



# Functional foods and legislation: the role of the European Food Safety Authority (EFSA)

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CIHEAM  
Zaragoza, 3-7 April 2006

European Food Safety Authority



## Content of presentation

- EFSA - mission and structure
- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel)
- Risk assessment of novel foods

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## What gave rise to EFSA's establishment?

- Succession of food scares (e.g. BSE, dioxins)
- The creation of food safety agencies to handle food issues at national level within the EU
- Dissension within EU over risk assessments

## Establishing EFSA

- White paper on Food Safety (January 2000)
- Proposal for EFSA Regulation (November 2000)
- EFSA "founding" Regulation EC 178/2002 adopted by the Council of the EU (January 2002)

## Mission of EFSA

- Provision of scientific advice for the European Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety, including nutrition
- Provision of independent information on all matters within these fields
- Risk communication
- High level of scientific excellence, independence and transparency
- Operational since 2003

## EFSA - The Main Changes

- Risk assessment (science) divorced from risk management (policy)
- EFSA not part of the European Commission
- EFSA controlled by a Board acting in independent capacity, not national representatives
- EFSA works in close cooperation with national food safety authorities
- Need to actively consider and meet stakeholder needs (including, in particular, consumers)

## EFSA structure

- Management Board
- Advisory Forum
- Scientific Committee and Panels
- Executive Director and Staff

## Management Board: role

- Primary role: ensure EFSA functions effectively and efficiently
- Establish budget and work programmes and monitor implementation
- Ensure EFSA stays within the remit of the Regulation
- Appoint Executive Director, Scientific Committee and Scientific Panels

## Management Board: composition

- 14 members appointed on basis of individual expertise and competence (independence important)
- Appointed by European Council based on suggestion from European Parliament
- Not EU Member State representatives
- Widely varying backgrounds (e.g. consumer, government, food safety authority, agriculture, retail and scientific experience)

## Advisory Forum: role

- Advise EFSA on scientific matters, priorities and work programme
- Ensure close collaboration between national bodies and EFSA
- Provide help in resolving contentious scientific issues
- Assist in avoiding duplication of scientific effort in the EU
- Assist in increasing scientific co-operation between EU Member States
- Play a key role in providing and disseminating information

## Advisory Forum: composition

- Comprises EU Member States representatives
- Representation from food safety authorities or other organisations with roles similar to EFSA
- One representative per EU Member State with option to bring in specialist support
- European Commission's representative
- Special invitees (e.g., Norway, Switzerland)

## Scientific Committee

### COMPOSITION

- Chairs of the 8 Scientific Panels
- 6 scientists not members of the EFSA Panels

### ROLE

- General co-ordination, interface with Panels
- Questions involving several Panels
- Questions out of the scope of any of the Panels

## Eight Scientific Panels

- Food additives, flavourings, processing aids and materials in contact with food (AFC)
- Additives and products or substances used in animal feed (FEEDAP)
- Contaminants in the food chain (CONTAM)
- Plant health, plant protection products and their residues (PPR)
- Genetically modified organisms (GMO)
- **Dietetic products, nutrition and allergies (NDA)**
- Biological hazards (BIOHAZ)
- Animal health and welfare (AHAW)

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

Questions on dietetic products (foods for particular nutritional needs), human nutrition and food allergy, and other associated subjects such as novel foods

## Risk assessment of novel foods

### Novel Foods Regulation (EC) N° 258/97:

- Definition of novel food – foods/food ingredients which have not been used for human consumption to a significant degree within the EU
- Entering into force – **15 May 1997**

## Novel Foods Regulation (EC) N° 258/97

### Categories of novel foods:

- a) Foods containing or consisting of *GMOs* (Directive 90/220/EEC);
- b) Foods produced from, but not containing, *GMOs*;
- c) Foods with a new/intentionally modified primary molecular structure;
- d) Foods consisting of/isolated from microorganisms, fungi or algae;
- e) Foods consisting of/isolated from plants and food ingredients isolated from animals, except for foods obtained by traditional propagating/breeding practices & having a history of safe food use;
- f) Foods to which has been applied a production process not currently used, where that process gives rise to significant changes in composition/structure of the food which affect its nutritional value, metabolism or level of undesirable substances.

*Categories a) & b) superseded by GMO Regulation (EC) N° 1829/2003*



## Novel Foods Regulation\*

### Pre-marketing authorisation procedure:

- Application to an EU Member State (MS)
- Initial assessment report by the MS - 3 months
- Comments/objections from other MS/Commission - 60 days
- If additional assessment is required OR objections are raised: *consultation of EFSA (NDA Opinion)*
- Authorisation decision by Commission & MS

\* Regulation (EC) N° 258/97

## Risk assessment of novel foods

### Scientific Committee on Food (SCF) Guidelines\*:

- Classes of NF:
  - Class 1 - Pure chemicals or simple mixtures
  - Class 2 - Complex NF
  - Classes 3 to 5 - *GM [superseded by GMO Regulation]*
  - Class 6 - Novel processes
- Data requirements

\* Commission Recommendation 97/618/EC

## Risk assessment of novel foods

### SCF Guidelines - Data requirements:

- I. Specification of the NF
- II. Effect of the production process
- III. History of the organism used as the source of the NF
- IX. Anticipated intake/extent of use of the NF
- X. Previous human exposure to the NF or its source
- XI. Nutritional information
- XII. Microbiological information
- XIII. Toxicological information

## SCF Guidelines - Data requirements

- I. Specification of the NF
  - Origin & composition of NF (identity of product tested & product to be marketed)
  - Relevant parameters: species, taxonomy, chemical composition (nutritional properties), possible anti-nutritional/toxicological concerns
  - Availability of specified reference material

## SCF Guidelines - Data requirements

### II. Effect of production process applied to the NF

- Processed foods
- Description of the manufacturing process
- New technologies - address any organic/inorganic residues or contaminants derived from equipments or chemical, physical or biological aids used in the novel process
- Critical aspects - final product comply with specifications given under scheme I

## SCF Guidelines - Data requirements

### III. History of the organism used as source of the NF

- Information on past & present use of the plant, animal or microorganism and its products in countries outside the EU
- Past & present methods to obtain raw materials and food
- Procedures for fermentation & preparation
- Description of transport & storage conditions
- Its traditional role in the diet

## SCF Guidelines - Data requirements

### IX. Anticipated intake/extent of use of the NF

- Intake estimations to evaluate the dietary and nutritional significance of the NF
- Information on the nature of the NF and its anticipated uses based upon its properties, e.g. as a fat replacer

## SCF Guidelines - Data requirements

### X. Previous human exposure to the NF or its source

- Documentation on previous use of the NF source and/or the NF in other parts of the world outside the EU

## SCF Guidelines - Data requirements

### XI. Nutritional information on the NF

- Systematic review of the NF's composition, preparation and role expected in the diet
- Full nutritional assessment (human studies)
- Nutritional effects at normal & maximum levels of consumption
- Effect of anti-nutritional factors

## SCF Guidelines - Data requirements

### XII. Microbiological information on the NF

- Characterization of microorganisms present in the NF and analysis of their metabolites
- Organism (e.g. intentionally used source of the NF) has to be non-pathogenic, non-toxigenic and of known genetic stability

# SCF Guidelines - Data requirements

## XII. Toxicological information on the NF

- Range of scenarios - substantial equivalence (SE)
- If SE to a traditional counterpart cannot be established, the safety assessment must consider (case-by-case):
  - Toxicity of individual chemical compounds
  - Toxicity studies (*in vitro* & *in vivo*) - mutagenicity, reproduction & teratogenicity, long-term feeding studies
  - Allergenicity studies

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

## Scientific Opinions on novel foods:

- Foods with added phytosterols
- Betaine
- Chia seeds
- Lycopene from *Blakeslea trispora*
- Enova oil
- Vegetable oils rich in unsaponifiable matter

## Novel foods authorised at EU level under the Novel Foods Regulation\*

- Salatrim (for use as reduced calorie fats) - *SCF Opinion*
- Noni juice - *SCF Opinion*
- Phospholipids from egg yolk
- Fruit-based preparations using high pressure pasteurisation
- Bacterial dextran
- Trehalose
- Coagulated potato protein and hydrolysates thereof
- DHA-rich oil
- Isomaltulose

\* Regulation (EC) N° 258/97

## Novel foods refused under the Novel Foods Regulation\*

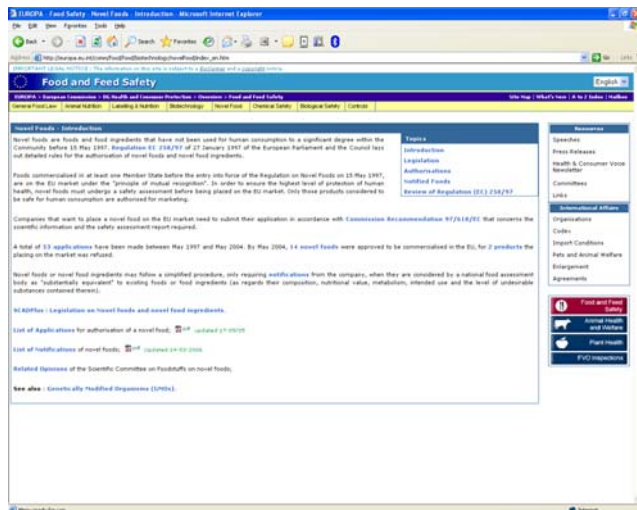
- Stevia rebaudiana - *SCF Opinion*
- Nangai nuts - *SCF Opinion*
- Betaine - *NDA Opinion*
- Iodine enriched wild-type eggs

\* Regulation (EC) N° 258/97



## European Commission - Health & Consumer Protection DG

[http://europa.eu.int/comm/food/index\\_en.htm](http://europa.eu.int/comm/food/index_en.htm)

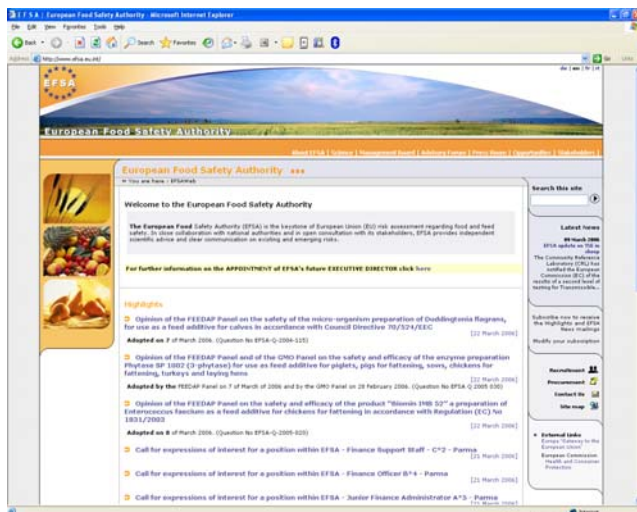


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*Thank you for your attention*

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