European Food Safety Authority

Brussels, 15 May 2006

EFSA Forum with National Experts on the risk assessment of GMOs

Summary report

Aims and objectives of the meeting

Dr. Herman Koëter (Acting Executive Director of EFSA) opened the meeting by explaining that EFSA's main objectives for this forum were to:

- Strengthen scientific co-operation with Member States on GMO risk assessment
- Clarify EFSA's role in the risk assessment process
- Provide an opportunity for Member State experts to exchange views and discuss concerns with EFSA's GMO Panel regarding GMO risk assessment

Presentations by EFSA, Member States and European Commission (morning session)

Dr. Suzy Renckens (Co-ordinator of EFSA's Scientific Panel on GMOs) 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 the input of Member States in the risk assessment process, explaining that the principal tool is via an Extranet developed by EFSA – "EFSAnet" – a secure online network which permits Member States to comment on EFSA risk assessments in progress.

Dr. Harry Kuiper (Chair of EFSA's Scientific Panel on GMOs) presented the risk assessment process itself and how the information is examined during the risk assessment. The key elements are: toxicological studies, allergenicity studies and environmental risk assessments. He emphasised that monitoring and post-marketing surveillance are key elements of environmental risk assessment, and that analysing long term effects and scientific uncertainties are central components of the risk assessment process.

Michel Haas (Austria, Federal Ministry of Health and Women) presented a paper detailing the main concerns of Austrian scientific experts with regard to GMO risk assessment explaining that, unfortunately, they 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.

Dr. José Juan Sanchez Saez (Spain, Food Safety Agency) and *Dr. Fernando Gonzáles Candelas* (Spain, University of Valencia) offered practical illustrations of handling GMO risk assessments on a national level, focusing on environmental risk assessment, and details on the Spanish experience of growing GM plants.

Paola Testori Coggi (European Commission, DG SANCO) confirmed EFSA's pivotal scientific role and independence and emphasised that, given the lack of consensus amongst EU decision makers on GMOs, the different actors involved in GMO risk assessment and risk management need to collaborate more closely in order to facilitate common understanding. 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.

Ladislav Miko (European Commission, DG ENV) outlined the current state of play on GMO applications in the EU and the fact that no GMOs have been approved for cultivation under the new regulatory framework, due to scientific concerns related to long-term effects and biodiversity.

Mark Cantley (European Commission, DG RTD) underlined that a considerable amount of scientific research in the field of biosafety is supported by the Commission and that so far it has not identified any adverse effects of the use of GMOs. The outcome of these research projects is unfortunately not currently in the public spotlight.

General discussion (afternoon session)
A range of issues were raised and debated including the following:

- Transparency of EFSA procedures
- Feedback from EFSA on comments from Member States
- The need for the GMO Panel to remain independent while dialoguing with Member States
- The requirement for EFSA to respect legal deadlines for delivering Scientific Opinions
- The need for more dialogue on certain scientific issues, including assessing long term effects and environmental impacts
- The nature and completeness of data submitted by applicants and the frequent requests made by EFSA to applicants for further data
- Terminology used in risk assessments
- Study protocols

Conclusions and follow up

Delegates agreed that this event should be the start of a process of reinforced collaboration between EFSA and Member States on GMO risk assessment. In his closing address, Herman Koëter summed up the meeting and outlined the actions EFSA would undertake in future to foster such collaboration. EFSA proposes to:

- Hold regular scientific meetings between GMO experts focussing on specific risk assessment issues, for instance long term effects, environmental impact assessment and allergenicity
- Optimise the use of EFSAnet, the Extranet tool developed by EFSA which allows a better exchange of information between EFSA and the Member States
- Make Member States' positions and comments explicit and more visible in EFSA Opinions
- Describe in more detail the scientific rationale underlying its risk assessments and communicate further about its working procedures in order to increase transparency