

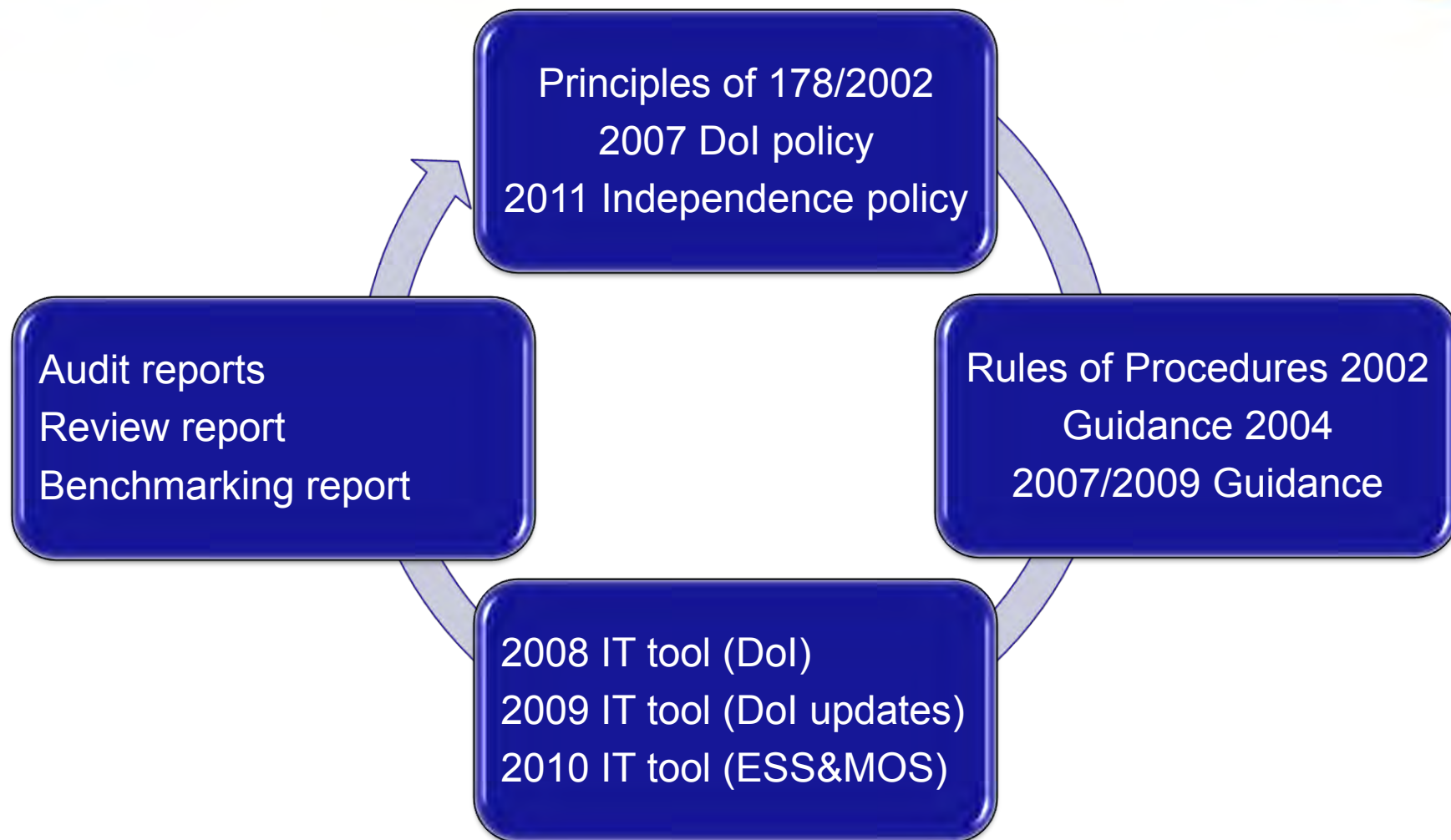


Draft Policy on Independence and Scientific Decision-making Processes of EFSA

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Independence Policy cycle



- Reflection paper discussed and endorsed by MB early 2011
- In June 2011 Draft Policy endorsed by MB
- On 16 September Public consultation closed
 - More than 80 comments from 25 submitters
- Today's consultative event
- Report on the consultation
- Draft amended and presented to the Board in December

The main sources of reflection besides the MB – up to now

- Discussion at the Advisory Forum
- External review of implementation of DoI Policy (2010)
- Benchmarking analysis (2010)
- Audits (2008 – 2009) + ECA in these months
- OECD Guidelines on managing CoI in public service
- EFSA's experience of implementing policy

- EFSA Founding Regulation 178/2002

- 1. Art 22

- Paragraph 7 *“The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference **by virtue of its independence**, the scientific and technical **quality of the opinions** it issues and the **information it disseminates**, the **transparency** of its **procedures and methods** of operation, and its **diligence** in performing the tasks assigned to it. It shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.”*

How this is translated into the draft policy

- 1. Organisational governance**
- 2. Scientific workflow**
- 3. Openness and Transparency**
- 4. Assessing interests**

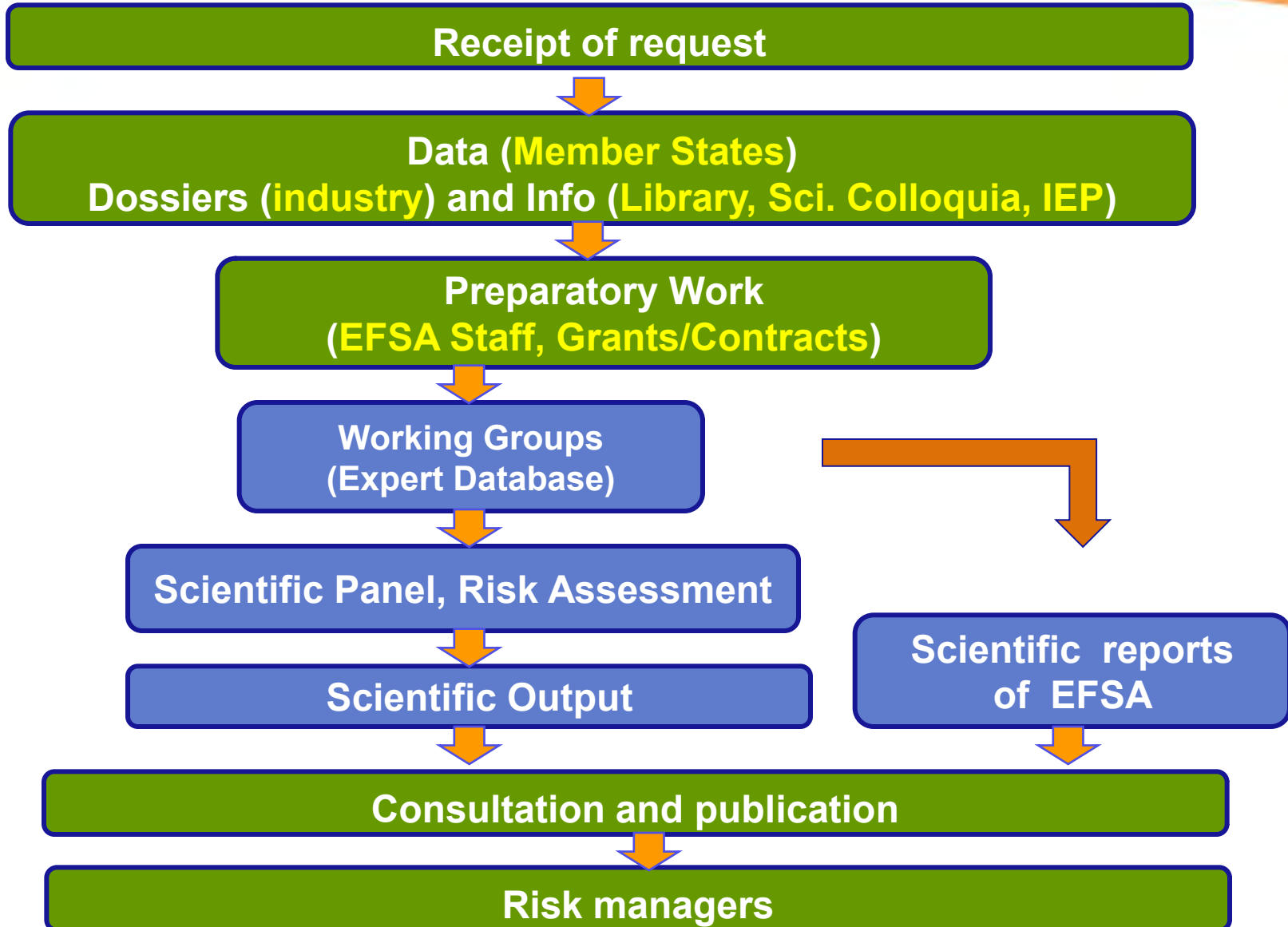
1. Organisational governance of independence: EFSA's Founding Regulation

- Institutional separation of Risk Assessment and Risk Management
- Mandate for independent risk communication
- Allocation of powers to different internal bodies in EFSA
 - Management Board
 - Advisory Forum
 - Executive Director
 - Scientific Committee and Scientific Panels
 - EFSA staff

1. Some comments from Stakeholders on governance

- Lack of willingness of EFSA to speak up and demand changes in legal acts/more support from Institutions needed to ensure appropriate legal instruments
- Changes to the procedure of appointment of MB members with closer involvement of stakeholders, composition of the MB
- Revolving door should be avoided with cooling off period, both for starters and for leavers

2. Scientific workflow



2. Some comments from Stakeholders on scientific workflow

- Caution in outsourcing
- Improvement in rules of selection of WG experts
- Broader base for supporting documents and data
- Reliability check of data gathered needed

3. Openness

- Public consultations (Criteria developed with stakeholders);
- Events, scientific colloquia, technical meetings with its partners, stakeholders and the public at large on scientific and policy matters webcast live on EFSA's website;
- Consultations, discussions and meetings with networks of NCAs (e.g. Network for Microbiological Risk Assessment; Network for Risk Assessment of GMOs etc);
- Invitation of hearing experts from interested parties to scientific meetings to provide their scientific point of view;
- Establishment of the Stakeholders Consultative Platform (since 2005).

3. Some comments from Stakeholders on openness

- NGOs should be more involved in scientific activities
- Applicants should be allowed bilateral meetings
- Stakeholders should be allowed to observe scientific meetings
- Access to EFSA's Expert data base

3. Transparency

- Publication of scientific outputs, background documents, minority opinions, meeting minutes, Annual Dols, remedial measures, Register of Question
- Guidelines of the Scientific Committee on Transparency in risk assessments;
- Quality review programme of scientific outputs both pre and post-adoption;
- Participation of observers to EFSA MB, AF and SHP meetings.

3. Some comments from Stakeholders on transparency

- All supporting documents to scientific outputs should be made available
- Minutes of scientific meetings should be more informative
- More transparency on dossiers submitted by industry

4. Assessing interests

EFSA Founding Regulation 178/2002

Article 37:

*“... shall make [annually] a **declaration of commitment and a declaration of interests** indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence.”*

“...shall declare at each meeting...”

4. Principles of assessing interests

- Members of the Management Board
- Members of Advisory Forum
- Executive Director
- Scientific experts
- EFSA Staff
- Contractors/Grant beneficiaries

4. Principles of assessing interests

- Interests to be declared:
 - Financial interest
 - Membership managing body
 - Membership advisory body
 - Employment
 - Consultancy or advice
 - Reserarch funding
 - Intellectual property rights
 - Interests of close family members

4. Principles of assessing interests

Conflict of interest:

Any situation whereby one or more of the interests held by, or entrusted to, a single person are considered incompatible with that person's role in the context of his or her cooperation with EFSA.

4. Principles of assessing interests

Interests
declared by an expert

Transparency
Independence

Mandate
of the group
Panel, WG

Role
Chair, Member,
Hearing expert...

4. Principles of assessing interests

- Annual Declarations of interest (Management Board, Advisory Forum, Executive Director, Staff members and Scientific experts)
- Oral declaration at the beginning of the meeting (Management Board, Advisory Forum, Executive Director, Staff members and Scientific experts)
- Specific Declarations of interest for Scientific experts

Annual Declaration of Interest ADol - for inviting to join

EFSA invites an expert to **join a group** of EFSA



Expert fills in / updates the ADol for this group


Need for clarification



Rejection



General conflicts identified



EFSA secretariat and management screens ADol



Role as hearing expert
Member with waiver



No general conflicts identified



Notification to expert Publication of ADol on the web Expert can now be invited to meetings of the group

Specific Declaration of Interest SDol – by agenda points

EFSA invites an expert to the **meeting** and sends agenda



Expert declare specific interests



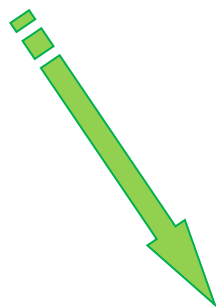
EFSA secretariat screens declared interest for each agenda points



No conflict identified



Conflict identified



EFSA decision



Preventive measures
1) Exclusion
**2) Limitation voting,
discussions,
drafting**



Minutes

4. Principles of assessing interests

- Preventive measures pre-defined depending on task, interest, potential conflict
 - Exclusion
 - Limitation regarding voting, discussions, drafting, chairmanship
- Breach of trust
- Review procedure of opinion

Declaration of interest in numbers from 01/01/2011 to 01/09/2011

ADoI level

- 1650 ADoI screened
- 24 CoI identified at the ADoI level

SDoI level

- 3431 SDoI screened corresponding to agenda items screened resulting in potential CoI prevented
- 30043
- 256

4. Some comments from Stakeholders on assessing interests

- EFSA should be more transparent re. remedial and preventive measures
- Involvement in a NCA should never be CoI
- Criteria leading to automatic conclusions are needed
- Audit needed to check implementation
- Bias derives also from political, religious ... interests
- Top quality scientists even from industry should not be excluded

- The core values of EFSA (scientific excellence, openness, transparency, independence) are to be viewed in the broader context of the quality of EFSA's outputs and its scientific decision-making processes
- Science and society
- The institutional independence of EFSA

The input from the public consultation/discussions will be used during the preparation of the revised policy