



Evaluation and re-evaluation of food additives

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**EFSA Stakeholder Consultative Platform Meeting
Brussels, 8th April 2011**

Evaluation and re-evaluation of food additives

- Legal framework
- Strategy of the ANS Panel for the re-evaluation (procedure)
- Re-evaluation of FAs (workflow)
- Calls for data (general & specific)
- Strengthening collaboration
- Exposure assessment
- Implementing measures: new application process
- 'ANS Panel Guidance on Fas'

- **Regulation No 1331/2008 and Regulation No 1333/2008 + Regulation 234/2011 (implementing measures)**
- **Regulation No 257/2010**
 - Re-evaluation finalised by 2020
 - Priority criteria
 - Functional class
- **Directives (consolidated)**
 - Food colours (94/36/EC)
 - Other than food colours & sweeteners (95/2/EC)
 - Sweeteners (94/35/EC)
- **SCF Guidance on Food Additives (2001)** - *Info on metabolites*
 - Technical part (specifications, manufacturing, etc.) &
 - Exposure
 - Biological/Toxicological (ADME, toxicity, genotoxicity, repro, etc.)
- Upcoming '**ANS Panel Guidance**' (2011 - 2012)

Re-evaluation of FAs

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
- Other than food colours & sweeteners 2018
- Sweeteners 2020

OBJECTIVES

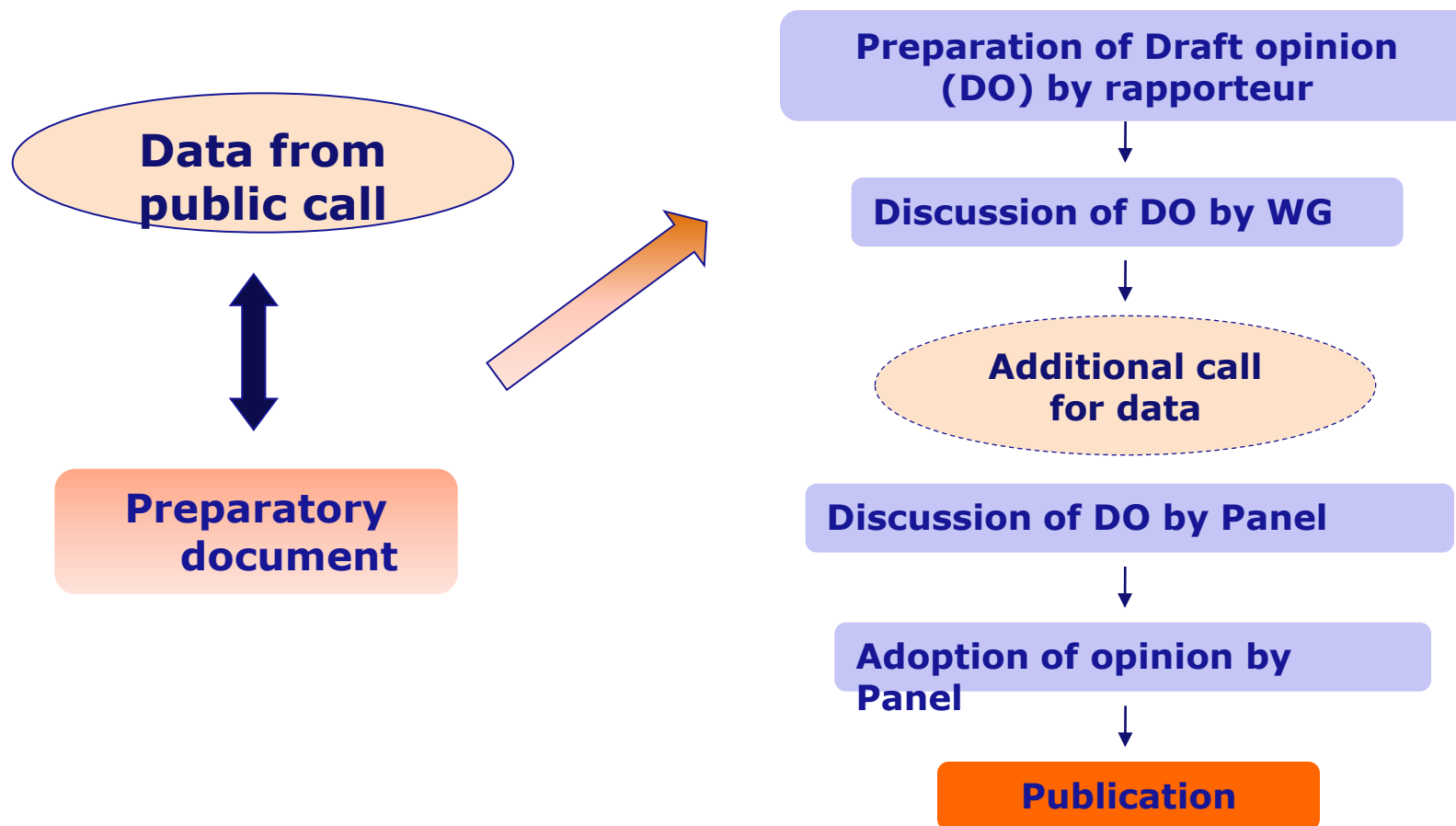
- **Regulation (EU) 257/2010**
 - priorities
 - criteria
- Re-evaluation according to the **functional class**
- Currently applicable **risk assessment approach**
 - Regulation 1333/2008
 - (SCF Guidance on FAs, 2001)
 - (ANS Panel Guidance on FAs – 2011 - 2012)

EVALUATION

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

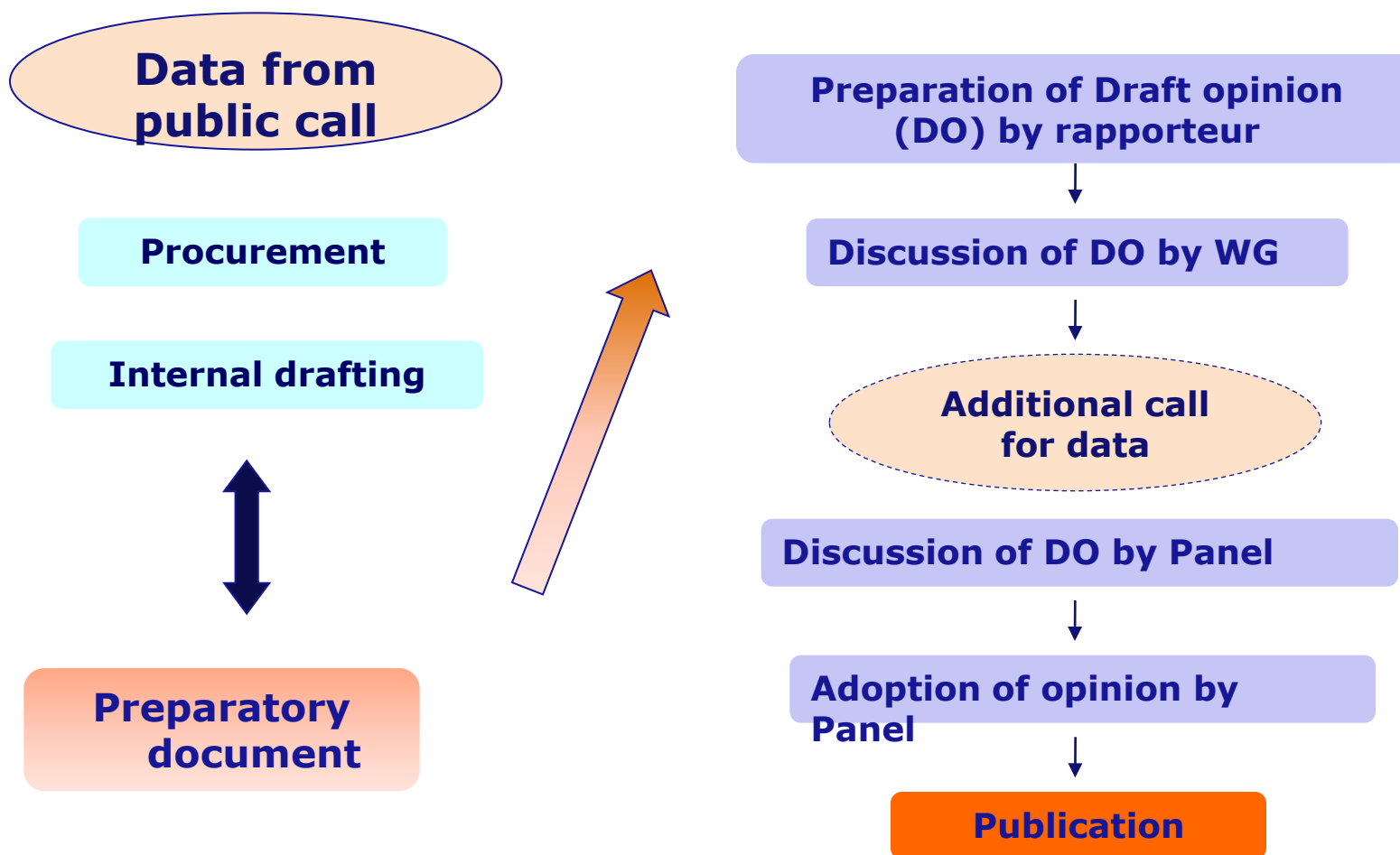
ANS Panel Strategy – Procedure

Objective - evaluation of relevant data



Re-evaluation of FAs – Workflow

Objective - evaluation of each additive



Objective: Identify & collect all relevant data

- **Key aspects**

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

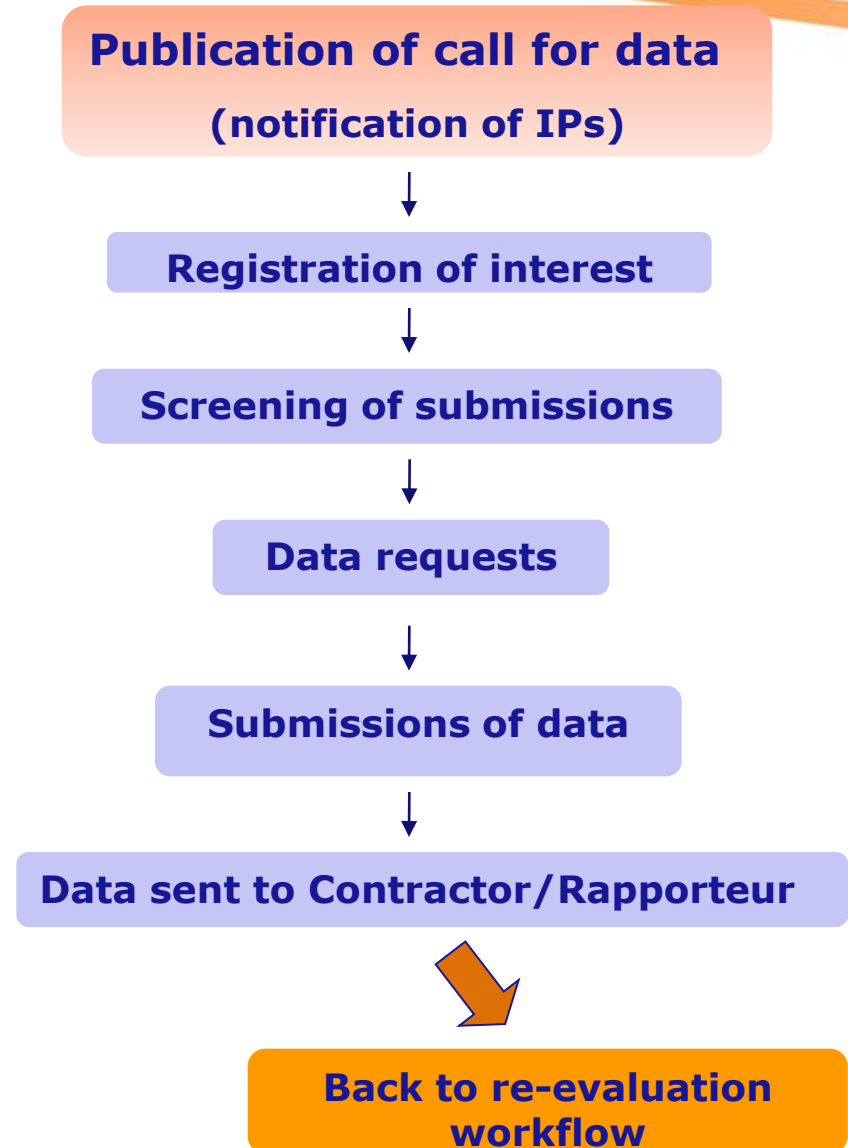
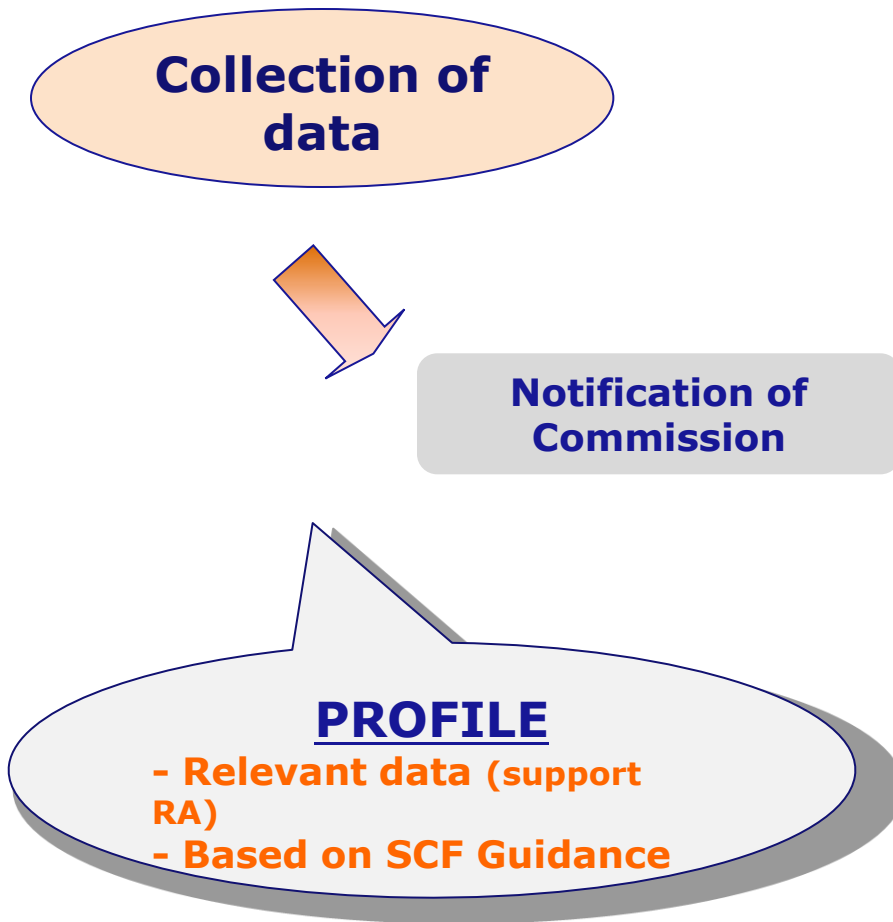
- **Information sought** (**based on SCF Guidance on FAs, 2001**)

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

- **Types**

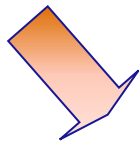
- General
- Specific

Call for data – General Workflow



Call for data – Specific Workflow

Identified need
(ANS WGs/Panel)



- i. Dialogue with *IPs
- ii. Call for data (need identification)

PROFILE

- Specific data
- Commitment (new data)

Notification of Commission and IPs



Publication of public call



**Submissions
of data**

**Commitment to
generate new data**



Assessment of submissions



Data sent to ANS WG/Panel



**Back to re-evaluation
workflow**

General calls for data

Timelines

Functional group	Launching date	Status
Food colours	December, 2006	Closed (March, 2007)
Other than food & colours		
Preservatives & Antioxidants	November, 2009	Closed (April, 2010)
Waxes	November, 2009	Closed (March, 2010)
Emulsifiers, stabilisers, gelling agents etc	November, 2009	Closed (May, 2010)
Remaining MFAs	June, 2010	Closed, pending requests
Sweeteners	2013 (???)	To be launched

Specific calls for data

Timelines

Functional group	Launching date	Status
Patent blue V (E131)	July, 2010	Closed
Calcium carbonate (E170i)	December, 2010	Closed
Indigo carmine (E132)	January, 2011	Ongoing (September, 2011)
Paprika extracts (E160??)	March, 2011	Ongoing (July, 2011)
Gold (E175) & Silver (E174)	February, 2011	Ongoing (August, 2011)

Intake/Exposure data

- Usage levels: Typical and maximum levels (Occurrence 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

- **Tools** (templates)
 - EXPOCHI database (children 1-4 years, excl UK)
 - Exposure calculation for FAs
 - EFSA comprehensive database

EFSA Comprehensive European Food Consumption Database in exposure assessment (**DATEX**)

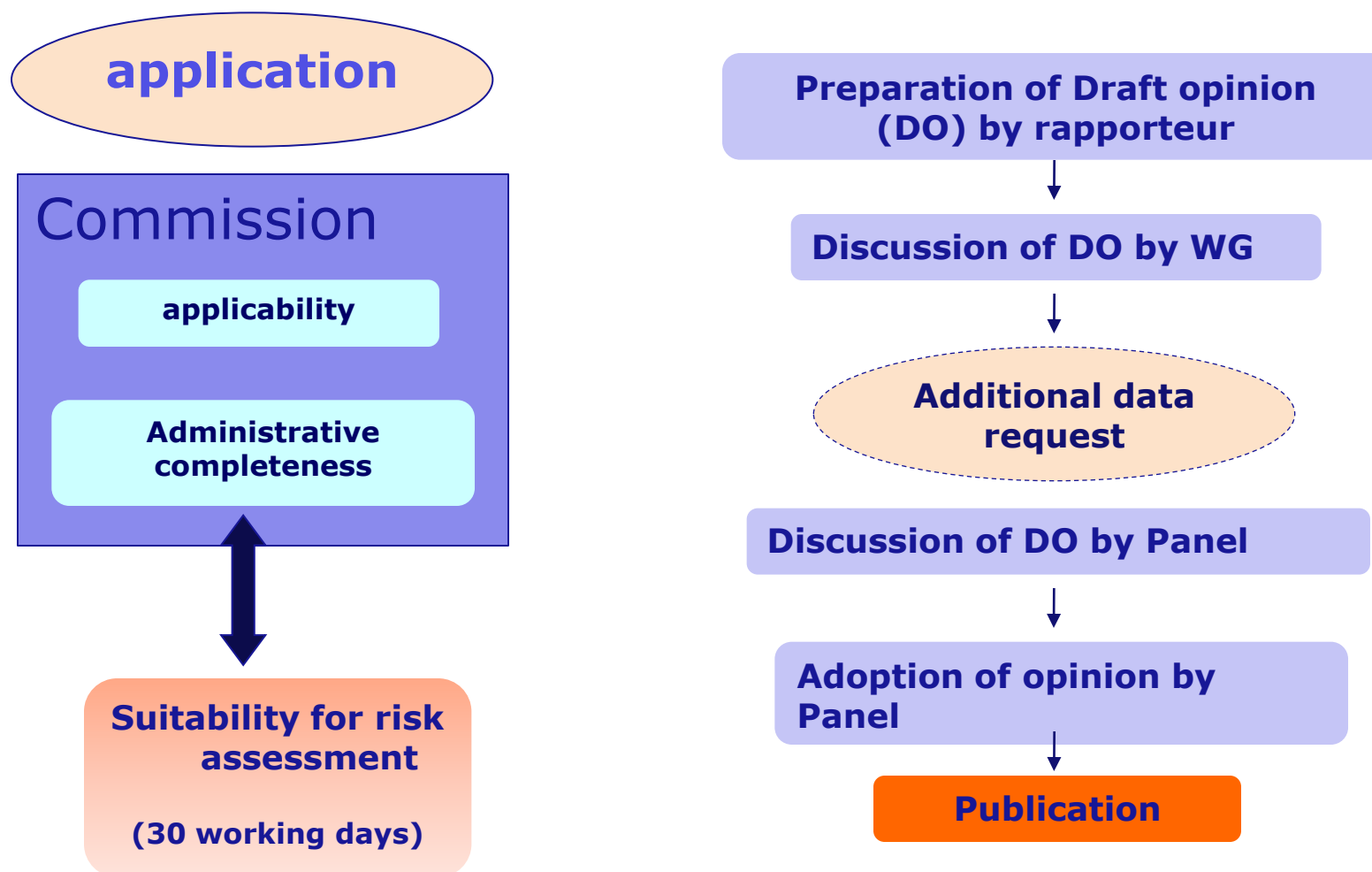
<http://www.efsa.europa.eu/en/datex/datexfooddb.htm>

- Statistics on food consumption across EU (**g/day** or **g/Kg bw/day**)
- **Categories** used:
 - i. Food group/type of consumption (regular/high)
 - ii. Age (infants to adults)
- '**FoodEx**': food classification system (foods & beverages)
- **Guidance** for the use of the EFSA Comprehensive database

- **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

New applications – Workflow

Starting point: 11 September 2011



Draft Guidance of the ANS Panel on FAs

- **Status**
 - ongoing (currently at Panel level)
 - interface with EFSA SC documents (under development)
- **Special applications:**
 - nanotechnology
 - extracts of plant
- **Impact on re-evaluation**
 - criteria
 - consistency & continuity of RA principles
- **Public consultation:** foreseen summer/autumn 2011
- **Final publication:** end 2011 - 1st semester 2012