



### **EFSA Forum Meeting with Scientific Experts from Member States on the Risk Assessment of Genetically Modified Organisms (GMOs)**

**Brussels, 15th May 2006**

**The list of participants and all presentations are attached to this report as annexes 1 to 8 respectively**

#### **Introduction to the meeting**

1. Dr. Herman Koëter, Acting Executive Director of EFSA and Chairman of the Meeting opened this first GMO forum meeting between EFSA and the invited national experts of all EU Member States, by explaining that EFSA's main objectives for this forum were: (i) to strengthen scientific co-operation with Member States on GMO risk assessment, (ii) to clarify EFSA's role in the risk assessment process and (iii) to provide an opportunity for Member States' experts to exchange views and discuss concerns with EFSA's GMO Panel regarding GMO risk assessment.

2. In order to address MS concerns raised at previous occasions, EFSA would like to explain (i) the level of details given in EFSA's risk assessment opinions with respect to the Member States' comments (ii) to ways EFSA assesses long term effects in toxicology and environment. He announced that the various presentations would cover these topics, including viewpoints from two Member States (Austria and Spain) and the European Commission, and followed by an open discussion with an independent moderator to facilitate ensuing discussions between participants.

#### **EFSA's role in the GMO legislative framework and interaction with the Member States**

3. Dr. Suzy Renckens, Scientific Coordinator of the GMO Panel, presented EFSA's role within the EU regulatory framework for GMOs, detailing the composition and working procedures of the GMO Panel. She clarified how EFSA integrates each input of a Member State in the risk assessment process, and promoted the principal tool for information exchange between EFSA and MSs via "EFSAnet" – a secure online network which permits Member States to comment GMO applications. A new strategy to increase the transparency of the risk

assessment was proposed that would entail the inclusion of an annex with each of the MS comments and a separate individual response in addition to the incorporation of responses directly in the scientific opinion. She stressed the importance of good involvement from the Member States for the risk assessment of cultivation dossiers for which EFSA has to delegate the environmental risk assessment.

## **Risk Assessment of GM plants**

4. Dr. Harry Kuiper, Chair of the GMO Expert Panel presented the scientific aspects of the risk assessment process and clarified how scientific information is examined during the risk assessment. The key elements discussed were toxicological studies, allergenicity studies and environmental risk assessment. He emphasised that post-marketing environmental monitoring and general surveillance are key elements supplementing an environmental risk assessment.

5. Dr. Harry Kuiper stressed that the analysis of potential long term effects for humans, animals and the environment and the analysis of scientific uncertainties are the core parts of the EFSA risk assessment process. Detailed molecular analysis of the genetic modification process and of the GM plants and derived foods/feed together with an analysis of the composition of the modified organism are key elements in the assessment. Furthermore a specific set of toxicological studies is required regarding newly expressed proteins and other compounds as well as specific data on the whole GM food/feed if deemed necessary. Animal feeding studies may mimic long-term exposure or accumulation. However it must be realised that studies with whole foods/feed are difficult to carry out because of nutritional imbalance, may be misleading due to masking effects, and should only be asked when there are profound compositional changes or if there are indications of an adverse effect from the other toxicological tests. A comprehensive set of data and all available evidence should be taken into account for the final risk assessment

6. The case-by-case risk assessment approach applied by EFSA has been developed originally within a cooperation between international organisations. Existing protocols for testing may be recommended for certain GM products, but not for others. For specific scientific aspects, for example toxicology studies, reference is made in the EFSA Guidance Document for the Risk Assessment of genetically Modified Plants and derived Food and feed to existing protocols, such as those of the OECD guidelines for chemical substances. Development of standard protocols to test whole foods is much more complex as each food comprises thousands of components.

## **Austrian Contribution**

7. Dr. Michel Haas of the Austrian Federal Ministry of Health and Women presented a comprehensive list, detailing the main concerns of Austrian scientific experts with regard to GMO risk assessment and explained that, unfortunately, the scientists themselves were not able to participate in the meeting. Their comments

included procedural, scientific, environmental and health related issues. He agreed with EFSA representatives in hoping that more dialogue could lead to better mutual understanding and improved co-operation. He welcomed the initiative of organising such a meeting.

## **Spanish Contribution**

8. Dr. José Juan Sanchez Saez of the Spanish Food Safety Agency (AESAs) and Dr. Fernando González Candelas, Member of the Spanish national Biosafety Panel and University of Valencia, offered practical illustrations of handling GM crops at a national level, focusing on environmental risk assessment. Many details were presented that illustrated the experience of growing GM plants in Spain and the way Spain deals with the control of potential long term effects. GM maize in Spain includes 25 varieties and covers 12% of the total maize area in Spain. Issues of the monitoring strategy include, among others, the division of responsibilities and co-operation between all the regional authorities and regional bodies and the choice of topics such as possible effects on non target insects and soil micro organisms. Currently also additional government funded research is carried out on ecological risks, gene transfer in soils and ecological effects of GM maize and cotton on weeds and insects.

## **European Commission**

9. Dr. Paola Testori Coggi, Director at DG SANCO, confirmed EFSA's pivotal scientific role and independence as risk assessor, but emphasised that, given the lack of consensus and common understanding amongst Member States' decision makers on GMOs (the risk managers), the different actors need to collaborate more closely. On the scientific level, the Commission emphasised its trust in the quality of EFSA's risk assessments. The Commission invited EFSA to address Member States' concerns in a more transparent way in its risk assessments. Scientific dialogue should facilitate greater consensus in the decision making process regarding GMOs. Dr. Paola Testori Coggi also stressed the European Commission's need to make sure that questions given to EFSA are formulated precisely so that EFSA can address all necessary issues. The independence of EFSA must remain intact and untouched.

10. Dr. Ladislav Miko, Director at DG ENV, outlined the current state of play for voting on GMO applications in the EU. No GMOs have been approved for cultivation under the new regulatory framework, due to scientific concerns related to long-term effects, while 10 have been approved for import and processing of seeds. Dr. Miko continued explaining the current approach with respect to the safety of the GMO applications: whilst prediction of any adverse effects is difficult, adverse effects should be preferably be detected or predicted during the risk assessment phase. However, since it is to be acknowledged that unpredicted effects may occur, a post-market monitoring plan is mandatory for each GM product and will help to find such unpredicted effects. Carrying out 25 years of research - to gain more information before going to the market - cannot be required for each GM product.

11. Dr. Mark Cantley of DG RTD brought to the table 15 years of biosafety research on GMOs in 83 projects financed by the European Commission. There has been good contact between EFSA and DG RTD to share the scientific knowledge of this research and some of EFSA's scientific experts were involved in the projects. Important conclusions are that no adverse environmental effects have so far been detected, but that broader issues such as land usages in the EU are raised (see the review of results online <http://ec.europa.eu/research/quality-of-life/gmo/contents.html>). Reaching the popular media with these results is a challenge and more ideas for disseminating this important scientific knowledge are welcomed. Important safety studies are for example the ENTRANSFOOD, NOFORISK and SAFE FOODS projects, while the GMOCOMPASS provides easy-to-read information on individual GM products and their status in the EU authorization procedure (see <http://www.gmo-compass.org/eng/home/>). Mark Cantley found it worrying that over the last years, the number of field trials in Europe dropped from about 200 to 30-60, meaning that there is much less opportunity to learn about GMO biosafety and GMO benefits in Europe.

## **General Discussion**

12. In order to guarantee a fully unbiased discussion EFSA had arranged for an independent moderator, Dr. Joerg Mayer Ries from Germany, to moderate and lead the general discussion. The discussion saw the intervention of several MSs and centered on long-term effects, a proposal for standard protocols for each GM product, the involvement of the Member States and the level of independence of the GMO Panel.

13. Member States' experts expressed themselves largely as being supportive of EFSA's Scientific work, but there was also criticism mainly on the level of details and justification of conclusions provided in the opinions of the GMO Panel. As requested, Dr. Herman Koëter and Dr. Harry Kuiper explained in detail the approach taken so far and proposed a number of changes for the future.

A more detailed overview of the discussion is provided in Annex 7.

## **Conclusions**

14. Dr. Koëter thanked all Member States for delegating their experts to this GMO Forum and the European Commission for its participation. Dr. Koëter expressed that EFSA had learnt a lot during this Forum and that closer collaboration with Member States' experts will be sought. It appeared that the best follow up of this meeting, in terms of efficiency and productivity, would be through smaller and focused technical meetings with invited experts on specific issues.

15. The scientific input and contributions of a MS in such meetings will be very much appreciated and will be considered by the Panel. At the end of the day,

however, it is the EFSA GMO Panel that will have to issue its own science based risk assessment opinion.

16. As regards setting out standard protocols, Dr. Koëter expressed the strong view that EFSA cannot prescribe study protocols but will continue to issue guidance on the kind of data it considers appropriate. Defining protocols could not only create loopholes for applicants, EFSA also considers that each application should be considered as unique, and needs a case-by-case approach.

17. Finally, EFSA asked MSs to volunteer for performing the environmental risk assessment of 1829/2003 dossiers and to reflect on the publication of the Member States' comments and individual responses in annex to the future opinions.

18. The Chair closed the meeting by stating that EFSA is committed to strengthen the co-operation with the Member States.

Annex 1: List of participants

Annex 2: Presentation by Dr. Suzy Renckens

Annex 3: Presentation by Dr. Harry Kuiper

Annex 4: Presentation by Dr. Michel Haas

Annex 5: Presentation by Dr. Jose Juan Sanchez Saez

Annex 6: Presentation by Dr. Fernando Gonzales Candelas

Annex 7: Presentation by Dr. Marc Cantley

Annex 8: Detailed report of the general discussion