Evaluation and re-evaluation of food additives

Scientific Panel on Food Additive and Nutrient Sources Added to Food (ANS)

Riitta Maijala, Director of Risk Assessment
Majlinda Lahaniatis, Deputy Head of the ANS Unit

Parma, 22 June 2010
Overview

- The ANS Panel
- Risk assessment procedures for food additives
- Guidance for new food additives
- Re-evaluation of authorised food additives
• Currently 19 members

• The members embrace expertise in toxicology, exposure, food chemistry, analytical chemistry, and food technology

• Chair: - John Christian Larsen

• Vice-chairs: - Iona Pratt
  - Ivonne Rietjens
Working groups supporting the Panel

- **Standing working groups:**
  - WG A on food additives and nutrient sources
  - WG B on food additives and nutrient sources

- **Ad hoc working groups:**
  - Guidance on food additives
  - Amaranth

- **Three new permanent working groups created recently on:**
  - chemistry, exposure assessment and toxicology
Evaluation process

European Commission

- Receipt of mandate
- Discussion with the Commission

Applicant

- Receipt of application dossier
- Pre-screening by ANS Secretariat
- Preparation template draft opinion (+ possible pre-drafting)
- Request for missing data

Rapporteur

N.B.: the first steps will change when Regulation 1333/2008 will fully be in force
Evaluation process (continued)

Rapporteur

Preparation draft opinion

ANS Secretariat

Working group discussion

Discussion and possible adoption by the Panel

ANS Secretariat

Publication of the opinion

Request for additional data

Applicant
Applicable guidance documents

1. Statement on data requirements for the evaluation of food additives applications (adopted on 9 July 2009): general data requirements

2. Two Guidances of the Scientific Committee on Food (endorsed provisionally by the ANS Panel, September 2008)
   - "Guidance on submissions for safety evaluations of sources of nutrients or of other ingredients proposed for use in the manufacture of foods“, reference SCF/CS/ADD/NUT/21 Final
   - “Guidance on submissions for food additive evaluations by the Scientific Committee on Food“, reference SCF/CS/ADD/GEN/26 Final

Establishment of a new guidance for food additives: foreseen to be finalised by ANS Panel, July 2011
General data requirements

Example for food additive applications

General scientific approaches defined in ANS Panel Statement ‘Data requirements for the evaluation of food additive applications’ (2009) in relation to the current state of the art of risk assessment, science and technology.

Specific scientific approaches suggested in the guidance applicable at the time of application.

Application dossier

- Administrative data
- Technical data
- Biological and Toxicological Data
Enables an assessment to be made and permits verification that the substance does not pose a safety concern to the health of the consumer at the proposed use level.

Includes the available data relevant for the purpose of the assessment:
- full published papers of all references,
- full copies of the original reports of unpublished studies and corresponding individual raw data,
- data gathering conducted and the literature search should be documented (i.e. search strategies, assumptions made, key words, databases, limitation criteria, etc.),
- comprehensive outcome of the literature search to be provided.

Individual results of examinations and raw data, including microscopic slides, should also be available upon request.

Safety evaluation strategy and the corresponding testing strategy should be described/justified with rationales for inclusion and exclusion of specific studies.
Applicants are also reminded to...

- Propose overall **conclusions** on the safety of the proposed uses of substance.
- Perform the overall evaluation of potential human risk in the context of known or likely human exposure, including that from other sources.
- Provide a **summary of the information** given in the dossier.
- Present information in the dossier in a **standard way** (EFSA will publish standard templates for the different sections of the application dossiers and for the reporting of the toxicological studies).
- Provide **details of any applications made to other evaluation bodies or regulatory agencies** together with their status and outcome.

*During the evaluation process, EFSA may request any additional data that is considered necessary for the safety assessment.*
General data requirements

Administrative data

- Applicant’s, Manufacturer’s and Contact person’s contact details,
- Type of application
- Date of submission of the dossier
- Table of contents of the dossier
- List of documents and other particulars.
- List of parts of the dossiers requested to be treated as confidential
General data requirements

Technical data

- identity and characterisation of the substance (including the proposed specifications and analytical method)
- manufacturing process
- stability, reaction and fate in foods to which the substance is added
- case of need and proposed uses
- existing authorisations and evaluations
- exposure assessment

Other substances with nutritional and/or physiological effects

Any possible effect of instability on biological properties including nutrient value
General data requirements

Biological and toxicological data

- Metabolism/Toxicokinetics
- Subchronic toxicity
- Genotoxicity
- Chronic toxicity/carcinogenicity
- Reproductive ad developmental toxicity

To state whether the test material in the studies performed conforms to the proposed or existing specifications

if not,

the relevance of these data to the substance under consideration should be demonstrated
Guidances and opinions by the Scientific Committee of EFSA

• In the new guidance, the opinions and guidances recently adopted by the Scientific Committee of EFSA will be taken into account:
  
  • Opinion on nanoscience and nanotechnologies (2009)
  • Opinion on the use of the benchmark dose approach in risk assessment (2009)
  • Opinion on replacement and reduction of animal testing (2009)
  • Guidance on transparency in the scientific aspects of risk assessments (2009)
  • Guidance on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (2008)
Process of preparation of the new Guidance for Food Additives

ANS Panel

Commentary document on the SCF (2001) Guidance

Comments from stakeholders

Elaboration by the ad hoc WG

Endorsement of draft by Panel

Public consultation

Final adoption by Panel

Finalisation foreseen for July 2011
Re-evaluation of food additives

- Regulation on the re-evaluation programme

- Strategy of the Panel – objectives:
  - re-evaluate in accordance with Regulation 257/2010
  - re-evaluate according to the main functional class
  - re-evaluate according to current risk assessment practice

- Public calls for data:
  - initial call for a given functional class / group of additives
  - possible additional specific public calls for data

- Preparation of pre-evaluation documents
Re-evaluation of colours

**Deadline 31.12 2010**

- Patent Blue V
- Indigotine
- Brilliant Blue FCF
- Calcium Carbonate

- Plain Caramel
- Caustic Sulphite Caramel
- Ammonia Caramel
- Ammonia Sulphite Caramel
- Lutein
- Canthaxanthin
Re-evaluation of colours

Deadline 31.12.2015

Riboflavin and Riboflavin-5’-phosphate; Cochineal, Carminic acid and Carmines; Chlorophylls and Chlorophyllins including Copper complexes; Vegetable Carbon; Annatto, Bixin and Norbixin; Carotenes, mixed Carotenes, Beta-Carotene; Paprika extract, Capsanthin and Capsorubin; Beta-apo-8’-carotenal; Ethyl ester of Beta-apo-8’-carotenonic acid; Beetroot Red and betain; Anthocyanins; Titanium dioxide; Iron oxides and hydroxides; Silver; Gold.
Re-evaluation of other food additives

Deadline 31.12.2013:
• Preservatives and antioxidants

Deadline 31.12.2016:
• Emulsifiers, stabilisers and gelling agents
• Silicon dioxide; Glutamates; Lysozyme and Invertase

Deadline 31.12.2018: remaining food additives other than sweeteners

Deadline 31.12.2020: sweeteners
Public calls for data for re-evaluation

• **Outcome of closed calls:**
  - preservatives and antioxidants
  - emulsifiers, stabilisers and gelling agents
  - waxes

  **Limited amount of data provided**
  **Almost no data on actual use and use levels**
  **=> Trade organisations will be contacted to provide use levels**

• **Recent public call:** published on 9 June 2010
  - preservatives and antioxidants (remaining ones)
  - acidity regulators
  - flavour enhancers
  - emulsifiers, stabilisers, gelling agents (remaining ones) and anticaking agents

  **Deadline: 9 December 2010**
**ANS - Food additives and nutrient sources added to food**

The Panel on food additives and nutrient sources added to food (ANS) deals with questions of safety in the use of food additives, nutrient sources and other substances deliberately added to food, excluding flavourings and enzymes.

### Scientific documents

- **Statement on nitrates in meat products**
  - Published: 11 May 2010
  - Adopted: 11 March 2010

- **Scientific Opinion on the re-evaluation of Lithiumblende (E 160) as a food additive**
  - Published: 7 May 2010
  - Adopted: 16 April 2010

- **Scientific Opinion on the safety of ferrous ammonium phosphate as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses**
  - Published: 4 May 2010
  - Adopted: 14 April 2010

### News

- EFSA publishes safety assessments of three food colours
  - 21 April 2014

- EFSA evaluates the safety of steviol glycosides
  - 14 April 2010

- EFSA updates safety advice on six food colours
  - 12 November 2008

### Calls & consultations

- Call for scientific data on miscellaneous food additives permitted in the EU and belonging to...

### Events

- 15th plenary meeting of the ANS Panel
  - Parme, 22 June 2010
Register of Questions

Displays all currently registered dossiers within EFSA

## Re-evaluation of food additives

### Main milestones

<table>
<thead>
<tr>
<th>Activity</th>
<th>Date</th>
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<tr>
<td>Re-evaluation of food colours (most of them)</td>
<td>2010</td>
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<td>New guidance document for food additives (new reference also for the re-evaluation)</td>
<td>July 2011</td>
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<td>Re-evaluation of preservatives and antioxidants</td>
<td>2013</td>
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<td>Re-evaluation of remaining food colours</td>
<td>before 2015</td>
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<td>Re-evaluation of emulsifiers, stabilisers and gelling agents</td>
<td>2016</td>
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<td>Re-evaluation of all miscellaneous food additives</td>
<td>2018</td>
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<tr>
<td>Re-evaluation of sweeteners</td>
<td>2020</td>
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