



# EFSA's risk assessment work in the area of plant protection products

STAKEHOLDER WORKSHOP  
FOOD SAFETY THROUGH SCIENCE - THE QUALITY OF RISK  
ASSESSMENT METHODOLOGY

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# Legislation

**Regulation (EC) No 1107/2009:** general procedures and criteria

**Regulation (EU) No 283 & 284/2013:** data requirements for

- ❑ Chemicals (includes natural origin products and semiochemicals)
- ❑ Preparations of chemicals
- ❑ Microorganisms including viruses
- ❑ Preparations of micro-organisms including viruses

**Regulation (EU) No 546 / 2011:** Uniform principles for evaluation and authorisation of products

# Legislation

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**Regulation (EU) No 546 / 2011:** Uniform principles for evaluation and authorisation of plant protection products

**Complete set of scientific information/data**

# Legislation Chemicals

## **Regulation (EC) 1107/2009 Annex II Criteria for approval(EU level)**

- Permit to establish where relevant toxicological reference values
- Permit any residue of concern in food or feed to be identified
- Not mutagen, carcinogen or toxic for reproduction category 1A or 1B
- Not endocrine disruptor
- Not POP / PBT or vPvB

# Legislation chemicals

## Regulation (EU) 546/2011

A chemical shall not be authorised if:

- occupational or bystander exposure exceeds reference values when these needed to be set or risk to these has not been addressed with another approach
- Consumer dietary exposure exceeds reference values when these needed to be set or consumer risk has not been addressed with another approach
- In soil the relevant residues persist for more than a year or in environmental matrices high levels of unextractable residues (>70%) combined with low mineralisation (<5%) occurs within 100 days unless

# Legislation chemicals

## Regulation (EU) 546/2011

A chemical shall not be authorised if:

- groundwater water quality parameters will not be respected (pesticides and their relevant metabolites, must  $< 0.1\mu\text{g/L}$ , where pesticide is defined by its approved use as a plant protection product or biocide)
- acceptable risk to birds and non target vertebrates has not been demonstrated including addressing potential of bioconcentration
- acceptable risk to aquatic organisms has not been demonstrated including addressing potential of bioconcentration
- acceptable risk to beneficial arthropods other than honeybees, earthworms and soil micro-organisms has not been demonstrated

# In summary....

.....A huge amount of studies,  
original data, publications has to be  
produced to conclude on all  
different aspects required by the  
legislation and, in principle,  
required by any scientist  
performing a risk assessment  
!

# How the authorisation process work

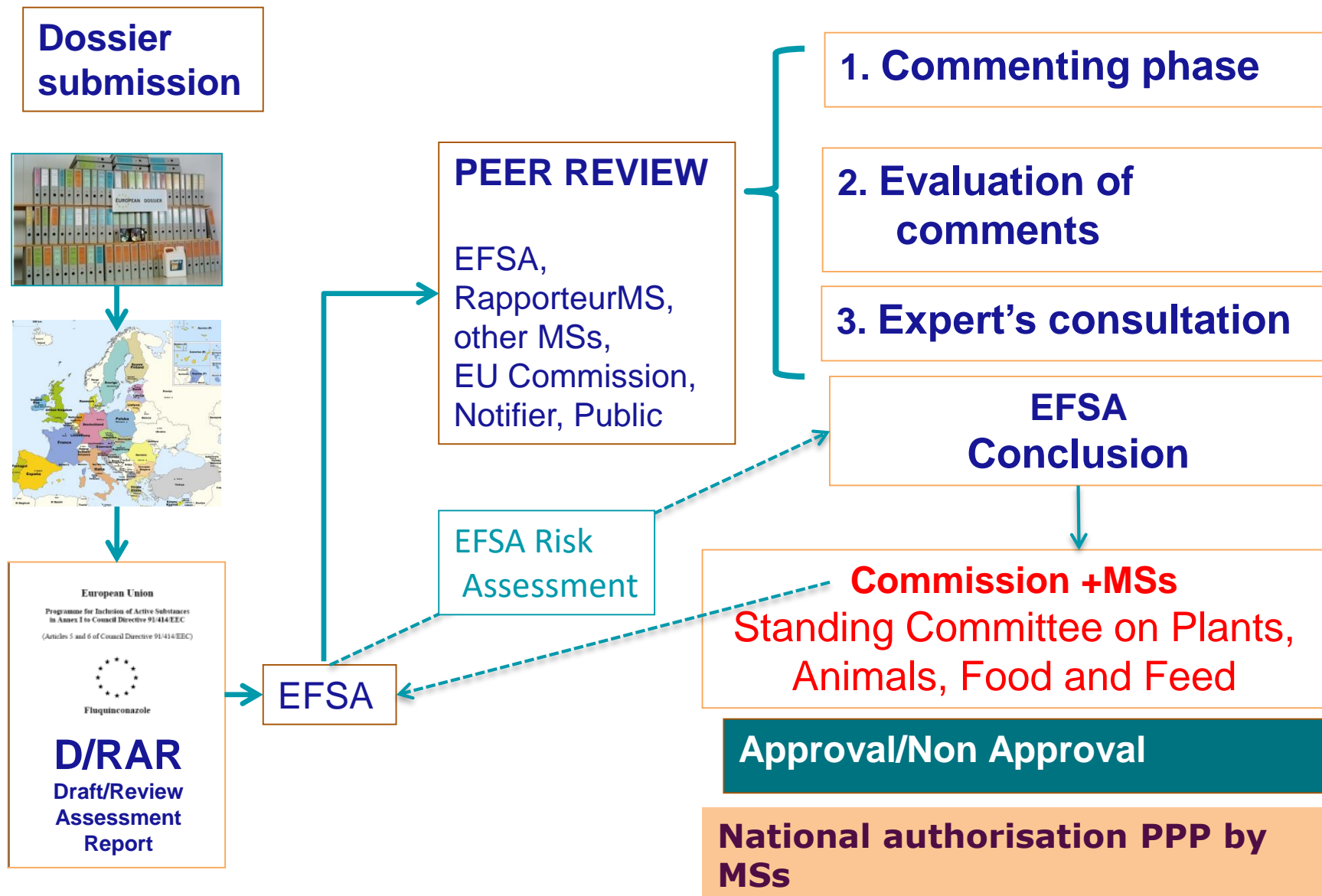
- Active substance evaluation at EU level
- PPP authorisation at Member State level
- Harmonised data requirements for both active substances and PPPs
- Harmonised evaluation principles and criteria for PPP authorisation
- Mutual recognition of PPPs between MSs with comparable conditions
- Review of all « existing » active substances



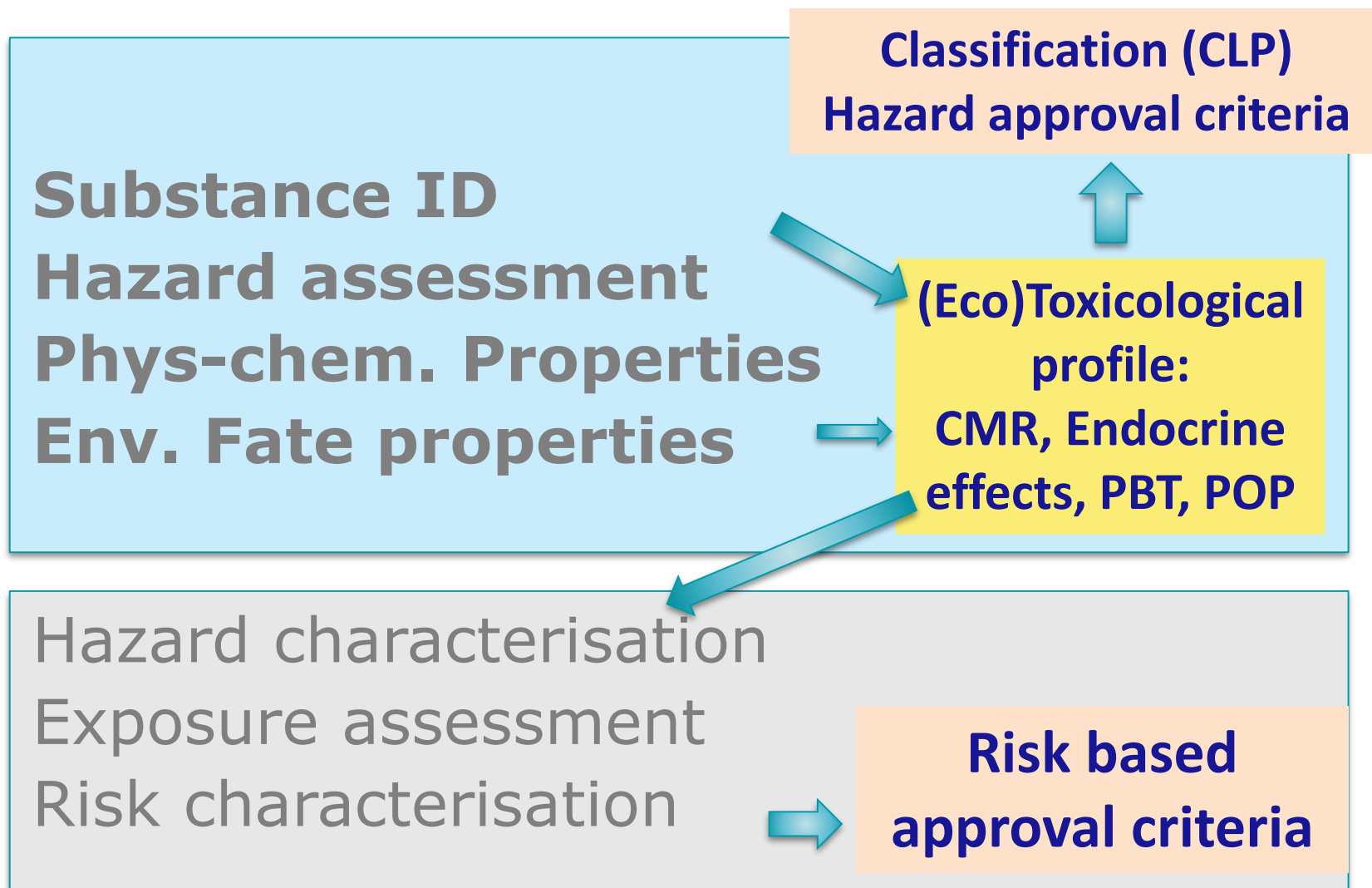
# EU review a.s.

- Dossier submitted to the RMS
- Completeness check by the RMS
- RMS drafts the draft assessment report
- EFSA organises a peer review on the a.s.
- EFSA drafts a conclusion on the a.s.
- EC prepares a decision (inclusion/non-inclusion in Annex I to Directive 91/414/EEC)
- Vote in SCoPAFF on Commission proposal
- MSs review PPPs containing a.s. concerned

# The Peer-Review Process



# EFSA Scientific assessment



# CONCLUSION & REASONED OPINIONS

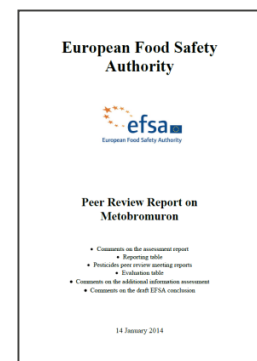
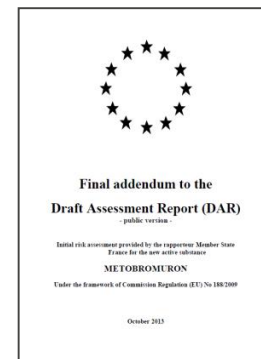
## Conclusions on Pesticides\*

- Identity and Phys/Chem properties
- Mammalian Toxicology & non dietary health risks
- Residues & Consumers risks
- Environmental Fate and Behaviour
- Ecotoxicology & environmental risks



## Reasoned Opinions on MRLs & Annual reports:

- Residues & Consumers risks



\*Some conclusions are limited to one or more areas

# Pesticides Units. Regular activities

Supports the Scientific Panel for pesticides PPR (Plant Protection Product and their Residues).



- Opinions
- Guidance documents
- Ad-hoc mandates

Coordinates the Peer Review of active substances



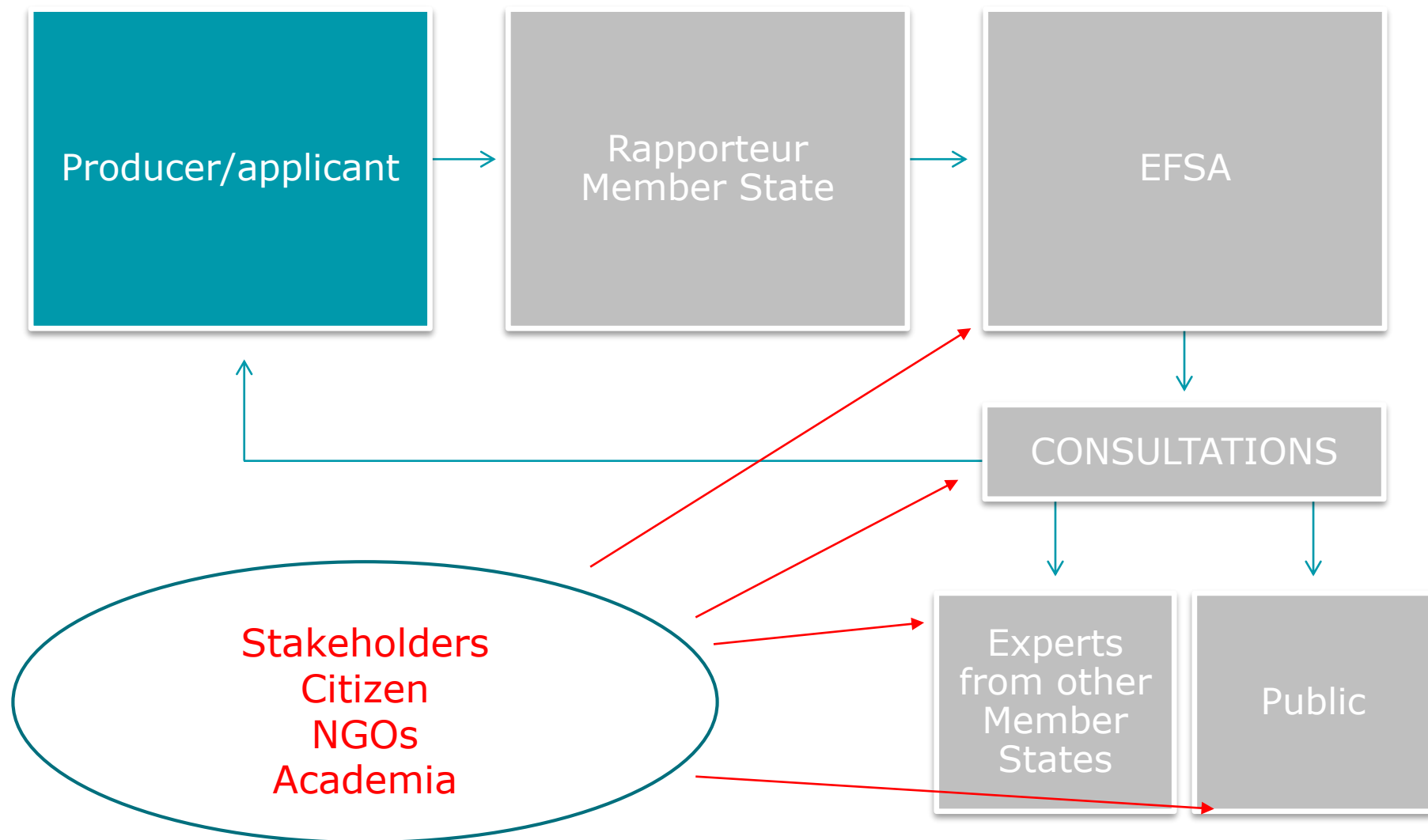
Provides Conclusions for single active substances to support the EU decision-makers

Maximum Residue Levels MRLs



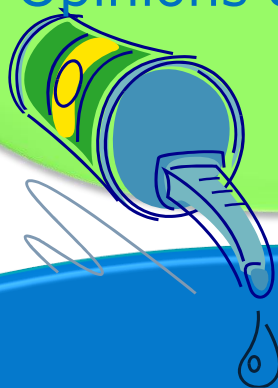
- Reasoned Opinions
- Annual report

# ASSESSMENT OF PESTICIDES: THE ACTORS



## PPR Panel

Opinions & Guidance documents

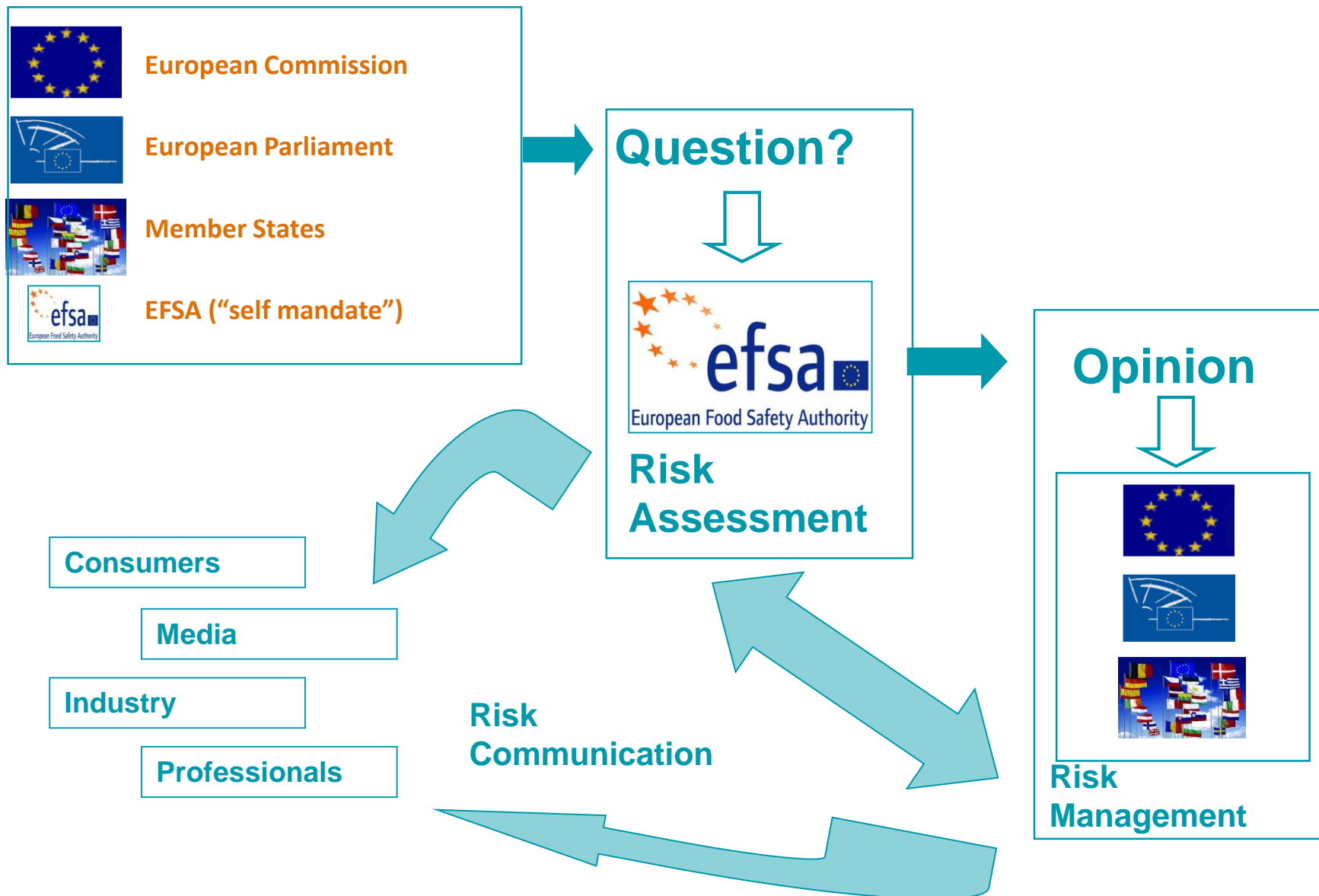


**Reg. 396/2005**  
MRL setting,  
pesticide  
monitoring

**Reg. 1107/2009**  
Evaluation of active  
substances including  
micro-organisms  
(representative  
uses)

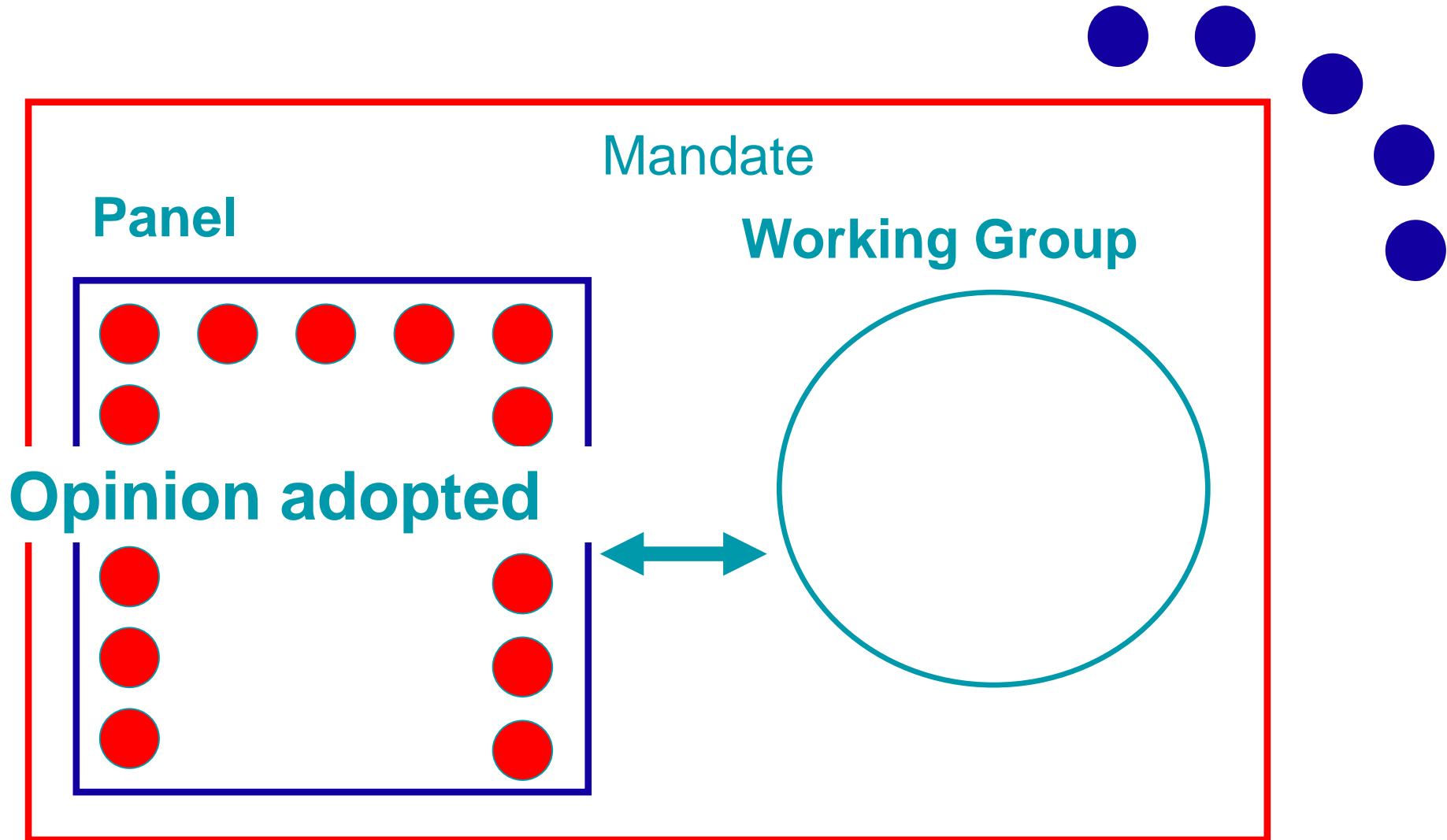
**Scientific staff  
working with Member  
States experts**

# How does EFSA work ?





# How does EFSA's Units work ?



# EFSA Panels, Working Groups, ad hoc and hearing experts

- EFSA has selected over 170 top scientific experts to take up the baton of the Authority's scientific panels in July. These experts play a leading role in providing independent scientific advice to protect EU consumers, animals and the environment.
  - Over 1,000 scientists applied to become EFSA panel members following a call for experts held in the summer of 2017. The 170-plus nominees were chosen after an exhaustive selection process and thorough screening of their declarations of interest.
- 
- Scientific Committee
  - Panel on Animal Health and Welfare
  - Panel on Food Additives and Flavourings
  - Panel on Biological Hazards
  - Panel on Food Contact Materials, Enzymes and Processing Aids
  - Panel on Contaminants in the Food Chain
  - Panel on Additives and Products or Substances used in Animal Feed
  - Panel on Genetically Modified Organisms
  - Panel on Nutrition, Novel Food and Food Allergens
  - Panel on Plant Health
  - **Panel on Plant Protection Products and their Residues**

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**Thank you!**



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