European Food Safety Authority

EU Risk Assessment of GMOs Roles of EFSA, Member States and European Commission

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GMO regulation in EU

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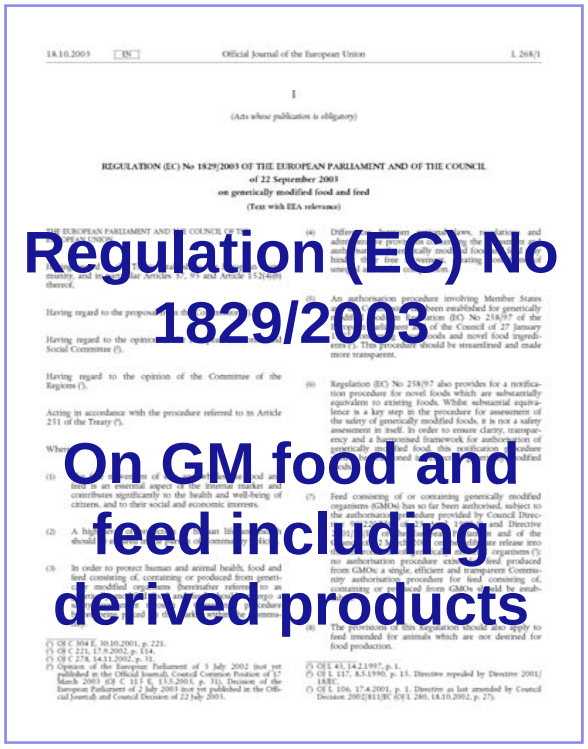
In the EU, products that are, contain, or are produced from GMOs must have an authorisation prior to entering the market

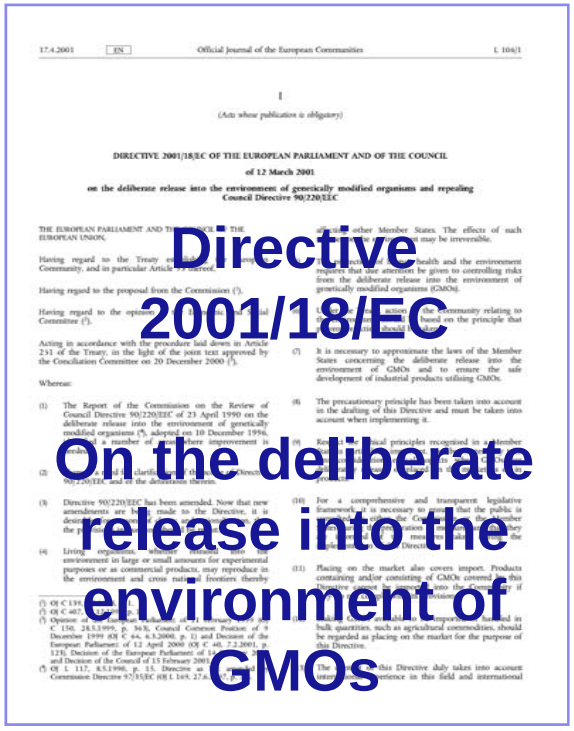
Legal framework for GMO risk assessment

1. EFSA's role is to carry out scientific Risk Assessment on GMOs under two regulatory frameworks:



Regulation (EC) No 1829/2003

On GM food and feed including derived products



Directive 2001/18/EC

On the deliberate release into the environment of GMOs

2. EFSA also provides independent scientific advice to Risk managers

Mandate of EFSA GMO Panel

- **GMO Panel** delivers opinions through guidance documents, applications and scientific questions regarding genetically modified organisms
- **Plenary meetings** every 1,5 months for adoption of opinions
- European Commission are observers
- GMO Unit to give scientific and administrative support to the GMO Panel

The GMO Panel

– Covering the necessary expertises
  - **For molecular characterisation:** biochemistry, food and environmental microbiology, soil microbiology, molecular biology, genetics, plant breeding
  - **For food feed safety:** toxicology, immunology, biotechnology, food chemistry, nutrition, animal feed,
  - **For the environment**: ecology, plant biology, agronomy, entomology, biometrics and statistics

– Assisted by 40 *ad hoc* experts in working groups, representing expertise in e.g. for, pesticides, natural toxins, environmental monitoring, food sciences, animal pathology

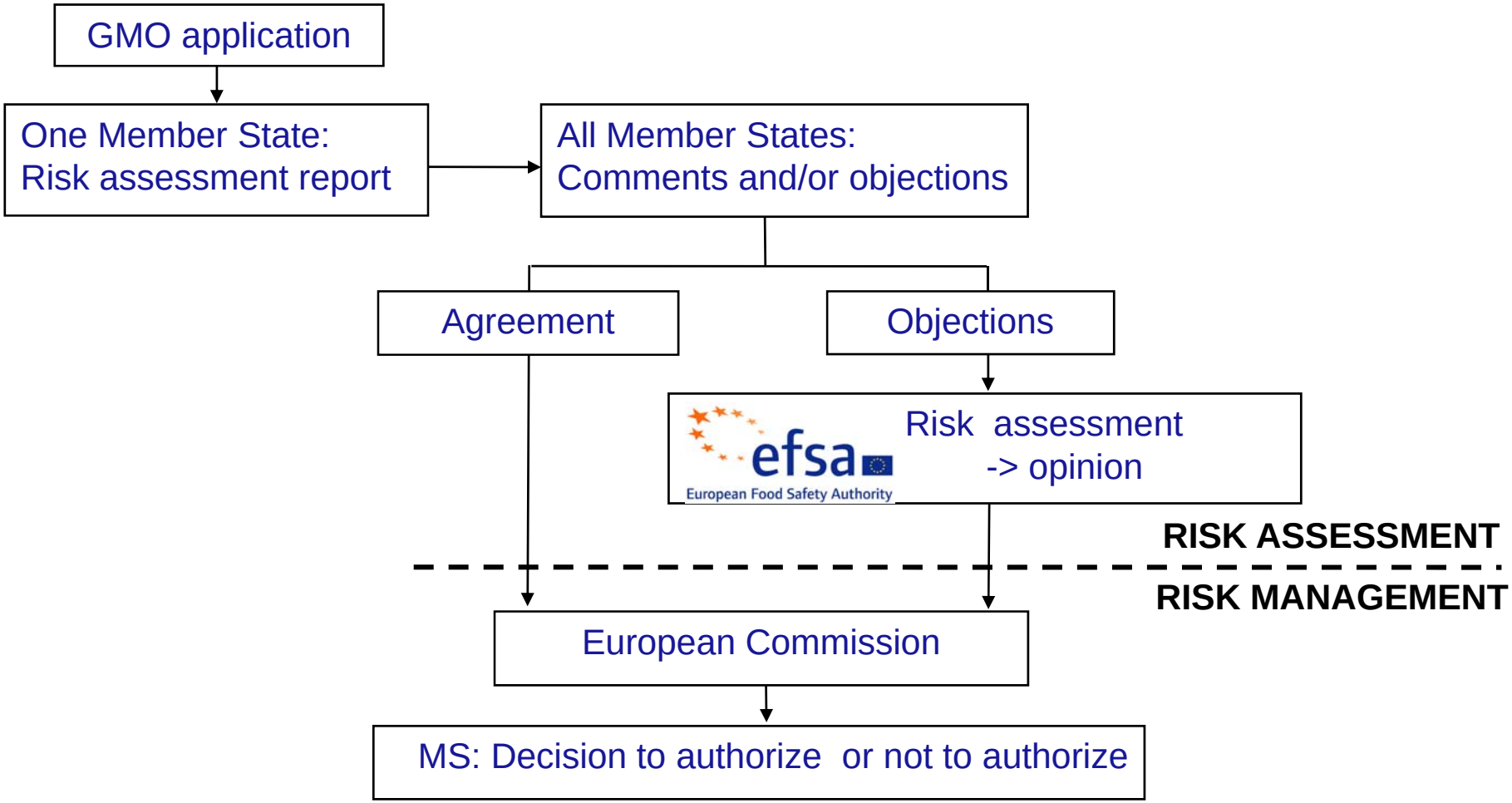
Role of EFSA in GMO authorisation process

1. EFSA's scientific Opinions on GMOs are published on EFSA's website and forwarded to the European Commission and Member States

2. It is the Risk managers who then take the decision to authorise a GMO or not

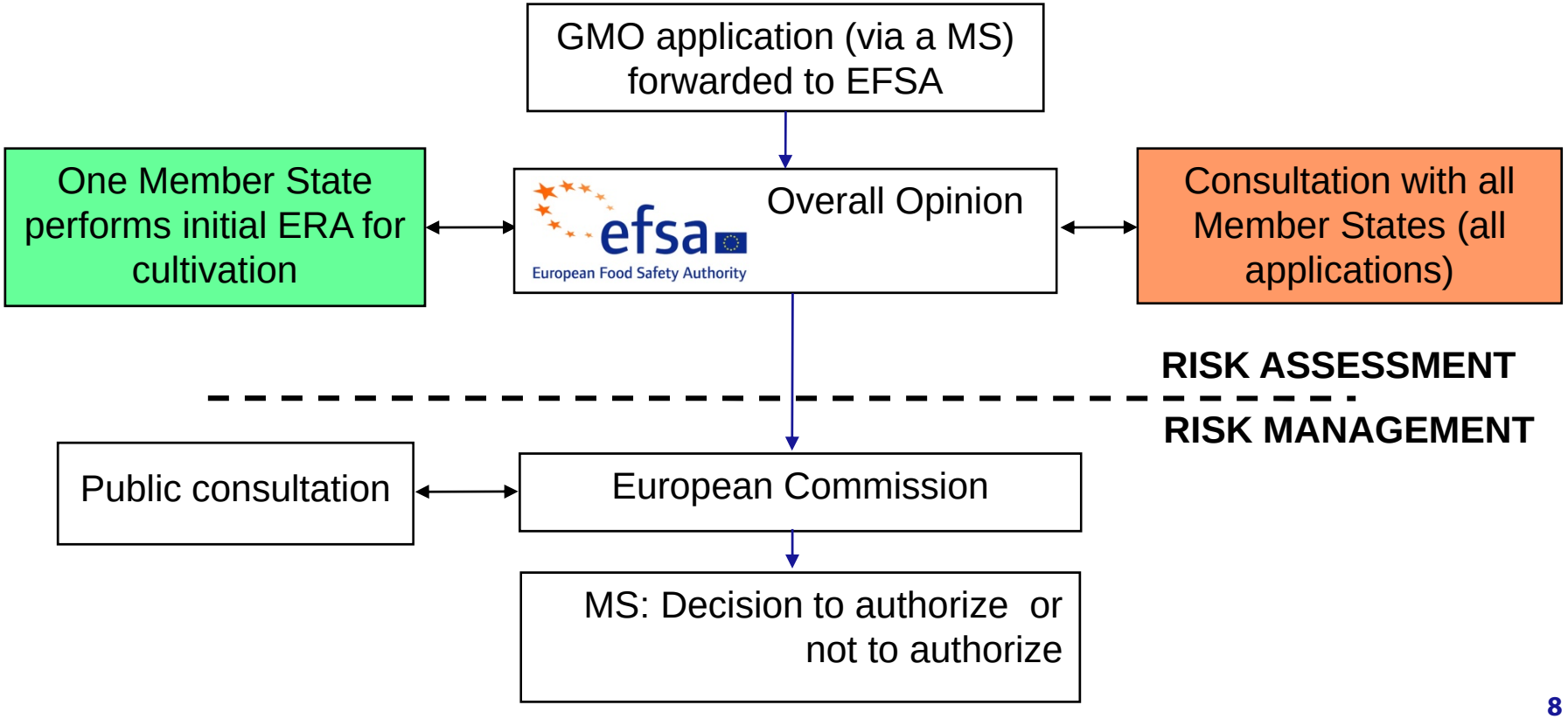
Roles under Directive 2001/18/EC

Member States perform risk assessment. EFSA is consulted in case of divergence of opinion



Roles under Regulation (EC) No 1829/2003

Member States have access to all GMO applications and provide input through “EFSAnet”. One member State performs the environmental risk assessment



ERA under Regulation (EC) No 1829/2003

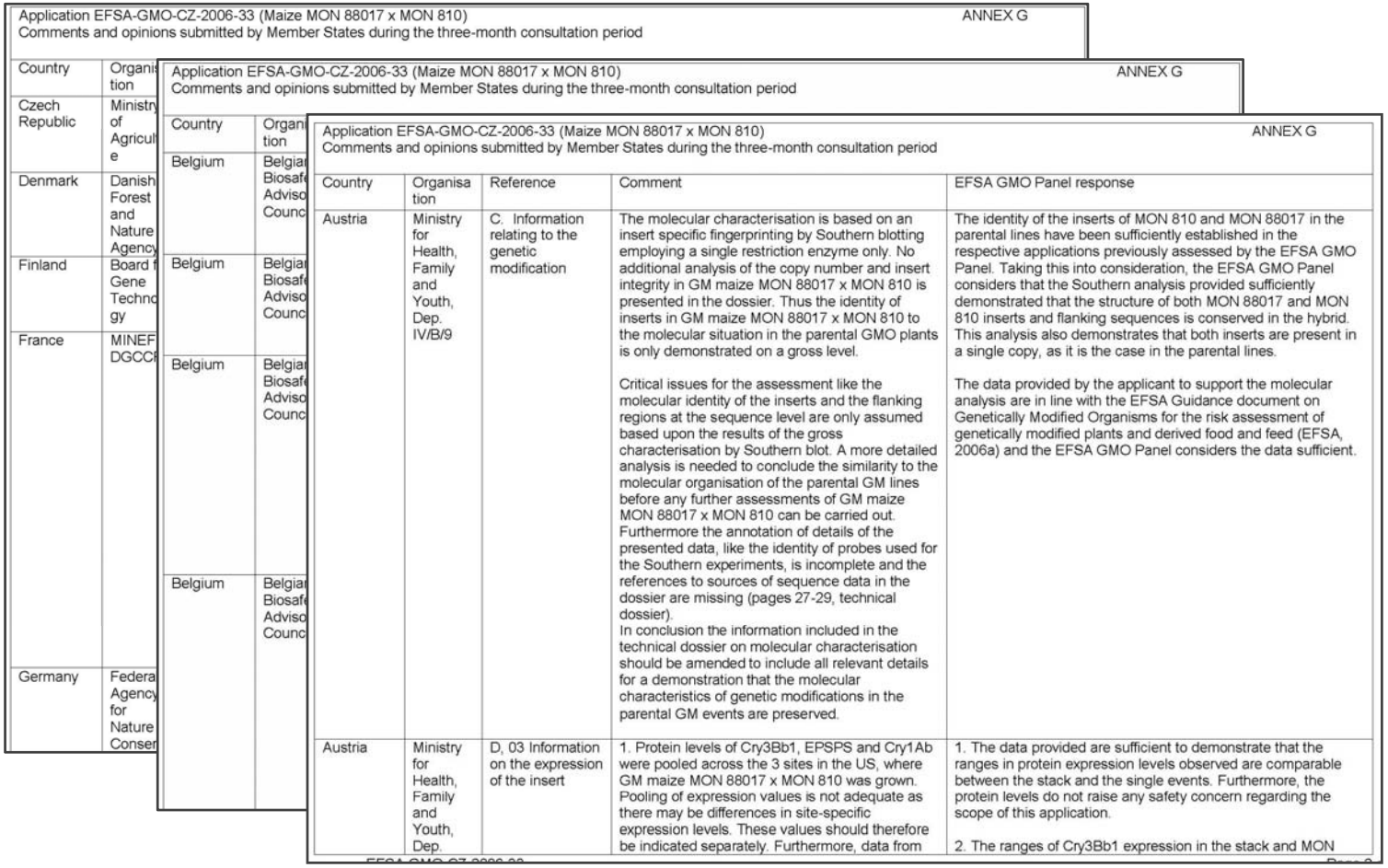
One MS performs initial ERA (cultivation dossier only)

If cultivation of GMO is applied for through Regulation 1829/2003 then Member States are asked to volunteer to carry out ERA

UK-2005-17	1507 x NK603 maize	Spain
NL-2005-22	NK603 maize	**Spain**
NL-2005-23	59122 maize	**The Netherlands**
NL-2005-24	40-3-2 soybean	**Germany**
NL-2005-26	MON810 x NK603 maize	Spain
NL-2005-28	1507 x 59122 maize	**The Netherlands**
UK-2006-30	59122 x1507 x NK603 maize	Belgium
NL-2007-46	T25 maize	UK
CZ-2008-54	MON88017 maize	Belgium
UK-2008-60	GA21 maize	Czech Republic
DE-2008-63	H7-1 sugarbeet	Germany
NL-2009-69	AV43-6-GT potato	Sweden
BE-2009-71	MON89034xMON8017 maize	Belgium
NL-2009-72	MON89034xNK603 maize	The Netherlands
RX-MON810 (20.a)	MON810 maize	**Spain**
RX-T25	T25 maize	UK

Member State input

Consultation with all Member States (all applications)



Application EFSA-GMO-CZ-2006-33 (Maize MON 88017 x MON 810) ANNEX G
Comments and opinions submitted by Member States during the three-month consultation period

Country	Organisation	Reference	Comment	EFSA GMO Panel response
Austria	Ministry for Health, Family and Youth, Dep. IV/B/9	C. Information relating to the genetic modification	The molecular characterisation is based on an insert specific fingerprinting by Southern blotting employing a single restriction enzyme only. No additional analysis of the copy number and insert integrity in GM maize MON 88017 x MON 810 is presented in the dossier. Thus the identity of inserts in GM maize MON 88017 x MON 810 to the molecular situation in the parental GMO plants is only demonstrated on a gross level. Critical issues for the assessment like the molecular identity of the inserts and the flanking regions at the sequence level are only assumed based upon the results of the gross characterisation by Southern blot. A more detailed analysis is needed to conclude the similarity to the molecular organisation of the parental GM lines before any further assessments of GM maize MON 88017 x MON 810 can be carried out. Furthermore the annotation of details of the presented data, like the identity of probes used for the Southern experiments, is incomplete and the references to sources of sequence data in the dossier are missing (pages 27-29, technical dossier). In conclusion the information included in the technical dossier on molecular characterisation should be amended to include all relevant details for a demonstration that the molecular characteristics of genetic modifications in the parental GM events are preserved.	The identity of the inserts of MON 810 and MON 88017 in the parental lines have been sufficiently established in the respective applications previously assessed by the EFSA GMO Panel. Taking this into consideration, the EFSA GMO Panel considers that the Southern analysis provided sufficiently demonstrated that the structure of both MON 88017 and MON 810 inserts and flanking sequences is conserved in the hybrid. This analysis also demonstrates that both inserts are present in a single copy, as it is the case in the parental lines. The data provided by the applicant to support the molecular analysis are in line with the EFSA Guidance document on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed (EFSA, 2006a) and the EFSA GMO Panel considers the data sufficient.
Austria	Ministry for Health, Family and Youth, Dep.	D, 03 Information on the expression of the insert	1. Protein levels of Cry3Bb1, EPSPS and Cry1Ab were pooled across the 3 sites in the US, where GM maize MON 88017 x MON 810 was grown. Pooling of expression values is not adequate as there may be differences in site-specific expression levels. These values should therefore be indicated separately. Furthermore, data from	1. The data provided are sufficient to demonstrate that the ranges in protein expression levels observed are comparable between the stack and the single events. Furthermore, the protein levels do not raise any safety concern regarding the scope of this application. 2. The ranges of Cry3Bb1 expression in the stack and MON

EFSA considers each and publishes all as part of each Opinion

Structure of the overall opinion

- EFSA shall publish an overall opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003

- List of annexes

Annex A:	Scientific opinion of the GMO Panel (EFSA)
Annex B:	Cartagena Protocol
Annex C:	Labelling
Annex D1:	Validation report (CRL)
Annex D2:	Validated detection method (CRL)
Annex E:	Certified reference materials
Annex F:	Monitoring plan
Annex G:	Member States comments

Published Guidance Documents for Risk Assessment

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1. GM plants and derived food and feed (2006)
2. GM microorganisms and their derived products intended for food and feed use (2006)
3. Renewal of authorisations of existing GMO products (2006)
4. Post Market Environmental Monitoring – PMEM (2006)
5. GM plants containing stacked transformation events (2007)
6. Use of animal feeding trials for safety assessment of whole GM food/feed (2008)
7. Guidance for non-food/non-feed use of GM plants (2009)
8. Statistical considerations for the safety evaluation of GMOs (2009)

Submissions and opinions under Regulation (EC) No 1829/2003

	1829/2003 Application Submitted	1829/2003 Opinion Adopted
2003	-	-
2004	8	-
2005	20	6
2006	8	3
2007	38	5
2008	13	5
2009	12	15

Ongoing work on Guidance for Risk Assessment

Further elaboration upon already published guidance

1. Update on molecular characterisation and food and feed sections of guidance for GM plants and derived food and feed (EFSA update 2008, in support of new EC regulation)
2. Update on ERA section of guidance for GM plants and derived food and feed (2010)
3. Self task on allergenicity assessment of GM plants (2010)

De novo guidance development

1. Guidance on GM animals (2011)
   a) For Import and processing - food and feed safety RA
   b) For Environmental release in Europe – ERA

Key messages

- EFSA performs public consultation on all guidance ensuring that views and experience are taken into account
- We aim to develop a shared understanding of the updated guidance that will support risk assessment
- GMO risk assessment work is done in close cooperation with Member States
- EFSA listens and learns, but cannot get drawn into wider debates

Thank you for your attention