Annex 6

Feedback from the Member States' questionnaire

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Topics

1. Highlights from the MS answers
2. Main conclusions
3. Scientific topics for discussion

Abbreviations:

- MS: Member State
- RA: risk assessment
- RM: risk management
- 1829: Regulation (EC) No 1829/2003
- 2001: Directive 2001/18/EC

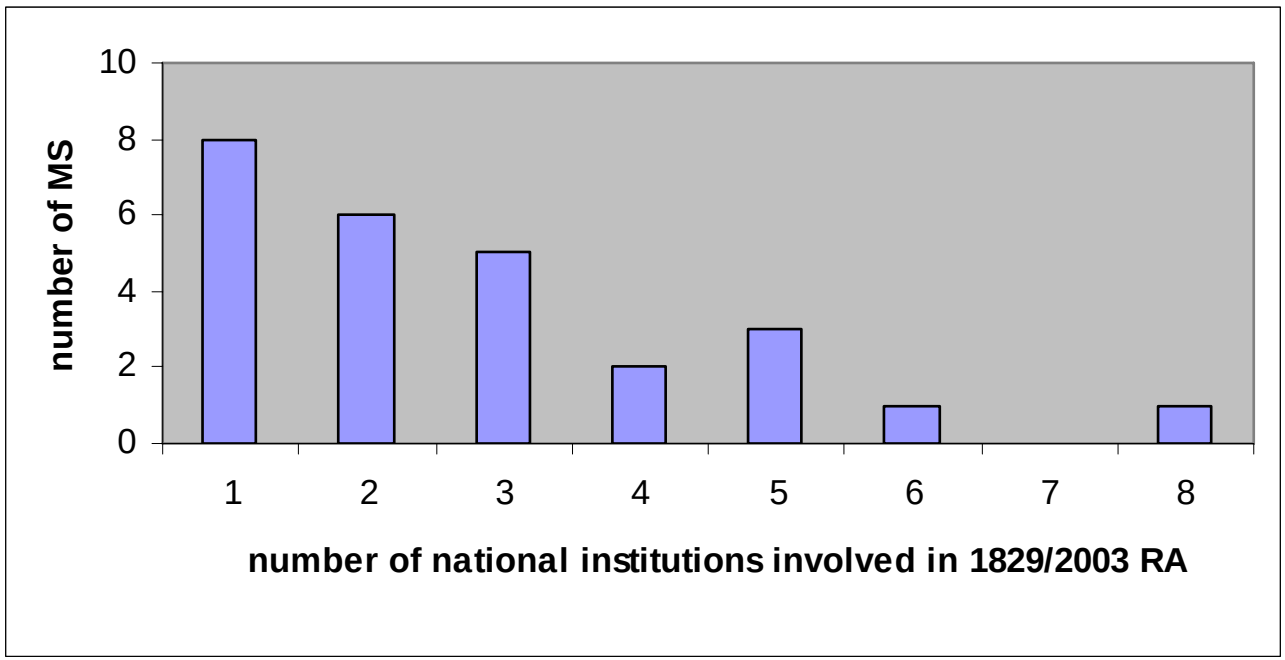
General

- Sent to 27 MS + Norway + Switzerland
- Return 24 MS + Norway + Switzerland
- No return: 3 MS
- Some incomplete returns
- Questions were interpreted differently
- Answers varied widely: max 26 different answers

- Thanks to EFSA AF members to coordinate

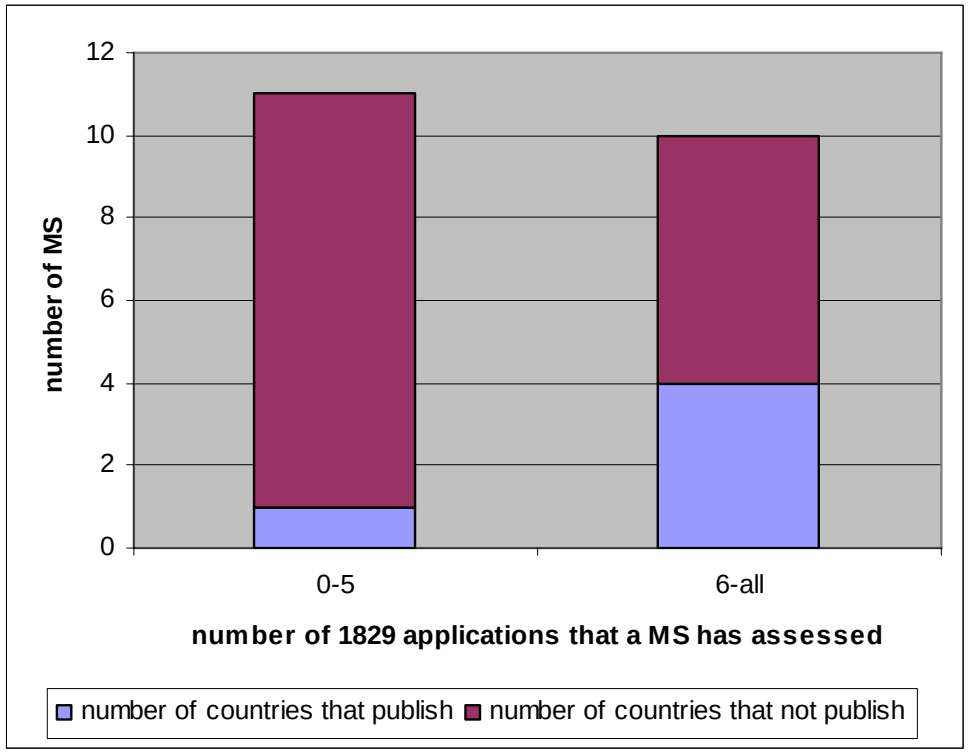
Number of institutes per MS for 1829/2003 GMO risk assessment

- Answers given comprise many different types of institutes e.g. Ministries for different competences, Advisory committees/bodies/boards for different competences, Food Safety Agencies, Risk assessment institutes, Research institutes, Environmental institutes
- All responding 26 MS provided an answer



Number of 1829/2003 GMO national risk assessment reports published

- Numbers in the answers can comprise or consist of (1) comprehensive risk assessment reports with an overall conclusion on the GMO, (2) partial assessment by one of the institutes involved in the risk assessment, (3) comments on 1829 dossiers, (4) assessments in progress.
- 21 MS provided an answer:



1829/2003 highlights

- Nearly all 1829 risk assessment institutes are member of the EFSA GMO EFSAnet
  - Direct online exchange of information
  - Direct access to all details and correspondence on each GMO dossier
  - Weekly updates on the activities of EFSA

- Most MS work with a (scientific) panel and adopt via consensus during meetings (and written procedure)

2001/18 highlights

- Number of national institutions for RA: 1 to 10
- Majority of institutes are members of EFSAnet
- Experience as lead MS with 2001/18 applications, only few MS e.g. BE, DE, SE, UK, ES, FR, NL

Number of applications	0	1-20	119,121,170,394
Part B	7MS	12MS	4MS
Part C	12MS	11MS	

National experts

- Number of experts performing RA per national institution: 3-19
- 4 or 6 out of 24 MS publish the CV of their experts under Dir. 2001/18 or Reg. 1829 respectively
- Duration of appointment ranges from 2 years to unlimited and varies widely according to MS and according to which of the national institutes
- National risk assessment experts are government officials and academics in a large majority of the Member states. Under Reg. 1829/2003, 4 MS have indicated to work also with independent consultants (1MS specified stakeholders). Under Dir. 2001/18, 7 MS work with independent consultants (3 MS specified stakeholders and associations).
- Most countries ask for a declaration of interest (17/24) and ask it per topic (8/17), but a minority publishes them (4/15)

Between national institutes

- Institutes for GMO risk assessment under Regulation 1829/2003 and under Directive 2001/18, can be
  - all different
  - partially the same
  - all the same

- When institutes differ, coordination is organized
  - By one appointed institute responsible for the coordination of GMO risk assessment under both legislations
  - Directly between the institutes via exchange of people, info and joint meetings
  - Organized by Ministries
  - No established coordination

- The interface between risk assessment and risk management is
  - The ministry hosting both RA and RM
  - Secured by one independent institute or advisory body
  - Advice given for the discretion of the RM

National risk assessment methodologies

- Refer to international guidelines
  - Half of MS refer to OECD
  - < half of MS refer to FAO/WHO
  - > half refer to Codex
  - All MS refer to EFSA guidance
  - No areas of divergence between national risk assessment and international guidelines have been indicated
- most MS have no national risk assessment guidance documents (1 MS uses input from research, 2 have guidance under development)
- Few MS have complete or partial guidance documents
- Some MS have indicated to refer directly to EFSA guidance
- Are methodologies different between 1829/2003 and 2001/18?
  - 17 MS responded, of which 14 said no and 3 indicated potential differences.

Main Conclusions

- Experience in GMO risk assessment and conclusive risk assessment reports very diverse
- National organisation very diverse
  - For different legislation 1829/2003 and 2001/18
  - For coordination between 1829/2003 and 2001/18
  - For division and separation between RM and RA
- Independence of risk assessor differently applied (e.g. some MS involve experts from stakeholders such private sector and NGO's)
- Most MS are aligned with international risk assessment methodologies and all refer (directly) to EFSA guidance documents

Issues raised by Member states

- All MS refer to EFSA Guidance document for national risk assessments
- in addition, the following aspects were raised by the Member states and are subject to the scientific discussion sessions of this meeting
- Thanks to all MS for their input!

Topics on risk assessment approaches

agenda item 4

- *Latvia: a **common** approach where possible*
- *Spain: more **harmonisation** on risk assessment methodologies between Directive 2001/18 and Regulation 1829/2003 procedures*
- *Denmark: in areas where no unexpected outcome or risks have been seen there could be more **simplified applications***
- *Portugal, Malta: envisage development of **more detailed** and defined approach for risk assessment for all EU applications*
- *Spain: whether or not a **different** GMO risk assessment approach could be followed **for food, feed or environmental issues**. The actual risk assessment decision procedure is not based only in purely scientific criteria protecting human, animal and environmental safety, but also in **other "legitimate factors"** that should also be taken into account. It seems to be clear that "legitimate factors" for the food (consumer opinion), environmental (environmental considerations and other parties opinion) or feed (raw material prices) are extremely different and, in some cases, non-compatible.*

Topics on biological relevance vs statistical significance agenda item 5

- *Austria: **Standardisation** of the experimental setup (especially for field trials) and the **statistical analyses** of the data obtained from all studies (e.g. feeding studies, field trials) is absolutely necessary*

- *Austria: Evaluation of data: how to define "**biological relevance**" and "**biological variation**"*

Topics on environmental risk assessment

agenda item 6 - *1. Detailed Protocols for ERA*

- *Austria: **Standardisation** of the experimental setup (especially for field trials) and the statistical analyses of the data obtained from all studies (e.g. feeding studies, **field trials**) is absolutely necessary. Existing guidelines (e.g. CODEX, OECD) should be followed where they exist.*

- *Austria: Parameters methods and **endpoints** have to be defined. The general guidance given by the EFSA Guidance document should be seen as a starting point only*

- *Asutria: Clear guidance on **the environments** which should be covered by the field trials is needed, i.e. tests in the receiving environment are necessary*

- *Hungary: national activities in the field of drafting which environmental impact studies should be carried out regarding first generation GM plants **in the Pannon Biogeographical Region**.*

Topics on environmental risk assessment

agenda item 6 – continued

- *Hungary: there is a need for a detailed protocol in the EU on the methodology for environmental impact assessment and studies **for each of the 9 different Biogeographical Region of the European Union**. The protocol should refer to the environmental analytical studies, microbiological studies, botanical studies, animal studies, dietetic studies of vertebrate species and technological studies*

- *Netherlands: Harmonisation of the **impact assessment of GM plants on non-target organisms (NTOs)** between various countries and developing guidance for applicants to allow the selection of (indicator) organisms and proper methods*

- *Portugal + UK: risks posed by **Bt crops on non-target organisms***

Topics on environmental risk assessment

agenda item 6 *2. Risk –Benefit Assessment and HT crops*

- *Norway, France: Assessment of **plant protection products** in relation to ERA.*
- *Norway ERA also assessed in a societal **cost-benefit** context*
- *Belgium: Baseline situation in ERA, including **agricultural practices** and including herbicide application*
- *Czech: Risk/benefit approach*
- *Denmark: More focus may be given to the risk-benefits*
- *France: A new approach of GMO, based on the identification of benefices could be developed in the framework of a benefices/risks balanc*

Topics on environmental risk assessment

agenda item 6 *3. Monitoring Methods*

- *Finland: Methodologies for environmental **monitoring***
- *Finland, France: Borderline between **general surveillance and case-specific monitoring***
- *Greece: Recommendations about post market monitoring*

Topics on environmental risk assessment

agenda item 7 *4. New GMOs guidance*

- *Portugal: Issue of guidance on **new technologies** (GM trees, GM fish, etc..)*

- *Ireland, Netherlands, UK: interested in EFSA's work on the assessment of GM crops modified to produce **non-food/feed products** such as pharmaceuticals*

- *Spain: a more detailed and stepwise procedure for the environmental risk assessment for genetically modified **plant hybrids**, especially on issues like a molecular characterisation and toxicological studies. It is CNB opinion that the current guidelines document for hybrids is not enough detailed and insufficient for carrying out the overall environmental risk assessment of these GMO products*

- *Netherlands: **Stacking** of genes*

Topics on animal models for safety testing

agenda item 7

- *Austria: **Standardisation** of the experimental setup (especially for field trials) and the statistical analyses of the data obtained from all studies (e.g. **feeding studies**, field trials) is absolutely necessary. Existing guidelines (e.g. CODEX, OECD) should be followed where they exist*

- *Austria: **Parameters** methods and **endpoints** have to be defined. The general guidance given by the EFSA Guidance document should be seen as a starting point only*

- *Belgium: What is the impact of **unsound feeding trials** on the evaluation (particularly in case we would not need the feeding trails according to our guidance document).*

Topics on animal models for safety testing

agenda item 7 - continued

- *Czech: What do we known on the **long-term effects** of GMO consumption, e.g. if several crops produce Bt endotoxin the consumption of the particular may increase (Bt corn, Bt potatoes, oils from Bt cotton, etc.). It is known that acute toxicity is extremely low. But we have no information of long-term exposure. It is possible to **rely on available model**? Should not be envisage to companies to run feeding study in a repetitive manner (same organisms , same genotype, numbers)*

- *Denmark: In cases where the need for animal test is decided, **guidelines for testing of whole food** is not in place and there are still need for further discussion on this topic.*

- *Netherlands: Harmonisation of more **uniform approaches to the design and analysis of animal feeding trials**, and in particular for appropriate statistical analysis of data; risk assessment of animal biotechnology*

Topics on Future developments

agenda item 8

- *Belgium, Finland, Sweden: **Allergenicity** testing should not only be on bioinformatics*
- *France: It could be interesting to carry out an evaluation of **national agencies contributions to EFSA** risk assessments in matter of GMO*
- *Netherlands, Portugal, Ireland: **GM animals***
- *Greece, Sweden, UK, Italy: development and validation of new **profiling methods**, such as DNA microarray technology, proteomics, and metabolomics*
- *Slovakia: **simplified procedures** for using GMO's with long time and safe use*

GRAZIE for working with us