



EFSA's Policy on Independence

Hubert Deluyker

Director

Scientific Cooperation & Assistance

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EFSA Founding Regulation 178/2002

Recital 34

1. Art 22

- Paragraph 2 *"The authority shall provide **independent information** on all matters within all fields which have a direct or indirect impact on food and feed safety and communicate on risks."*
- 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 ..."*

2. Art 37

*"... shall make 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. "*

Why review the policy now?

- Scientific independence is critical in building trust in the EU food safety system
- Independence of scientific advice/experts in many sectors coming under increasing public scrutiny
- A series of high-profile controversies in pharmaceutical, environment sectors etc.
- EFSA is challenged about its independence, e.g. on GMOs
- EFSA's Policy on Declaration of Interests (2007) is scheduled for review this year

Eurobarometer survey on perceptions of food-related risk (2010)

- The majority of EU citizens think that public authorities:
 - take into account the most recent scientific advice (63%)
 - are quick to act when there is a health problem (63%)
 - consider citizens' concerns (63%)
- There is a high level of trust of EU citizens in both scientists (73%) and national and European food safety agencies (64%) as sources of information on food risks

but.....

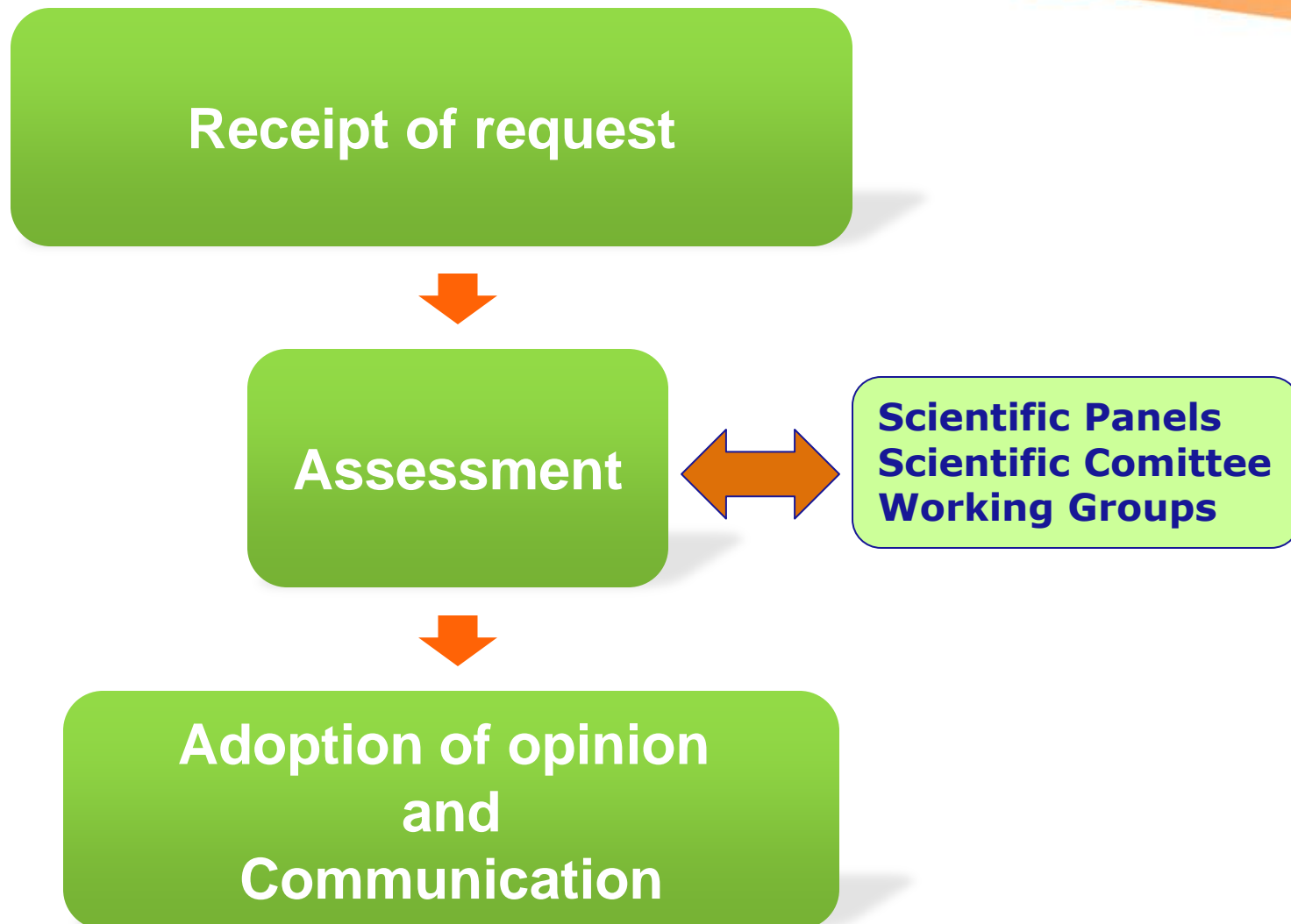
- Less than half of the EU citizens (47%) think that scientific advice on food related risks is independent of commercial or political interests

Eurobarometer survey on science & technology (2010)

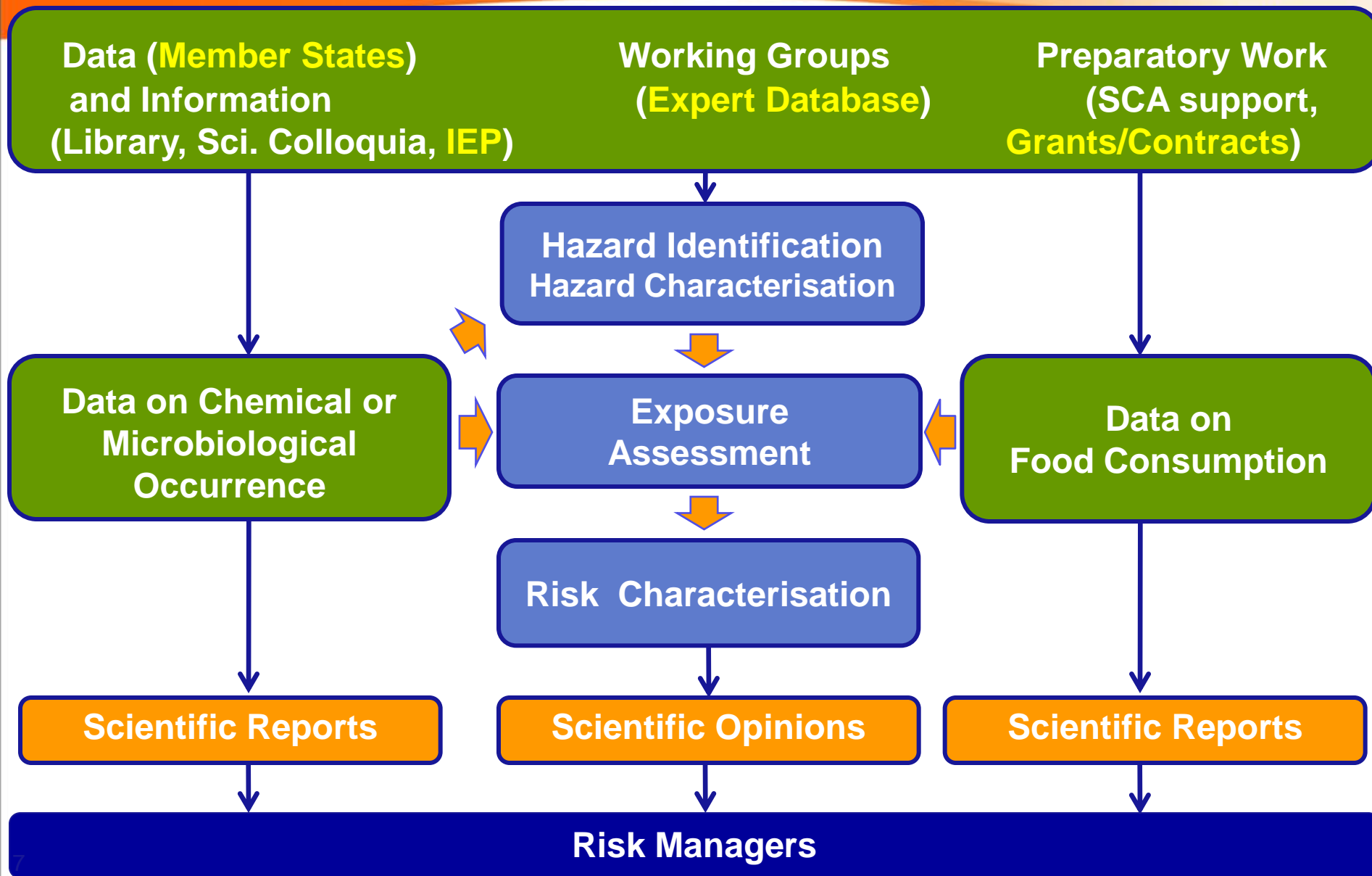
- 58% of Europeans feel that scientists cannot be trusted to tell the truth about controversial scientific and technological issues because they depend more and more on money from industry

Organisational governance

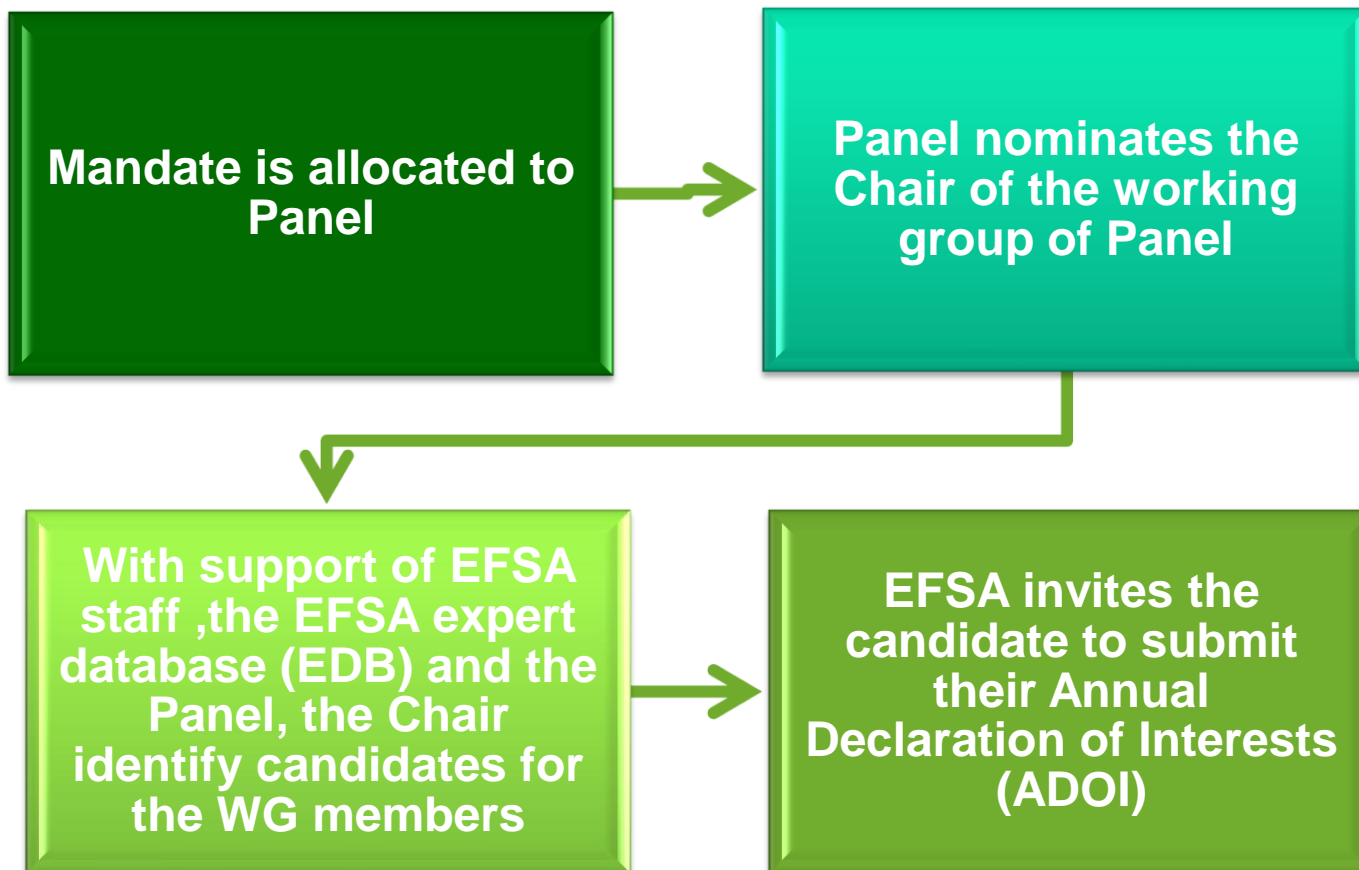
- Institutional separation of Risk Assessment and Risk Management
- Separation between Risk Assessment, Advisory Forum (strategic advice) and Management Board
- Mandate for independent risk communication



Scientific Support: workflow



Identification of Working Group (WG) members



WG composition + ADOIs published on EFSA's Website

1. Transparent workflows

2. Risk assessment process

- Selection of experts
- Data validation
- Rules of procedure of Panels/SC/WGs: Collegial decision making (minority opinions)
- Consultation

3. Quality review programme (INEX)

Ensuring pluralism in scientific debate on GMO

- Within working groups
 - Composition of members of working groups
 - Inviting hearing experts
- With Member States experts
 - MS comments on all applications (over 200 experts)
 - Specific meetings with MS experts
 - GMO risk assessment network
 - Art 30 of EFSA's Founding Regulations (Diverging opinions)
- With other experts
 - Public consultations
 - Hearing meetings and workshops

Dols: Who should declare interests?

- A) Members of the Management Board
- B) Members of the Advisory Forum
- C) Members of the Scientific Committee, Panels, Working Groups and other EFSA experts, including hearing experts
- D) EFSA's Executive Director and scientific staff members

Nature of activities in which the experts are required to declare interest (including details on period of time, organization and subject matter)

- I. Ownership or other investments, including shares**
- II. Member of a Managing Body or equivalent structure**
- III. Member of a Scientific Advisory Body**
- IV. Employment**
- V. Consultancy/Advisory**
- VI. Research funding**
- VII. Intellectual property**
- VIII. Other membership or affiliation**
- IX. Other**
- X. Interest of close family members**

ADOIs are published on EFSA's website

Dols: when there is a conflict of interest?

Interests
declared by an expert

Transparency
Independence

Mandate

Panel, WG,
AF, network...

Role

Chair, member,
Hearing expert...

- 5,000 annual or specific Dols screened
- 35,000 agenda items checked for SDol
- 24 experts excluded from EFSA activities
- 280 experts excluded from drafting
- 53 experts excluded from specific agenda items
- Resources committed: 3 FTEs and €180 k

External review of implementation of DoI Policy

Review of implementation of 180+ screenings by independent consultants

Outcome: EFSA is effectively implementing policy with only minor compliance issues

Recommendations:

- Increasing experts' contribution to and awareness of conflicts of interest
- Shifting the focus from individual measures to a more balanced, group-level approach
- Enhancing the level of detail provided on how conclusions regarding conflicts of interest are reached
- Reducing the retrospective period for declaring an interest from 5 years to 2 years.

Independent comparison of EFSA with ten peer organisations carried out by external consultancy

Focus on: governance; policies for development of scientific advice; appointment of external scientific experts; declaration of interests; and management of potential conflicts of interest.

Peer organisations:

- European Chemicals Agency
- European Medicines Agency
- DG SANCO
- Codex Alimentarius Commission /joint FAO/WHO committees
- ANSES (France)
- BfR (Germany)
- Food Standards Agency (UK)
- Health Canada
- FDA (US)
- National Academy of Sciences (US)

Outcome: EFSA has one of the most advanced and robust systems in place for ensuring the independence of its scientific advice

Recommendations:

- More comprehensive definition of conflict of interest
- Reinforcement of the positive obligations of experts
- Emphasis on the application of ethical standards
- Focus on scientific work carried out by EFSA's own staff members
- More opportunity for input from the public on independence
- Better definition of consequences if a conflict of interest is identified
- Shortening of the retrospective period in which an interest has to be declared
- Increased opportunities for stakeholder involvement

Proposal on how to take the review forward

- Creation of an integrated *Policy on Independence and Scientific Decision-Making Process* drawing together the various strands of EFSA's policies and scientific decision-making processes
- Making it easier to implement while maintaining its strength

- Initial discussion on approach at March MB meeting
- Draft Policy discussed at the MB meeting in June
- Submitted for public consultation beginning in July
- MB deliberations and possible adoption of Policy at October meeting