



EFSA and GMO Risk Assessment for Human and Animal Health and the Environment



15 September 2009
BRUSSELS





The European Food Safety Authority is tasked with providing a robust scientific basis for decision makers to help protect consumers from risks in the food chain in Europe. Our most critical commitment is to provide independent, evidence-based advice and clear communications, grounded in the most up-to-date scientific information and guided by the principles of scientific excellence, transparency, openness and responsiveness.

In the field of GMOs, EFSA serves the European Union mainly by providing independent scientific risk assessments on new GMO applications and renewals of existing authorisations for the use of GMOs in the internal market. The Authority has developed a range of Guidance Documents to describe its approach to risk assessments, define data requirements for applicants and generally provide guidance on the application process. These documents, which are subject to public consultation, are regularly updated to reflect the current state of scientific knowledge.

In delivering its scientific advice, EFSA pursues an active policy of consultation with stakeholders and interested parties. Through the regulatory framework, the competent authorities in Member States are engaged in the evaluation process. Consultation is particularly important



FOREWORD

in fields such as GMOs where there are differing views and where the scope of EFSA's mandates extends beyond the traditional remit of food safety to include, for example, environmental risk assessment. It is crucially important that EFSA clearly describes its role in the assessment of new technologies, strengthens its understanding of consumer perception of risk and builds its dialogue with stakeholders.

This EFSA conference therefore has a dual purpose: (i) to describe and discuss the roles and responsibilities of EFSA, Member States and the European Commission in the GMO risk assessment process; and (ii) to hear the views and experiences of key stakeholders in the GMO field. The event will, I trust, prove to be informative for all participants and provide a valuable platform for an enhanced understanding and tangible progress in this area.

I look forward to welcoming you in person to the conference.

Catherine Geslain-Lanéelle, EFSA Executive Director

14 Afternoon Session

| 13.00 | Registration and welcome lunch |
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| 14.00 | Welcome by Catherine Geslain-Lanéelle, Executive Director, EFSA |
| 14.10 | Opening address by Robert Madelin, Director General, DG Health and Consumers, European Commission |
| Session 1 | GMOs: assessing the risks for human and animal health and the environment Chair: Riitta Maijala, Director of Risk Assessment, EFSA |
| 14.30 | 01. EU risk assessment of GMOs – roles of EFSA, Member States and European Commission Speaker: Per Bergman, Head of the GMO Unit, EFSA |
| 14.45 | 02. Development of EFSA's Food and Feed Guidance Document on GM plants Speaker: Howard Davies , EFSA GMO panel |
| 15.15 | 03. Statistical evaluation of field trials for food and feed safety Speaker: Claudia Paoletti , Senior Scientific Officer Risk Assessment GM Plants, EFSA |
| 15.45 | Coffee break |
| 16.15 | 04. Perspective of a Member State: Austria's scientific view on how to perform environmental risk assessment of GM plants Speaker: Andreas Heissenberger, Federal Environmental Agency of Austria |
| 16.45 | 05. Assessment of effects on non-target organisms in EFSA's guidance Speaker: Salvatore Arpaia , EFSA GMO panel |
| 17.15 | 06. Assessment of long term environmental impacts in EFSA's guidance: herbicide tolerance as a case study Speaker: Jeremy Sweet, EFSA GMO panel |
| 17.45 | 07. Post Market Environmental Monitoring: how it works for risk managers Speaker: Chantal Bruetschy , Head of Biotech Unit, DG Environment, European Commission |
| 18.15 | Summary of the chair and discussion |
| 18.45 | Cocktail |

14 15 Morning Session

| | PROGRAMME |
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| 08.30 | Welcome coffee |
| Session 2 | The impact of GM crop cultivation on the environment Chair: Hubert Deluyker, Director of Scientific Cooperation and Assistance, EFSA |
| 09.00 | 01. OECD Working Group on Biosafety: environmental considerations for risk/safety assessment <i>Speaker: Peter Kearns, OECD</i> |
| 09.30 | 02. EC/JRC research on global aspects of GM adoption and agricultural benefits of GM in Euro Speaker: Emilio Rodriguez Cerezo, JRC, European Commission |
| 10.00 | 03. Potential outstanding concerns for the environment Speaker: Helen Holder , the European coordinator: GMOs, food and farming campaign, Friends of the Earth |
| 10.30 | 04. Experiences and views from EU farmers Speaker: Arnaud Petit , Director of Commodities and Trade, Copa-Cogeca |
| 11.00 | Coffee break |
| 11.30 | 05. Experiences and views from the biotech industry Speaker: Willy De Greef, Secretary General, Europabio |
| 12.00 | 06. Experience with GM crop cultivation by a Member State: Spain Speaker: Esther Esteban , General Direction of Sustainable Development of the Rural Environment, Ministry of Environment, and Rural and Marine Affairs - Spain |
| 12.30 | Summary of the chair and discussion |
| 13.00 | Closing address by Karl Falkenberg, Director General, DG Environment, European Commission |
| 13.20 | End of meeting |



Per Bergman

Salvatore Arpaia

Salvatore Arpaia holds a PhD in entomology from Wageningen University, The Netherlands. He is currently a senior scientist with the Department of Biotechnology of ENEA (Italian National Agency for New Technologies, Energy and Environment) in Rotondella (MT), Italy. His field of research is insect ecology, with a special interest in the biosafety of genetically modified (GM) plants. Dr Arpaia has published 65 full papers, including book chapters and reviews in the area of biosafety of GM crop plants and he has been invited to lecture in several international workshops on this subject. Dr Arpaia teaches entomology and zoology at the University of Basilicata, and has been a member of EFSA's GMO Panel since 2006.

Per Bergman did both his BSc in biology and his PhD in medical genetics at Uppsala University, Sweden. Thereafter he worked 16 years at the Swedish University of Agricultural Sciences (SLU) where he is an associate professor in genetics and plant breeding. At SLU he performed research on the molecular genetics of floral organ development and mitochondrial-nuclear communication, and was active in teaching gene technology and in science communication in relation to the GMO debate. During his last five years at SLU he was chairman of the department and a member of the Swedish Gene Technology Advisory Board. He has subsequently worked as a senior advisor on GMO issues at Sweden's Ministry of Agriculture in Stockholm and is currently Head of the EFSA's GMO unit.





Chantal Bruetschy

Chantal Bruetschy is Head of the "Biotechnology, Pesticides & Health" Unit at the European Commission's Directorate-General for the Environment. A French national, she has studied international law and economics in France, UK and Germany, and has followed courses on risk management and risk assessment for managers. Before joining the Commission, she worked with Air France in Paris on international air agreements, and then in a private law office in Brussels on copyright and audiovisual issues. In the Commission she has worked in different departments in charge of competition, transport, aerospace, negotiations with US and Japan on industrial issues, before being in charge of the enlargement negotiations on food safety in DG Health and Consumers. She joined DG Environment in 2004 to deal with urban and health issues. Since 2006 she has been in charge of biotechnology, pesticides, biocides and health.



Howard Davies

Howard Davies completed his first degree and PhD at the University of Bristol, UK, and then held a four year postdoctoral position in London. He joined the Scottish Crop Research Institute, Dundee, UK in 1981 and progressed through several senior research management positions to become the Institute's Director of Science Coordination. He also coordinates the Scottish Government's research programme on profitable and sustainable agriculture-plants. A biochemist by background, he has published more than 150 papers including those on the use of transgenic biology to understand the control of plant metabolism and development. Previously a member of the EU Scientific Committee on Plants, he is now in his third term as a member of FESA's GMO Panel.





Willy De Greef

Willy De Greef is a plant biologist with extensive experience in tropical crop breeding (through research management positions in the Democratic Republic of Congo, Malawi and Cameroon) and in technology transfer related to agricultural biotechnology. He has been head of regulatory affairs for two biotechnology leaders, Plant Genetic Systems in the 1980s, and Syngenta Seeds from the late 1990s until 2003. He has been involved in the policy and public debate on agricultural biotechnology (OECD, UNIDO, Biodiversity Convention, Cartagena Biosafety Protocol) and in the development of the regulatory framework since 1986. He has contributed to the development of rational regulatory frameworks for biotechnology for developing countries and in capacity building for biotechnology researchers in the developing world in biosafety assessment and regulatory compliance. Recently, he has been head of regulatory affairs and new projects for D1 Oils Plant Science, a biofuel company.



Esther Esteban

Esther Esteban graduated as an agricultural engineer from the Polytechnic University of Madrid and did her PhD at the University of Cordoba (Spain) on plant breeding. She completed a two years postdoctoral position at Michigan State University (USA), also working on plant breeding. In 2004, she started working at the Ministry of Agriculture, Fisheries and Food (now the Ministry of Environment, and Rural and Marine Affairs). Here, she worked in fisheries for two years, then in the Prospective and Analysis Unit and finally, since March this year she has been Head of the GMO area in the Sustainable Development for Rural Areas Directorate-General.



Andreas Heissenberger

Andreas Heissenberger studied biology and graduated in microbial ecology in 1996. He also finished a Masters in international relations in 2009. He joined the Austrian Environment Agency in 1996 and worked for several years as head of the GMO detection laboratory. He was involved in several studies on risk assessment and monitoring of GMOs. His current tasks also include international capacity building activities in GMO risk assessment and providing scientific input to discussions on EU level including consultation with EFSA on environmental risk assessment of GMO applications and risk assessment issues related to implementation of the Cartagena Protocol on Biosafety.





BIOGRAPHIES

Helen Holder

Helen Holder has a degree biochemistry from Bristol University, UK and a Masters in Business from E.M. Lyon, France. Helen has worked on biotech and farming issues since 1998 and joined the European secretariat of Friends of the Earth as campaign coordinator in 2005.





Peter Kearns

Peter Kearns is head of OECD's (Organisation for Economic Co-operation and Development) biosafety programme and is responsible for the OECD's Working Group for the Harmonisation of Regulatory Oversight in Biotechnology and the Task Force for the Safety of Novel Foods and Feeds. Peter is also responsible for activities related to the safety of manufactured nanomaterials as part of OECD's Chemicals Programme. As such, he is also managing OECD's Working Party on Manufactured Nanomaterials, Peter has a BSc in genetics from the University of Nottingham and a PhD in population genetics from the University of Cambridge, where he is a member of Darwin College. After a period of postdoctoral work at the Department of Genetics, Cambridge, he went to work at the UK government's Department of the Environment, where he was responsible for activities to regulate GMOs. During his time at the OECD, he has mainly focused on promoting international harmonisation in the regulation of biotechnology, and other emerging and converging technologies.



Claudia Paoletti

Claudia Paoletti did her Master in biology at the University of Rome, Italy, and her PhD in plant genetics at the University of Connecticut, USA. She studied plant population genetics and biometry for three years at Dalhousie University, Canada. She continued her research at the Research Institute for Industrial Crops in Bologna, Italy, focusing on risk assessment and biostatistics. She has been the Italian expert delegate for the EU Working Party on Seed Legislation for defining GMO sampling plans. She was responsible for the EU GMO sampling research programme and she was the biometric officer of the EU's Community Reference Laboratory for GMOs. She has over 50 contributions either as book chapters or as scientific papers. Currently, she is a senior scientist in the GMO Unit of EFSA.



BIOGRAPHIES

Emilio Rodríguez-Cerezo

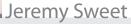
Arnaud Petit

Arnaud Petit is agronomist engineer and has a Master in economy. In 2005 Arnaud joined COPA-COGECA (Committee of Professional Agricultural Organisations - General Confederation of Agricultural Cooperatives in the European Union), the association of European farmers and agricultural cooperatives which represents 76 organisations from the 27 EU Member States. Since May 2009, Arnaud has been responsible for the Commodities and Trade Department and follows particularly biotechnologies in agriculture.

Emilio Rodríguez-Cerezo has a degree in agronomy (1983) and a PhD in plant pathology (1988). He has been active in the interface between biotechnology and policy since 1997 when he was elected member of the first EU Scientific Committee for Plants managed by the European Commission's DG for Health and Consumers. In 2001, he joined the European Commission's Joint Research Center (JRC) at the Institute for Prospective Technological Studies (IPTS) in Seville, Spain. Since then he has run research and policy support in the fields of coexistence between GM and conventional production, and in the economic impacts of GM crops.







Jeremy Sweet has spent the last 20 years conducting research on the risk assessment of GMOs. Much of this work has been studying the environmental and agronomic impacts of GMOs, and gene flow to crops and wild relatives. He was coordinator of the UK BRIGHT project which studied herbicide tolerance, and he was also coordinator of the ESF programme 'Assessing the Impact of GMOs' that brought together all the major research groups in this area in Europe. He was a coordinator of the EU SIGMEA project bringing together data on gene flow and gene impacts, and is a participant in the EU CO-EXTRA programme. He currently runs his own environmental consultancy and is a vice-chairman of the EFSA GMO panel. He is a consultant and advisor on GMOs to the European Commission, FAO, and scientific organisations and academies of several countries





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