European Food Safety Authority

Working methods of the Scientific Panel on Food Additives and Nutrient Sources added to Food (ANS Panel)

Alicja Mortensen, Chair of the ANS Panel

Stakeholder Workshop, Brussels, 28th April 2014

Mandate of the ANS Panel

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 (i.e. botanicals)**, excluding flavourings and enzymes.

Food additives

Food colours

Food supplements

ANS Panel (I)

- 19 members
  - Chemists
  - Food technologists
  - Experts in exposure
  - Toxicologists:

    (Genotoxicity, reproductive & developmental toxicology, carcinogenicity)

  - Toxicopathologists
- Independant experts

  (declaration of interest)

ANS Panel (II)

Working Groups:

- WG: A, B
- WG Chemistry
- WG Exposure
- WG Toxicology
  - Panel experts + invited experts
- 1 or 2 meetings/month (2 days)

ANS Panel, EFSA 2011-2014

Alicja Mortensen, Chair; David Gott, Vice-chair; Claude Lambré, Vice-chair; Fernando Aguilar; Riccardo Crebelli; Birgit Dusemund; Pierre Galtier; Ursula Gunder-Remy; Jürgen Köning; Jean-Charles Leblanc; Pasquale Mosesso; Agnieta Oskarsson; Dominique Parent-Massin; Martin Rose; Ivan Stankovic; Paul Tobback;Ine Waalkens-Berendsen; Rudolf Antonius Wourtersen; Matthew Wright

ANS Panel: Support

- ANS Panel is supported by Food Ingredients and Packaging unit (FIP) of EFSA and if needed by other EFSA units such as APDESK, DATA and AMU

ANS Panel outputs 2008-2013

Nutrient Sources 51%

Food Additives 49%

- The ***ANS Panel*** issued ***165 outputs***; this includes:
  - 1 statement on data requirements for food additive applications (2009)
  - 1 guidance document for submission of food additive evaluation (2012)

ANS Panel

Safety evaluation of food additives by ANS Panel

Food additives may only be approved for the EU market if they fulfil the following criteria:

- there is a technological need for their use which cannot be attained by other more economical and technological practical solutions
- **they present no health hazard to the consumer at the level of proposed use**
- they do not mislead the consumer.

Safety evaluation = Risk assessment

Risk assessment steps

HAZARD IDENTIFICATION

Toxicokinetic (ADME), acute/sub/ chronic/reproductive & developmental toxicity, human data, genotoxicity,

EXPOSURE ASSESSMENT

Occurrence in food × Food consumption

dietary EXPOSURE in EU

Relevant food groups, adults and specific groups of the population,

HAZARD CHARACTERISATION

dose-response for critical effect, POD, derivation of a health based guidance value (e.g ADI)

RISK CHARACTERIZATION

Relating exposure to health-based guidance value

Vulnerable groups (children – high level consumers)

ANS Panel – the guidances

Guidance documents on data requirement to establish safety of food additives by ANS Panel

- ***ANS Panel Guidance*** *for submission for food additive evaluations (2012)*

http://www.efsa.europa.eu/en/efsajournal/doc/2760.pdf

- ***SCF Guidance on Food Additives*** *(2001)*

http://ec.europa.eu/food/fs/sc/scf/out98_en.pdf

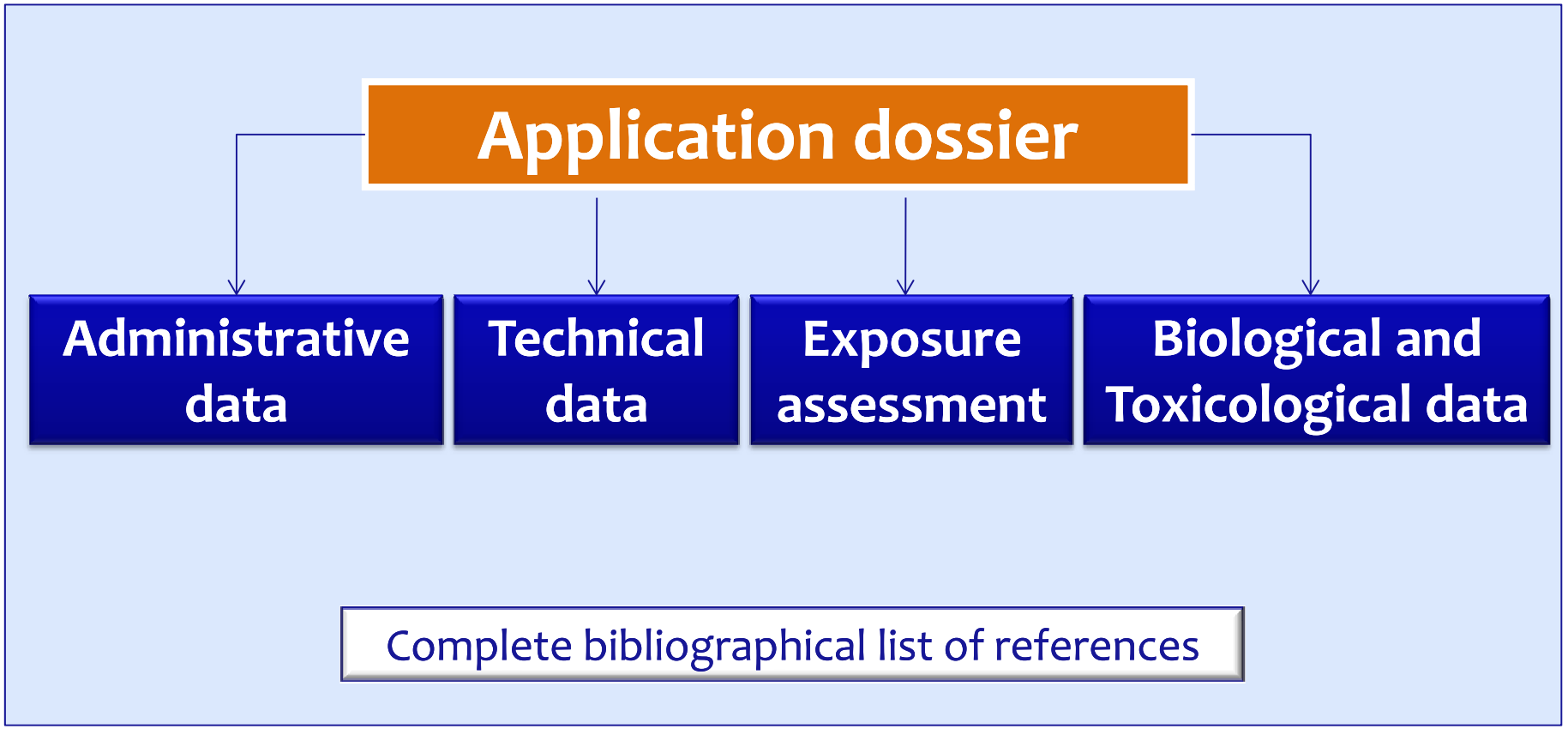
ANS Panel

Guidance for submission for food additive evaluations (adopted July 2012; replacing SCF Guidance, 2001)

- **Rationale**
  - Reflect Panel's experience and recent scientific developments;
  - Reflect EFSA Scientific Committee decisions
  - Address animal welfare and 3Rs

- **Key changes**
  - flexible **tiered approach**
  - changes in **toxicological testing**
    (i.e. genotoxicity, carcinogenicity, reproductive toxicity)
  - new exposure assessment tool **(FAIM)**

General data requirements



General data requirements (2)

Technical data

- Chemical identity and characterisation of the substance (including the proposed specifications and methods of analysis)
- Manufacturing process
- Stability, reaction and fate in foods
- Case of need and proposed uses
- Existing authorisations and evaluations

General data requirements (3)

Examples of biological and toxicological data

- ADME /Toxicokinetics
- (Absorption, distribution, metabolism & excretion)
- Subchronic toxicity
- Genotoxicity
- Chronic toxicity/carcinogenicity
- Reproductive and developmental toxicity
- Other studies (human studies, allergenicity etc.)

NB! Tier approach

Test material in the studies performed must conform to the proposed or existing specifications. If not, the relevance of these data to the substance under consideration should be demonstrated/explained.

General data requirements (4)

Exposure data

- Uses and uses levels (typical and maximum)
- Known or anticipated human exposure taking into account different populations groups (adults and children)
- Other sources of exposure

Data sources in re-evaluation of food additives

- No new dossier
- Previous evaluations (i.e. by SCF, JECFA) and reviews
- Additional literature that became available since last evaluation
- The data available following a public call for data.
- NB. Not all original studies on which previous evaluations or reviews were based are available for re-evaluation by the Panel.

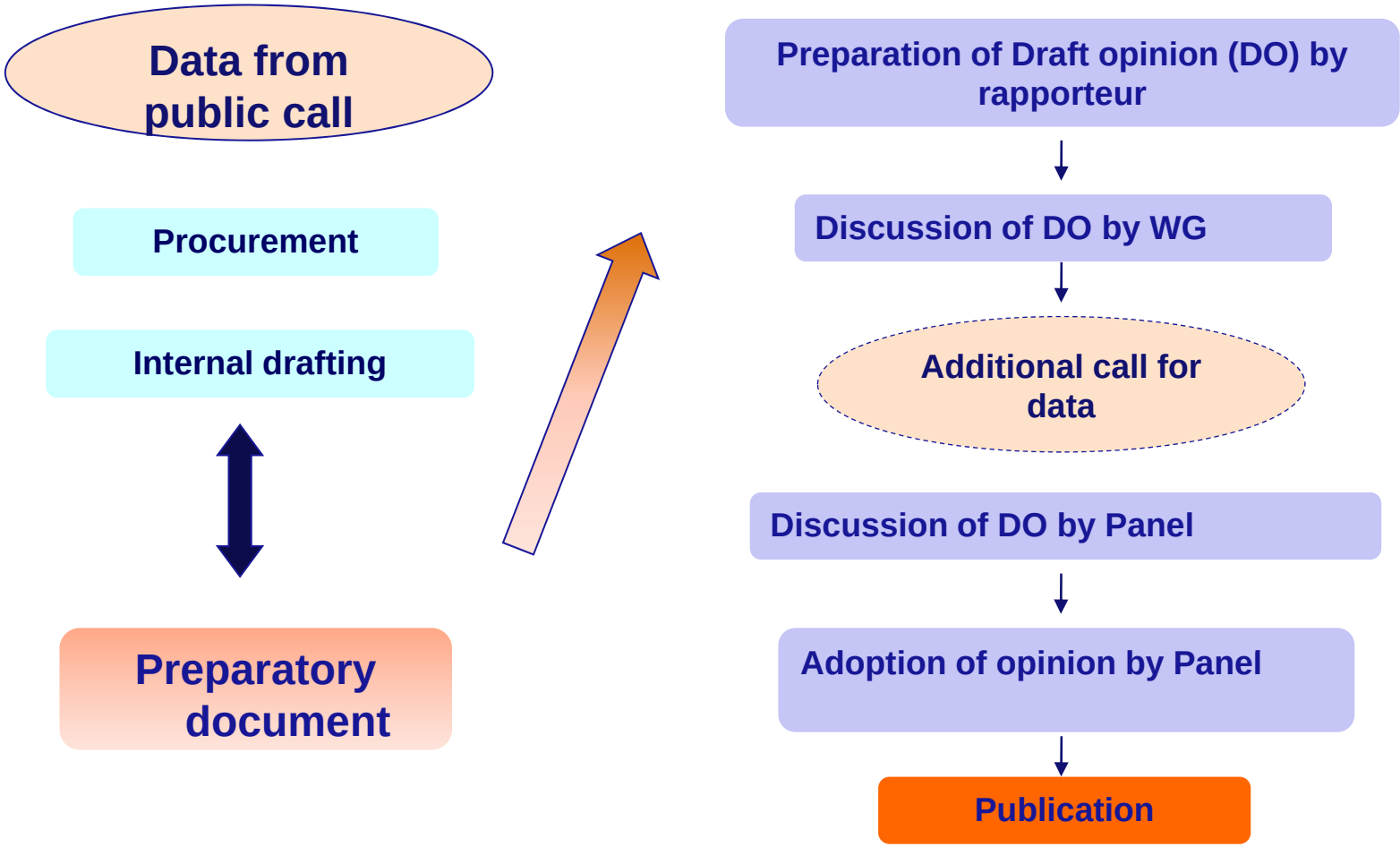
EFSA's public calls for data

- Public open calls for scientific data (as requested in the SCF Guidance (2001)) for a group of food additives :
  - ❖Technical data: identity of the food additive, manufacturing process, method of analysis in food, exposure (use and use levels)
  - ❖Toxicological data: studies on ADME, acute toxicity, subacute and subchronic toxicity, genotoxicity, chronic toxicity and carcinogenicity, reproductive and developmental toxicity and any other relevant studies
- Public calls for data for a specific food additive (specific scientific data) during the re-evaluation process (discussion at the WG/Panel)

Overview of the re-evaluation process

efsa
European Food Safety Authority

Objective - evaluation of each additive



ANS Panel: Challenges

- Re-evaluation programme of authorised food additives (data gaps, to deliver outputs in time)
- Align the assessment of food additives (e.g. colours) with other panels (e.g. FEEDAP)
- Assessment of substances falling under the scope of Art. 8 of Regulation 1925/2006 (botanical substances)
- Short timeline (9 months) for applications of food additives

Thank you for your attention !

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ANS: http://www.efsa.europa.eu/en/fip/anspanelmembers.htm