

Parma, 3 May 2007
EFSA/GMO/344
Minutes

MINUTES OF THE SCIENTIFIC HEARING WITH APPLICANTS HELD ON 21 MARCH 2007

PARTICIPANTS

Applicants: Patricia Ahl Goy (Syngenta), Firoz Amijee (Pioneer Hi-Bred International), Linda Castle (Pioneer Hi-Bred International), Alistair Clemence (Monsanto), Gaston Legris (Dow), Matthias Pohl (BASF Plant Science), Erich Sachs (ROC – GBE / Europabio), Alessandra Salamini (Renessen), Bruno Tinland (Monsanto) and Christine Wandelt (BASF Plant Science).

Invited speaker: Richard Phipps (University of Reading)

GMO Panel: Hans Christer Andersson, Salvatore Arpaia, Detlef Bartsch, Josep Casacuberta, Howard Davies, Marc De Loose, Lieve Herman, Sirpa Kärenlampi (Vice-Chair), Jozsef Kiss, Ilona Kryspin-Sorensen, Harry Kuiper (Chair), Ingolf Nes, Joe Perry, Nickolas Panopoulos, Annette Pötting, Joachim Schiemann, Willem Seinen, Jeremy Sweet (Vice-Chair) and Jean-Michel Wal.

GMO Unit: David Carlander, Ana Gomes, Karine Lheureux, Sylvie Mestdagh, Claudia Paoletti, Suzy Renckens, Reinhilde Schoonjans, Ellen Van Haver.

European Commission (DG SANCO):
Sabine Pelsser, Marco Valletta and Michael Walsh.

Apologies: Niels Bohse Hendriksen (GMO Panel), Dominique Rouan (Bayer Crop Science), Jean-François Sarrazin (Bayer Crop Science) and Hilde Willekens (GBE – EuropaBio).

1. OBJECTIVE OF THE MEETING

The scientific hearing with applicants was organised by EFSA and its GMO Panel in order to be informed about forthcoming developments in the area of plant biotechnology which may lead to further issues to be addressed in risk assessments (e.g. guidance documents, self tasking activities). EuropaBio was asked in advance of the meeting to coordinate the representation of, and the presentations given by, applicants.

The meeting was organised in line with EFSA's policy on engaging with organisations with a legitimate interest in the work of EFSA. Previously, technical meetings between EFSA and

stakeholders have been organised with national experts from Member States and with scientists from environmental non-governmental organisations¹.

Procedural and legislative matters and discussion of specific applications were outside the scope of the meeting.

2. PRESENTATION OF THE ILSI MONOGRAPH

Richard Phipps, a member of the Expert Working Group of the ILSI International Food Biotechnology Committee, presented the concept and principles of the ILSI monograph on “Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology”. The executive summary of this report has been published in April 2004 as a PDF downloadable file in the online journal, Comprehensive Reviews in Food Science and Food Safety (<http://members.ift.org/IFT/Pubs/CRFSFS/>).

As a follow-up to this report, particular cases of nutritionally enhanced crops and feed have been studied and a safety and nutritional assessment has been carried out using the recommendations that have been outlined in the report. Case studies included GM crops such as double embryo maize, golden rice 2, ASP-1 modified sweet potato, lysine maize, and one non-GM crop, namely β -carotene-enriched sweet potato. The report on these case studies will be soon finalised and published.

3. PRESENTATIONS BY APPLICANTS

Applicants presented the EFSA GMO Panel with information on new products that they intend to submit for market authorisation in the near future. New techniques for the production of next generation GMOs were also presented.

The presentations of the applicants will be published on the EFSA website and are summarised below:

Optimizing Gene Function in Plants

By Linda Castle, Research Coordinator, Pioneer Hi-Bred International Inc.

Summary: Gene shuffling technology used by Pioneer Hi-Bred International is a fast and powerful method which uses the principle of natural genetic diversity in genes to optimize traits for crop plants. Gene shuffling is used to generate recombinations of DNA sequences in genes to modify the properties of encoded proteins. The technology has been used to produce a bacterial glyphosate N-acetyltransferase activity capable of providing a new mode of tolerance to glyphosate in maize and soya. Pioneer is also using this technology for other traits in its product pipeline, including insect resistance and yield improvement.

Combined Trait Products - Addressing the Market Needs

By Patricia Ahl Goy, Syngenta Crop Protection AG

Summary: Many new traits obtained through genetic engineering have recently appeared on the market. GM crops with single traits are being crossed by conventional breeding to produce plants combining (stacking) various GM traits (referred to by Syngenta as “breeding stacks”). Countries have taken a different regulatory approach for products with stacked traits. In Europe, when transgenic events are stacked, each “new stack” is considered as a new GMO which needs to be

¹ http://www.efsa.europa.eu/en/stakeholders_efsa/technical_meetings.html

assessed and approved, even though individual events may have market approval. The USA and Canada consider such crosses as products from conventional breeding with a presumption of safety; registration is only needed when a specific hazard is identified, e.g. when combining various insecticidal proteins which could have synergistic effects. Other countries have an intermediate approach, whereby registration is needed, but the product benefits from the presumption of safety and a limited data package showing that the product behave as expected is requested (unless a specific hazard is identified). Some practical proposals for assessing stacked events were presented. For example, where a risk analysis has been completed for a five event stack it was proposed that this risk assessment should automatically cover any reduced combinations of the five events in question.

BASF Plant Science - Future Products

By Christne Wandelt, Manager Regulatory Affairs, BASF Plant Science Holding GmbH

Summary: All BASF activities involving plant biotechnology are incorporated in BASF Plant Science Holding. The research activities of BASF Plant Science are concentrated in the areas of more efficient agriculture, renewable raw materials and in the development of healthier products for humans and animals. These include, for example, plants with higher contents of vitamins and omega-3 fatty acids.

Monsanto and Renessen's Pipeline Products

By Bruno Tinland, Regulatory Affairs Manager, Monsanto Europe S.A.

Summary: Research activities are targeted towards benefits to primary producers such as increased productivity, and reduced production cost, e.g. through improvements in protection from biotic and abiotic stresses. Other research interests are focussed on developing more effective processing characteristics and benefits to consumers (e.g. flavour) and in developing healthier products including oils with modified fatty acid composition.

Crop Improvement Trends for the Next 10 Years²

By Dominique Rouan & Jean-François Sarrazin, Bayer BioScience N.V.

Summary: This presentation also pointed out that the seed market for GM crops has shifted from single-trait products to products with traits stacked using conventional breeding to offer multiple benefits. Bayer's approach considered that the most relevant comparator for the safety assessment of stacked events and traits could be a commercial GM variety carrying the "enabling trait" (single trait) alone, where the event and trait in question is already recognized as safe. Bayer considered this as more relevant than the development of specific non-GM comparators which may be less well adapted to the current agricultural environment.

Dow AgroSciences Pipeline Products

By Gaston Legris, Regulatory Affairs Manager, Dow AgroSciences

Summary: At Dow AgroSciences, the focus is on advancing science in plant genetics and biotechnology through seeds and traits, producing, for example, healthier oils and vaccines for animal health.

Considerations from Conventional Plant Breeding Relative to the Safety Assessment of GM Crops Developed Through Modification of Endogenous Plant Genes and Pathways.

By Eric Sachs, representing the Regulatory Operating Committee of Green Biotechnology in Europe, Europabio

² No oral presentation, a written contribution was provided after the meeting.

Summary: Over the centuries, breeding has produced large and important changes to crops. These modifications are generally regarded as safe and have enabled dramatic improvements in crop yield and human nutrition. The modification of the expression of certain genes (for instance through transcription factors and RNA interference [RNAi]) already present in the plants has been, and remains, a key element driving crop domestication generated by conventional breeding. This approach of modifying gene expression through the use of RNAi and/or expression of transcription factors is expected to play a key role in the development of new genetically modified crops.

EuropaBio - Organization and Activities

By Firoz Amijee, Vice-Chair of the Regulatory Operating Committee of Green Biotechnology in Europe, EuropaBio

Summary: The Regulatory Operating Committee, comprising expert representatives from EuropaBio member companies, aims to promote science based regulations and procedures for biotechnology research and commercial approvals. The GMO Panel's work on risk assessment is appreciated and based on existing experience, there is good justification to streamline the assessment of stacked products derived from GMOs already assessed for safety. The EFSA initiative for the scientific hearing was welcomed and it was considered important that dialogue with applicants on forthcoming developments in the area of plant biotechnology should continue.

4. GENERAL DISCUSSION

The current approach for the risk assessment of GM plants as outlined in the EFSA GM plant guidance document³ appears to be applicable to products that are expected to be submitted within the next 5 years.

Some further questions might need to be addressed for plants with modifications influencing, more extensively, metabolic pathways. Profiling technologies (transcriptomics, proteomics, metabolomics) could offer supplementary approaches to address possible unintended effects in these cases, both during the experimental and product development phase, and possibly in the final risk assessment process. Data obtained through the application of these profiling techniques need to be considered against the necessary background data, which encompass the genotypic natural variation of conventional and GM crops, and variation due to geographical differences and crop management practices. The choice of the appropriate comparator, availability of extensive databases on metabolic pathways, proposed dietary uses and consequent exposure, relevance and appropriateness of human studies are more potential elements for the risk assessment of future products that have been raised.

³ Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed, the EFSA Journal (2006) 99, 1-100 (http://www.efsa.europa.eu/en/science/gmo/gmo_guidance/660.html).