European Food Safety Authority

Update on EFSA's activities in the area of Nutrition

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Outline

- Nutrition and Health Claims
- Nutrient recommendations (PRIs)
- Food allergy
- Others (dietetic foods, novel foods)
- Other activities

Nutrition and Health Claims

- **EFSA's scientific advice on scientific substantiation of health claims**
  - Claims subject to authorisation procedure
    - EFSA Guidance to applicants for disease risk reduction claims + claims for development & health of children (Art. 14)
    - Function claims based on new science/proprietary data (Art. 18)
  - Function claims based on generally accepted scientific evidence (Art. 13)

- **EFSA's scientific advice on nutrient profiles**

EFSA scientific advice on substantiation of claims - scope

- Evaluation of claims subject to authorisation procedure
  - Reduction of disease risk claims (Art. 14, July 2007-)
  - Claims for development and health of children (Art 14, July 2007-)
  - Function claims based on newly developed scientific data/ proprietary (Art. 18, 2010-)
- Guidance on preparation and presentation of applications for authorisation (adopted for Art 14. claims, July 2007 following public consultation)
- Evaluation of function claims based on generally accepted scientific evidence (Art. 13, 2008-9)
  - Community list of permitted claims (2010)
- Other
  - Amendments to Annex (nutrition claims), if appropriate

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

- **NDA Panel**
  - 19 members: Chair (A. Flynn); Vice-chairs (H. Przyrembel; A. Palou)
  - Adopts scientific opinions
  - All opinions published - EFSA Journal (web)
- **Procedures for claims**
  - NDA WG Claims prepares draft scientific opinions
  - 11 Panel members currently
  - Additional independent experts will be added as needed
    - Evaluation of claims in specific areas
- **EFSA staff**
  - Support work of Panel and WG

Authorisation of Article 14 claims

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Reduction of disease risk/development and health of children

- Application submitted through Member State to EFSA
  - EFSA validation of application
- EFSA to inform other MS, EC, publish summary
- EFSA evaluation - opinion (5 months)
  - additional time (2 months) if supplementary information needed
- EFSA Opinion published, sent to EC
  - 30 days for comment to EC
- Community authorisation (2 months)
  - EC adopts decision through Regulatory Committee, EP scrutiny?
  - Decision is notified to applicant and published in OJ

EFSA guidance on Art. 14 claims

Opinion of the EFSA NDA Panel on:

scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim

- Adopted 6 July 2007

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592448.htm

- EFSA Conference on Health Claims, Bologna, 2006
- Consultation - draft opinion published 16 May, 2007
  - EFSA Stakeholders Consultative Platform, June 2006
  - About 300 responses received
  - All responses taken into consideration

Objectives of guidance

- To assist applicants in preparing and presenting their applications for authorisation of Art. 14 health claims
  - Common format - for a well-structured application
  - Content - information and data required/optional
  - Criteria for substantiation - the key issues to be addressed to substantiate a health claim
  - To be reviewed and updated in light of experience gained in evaluation of claims
  - To be reviewed and updated for Art. 18 claims

EFSA opinion (Reg. 1924/2006)

- verify that
  - the claim is substantiated by scientific evidence
  - wording complies with the criteria laid down in the Regulation
- include
  - characteristics of the food/constituent
  - a proposal for the wording of the claim
  - specific conditions of use of the claim
    - the target population for the intended claim
    - food quantity/pattern of consumption required to obtain the claimed effect
    - whether this could reasonably be consumed as part of a balanced diet
  - restrictions of use (if appropriate)
    - Statement/warning for persons who should avoid using the food/constituent
    - Statement/warning for health risk if consumed to excess
    - Other

Requirements for application

Application must contain all scientific data pertinent to the claim

- published and unpublished, in favour/against, indicating proprietary data
- data from studies in humans required for substantiation
- intervention and observational studies considered
  - data from animals or model systems may provide supporting evidence
- comprehensive review of the data from human studies
- identification of data pertinent to the claim
  - systematic and transparent to show application is balanced
- templates provided for presentation of data
- guidance on hierarchy of evidence - relative strength of evidence from different types of studies

Criteria for substantiation

Regulation - health claims should be substantiated by

- "generally accepted scientific evidence"
- "taking into account the totality of the available scientific data"
- "weighing the evidence"

Criteria:

- Relevance to human health
- Causality of the relationship
- Food quantity required for claimed effect
- Representativeness of data for target population

Consumer understanding

"claims shall only be permitted if the average consumer can be expected to understand the beneficial effects as expressed in the claim"

- consumer understanding not assessed by EFSA

However

- wording of claim should reflect the scientific evidence
- wording should be understandable in terms of its relevance for human health
- claims considered from a scientific point of view to be vague, confusing or misleading will not receive a favourable opinion from EFSA

Nutrient profiles (Art. 4)

- By 19 January 2009 the EC shall establish specific nutrient profiles, including exemptions, which foods should respect in order to bear claims

- Profiles to be adopted by the EC through Regulatory Committee following the advice from EFSA

EFSA's scientific advice on nutrient profiles (1)

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Setting of profiles should include:

- Dietary recommendations
- Public health
- Scientific evidence – relationship diet/nutrition/health

- As well as other "non-scientific" considerations:
  - Industrial/commercial; cultural; and dietary/culinary nature
  - Profiles should permit product innovation
  - Variability of dietary habits and traditions
  - Concept of better regulation
  - Criteria: feasibility, simplicity, ease of use (stakeholders & control authorities), consumer protection

EFSA's scientific advice on nutrient profiles (2)

- Scientific advice on nutrient profiles
  - NDA WG on Claims to prepare draft scientific opinion
  - NDA Panel to adopt scientific opinion by January, 2008
  - Opinion to be published - EFSA Journal (web)
- NDA Panel, WG Claims and EFSA staff to assist EC and Member States to develop a nutrient profile scheme (by January 2009)
- Consultation
  - Reports, papers on nutrient profiles
  - EFSA Conference on Nutrition and Health Claims (November 2006)
  - EFSA Scientific Colloquium on Nutrient Profiling (October 2007)

EFSA's scientific advice on nutrient profiles (3)

- Mandate received by EFSA (web)
- EFSA's advice will address:
  - Across the board/food categories
    - Vegetable oils, spreadable fats, dairy products, cereal products, fruit products, others (e.g. meat products)
  - Choice of nutrients
    - Fat, saturated fat, trans-fatty acids, sugars, salt/sodium
    - Poly- and mono-unsaturated fats, vitamins, minerals, protein, fibre
  - Reference quantity
    - /100 g, /100 kcal, /portion
  - Calculation
    - Thresholds/scoring
  - Feasibility
    - Testing of models – which foods are eligible/not eligible to bear claims

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

- **Nutrient recommendations (PRI)**
  - Macronutrients (energy, fats, carbohydrates & fibre, protein, and water)
    - Public consultation - early 2008
  - Translating PRI into FBDG (methodology)
  - Micronutrients
- **Food allergy**
- **Others**

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

- **Nutrient recommendations (PRI)**
- **Food allergy**
  - 21 opinions recently adopted on allergen derivatives for permanent exemption from mandatory labelling
  - Huge task accomplished (legal deadlines)
    - 50 opinions on derivatives (overall) – 2004/5 & 2007
    - 4 opinions on allergenic foods (Annex IIIa of allergenic ingredients)
- **Others**
  - Novel foods: alpha-cyclodextrin; allanblackia oil
  - Dietetic foods: lutein (on-going)

Other EFSA activities on nutrition

- **Cooperation with MS – Cooperation strategy**
  - Data collection (food composition; food consumption)
  - Current MS practices on FBDG
  - Regulations: novel foods, claims
- **Platform on Diet, Physical activity and health**
  - Founding member
  - Observer
  - Technical assistance if needed

Thank you for your attention

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