



EFSA's activities related to the risk assessment of GMOs

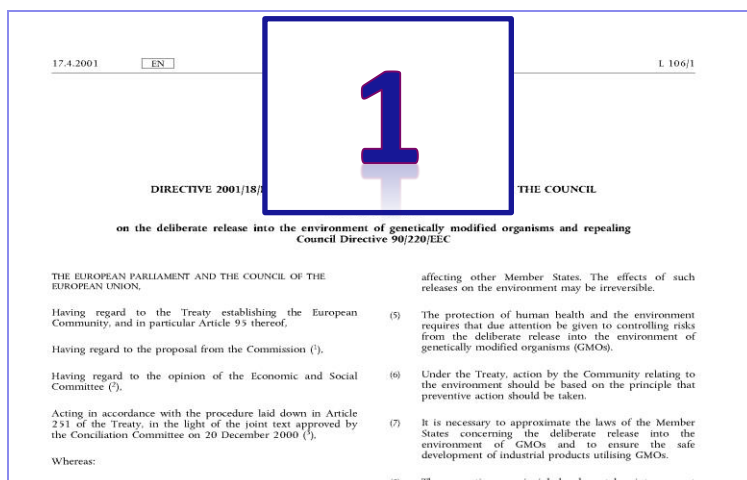
Public Hearing
on
"The Future of GMOs in Europe - Experiences and Best practices"

Brussels, 18 November 2015

Elisabeth Waigmann
Head of GMO Unit

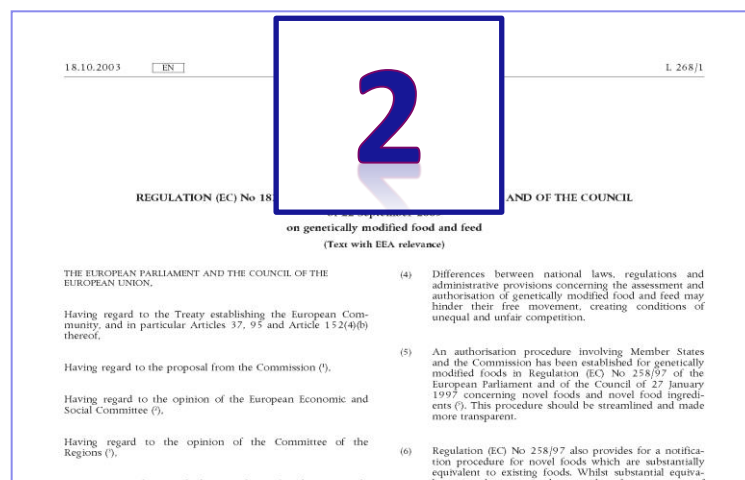
LEGAL FRAMEWORK FOR GMO RISK ASSESSMENT

EFSA's role: to carry out a science-based risk assessment of GMOs, mainly GM plants



Directive 2001/18/EC

On the deliberate release of GMOs into the environment



Regulation (EC) No 1829/2003 & Implementing Regulation (EC) No 503/2013

On GM food and feed including derived products



RISK ASSESSMENT PERFORMED BY...

- ❑ **The GMO Panel** (18 external experts) for a 3-year mandate (2015-2018)

elaborates guidance documents

delivers scientific opinions on applications for market authorisation regarding GMOs

- ❑ Approximately **40 ad-hoc experts** support the GMO Panel in various **working groups**

Four standing WGs

Currently, two *ad hoc* WGs (depending on requests)

- ❑ 15 scientists of the **EFSA GMO Unit** provide support to the GMO Panel and its working groups

- ❑ **210 Member State** experts from 108 MS organisations and authorities comment on each application



WHAT ARE THE MAIN ACTIVITIES?

Applications for placing on the market

Uses : food/feed import and
processing, cultivation

Scope: new GM products or their
renewal

Guidance documents for the risk assessment

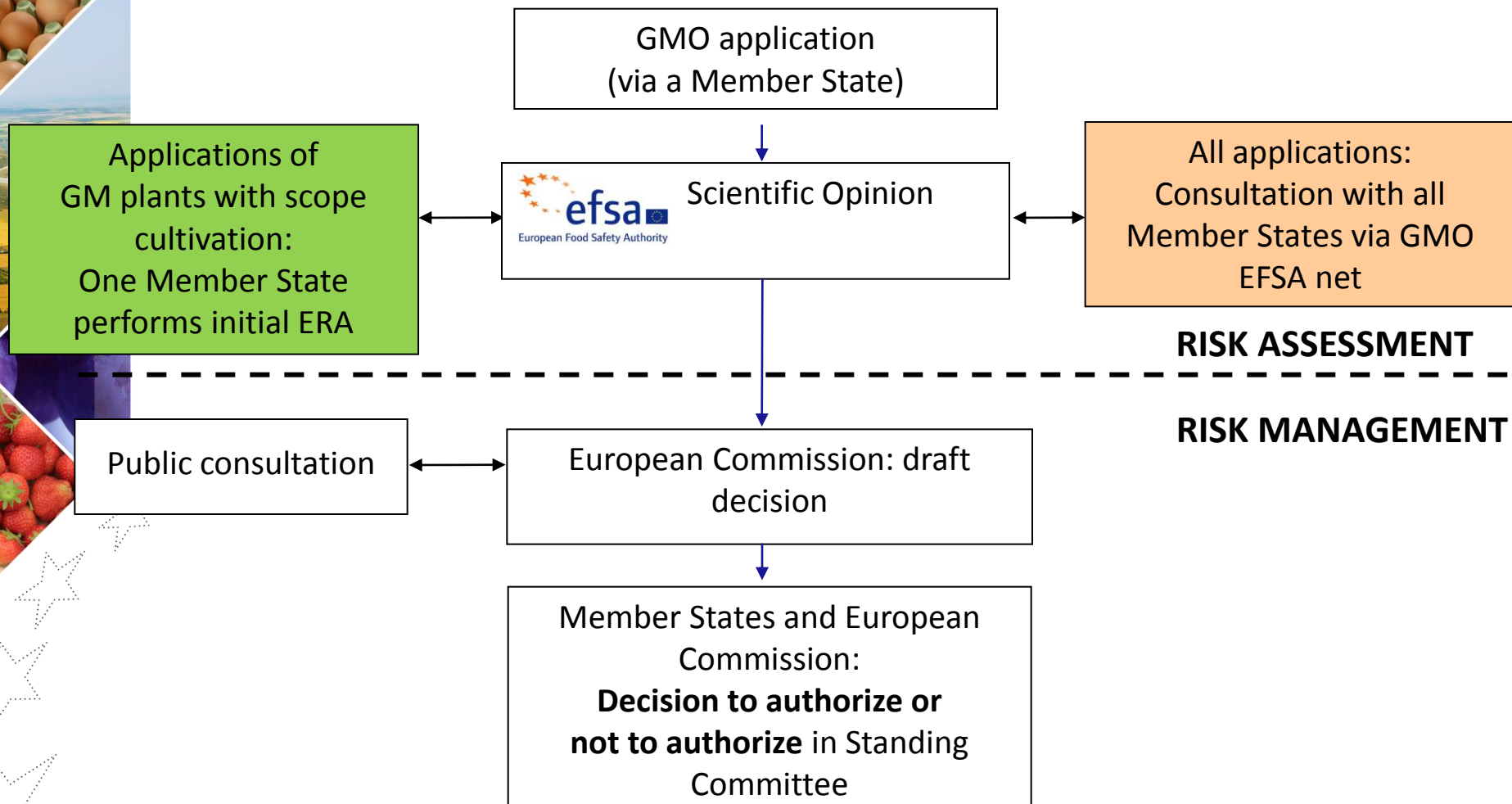
Specific mandates from EC/DG SANTE

E.g. evaluation of reports/papers

Recurrent requests from EC/DG SANTE

E.g. annual PMEM reports, evaluation
of public comments

PATHWAY OF AN APPLICATION



OVERVIEW OF GMO APPLICATIONS

Year	GM Plants for food/feed uses* and/or cultivation (Reg (EC) 1829/2003)		GM Plants for deliberate release into environment (Dir 2001/18/EC)	
	Received	Finalised	Received	Finalised
2003 - 2012	135	63	15	13
2013	9	11	2	-
2014	3	5	1	3
2015	4**	7	2	-
Total 2003-2015	151	86	20	16

* Including applications on new GMOs and on existing GMOs for the renewal of their authorisations

** Including 1 application to renew the authorisation of maize 1507 for import and processing

Ongoing applications

under Regulation 1829/2003/EC: **36**; under Directive 2001/18/EC: **2**

Withdrawn applications

under Regulation 1829/2003/EC: **29**; under Directive 2001/18/EC: **2**



GUIDANCE DOCUMENTS

- ❑ Guidance on Environmental Risk Assessment of GM Plants (2010)
- ❑ Guidance on Risk assessment of food and feed from GM plants (2011)
 - was incorporated into Implementing Regulation 503/2013 on genetically modified food and feed (2013)
- ❑ Guidance on Post-Market Environmental Monitoring (2011)
- ❑ Guidance on Risk assessment of GM plants for continued marketing ('renewal') (2015)

Supplementary guidelines on specific aspects of the RA

- ❑ Agronomic and phenotypic characterisation of GM plants (2015)

Under development

- ❑ Supplementary guidelines for the allergenicity assessment of GM plants (end 2016) – pilot project: focus group
- ❑ Guidelines for the risk assessment of the Low Level Presence (LLP) of GM food and feed (May 2017)

OTHER RECENT MANDATES FROM EC



June 2015

EFSA report to clarify previous GMO Panel recommendations on the insect-resistance management plan for maize MON 810

September 2015

EFSA statement on the risk assessment of new sequence data on maize MIR604

October 2015

EFSA statement on the risk assessment of new sequence data on maize GA21

October 2015

Scientific opinion of the GMO Panel on (partial) outcome of the 2013 PMEM report on maize MON 810 (Part II)