

## **EFSA Consultative Workshop on Selection of Comparators Brussels 31/03/2011**

### **Biographies**

#### **I. SETTING THE SCENE: THE CONCEPT OF SUBSTANTIAL EQUIVALENCE**

##### **Principles of risk assessment in the EU legal framework**

*Sébastien Goux - European Commission DG SANCO*

Dr. Goux has a scientific background (Bioengineer, MSc in Soil Science and Environmental Pollution, and PhD in Agronomy). For 5 years, he worked in the Belgian Ministry of Health where he contributed to the implementation of the Novel Food legislation and to the co-ordination of official controls on GMOs and food contaminants. He joined the European Commission in 2005. Since that time, he has contributed to the implementation of the EU legislation on GMOs and in particular on GM food and feed.

##### **GM plant environmental risk assessment: pros and cons of different approaches**

*Hartmut Meyer - ENSSER*

Since 2009, Dr. Meyer has been Scientific Coordinator of the European Network of Scientists for Social and Environmental Responsibility (ENSSER). He has a diploma in biology, a PhD in the field of plant biochemistry and molecular biology and a post-doc in the field of microbial and biochemical processes in forest soil ecosystems. He has participated in the German debate on biosafety and genetic engineering since 1984 and, since 1997, has also been a freelance consultant for biopolitical issues (biosafety, access to genetic resources and benefit-sharing, intellectual property rights on genetic resources). He has participated in the negotiations of the Cartagena Protocol on Biosafety since 1998.

##### **The concept of substantial equivalence and the comparative approach**

*Peter Kearns - OECD*

Dr. Peter Kearns is a Principal Administrator at the OECD (Organisation for Economic Co-operation and Development). He works in the Environment, Health and Safety Division which addresses issues related to the safety of chemicals, pesticides and biotechnology. He is head of OECD's nanosafety programme which includes activities related to the safety testing and assessment of manufactured nanomaterials. In this position, he is responsible for OECD's Working Party on Manufactured Nanomaterials and its various steering groups. He is also head of OECD's Programmes on: i) the Harmonisation of Regulatory Oversight in Biotechnology which covers environmental safety aspects of genetically modified organisms; ii) the Safety of Novel Foods and Feeds, which is concerned primarily with the safety of foods and feeds derived from GMOs, and; iii) OECD's programme on Chemical Accident Prevention, Preparedness and Response. Dr. Kearns has 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 (then) UK Government Department of the Environment, where he was responsible for activities to

regulate transgenic organisms. During his time at the OECD, he has mainly focused on promoting international harmonisation in regulatory aspects of biotechnology and nanotechnology.

## II. EXCHANGING VIEWS ON EFSA DRAFT COMPARATOR OPINION

### **Presentation of the draft comparator opinion**

*Howard Davies - Chair EFSA Comparators WG*

Professor Davies is Director of Science at the Scottish Crop Research Institute. Responsibilities include co-ordinating delivery of the Scottish Governments Research Programme (2006-2011) on “Profitable and Sustainable Agriculture Plants”. His research has a particular focus on integrating outputs from "omics" platforms to understand functional diversity (crop quality traits) and to provide benchmark data for food safety evaluations. For the last 12 years he has been a risk assessor with European Commission and European Food Safety Authority GMO Panels.. He has also been involved in a range of UK and EU funded research projects on GMOs and food safety including SAFE FOODS, NOFORISK, GMO CARE and ENTRANSFOOD.

### **Specific FF/MC and ENV needs for selection of comparators**

*Joe Perry - EFSA Comparators WG*

Professor Joe Perry worked for Rothamsted Research for 30 years, publishing over 150 refereed papers in the area of quantitative methods applied to ecology. He invented the SADIE system for spatial patterns and was jointly responsible for the design and analysis of the Farm Scale Evaluations of GM crops. He has a DSc degree from the University of Reading; the Distinguished Statistical Ecologist Award of the International Association for Ecology; is a Fellow of the Society of Biology; and is Visiting Professor of Biometry at the University of Greenwich. Since 2006 he has sat on the GMOs Expert Panel of the European Food Safety Authority, of which he is now vice-chair.

### **Risk assessment of single events - Comments received**

*Antoine Messéan - EFSA Comparators WG*

Dr. Antoine Messéan is Research Manager at the National Institute for Agricultural Research (INRA). He has a Masters in Agronomy and a PhD in Statistics. He co-ordinates interdisciplinary projects on the impact of innovations in Plant Production and is the co-ordinator of the European Research Group ENDURE on Integrated Pest Management. His research has a particular focus on modelling impacts of cropping systems on gene flow and environmental impacts. He has been involved in a range of National and EU funded research projects on GMOs including ECOGEN, SIGMEA and Co-Extra. For the last 15 years, he has been a risk assessor for the French government and has recently joined the EFSA GMO Panel.

### **Invited comments on risk assessment of single events**

*Wolfram Reichenbecher - Fed. Agency for Nature Conservation (DE)*

Since 2004, Dr. Wolfram Reichenbecher works with the Federal Agency for Nature Conservation (BfN) in Bonn, Germany, in the GMO regulation/biosafety division. After studying biology, he did a PhD in microbiology and worked as a postdoc in molecular biology in the UK. His comments to the draft guidance on selection of comparators are a joint effort of the BfN division he works for. Other contributors are also biologists but specialise in other areas such as entomology, molecular biology, immunology and toxicology.

*Pieter Windels - EuropaBio*

Dr. Windels works in the BioScience Regulatory Affairs department of Bayer CropScience, Brussels (Belgium), and has responsibility for plant biotech regulatory affairs for the EU, Switzerland, Turkey and CIS states, including Russia and Ukraine. Dr. Windels received his PhD degree in plant genetics from the University of Ghent (Belgium) and graduated with a Master of Science in Biotechnology from the same university.

**Risk assessment of stacked events - Comments received**

*Howard Davies - Chair EFSA Comparators WG*

See above biography

**Invited comments on Risk assessment of stacked events**

*Annick Pleyesier - EuropaBio*

Annick Pleyesier is MSc in Bioengineering from the Catholic University of Leuven (Major Crop Protection, Minor Environmental Science). She has been working for Monsanto since 2001, where she is currently Director Regulatory Affairs, Europe, Middle East, Africa. She is also a member of the Regulatory Operating Committee of EuropaBio.

*Andreas Heissenberger - Environment Agency Austria (AT)*

Deputy Unit Head of the Department “Landuse and Biosafety” at the Umweltbundesamt (Federal Environment Agency, Austria). Dr. Heissenberger is an ecologist and biochemist by training and has worked in the field of detection, risk assessment and monitoring of GMOs since 1996. He was head of a GMO analysis laboratory until 2004 and was a member of the steering committee of the European Network of GMO laboratories (ENGL) until 2008. He has carried out or co-ordinated several studies regarding monitoring and risk assessment of GMOs. Since 2003 he has been responsible for several capacity building projects such as training courses and workshops on the implementation of EU legislation, enforcement, detection and risk assessment with regard to GMOs, mainly in Accession Countries to the European Union. Other responsibilities include the Cartagena Protocol on Biosafety, as well as scientific support to the competent authorities of Austria.

**Stacked events not from conventional crossing - Comments received**

*Howard Davies - Chair EFSA Comparators WG*

See biography above

**Invited comments on stacked events not from conventional crossing**

*Inge Broer - University of Rostock (DE)*

Prof. Dr. Inge Broer did her PhD in Genetics 1989 at the University of Bielefeld, Germany. She was qualified at the same University in Genetics and Cell biology. Since 2003 she holds the professorship for Agrobiotechnology and risk assessment for Bio- and Gene technology at the University of Rostock. Her research is focussed on the usage of transgenic plants for a sustainable agriculture. She is involved in the production of vaccines and biodegradable polymers in transgenic plants. In order to enable a holistic, sensitive but cost effective analysis of potential risks for environment and consumers, she participated in the establishment of an interdisciplinary network of scientists (BioOK) that collaborated closely in the development of new methods to optimize risk assessment on transgenic plants.

*Jan W Pedersen - National Food Institute (DK)*

Jan Pedersen is a Senior Advisor in the Division of Toxicology and Risk Assessment for the National Food Institute, Technical University of Denmark. He is also co-ordinator at the

National Food Institute for the risk assessment of GMO and involved in regulatory risk assessments concerning production with GMO, deliberate release of GMO and marketing of GMO. He is a consultant for the Danish Environmental Protection Agency and Danish Veterinary and Food Administration concerning the genetic engineering technique and health risk assessment of transgenic plants and microorganisms. During many years of experience in this area he has participated as a Danish expert in several international meetings and working groups (CODEX, EU, OECD, WHO/FAO) concerning regulation and health risk assessment of GMO's.

### **Risk assessment when no comparator is available - Comments received**

*Harry Kuiper - Chair EFSA GMO Panel*

Dr. Kuiper has been involved in safety assessment of residues of agrochemicals in food, of health protecting compounds and of genetically modified foods since 1980. He has been leader of various national and EU-financed projects concerning food safety, and served as member of the EU Scientific Committee on Plants from 1997 to 2003. Since 2003 he has chaired the Scientific Panel on GMOs of the European Food Safety Authority (EFSA), and is member of the EFSA Scientific Committee. He was member of the OECD Task Force on the Safety of Genetically Modified Foods and of the IUPAC-Committee on Agrochemicals and the Environment. Furthermore, he participated in the FAO/WHO Expert Consultations on the Safety of Genetically Modified Foods (1996), chaired the FAO/WHO Consultation on Foods Derived from Biotechnology (2000) and participated in the FAO/WHO Expert Consultation on Allergenicity of Genetically Modified Foods (2001).

### **Invited comments on risk assessment when no comparator is available**

*Cristoph Then - Testbiotech (DE)*

Dr. Christoph Then is executive director of Testbiotech ([www.testbiotech.org](http://www.testbiotech.org)). He also acts as a co-ordinator for the Coalition "No Patents on Seeds" ([www.no-patents-on-seeds.org](http://www.no-patents-on-seeds.org)). Christoph Then studied veterinary science and has been working for about 20 years on issues in the field of biotechnology. From 1992 until 1998 he co-ordinated the No Patent On Life! campaign in Germany. From 1999 until 2007 he was Greenpeace Germany's expert and also head of department on agriculture, genetic engineering and consumer affairs. Testbiotech is acting as an independent expert group, dealing with impact assessment of biotechnology. Testbiotech promotes independent research, examines ethical, social and economic issues and assesses risks to health and the environment.

*Boet Glandorf - National Institute of Public Health and the Env. (NL)*

Dr. D.C.M. Glandorf is senior risk assessor for GMOs at the National Institute for Public Health and the Environment / Expert Centre on Substances / GMO Office, Bilthoven, The Netherlands. Her main tasks include the co-ordination, handling and environmental safety assessment of technical 2001/18/EC dossiers (both part B and C) and EC/1829/2003 dossiers and the scientific support for all issues related to GMOs and their environmental safety for the Dutch ministry of Environment.