European Food Safety Authority

EFSA's role as a risk assessor and provider of scientific opinions

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What EFSA does

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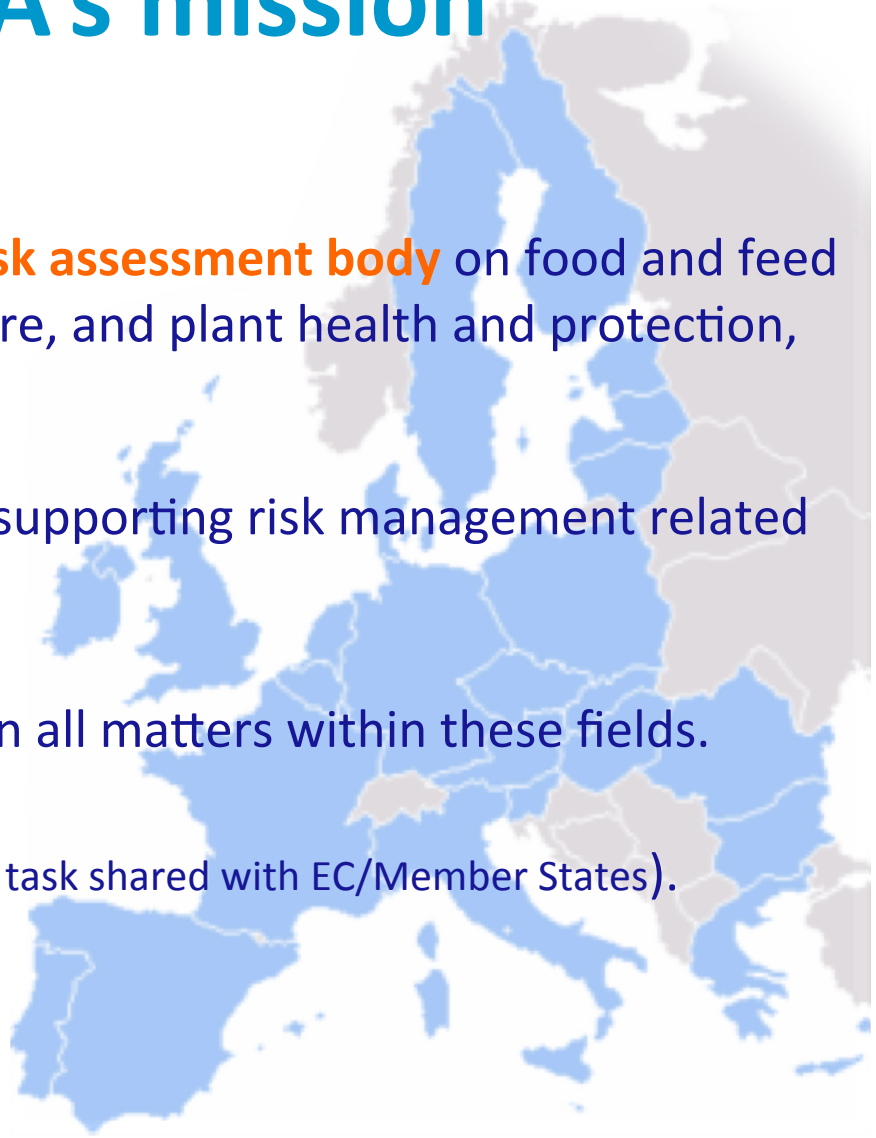
EFSA and EFSA's mission



- EFSA is the European Union's **scientific risk assessment body** on food and feed safety, nutrition, animal health and welfare, and plant health and protection, tackling issues **all along the food chain**.
- Provides **science based** risk assessments supporting risk management related to food/feed safety.
- Provides **scientific** and technical **advice** on all matters within these fields.
- EFSA **communicates** all findings publicly (task shared with EC/Member States).

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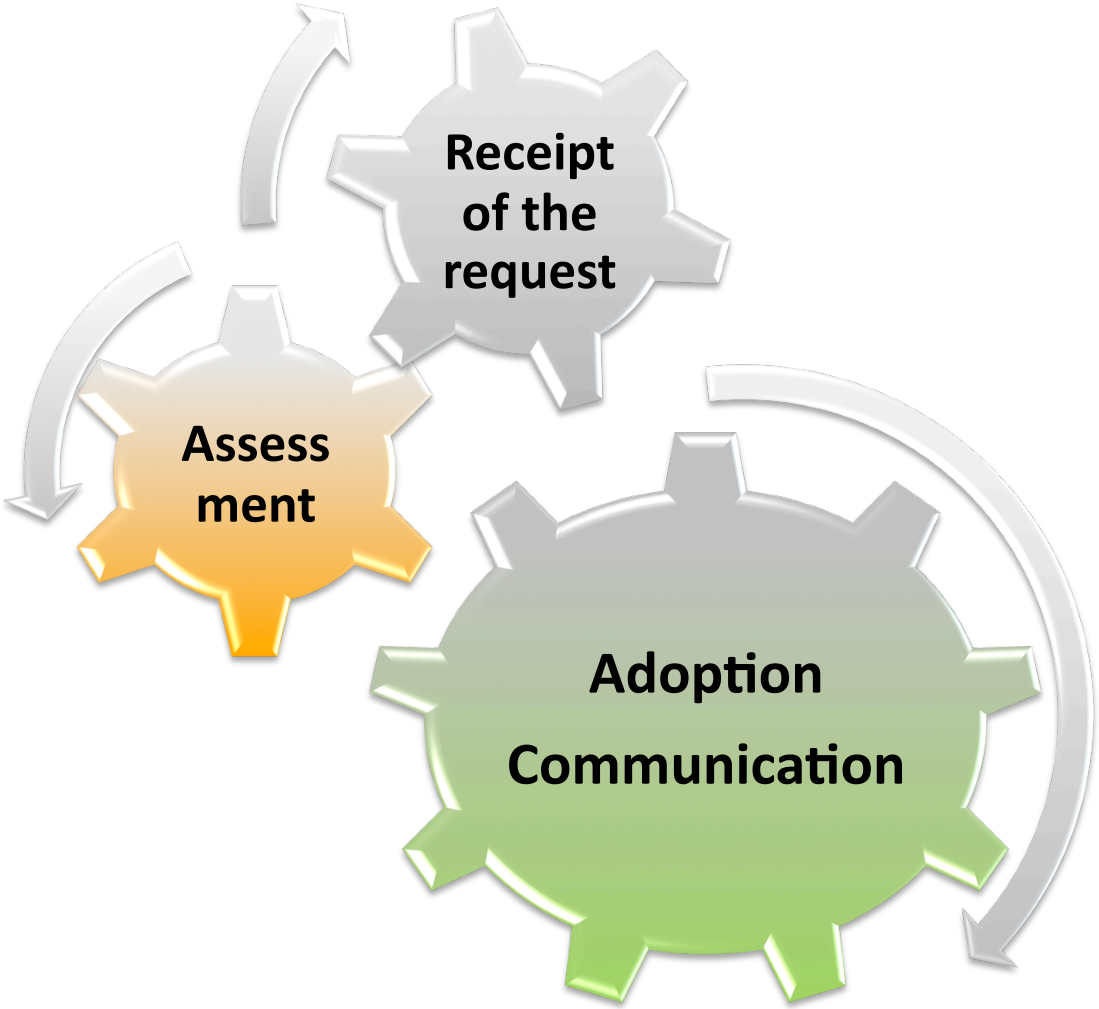
What EFSA cannot do

- Be responsible for food safety legislation
- Take charge of food safety/quality controls, labelling or other such issues
- Act as a substitute for national authorities

How does EFSA work?



How does EFSA work?

Receipt of the request

European Commission (EC)

European Parliament

Member States (MS)

EFSA (“*self mandate*”)

Question?

Risk Assessment
Risk Communication

10 Scientific Panels
1 Scientific Committee
17 Scientific Units

Examination → Allocation to Scientific Panel → Acceptance → Register of questions

EFSA´s Scientific Panels and Scientific Committee

Mainly opinions on applications

- Food additives and nutrient sources (ANS)
- Food contact materials, enzymes, flavourings (CEF)
- Feed additives (FEEDAP)
- Genetically modified organisms (GMO)
- Nutrition (NDA)

Mainly generic opinions

- Animal health and welfare (AHAW)
- Biological hazards (BIOHAZ)
- Contaminants (CONTAM)
- Plant health (PLH)
- Plant protection products (PPR)
- Scientific Committee (SC)

Since 2003 >1000 scientific outputs

Overview

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

ANS Panel

- 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

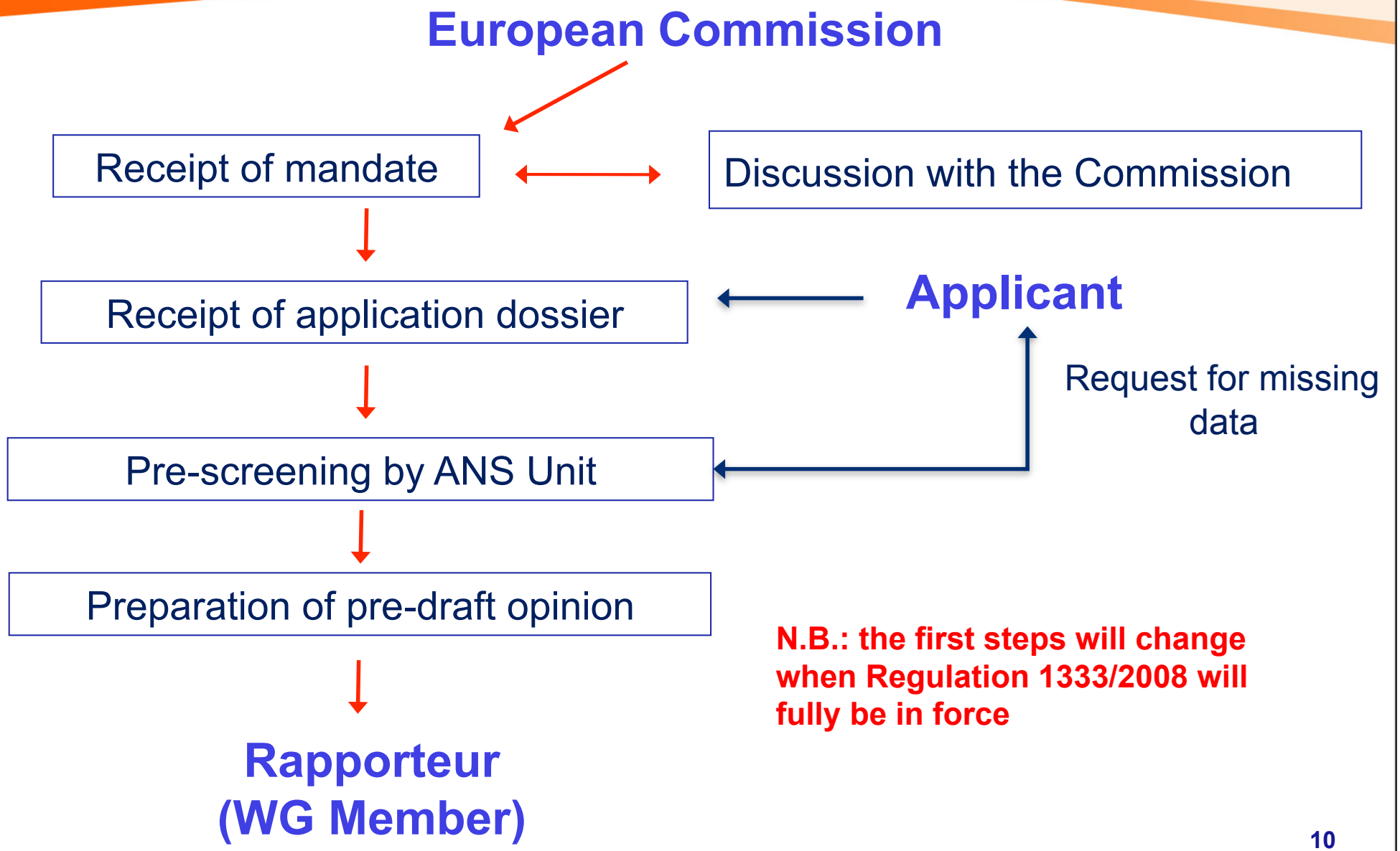
Working groups supporting the Panel

- 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

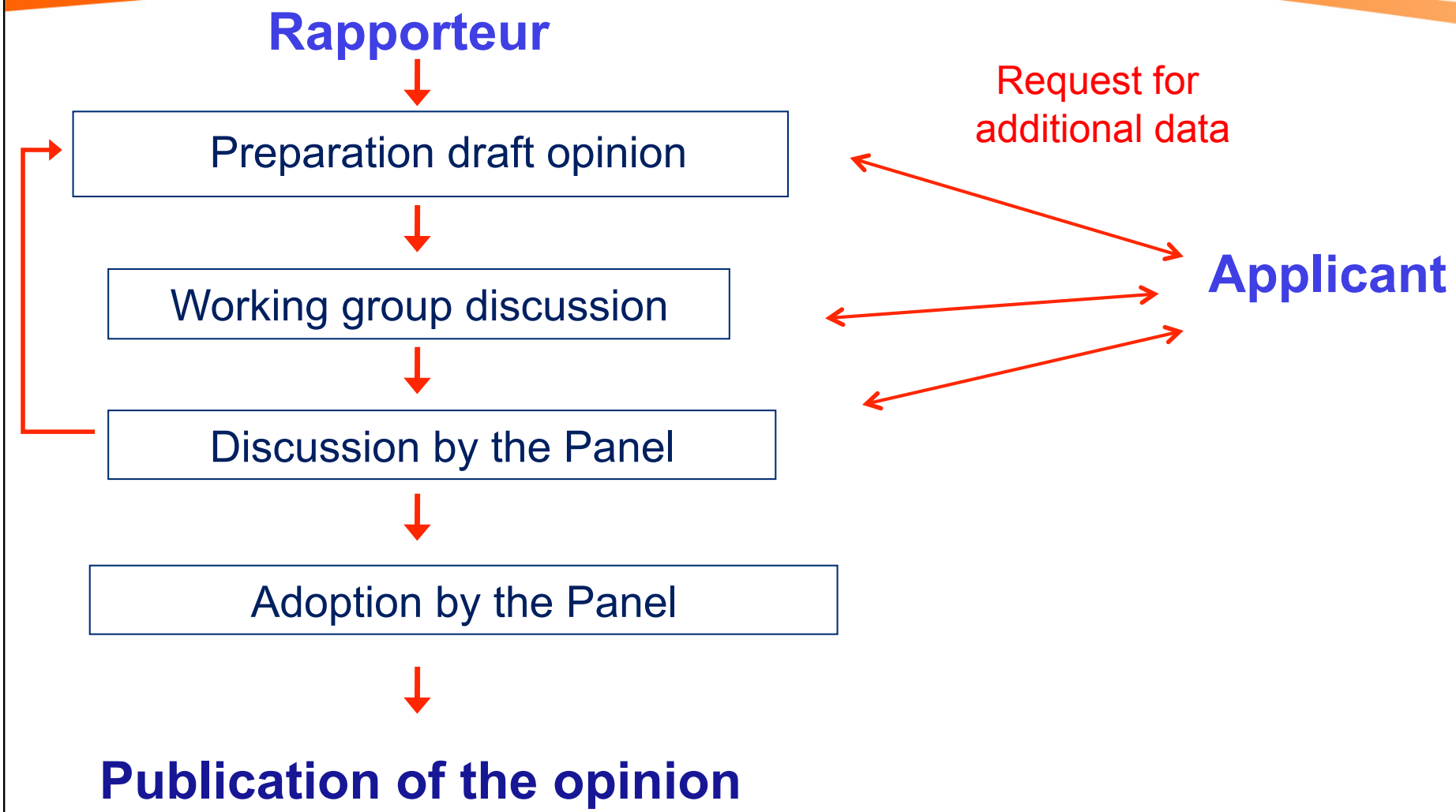
- Three new permanent working groups created recently on:
  - chemistry, exposure assessment and toxicology

Evaluation process



N.B.: the first steps will change when Regulation 1333/2008 will fully be in force

Evaluation process (continued)



2. Chemical RA - Principles

HAZARD IDENTIFICATION

EXPOSURE ASSESSMENT

Levels in food, dietary exposure, food consumption, relevant food groups, time trends

HAZARD CHARACTERISATION

ADME, acute/sub-chronic/chronic toxicity, human data, genotox, reprotox, mode/mechanism of action, mathematical modelling (BMD), derivation of a health based guidance value(*e.g.* ADI)

RISK CHARACTERIZATION

Relate **exposure** to **Health Based Guidance Value** or Margin of exposure (MOE)

2. Chemical RA - Principles

Food consumption data is an integral component of EFSA's risk assessment process.

Reliable and detailed information is essential to enable EFSA to carry out its mandate.

It is essential to take into account **specific groups of the population**.

Vegetarians, diabetics, pregnant women, children, infants, elderly...

Within a RA process, mean consumption levels are not sufficient.

It is essential to consider also **non-average individuals**, and in particular high consumers (those who consume relatively large quantities of foods).

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 documents of the Scientific Committee on Food

"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

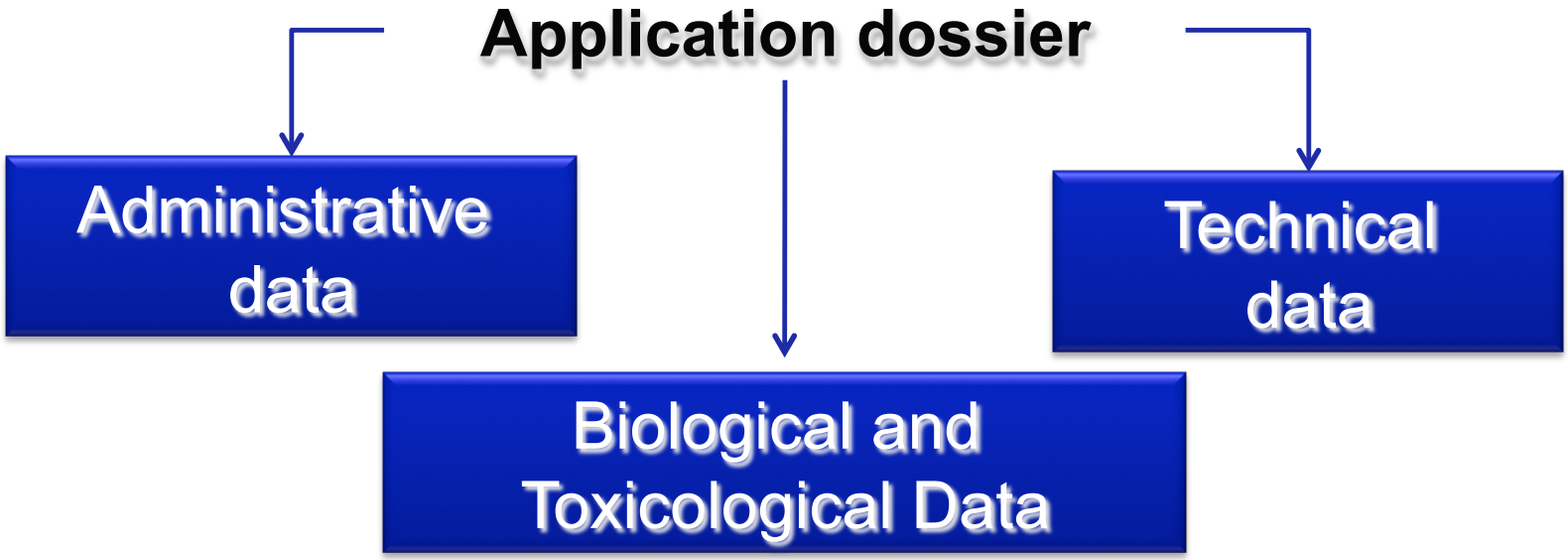
Establishment of a new guidance for food additives: foreseen to be finalised by ANS Panel, July 2011

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

- **Helps** the assessment process and supports the verification process 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 compilation 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 and justified** with rationales for inclusion and exclusion of specific studies

Application dossier

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** based on EFSA templates.
- 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 are considered necessary for the safety assessment

General data requirements

Administrative data

- Details of Applicant, Manufacturer and Contact person
- 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

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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
- proposed uses
- existing authorisations and evaluations
- exposure assessment

Other substances with nutritional 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 and developmental toxicity
- Immunotoxicity

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

if not,

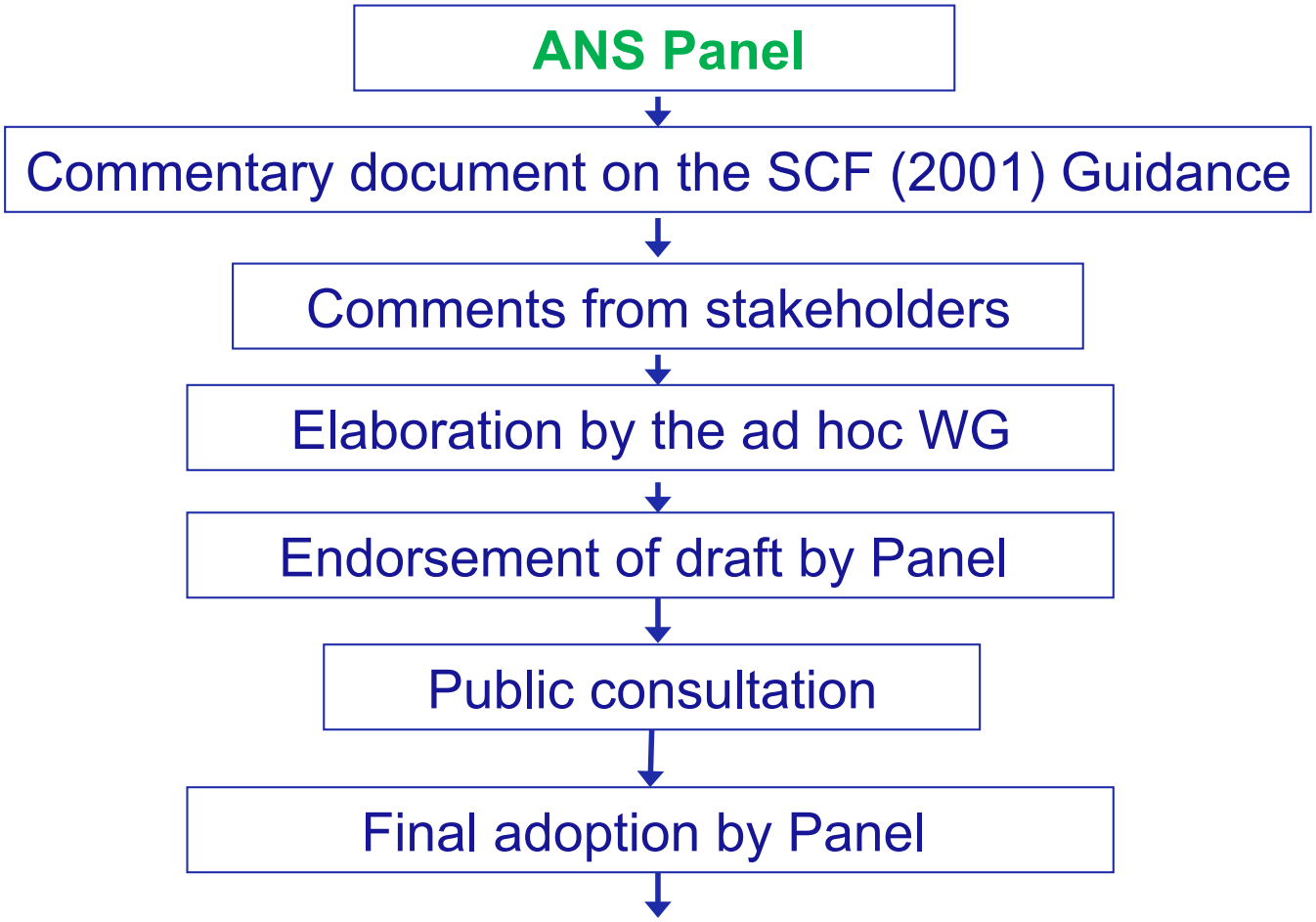
the relevance of these data to the substance under consideration should be demonstrated

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



Re-evaluation of food additives

Commission Regulation (EU) No 257/2010

of 25 March 2010

setting up a programme for the re-evaluation of approved food additives in accordance with

Regulation (EC) No 1333/2008 of the European Parliament and the Council

on Food Additives

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'-carotenic 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

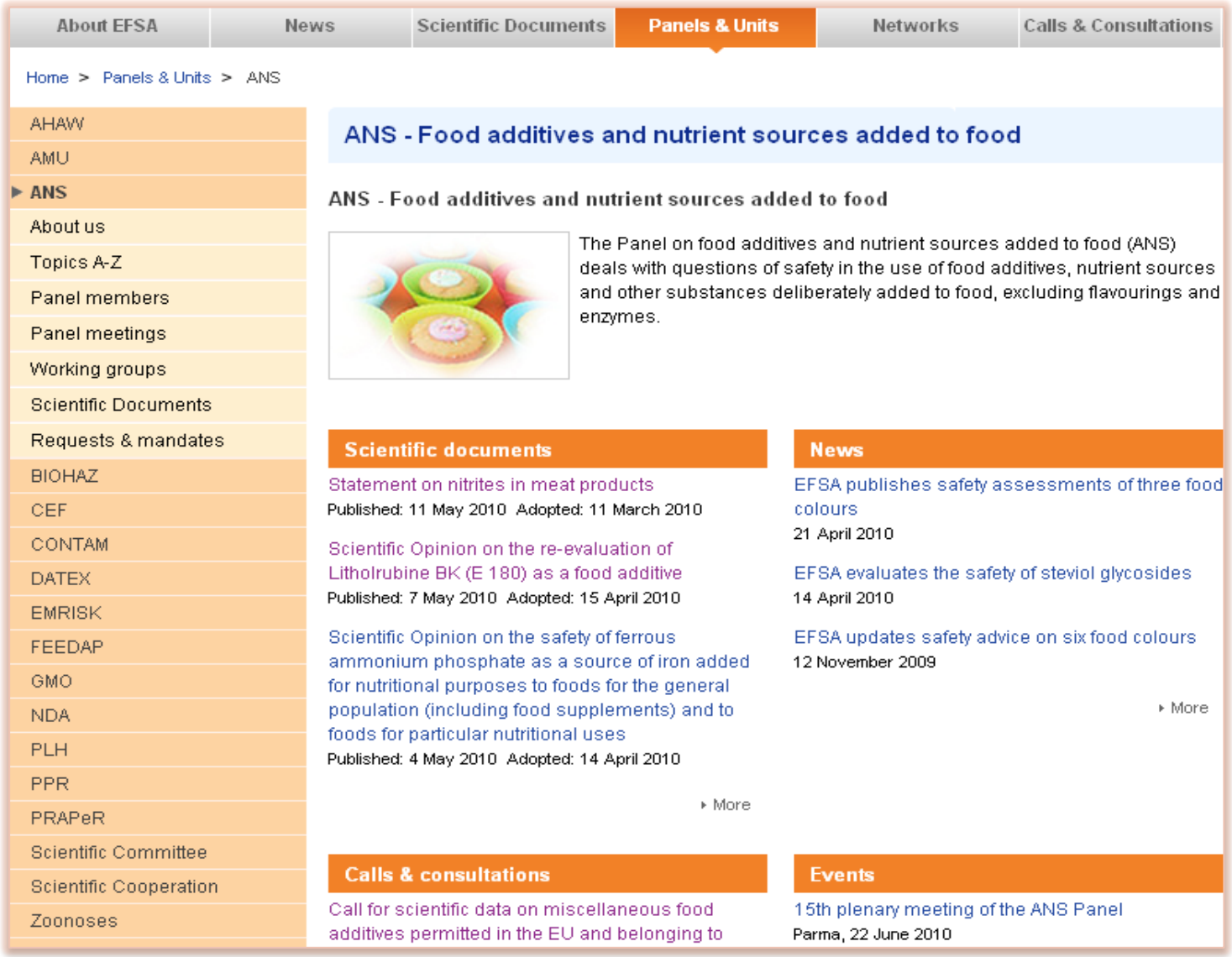
  Deadline: 9 December 2010

Re-evaluation of food additives

Main milestones

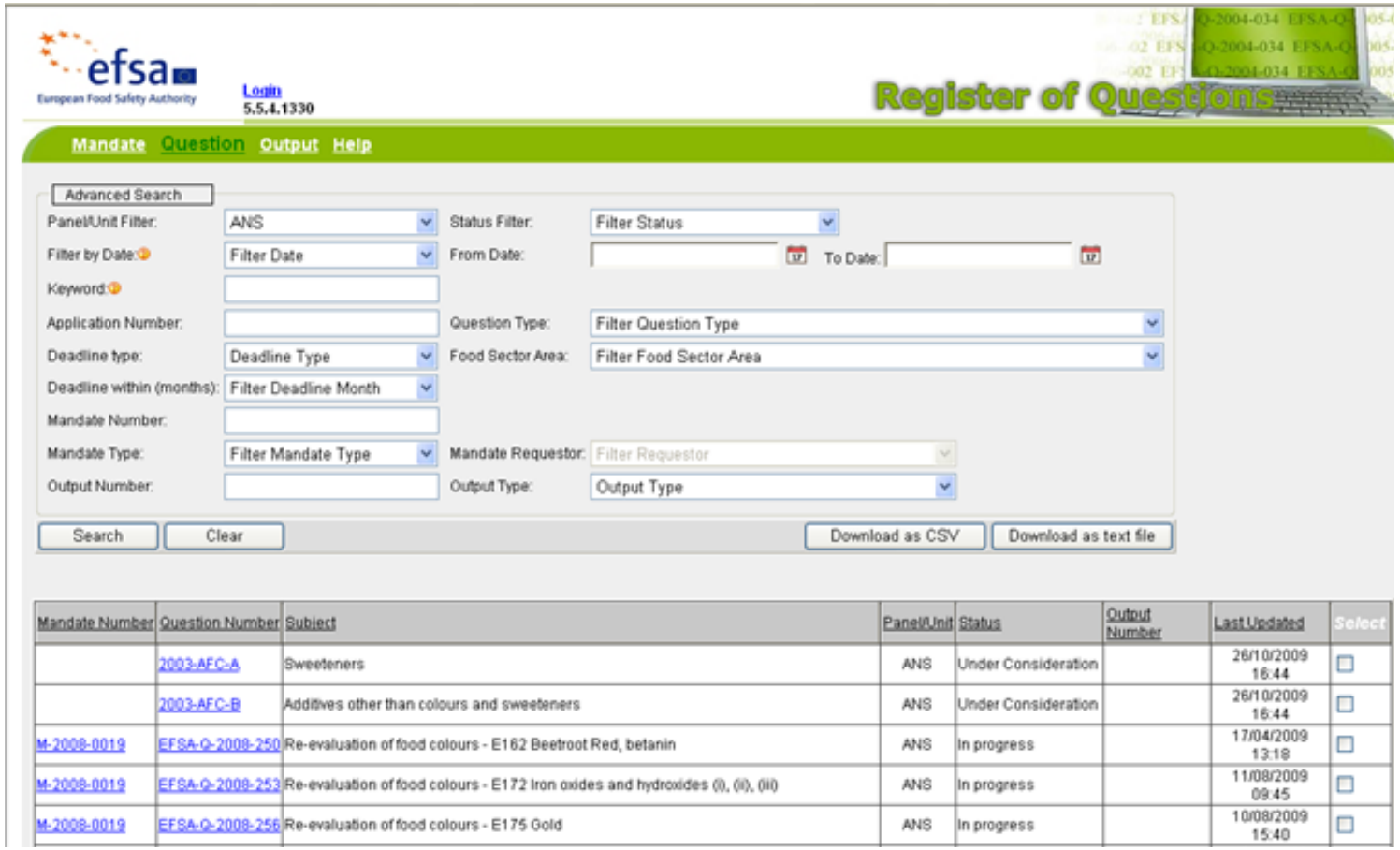
Re-evaluation of food colours (most of them)	2010
New guidance document for food additives (new reference also for the re-evaluation)	July 2011
Re-evaluation of preservatives and antioxidants	2013
Re-evaluation of remaining food colours	before 2015
Re-evaluation of emulsifiers, stabilisers and gelling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

More information



Register of Questions

Displays all currently registered dossiers within EFSA



Mandate Number	Question Number	Subject	Panel/Unit	Status	Output Number	Last Updated	Select
	2003-AFC-A	Sweeteners	ANS	Under Consideration		26/10/2009 16:44	
	2003-AFC-B	Additives other than colours and sweeteners	ANS	Under Consideration		26/10/2009 16:44	
M-2008-0019	EFSA-Q-2008-250	Re-evaluation of food colours - E162 Beetroot Red, betanin	ANS	In progress		17/04/2009 13:18	
M-2008-0019	EFSA-Q-2008-253	Re-evaluation of food colours - E172 Iron oxides and hydroxides (i), (ii), (iii)	ANS	In progress		11/08/2009 09:45	
M-2008-0019	EFSA-Q-2008-256	Re-evaluation of food colours - E175 Gold	ANS	In progress		10/08/2009 15:40	

http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL

Thank you!