European Food Safety Authority

EFSA's role and work with regard to health claims

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Seminar on health claims
National Food Institute/Technical University of Denmark
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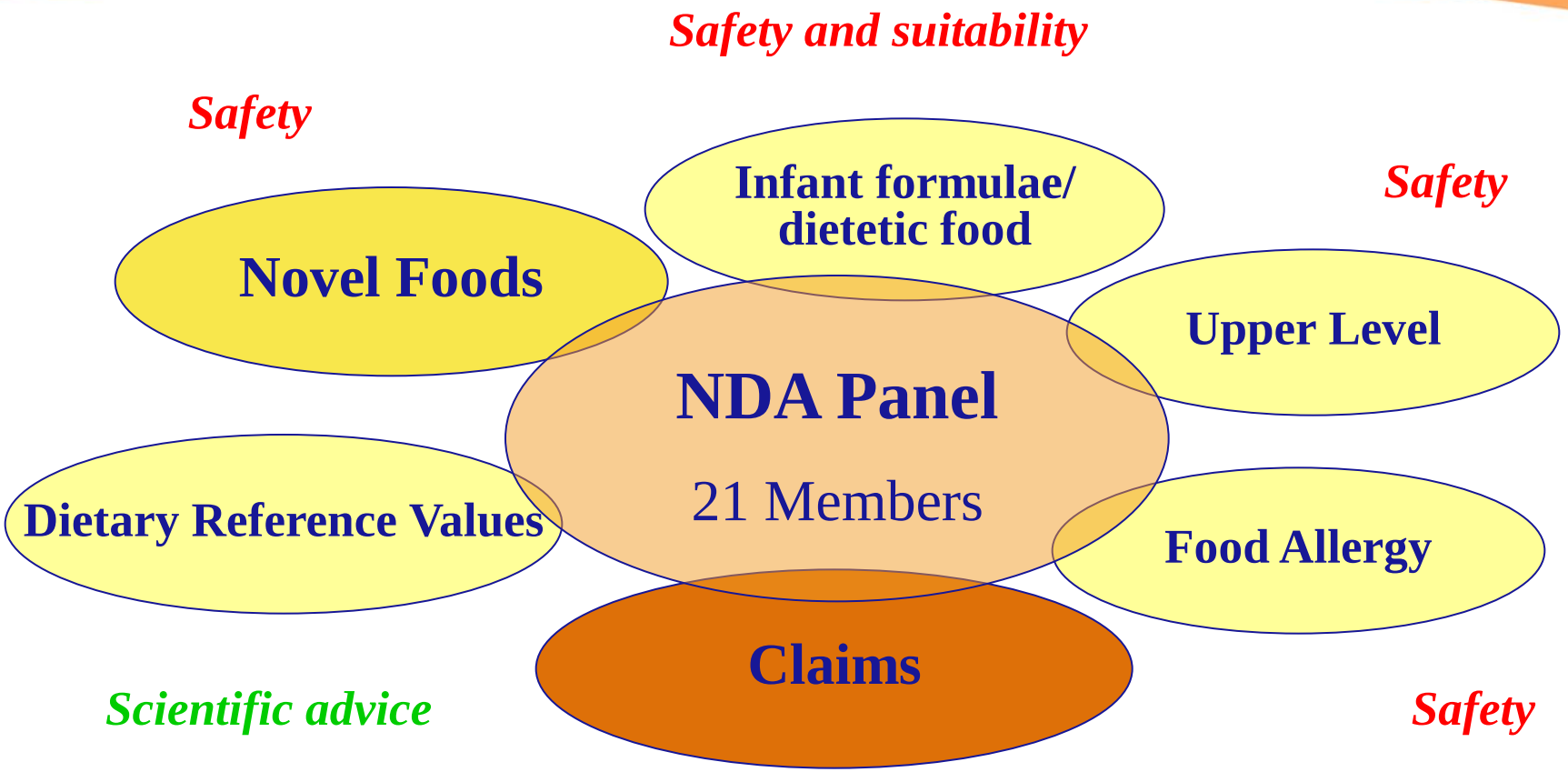
NDA Panel & Working Groups



Supported by the EFSA Secretariat (Nutrition Unit)

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Regulation (EC) No 1924/2006 of the European Parliament and of the Council

of 20 December 2006

on nutrition and health claims made on foods

EFSA's role in the evaluation of health claims

- **EFSA** is responsible for **assessing** the scientific evidence of submitted claims

- This information serves as a basis for the **European Commission and Member States** to decide whether to **authorise** the claims.

- **EFSA's work includes providing scientific advice on:**
  - **General function health claims** (Article 13.1 of the EU Regulation)
  - **New function health claims** (Article 13.5 of the EU Regulation)
  - **Claims regarding disease risk reduction and child development or health** (Article 14 of the EU Regulation)
  - **Nutrition claims**, as the case may be
  - Criteria for setting **nutrient profiles**

Different types of health claims

- **"General function" claims (Article 13.1) refer to:**
  - the role of a nutrient or substance in growth, development and body functions
  - psychological and behavioural functions
  - slimming & weight control, satiety or reduction of available energy from the diet

- **New function health claims (Article 13.5) are based on:**
  - new scientific evidence and/or
  - for which protection of proprietary data is requested

- **Article 14 claims refer to:**
  - claims regarding child development or health and
  - disease risk reduction

Scientific criteria for evaluation of health claims

- Regulation (EC) No 1924/2006 –
  health claims substantiated by:
  - **"generally accepted scientific evidence"**
  - "taking into account the **totality of the available scientific data**, and by **weighing the evidence"**

- The NDA Panel makes a scientific judgment on whether there is sufficient evidence to support the claim
- EFSA NDA Panel criteria not different from those applied by US Food & Drug Administration and Health Canada

Process for children, disease risk reduction & new science health claims

- Applications are transmitted to EFSA by competent authorities of Member States
- **Validation of application**
  - Submission to Member State: admissibility check; when ok, sent to EFSA
  - EFSA checks completeness; when 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 European Commission and Member States
- **EC takes decision through regulatory procedure with scrutiny**
  - 30 days for public to comment on opinion to European Commission
  - EFSA to respond on scientific comments received

Health claims applications received

Year	No of applications	Status
Aug-Dec 2007	5	3 adopted/ 2 withdrawn
2008	226	62 adopted/ 114 withdrawn 50 under validation (children c.)
2009	36	23 adopted/ 12 withdrawn 1 in progress
2010	29	15 adopted/ 14 withdrawn
2011	27	20 adopted/ 3 withdrawn 4 in progress
Jan-May 2012	37	5 adopted/ 1 withdrawn 15 in progress, 16 under validation

Process for "general function claims"

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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

452
Claims submitted by EC to EFSA in March 2010

1548
"Botanical" claims on hold

2758
Claims to be published in 6 batches

Authorisation of 222 claims by risk managers

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
35 Claims

Favourable health claim evaluations - disease risk reduction claims

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Food/constituent	Health relationship
Plant sterols/stanols Oat beta-glucans MUFA/PUFA replacing SFA	Blood LDL -cholesterol/heart disease
Sugar-free chewing gum	Dental plaque/caries Plaque acids/caries Demineralisation/caries
Calcium Calcium and Vitamin D	Bone density/osteoporotic fracture
Vitamin D	Falling/osteoporotic fracture

Favourable health claim evaluations - function claims (>200)

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Food/constituent	Health relationship
Sugar replacers, fluoride	Tooth enamel
Calcium, vit. D, vit. K	Bone
Meal replacement, VLCD	Body weight
Cereal fibres (wheat, barley, oat, rye)	Bowel function
Pectins, guar gum, resistant starch, sugar replacers, slowly digestible starch	Blood glucose after meals
Potassium, reduced sodium	Blood pressure
Water soluble tomato concentrate	Platelet aggregation (healthy blood flow)
Live yoghurt bacterial cultures	Lactose digestion

Unfavourable health claim evaluations

Main reasons

- Lack of suitable human studies on which to base the claim for the intended population group
  - No human studies at all
  - Studies in patients only and not relevant to the intended population group
  - Studies relevant to the intended population group but of poor quality, or with unsuitable measurements, etc.
- Claimed effect not defined or not considered a beneficial physiological effect, or not related to a function
- Food/substance not sufficiently characterised

Work in progress

Health claims – further assessment (Article 13)

- Initial assessment of Article 13 claims:
  - 2,758 claims assessed in 341 opinions
  - about 2,000 claims on botanicals 'on hold'
- Around 300 claims considered eligible for further assessment by COM
  - Health claims on micro-organisms which the Panel considered as insufficiently characterised (261 ID qualifying)
  - Health claims with 'insufficient evidence' in initial assessment (42 ID qualifying)
- 91 IDs (74 IDs for micro-organisms, 17 IDs for "insufficient evidence" claims) coordinated by MS, submitted to EFSA – deadline December 2012, first publications beginning of June 2012

Insufficient evidence – further assessment

Food	Health relationshp
Prunes	Normal bowel function
Lactotripeptides (IPP and VPP)	Maintenance of blood pressure
Alpha- cyclodextrin	Reduction of post-prandial glycaemic responses
Vitamin K2	Normal function of the heart and blood vessels
Lutein	Maintenance of normal vision
Soy isoflavones	- Reduction of menopausal vasomotor symptoms - Maintenance of bone
Olive polyphenols	Maintenance of HDL-cholesterol concentrations

Micro-organisms – further assessment

- 74 IDs concerning 13 combination of strains and around 30 single strains
- Data submitted for majority of strains may probably allow sufficient characterisation
- Claimed effects: defence against pathogens at various sites of the body, bowel function and intestinal transit, gastro-intestinal discomfort, stimulation of immunological responses, skin and hair, alleviation of stress, not given
- Challenge: in some cases to link the strains which are used in the studies submitted to the strains which are the subject of the claim

Assistance to applicants

EFSA guidance on scientific requirements

- Health claims **technically complex**
- **There is no precedent** for the evaluation of most claims. Scientific requirements for many claims are defined for the **first time**.
- **EFSA guidance:**
  - To help the applicants with preparation and presentation of their applications (2007, revised 2011)
  - To establish general principles for substantiation (2009, 2011)
  - To set scientific requirements for substantiation of specific types of health claims (2010-2012)

Status of guidance documents in specific areas

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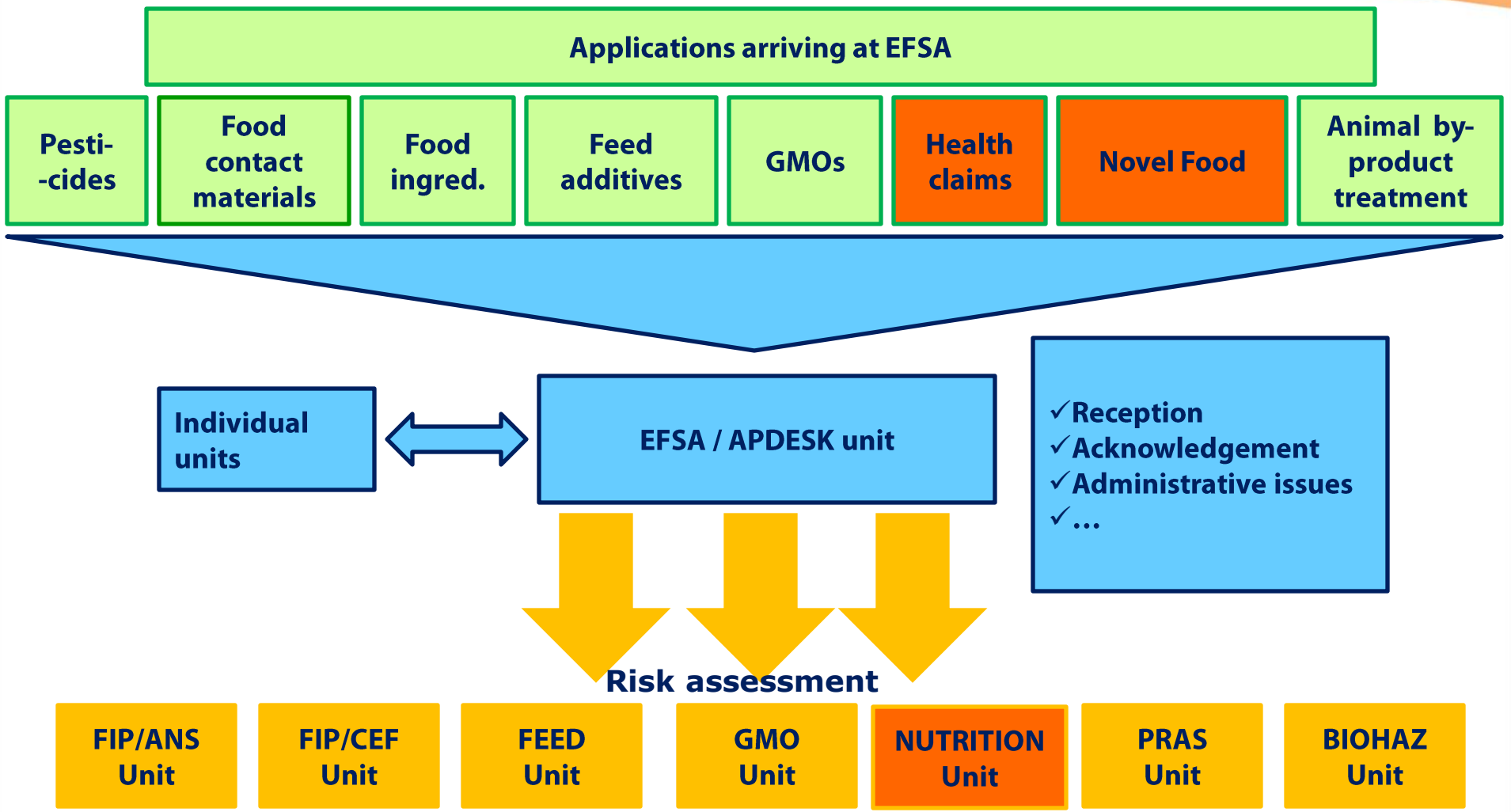
- Scientific requirements for health claims related to **gut and immune function** – adopted in January 2011
- Scientific requirements for claims related to **antioxidants, oxidative damage and cardiovascular health** – adopted in November 2011
- Scientific requirements for health claims related to **appetite ratings, weight management and blood glucose** concentrations – adopted in February 2012
- Scientific requirements for health claims related to **bone, joints and oral health** – adopted in April 2012 Plenary
- Scientific requirements for health claims related to **neurological and psychological function** – adoption expected in June 2012 Plenary
- Scientific requirements for health claims related to **physical performance** – adoption expected in June 2012 Plenary

Dialogue with stakeholders

- **EFSA's dialogue** with applicants
  - Stakeholder meetings to discuss general principles and specific topics
  - Dialog with applicants before acceptance, during the evaluation
  - NDA Panel's opinions + EFSA's response to comments after publication of the opinion
- **EFSA's** Application Desk
  - Provide a front office and support desk for applicants, MS, other stakeholders
  - Support submission of applications
  - Harmonise workflows from reception to validation

APDESK tasks

Centralize entries of applications within EFSA



APDESK Plan 2012-2015

Continued support to submission of applications:

✓ Provide pre-submission support to applicants:

- Develop an EFSA strategy paper for interaction with applicants

✓ Provide dedicated support to SMEs and/or new applicants:

- Develop an APDESK SME team **(on-going)**
- Operate an APDESK network in the Member States
- Develop a specific area in EFSA APDESK webspace **(on-going)**

✓ Support scientific units in the organisation of technical workshops and trainings **(on-going)**

Development of E-submission for applications

✓ Feasibility study

✓ Electronic submissions Project

APDESK – front office, support desk

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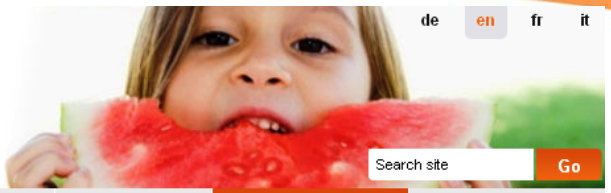

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Print

- Animal by-products
- Decontamination
- Feed additives
- Food contact materials
- Food ingredients
- Food processing
- GMO
- Nutrition
- Pesticides
- ▸ **Ask a question**

Ask a question about applications

Email*	
First name	
Last name	
Affiliation	– Select –
Name of organisation	
Country	– Select –
Scientific area*	Animal by-products
Subject*	– Select –
Application registration number	

Your question*

* Mandatory field

Submit

www.efsa.europa.eu/it/applicationshelpdesk.htm

APDESK 2012 - Survey stakeholders' needs

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- Launch a **survey on stakeholders' needs** for the future development of services to stakeholders

- **Objective**: to launch a questionnaire to stakeholders on their expectations on the type, nature, quality of services they would like to be put at their disposal by EFSA and its new APDESK unit in the area of regulated products (targeted audience)

- **Stakeholders**: applicants, Member States, European institutions and bodies, MSs and national agencies, other stakeholders, specialized media

- **Timeline**: call for tender published on 29th May 2012

THANK YOU