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

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EFSA GMO Unit
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
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
Plant Health

Plant Protection

Genetically modified organisms

Biological hazards

Animal health and welfare

Animal feed

Chemical contaminants

Food additives

Food packaging

Nutrition

EFSA’S SCIENTIFIC ADVICE FROM FIELD TO FORK
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
COMMUNICATION CHANNELS

Who does EFSA communicate with?

- **Risk Managers** (EC, EP, MS)
- **Stakeholders** (Environment, Consumer, Health NGOs, Industry)
- **Media** (Food, Health, EU Affairs)
- **Stakeholders** (Scientists/Academics)
- **Policy Makers** (EU & beyond)
- **Risk Assessors** (e.g. MS & beyond)
- **Concerned Individuals**
REGULATORY FRAMEWORK FOR APPLICATIONS

1. Directive 2001/18/EC
On the deliberate release into the environment of GMOs

Regulation (EC) No 1829/2003 on GM food and feed including derived products
(Directive 2001/18 on deliberate release into the environment)

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
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
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

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

One MS performs initial ERA (cultivation dossiers only)

Consultation with all Member States (all applications)

Risk assessment
Risk management

Public consultation

European Commission

Decision to authorize or not to authorize

EURL-GMFF (JRC)
Detection method
WORKFLOW OF THE ASSESSMENT OF GMO APPLICATIONS

Completeness Check → Delegated MS ERA → WG Molecular Characterisation → WG Food & Feed Safety → WG Environmental Risk Assessment → GMO Panel Output: scientific opinion → Communication Output: EFSA overall opinion

Other particulars of the overall opinion: Cartagena protocol, detection & extraction method, reference material, PMEM report, MS comments

Legal timeline: 6 month

valid application → published opinion

Only in the case of cultivation dossiers
GMO RISK ASSESSMENT

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

ENVIRONMENTAL RISK ASSESSMENT (ERA)

(1) Problem formulation (including identification of hazard and exposure pathways)

(2) Hazard characterisation

(3) Exposure characterisation

(4) Risk characterisation

(5) Risk management strategies

(6) Overall risk evaluation and conclusions

Overall Risk Management, including Post-Market Environmental Monitoring (PMEM)
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 guidelines

• 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

Number of applications

In progress
Withdrawn
Adopted
Thank you for your attention!

Questions?