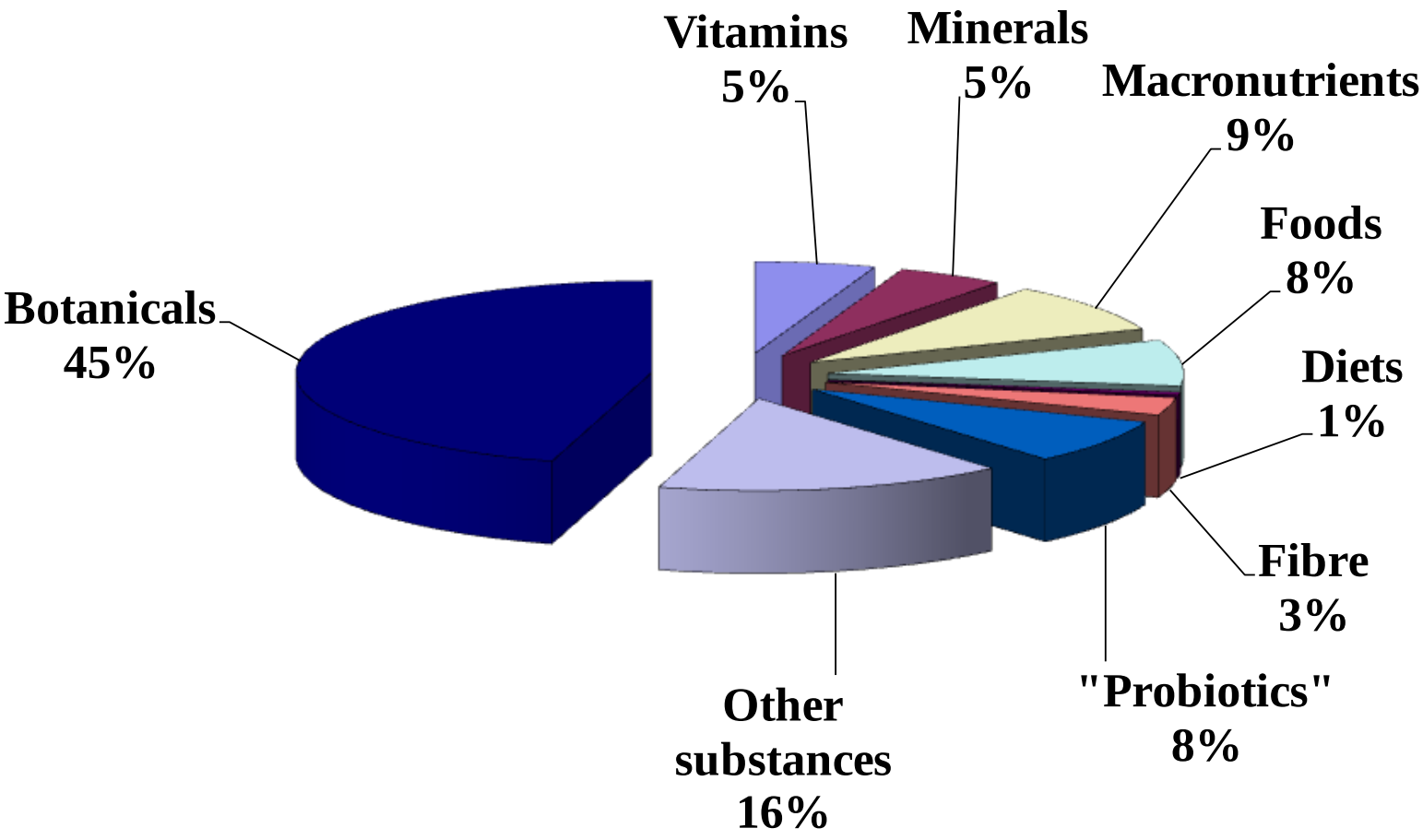
5th batch June 11
73 Opinions
536 Claims

6th batch July 11
5 Opinions

452
Claims submitted by EC to EFSA in March 2010

1548
"Botanical" claims on hold

Art 13.1 Claims received by EFSA



Process for Art 14 Claims
(new science, children, risk reduction)

- **Validation of application**
  - Submission to Member State: admissibility check; if ok, sent to EFSA
  - EFSA checks completeness; if ok, clock starts

- **EFSA evaluation**
  - Evaluation and adoption of opinion within 5 months; in case additional information is needed, the evaluation time is extended (clock stop time plus 1 or 2 months)
  - Pre-notification of applicant
  - Publication of opinion, informing EC and Member States

- **EC takes decision through regulatory procedure with scrutiny**
  - 30 days for public to comment on opinion to EC
  - EFSA to respond on scientific comments received

Nutrition Claims

= claim which states or suggests that a food has particular beneficial nutritional properties due to the content of energy, nutrient(s) or other substances

Art 8: only be permitted if they are listed in the Annex and are in conformity with this Regulation.

Art 28: Nutrition claims which are not included in the Annex shall be communicated by MS to the EC (31 Jan 08). EC/MS to decide. (EFSA consultation if appropriate).

EFSA Review of the Evidence

1. Characterisation of food/substance
2. Beneficial to human health
3. Cause and effect relationship
4. Food quantity required for claimed effect
5. Representativeness of data for target population

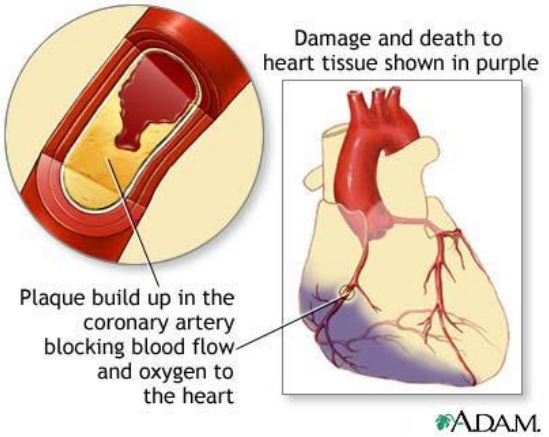
1. Characterisation

Valeriana officinalis

Essential for the assessors and for the regulators

2. Beneficial Effect

- Is the claimed effect beneficial for human health?
  - Validity of end-point used
  - Size of effect
  - Benefit in EU population groups



3. Cause and Effect Relationship

- Is a cause and effect relationship established between the consumption of the food/constituent and the claimed effect in humans?
- Characteristics of the food-health relationship
  - strength
  - consistency
  - specificity
  - dose-response
  - biological plausibility, mechanistic studies

4. Food Quantity

- Is the quantity of food/constituent proposed for the claimed effect adequate? *(dose tested vs dose proposed)*

- Could the quantity of the food/constituent and pattern of consumption required to obtain the claimed effect reasonably be consumed as part of a balanced diet?

5. Representative Study Population

- Is the specific study group(s) in which the evidence was obtained representative of the target population for which the claim is intended?
  - Patients vs. healthy subjects?
  - Obese vs. normal weight?
  - Adults vs. children?
  - Case-by-case judgement

Evidence Review: Cause - Effect

a. Selection & review of relevant human studies

b. Review of studies on biological plausibility - mechanisms, bioavailability

c. Weighing the evidence - combining the relevant human studies + other studies to conclude on substantiation

Relevant Human Studies

- studies carried out with the food/constituent for claim
- appropriate outcome measure(s) for the claimed effect
- conditions for studies comparable to conditions of use for claim (e.g. quantity of food/constituent)
- study groups representative of the target group or extrapolation to the target population possible

Review of Relevant Human Studies

- Published and unpublished studies accepted
- Review by study type – e.g. intervention, observational
- Study quality – design, execution, analysis, reporting
- Additional information may be requested from the applicant
- Studies of low quality may be excluded

Weighing the Evidence

- combine the relevant human studies by study type (RCT strongest evidence): number of studies for and against, taking into account study population, study quality, study size, effect size, dose-response, consistency among studies
- evidence for biological plausibility – bioavailability, mechanisms; studies in humans, animals, *in vitro*
- no pre-established formula (number/type of studies)

case by case judgement by NDA Panel experts

➢ **Transparent description in the published opinion**

EFSA Health Claims Evaluation Status

12/10/2012

Claim type	Received	Withdrawn	Adopted	In progress	Under Validation
Children (Art. 14)	220	110	53 op. covering 60 applications	1*	49
Disease risk reduction (Art. 14)	58	23	32 op. covering 33 applications	0**	2
New science/ proprietary (Art. 13.5)	107	18	65 op. covering 66 applications	19***	4
Conditions of use (Art. 19)	2	0	2	0	0
Total applications	387	151	152 opinions covering 161 applications	20	55
Art 13 list of health claims	4728[#]	331	2849[#] (2849 published)	0	1548 (on hold)

[#] 4730 & 2851 questions in RAW because of 2 duplicated items

* 0 in clock stop ** 0 in clock stop *** 11 in clock stop

Guidance & Dialogue with Stakeholders

- **EFSA guidance:**
  - preparation and presentation of applications (2007)
  - general principles for substantiation of claims (2009, 2010)
  - scientific requirements for substantiation of specific types of health claims (2010-2012)
- **EFSA dialogue with applicants** before acceptance and during evaluation, clock stops, EFSA's response to comments after publication
- **Stakeholder meetings** to discuss general principles and specific topics, Scientific colloquium
- **Presentations at conferences**

Ongoing and Near Future

- EFSA committed to maintain the quality and timeliness of the applications
- EFSA to further assist applicants by providing additional guidance and through ongoing dialogue with applicants and other stakeholders
- Web-consultations and where appropriate scientific meetings during 2012 and 2013
- Establishment of “Application Helpdesk”
- EFSA awaits regulatory decision on „botanicals“

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THANK YOU

efsa anniversary 10 efsa anniversary

Committed *since 2002*
to ensuring that Europe's food is safe