



Risk assessment of food additives and nutrient sources

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Risk assessment of food additives and nutrient sources

- EFSA's Scientific Panel on food additives and nutrient sources added to food (ANS Panel)
- Remit and areas of work of the ANS Panel
- Work programme of the Panel for 2011 – 2014
- Mission and objectives of the ANS Unit
- Re-evaluation of Food additives: legal framework
- Overview of the re-evaluation process
- Public calls for data
- Risk assessment approach of the ANS Panel

ANS Panel 2011 - 2014



- Food additives (safety)
 - re-evaluation of food additives, which were permitted before 20 January 2009
 - new applications
- Nutrient sources (safety and bioavailability)
 - Sources of vitamins and minerals for food supplements
 - Sources of vitamins and minerals for dietetic products and fortification of food
 - Other substances added for nutritional or functional purposes
- Other substances deliberately added to food (excluding flavourings and enzymes).

- Food additives – re-evaluations: 250 (till 2020)
- Food additives – new applications: 10 – 20 / year
- Nutrient sources (vitamins and minerals): 2 ongoing dossiers – variable (1 – 5 / year)
- Other substances added for nutritional or functional purposes ?
- General questions: ~1 - 2 per year
- Emergency questions: ~ 1 – 2 per year

- Re-evaluation of food additives:
 - **Aspartame: September 2012**
 - Remaining food colours: 2015 (~ 15 opinions)
 - Preservatives and antioxidants: 2015 (~ 30 - 40 opinions)
- food additives guidance: **deadline: July 2012**
- nutrient sources for food supplements:
 - **deadline: December 2012**
 - 2 dossiers
- Evaluation of new applications for food additives:
 - Standard 9 month deadline since 11 September 2011
- Other substances: ?

- 1st priority: aspartame:
 - Deadline: September 2012

- 2nd priority: food additives guidance
 - Deadline: July 2012

- 3rd priority: re-evaluation of food colours, preservatives and antioxidants:
 - deadline: December 2015
 - ~ 40 to 60 opinions

Evaluation process for new applications (food additives)

European Commission ← Applicant

Receipt of mandate

Receipt of application dossier

Pre-screening by the ANS Unit

Suitable for risk assessment?

Validation decision by the Commission

Preparation template draft opinion (+ possible pre-drafting)

Rapporteur

Evaluation process for new applications(continued)

Rapporteur

Preparation draft opinion

ANS Unit

Working group discussion

Discussion and possible adoption by the Panel

Publication of the opinion

Request for additional data

Applicant

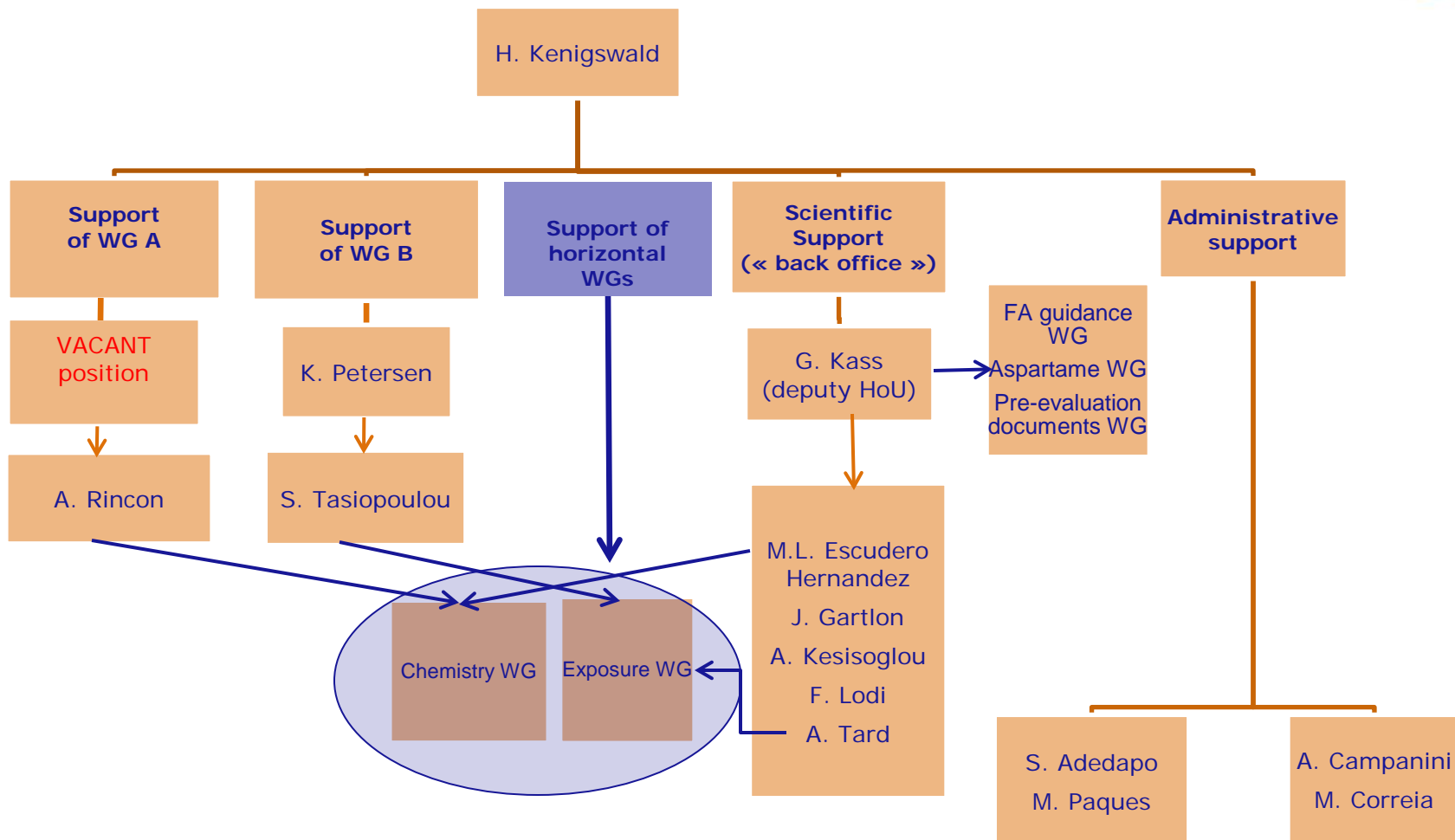
- standing working groups:
 - WG A on food additives and nutrient sources
 - WG B on food additives and nutrient sources
 - WG on chemistry and specifications
 - WG on exposure assessment
 - WG on toxicology

- ad hoc working groups:
 - WG on food additives guidance
 - WG on aspartame

- Effective and efficient delivery of all activities related to the safety evaluations within the remit of the ANS Panel
- Support the ANS Panel and its working groups
- Verification of the suitability of the data for risk assessment
- Monitor emerging safety issues within the remit of the Panel
- Support to the related communication activities

- Manage the workload
 - Meet deadlines
 - Panel outputs
 - Internal outputs
- Apply rules and procedures (efficiently and effectively)
- Support the ANS Panel and its working groups
 - Quantitative objectives (Cf. workload): planning, anticipation, adequate resources
 - Qualitative objectives (quality of scientific outputs: scientific, consistency, editorial)
 - Administrative support (direct and indirect)
- Support the REPRO Directorate (and EFSA)
- Support the Communication Directorate
- External relations: European Commission, European Parliament, Member States, other RA bodies, stakeholders, etc.

Organisation of the ANS Unit and responsibilities



Re-evaluation of Food additives

Legal framework

- **Priority criteria**

- Last evaluation (SCF)
- New scientific evidence
- Extend of use/human exposure
- Commission request
- Emerging concern

- **Procedure**

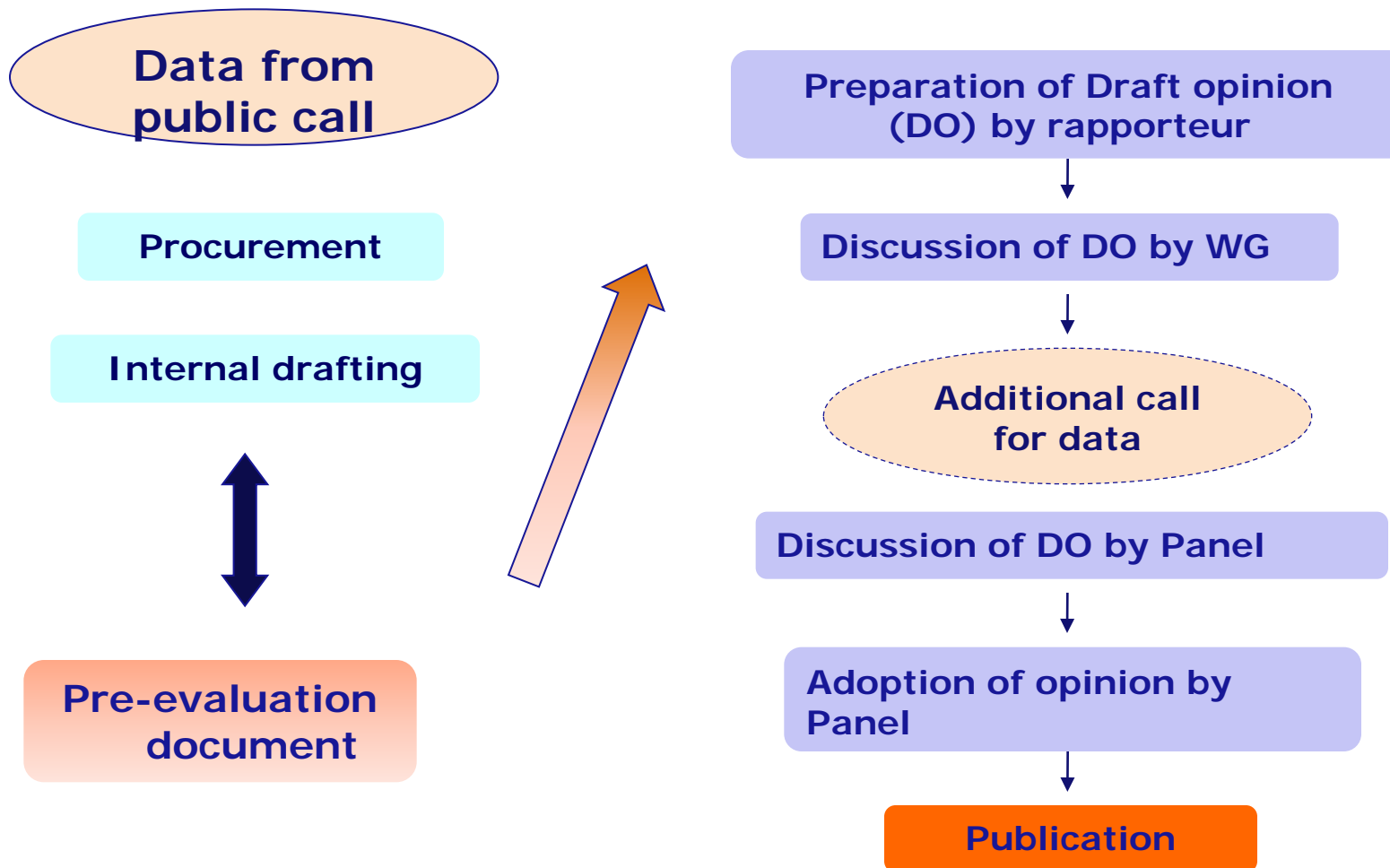
- Mandate from Commission
- Data availability (public call for data)
- Additional information/data

- **Timelines** (Regulation 257/2010)

- **Food colours** **2015**
- FA other than food colours & sweeteners **2018**
- Sweeteners **2020**

Overview of the re-evaluation process

Objective - evaluation of each additive



Objective: Identify & collect all relevant data

- **Key aspects**

- Data availability (public call for data)
- Interested parties (business operators and others)
- Additional information/data
- Duration (3-6 months)
- Confidentiality (**Commission's decision**)
- Lack of data: additive might be removed from EU list

- **Information sought** (**reference to SCF Guidance on food additive applications, 2001**)

- Technical (specifications, analytical methods, manufacturing, etc.)
- Toxicological
- Human Exposure
- Original dossier (SCF/JECFA)

- **Types**

- General
- Specific

- **Data type & availability**

- unpublished reports
- studies including historical studies
- scientific papers published in the open literature
- compliance with international guidelines

- **Data handling & specifications**

- Guidance document on Food additives (SCF, 2001); **future guidance of the ANS Panel**
- Technical Specifications

- **Data to be considered by the Panel**

- Data received from public calls
- Other relevant data, made available to EFSA

Specific calls for data

Timelines

Food additives	Launching date	Status
Patent blue V (E131)	July, 2010	Closed
Calcium carbonate (E170i)	December, 2010	Closed
Paprika extracts (E160c)	March, 2011	Closed
Patent blue V (E131)	June, 2011	Closed (September, 2011)
Gold (E175) & Silver (E174)	February, 2011	Closed (August, 2011)
Indigo carmine (E132)	January, 2011	Closed (September, 2011)
Patent blue V (E131)	September, 2011	On going (January, 2012)

OBJECTIVES

- **Regulation (EU) 257/2010**
 - priorities
 - criteria
- Re-evaluation according to the **functional class**
- Currently applicable **risk assessment approach**
 - SCF Guidance on FAs, 2001
 - ANS Panel Guidance on food additives – 2012

EVALUATION

- Steps
- Adoption of opinion (based on the data available at the time of the discussion)

Technical data

- Identity, specifications, manufacturing process, methods of analysis in food, reaction and fate in food
- Information on existing evaluations and authorisations

This information is crucial because by-products and impurities are also taken into consideration in the risk assessment.

- **Intake/Exposure data**

- Maximum Permitted Levels (MPLs)
- Usage levels: Typical and maximum levels
(Occurrence data + Monitoring data)
- Additional (but relevant) sources

- **Calculations/Assessment:**

Tiered approach (SCOOP task report 4.2) on adults & children

- Tier 1: Budget method
- Tier 2: MPLs and consumption data
- Tier 3: Usage levels and consumption data

Hazard identification

- Based on the available toxicological studies. Important sources of information: previous JECFA and SCF evaluations.

Hazard characterisation

- Identification of NOAEL and derivation of ADI (when possible).

Risk assessment

- Compare ADI with estimated exposure.

Colours already re-evaluated

- Red 2G
- Tartrazine
- Sunset Yellow FCF
- Azorubine
(Carmoisine)
- Ponceau 4R
- Allura Red AC
- Brown HT
- Brown FK
- Amaranth
- Brilliant Black BN
- Litholrubine BK
- Quinoline Yellow
- Lycopene
- Lutein
- Curcumin
- Canthaxanthin
- Caramel colours
- Erythrosine
- Brilliant blue
- Green S
- Calcium carbonate

- 2011:
 - Indigotine

- 2012:
 - Patent blue

- 2015:
 - Riboflavin
 - Cochineal, carminic acid, carmines
 - Chlorophylls and chlorophyllins
 - Copper complexes of chlorophylls and chlorophyllins
 - Vegetable carbon
 - Carotenes
 - Annatto extracts, bixin, norbixin
 - Paprika extract
 - Beta-apo-8'-carotenal
 - Ethyl ester of beta-apo-8'-carotenoic acid
 - Beetroot red
 - Anthocyanins
 - Titanium dioxide
 - Iron oxides and hydroxides
 - Silver
 - Gold

Strengthening collaboration with stakeholders

- **Enhanced interaction throughout the process**
 - Early exchanges
 - Pre-notifications
 - Anticipation of needs

- **Coordination of contribution to calls for data**
 - Raising awareness
 - Coordinated response
 - Common understanding /shared knowledge
 - Key contact persons