EFSA's role in the risk assessment of GMOs in the EU and in international context

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‘COMMITTED TO ENSURING THAT EUROPE'S FOOD IS SAFE’

EFSA…

- is the EU reference body for risk assessment
- provides independent scientific advice and support for EU law / policies on food and feed safety
- provides independent, timely risk communication
- promotes scientific cooperation
- covers the entire food chain – from field to fork

‘COMMITTED TO ENSURING THAT EUROPE'S FOOD IS SAFE’

EFSA does not…

- develop food safety policies and legislation
- adopt regulations, authorise marketing of new products (→ risk management)
- enforce food safety legislation
- take charge of food safety/ quality controls, labelling or other such issues, like inspections and traceability

EFSA WORKFLOW

EU Commission

EU Parliament

Member States

EFSA self mandate

EFSA receives question

EFSA's scientists evaluate, assess, advise

Adoption and communication

EFSA GOVERNANCE

Management Board + Advisory Forum + EFSA Staff + Scientific Committee and Panels

= European Food Safety Authority

EFSA'S SCIENTIFIC ADVICE FROM FIELD TO FORK

Plant Health

Plant Protection

Genetically modified organisms

Animal feed

Animal health and welfare

Biological hazards

Chemical contaminants

Food additives

Food packaging

Nutrition

DIFFERENT ROLES

Scientific Panels

- Owners of scientific opinions

Scientific Committee

- Ensures consistency
- Issues guidance
- Assess emerging risks

Staff

- Support panel work
- Produce scientific and technical advice
- Communication

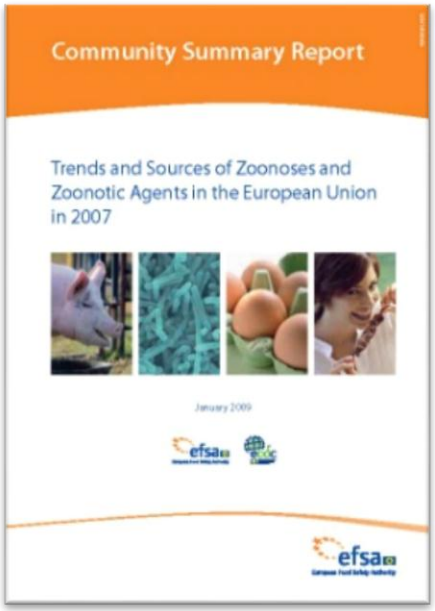
EXPERTS ARE CAREFULLY SELECTED

EFSA seeks high-calibre experts to serve on its Scientific Committee and Scientific Panels

- Open call to scientists from all EU Member States and beyond
- EFSA chooses candidates with proven excellence in one or more scientific fields within its remit
- Open, transparent selection procedure

NETWORKING WITHIN EUROPE…

- National food safety agencies / research organisations (Art. 36)
- 400 research institutes
- 1,500 experts
- MS networks
- Knowledge transfer: visiting scientists scheme
- EU Agencies:



OUTSIDE EUROPE…

Working with national food safety organisations:

- US: FDA, USDA APHIS, USDA FSIS, ARS, EPA
- Health Canada
- Food Safety Commission of Japan
- Food Standards Australia
- New Zealand Food Safety Authority

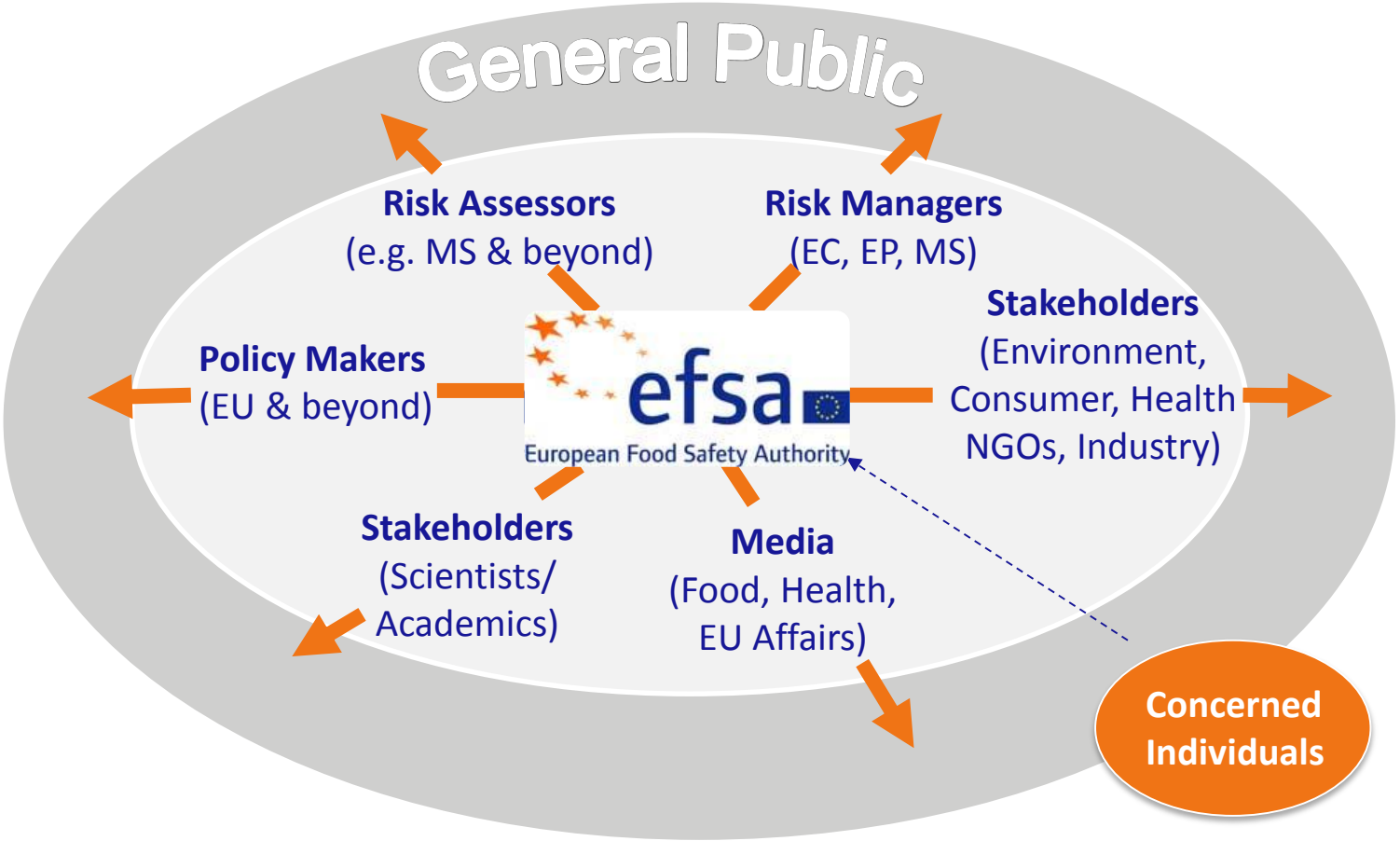
Working with international organisations:

- Supporting EU delegation at OECD WGs
- Supporting EU delegation at Codex
- Biosafety Clearing House
- OIE

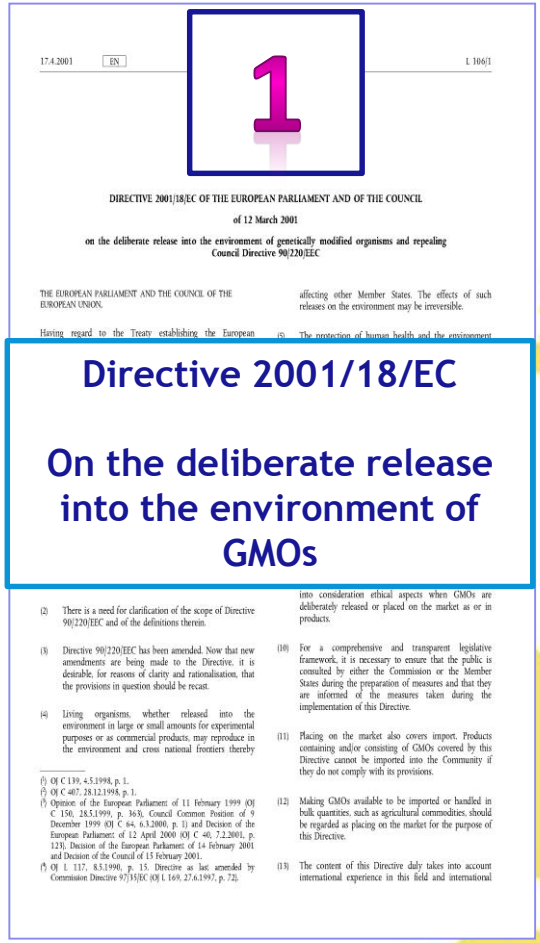
… AND A STAKEHOLDER CONSULTATIVE PLATFORM

- Mission: assist EFSA with the development of its overall relations and policy with regard to stakeholder involvement
- Members: EU-wide stakeholder organisations representing consumers, food chain operators and other NGOs active within EFSA's mandate
- A forum for regular dialogue and exchange
- Almost 10 years of operation

Who does EFSA communicate with?



REGULATORY FRAMEWORK FOR APPLICATIONS


17.4.2001 EN L 106/1

1

DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 12 March 2001

on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European

affecting other Member States. The effects of such releases on the environment may be irreversible.

(2) There is a need for clarification of the scope of Directive 90/220/EEC and of the definitions therein.

(3) Directive 90/220/EEC has been amended. Now that new amendments are being made to the Directive, it is desirable, for reasons of clarity and rationalisation, that the provisions in question should be recast.

(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby

into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.

(10) For a comprehensive and transparent legislative framework, it is necessary to ensure that the public is consulted by either the Commission or the Member States during the preparation of measures and that they are informed of the measures taken during the implementation of this Directive.

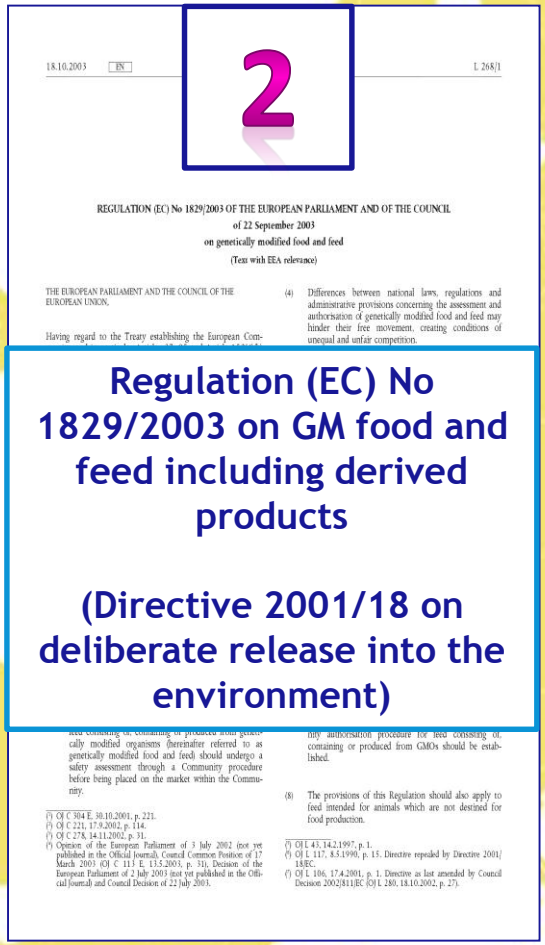
(11) Placing on the market also covers import. Products containing and/or consisting of GMOs covered by this Directive cannot be imported into the Community if they do not comply with its provisions.

(12) Making GMOs available to be imported or handled in bulk quantities, such as agricultural commodities, should be regarded as placing on the market for the purpose of this Directive.

(13) The content of this Directive duly takes into account international experience in this field and international

Directive 2001/18/EC

On the deliberate release into the environment of GMOs


18.10.2003 EN L 268/1

2

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

on genetically modified food and feed

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Com-

(4) Differences between national laws, regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may hinder their free movement, creating conditions of unequal and unfair competition.

cally modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

fully authorisation procedure for feed containing or, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production.

Regulation (EC) No 1829/2003 on GM food and feed including derived products

(Directive 2001/18 on deliberate release into the environment)


8.6.2013 EN L 157/1

3

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 503/2013

of 3 April 2013

on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

modified food and feed satisfy the requirements laid

genetically modified food or feed must not mislead the consumer or the user and must not differ from the food or feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for humans or animals.

(2) Regulation (EC) No 1829/2003 provides, in particular, that applications for authorisation are to adequately and sufficiently demonstrate that the genetically

(5) The rules laid down in this Regulation should only cover applications concerning genetically modified plants for food or feed uses, food or feed containing or consisting of genetically modified plants and food or feed produced from such plants. Genetically modified plants, for which sufficient experience is available to date, constitute the vast majority of current applications.

Implementing Regulation (EU) No 503/2013

On applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003

SOURCES OF INFORMATION

- Information included in the application and asked later during the Risk Assessment

- General vigilance – Art 22(4) of Regulation (EC) 178/2002 „the Authority shall collect and analyse data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.”
  - Scientific literature
  - Authorisation requests submitted outside EU → also a requirement in Implementing Regulation (EU) 503/2013

SCOPE OF GMO APPLICATIONS

GM Food

- Containing or consisting of genetically modified plants
- Produced from genetically modified plants or containing ingredients produced from genetically modified plants

GM Feed

- Containing or consisting of genetically modified plants
- Containing produced from genetically modified plants

GM plants for food or feed uses

- Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
- Seeds and other plant propagating material for cultivation in the Union

EFSA carries out **scientific risk assessment** on GMOs to ensure that they are as safe as their conventional equivalent

RISK ASSESSMENT PERFORMED BY

- **The GMO Panel (18 external experts) for a 3 year mandate (currently 2015-2018)**
  - elaborates Guidance Documents
  - delivers scientific opinions on applications for market authorisation regarding GMOs

- **Ad-hoc experts** support the GMO Panel in **Working groups** (4 standing WG and several temporary WGs)

- 17 **GMO Unit scientists** provide support to the GMO Panel and its Working Groups

REGULATORY FRAMEWORK: INTERPLAY BETWEEN THE ACTORS

GMO application (via MS) forwarded to EFSA

One MS performs initial ERA (cultivation dossiers only)

Scientific opinion adopted by the GMO Panel
Overall Opinion issued by EFSA

Consultation with all Member States (all applications)

Risk assessment

Risk management

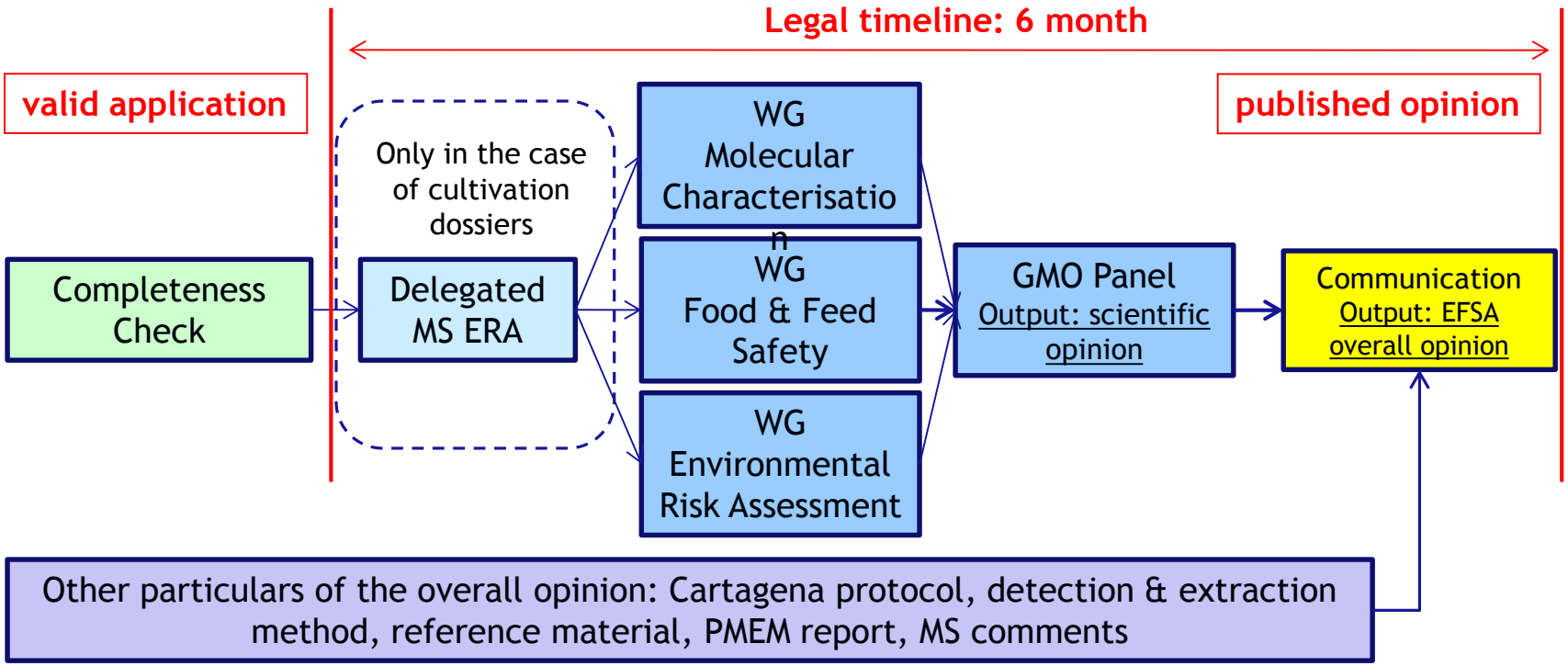
Public consultation

European Commission

EURL-GMFF (JRC)
Detection method

Decision to authorize or not to authorize

WORKFLOW OF THE ASSESSMENT OF GMO APPLICATIONS



Risk assessment methodology and principles

- Science- and evidence-based
- Case-by-case
- Step-by-step
- Comparative approach (GM vs non-GM)

KEY PRINCIPLES OF GMO RISK ASSESSMENT

COMPARATIVE APPROACH =

comparison between the GMO (and derived products) and its conventional counterpart

Assessment of the identified differences regarding:

Food/Feed safety

Nutritional impact

Environmental impact

- **Intended effects**: those occurring because of the genetic modification
- **Unintended effects**: additional effects which were NOT the objective of the genetic modification

GMO RISK ASSESSMENT OF GM FOOD AND FEED

Molecular Characterisation

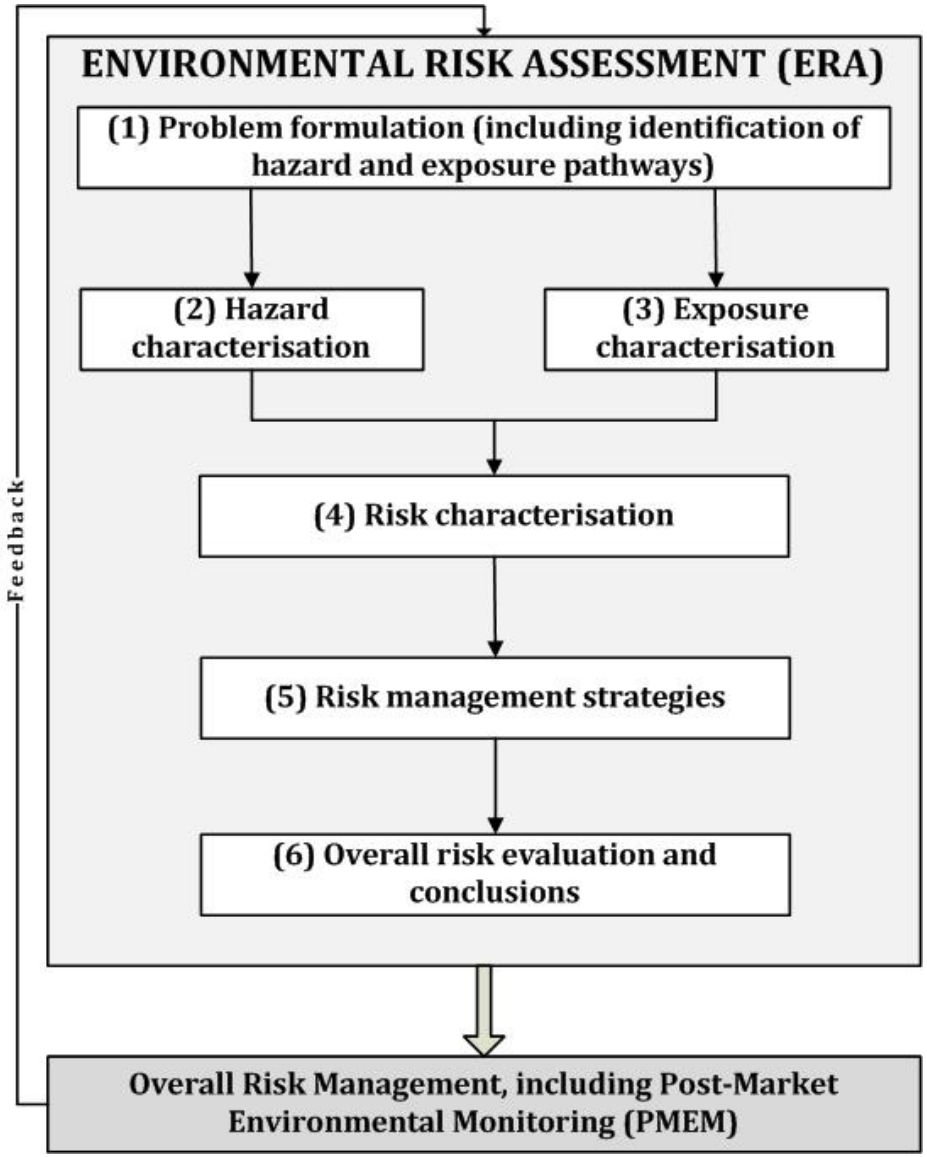
- Genetic modification
- Characteristics of the GM plant

Food and Feed safety

- Compositional and agronomic assessment
- Toxicological assessment
- Allergenicity assessment
- Nutritional assessment

KEY PRINCIPLES OF GMO RISK ASSESSMENT

The 6 steps of the ERA



EFSA Guidance documents

- Provide guidance for applicants how to prepare and present the applications
- Detailed guidance needed as only full dossiers are considered
- Based on internationally agreed principles and protocols (Codex Alimentarius, OECD)
- Regularly updated
- Undergo public consultation

EFSA GUIDANCE DOCUMENTS

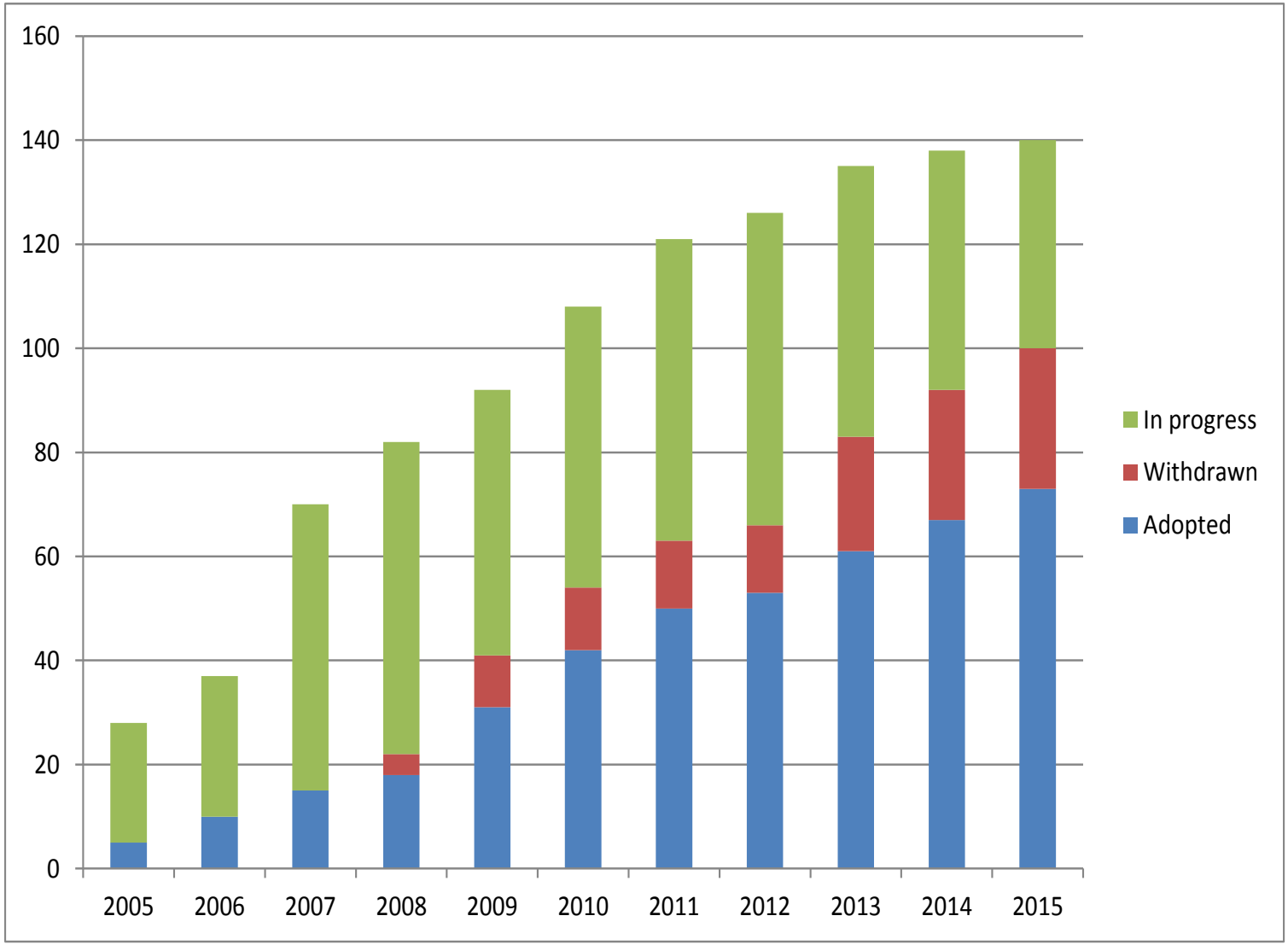
"Main" guidance documents

- Guidance for risk assessment of food and feed from GM plants (2011), includes
  - Selection of comparators for the risk assessment of GM plants (2011)
  - Statistical considerations (2010)
  - Allergenicity assessment of GM plants and microorganisms (2010)
- Environmental Risk Assessment (ERA) of GM Plants (2010), includes
  - Potential impacts on non-target organisms (2010)

Additional guidances

- Guidance on the agronomic and phenotypic characterisation of GM plants (2015)
- Guidance for the authorisation renewal of GM food and feed (2015)
- Post market environmental monitoring – PMEM (2011)

STATUS OF APPLICATIONS – JULY 2015



Thank you for your attention!

Questions?