European Food Safety Authority

GMO UNIT

EFSA/GMO/509

Parma, 5 June 2009

Technical meeting between EFSA GMO Panel environmental experts and environmental experts from Member States

Letter from certain Member States concerning the environmental risk assessment of genetically modified maize MON810

EFSA meeting report of the meeting on 26 May 2009 (9.30 – 15.30)
Hotel Star Hotel du Parc, Parma (Italy)

The below report does reflect EFSA's understanding of the meeting. This report is not, and cannot be regarded as, representing the position, the views or the policy of the European Food Safety Authority or of any national or EU Institution, agency or body.

1. PARTICIPANTS

The list of participants is enclosed (see the Annex).

2. OPENING OF THE MEETING BY THE EXECUTIVE DIRECTOR OF THE EFSA

The Executive Director of the European Food Safety Authority (EFSA), Catherine Geslain-Lanéelle, opened the meeting and welcomed the participants. She thanked the attending delegations from EU Member States, members of the EFSA GMO Panel and observers (Norway, European Commission/DG Environment). Following the letter to EFSA signed by 18 Ministers of 12 Member States concerning the environmental risk assessment of genetically modified (GM) maize MON810, EFSA decided to call this technical meeting to address the scientific comments received on the renewal of MON810 authorisation from the 12 signing Member States. In a spirit of cooperation with Member States, all 27 Member States have been invited to this technical meeting.

The discussion will be reported to the whole EFSA GMO Panel that will meet on 27 and 28 May to discuss the MON810 renewal applications[1]. The outcome of the meeting will be fully considered by the GMO Panel when finalising its scientific opinion on the renewal applications of maize MON810. In addition, a written report will be prepared by EFSA and circulated to all participants for comments at the latest by early June. The EFSA meeting report is foreseen to be finalised by 5-6 June.

[1] The applicant has submitted 3 applications for MON810 renewal each with a different scope, including one application covering cultivation purposes.

3. WELCOME BY THE HEAD OF THE EFSA GMO UNIT

The Chairman of the meeting and the Head of the EFSA GMO Unit, Per Bergman, presented the historical background of the renewal application of maize MON810 that includes cultivation purposes. According to the requirements of Regulation (EC) 1829/2003, the initial Environmental Risk Assessment (ERA) of the MON810 application was delegated to the Spanish Competent Authority. In order to be able to complete its assessment, the Spanish Competent Authority required additional data from the applicant. Later on, the EFSA GMO Panel started its risk assessment taking into account a comprehensive set of data, the available scientific information, the environmental risk assessment report from the Spanish Competent Authority as well as the comments from national risk assessment bodies through the EFSA and Member States exchange mechanism, GMO EFSAnet. Most of the comments raised by Ministers in the aforementioned letter were previously made available through the GMO EFSAnet. Finally the EFSA GMO Panel will complete its risk assessment and issue a scientific opinion on MON810 renewal.

An agenda aiming to allow sufficient time for an open discussion was proposed and accepted by the meeting delegates. The Head of the EFSA GMO Unit reminded the meeting that, in line with the agenda of the meeting, the objective of the meeting is to hold a discussion on technical issues.

4. TOUR DE TABLE

Participants introduced themselves during a tour de table (see the Annex).

5. INTRODUCTION BY THE EFSA GMO PANEL

Note: Please note that the slides of EFSA GMO Panel members presented at the meeting will be circulated to participants.

The Chairman of the EFSA GMO Panel, Harry Kuiper, briefly introduced the Risk Assessment (RA) guidelines developed by the EFSA GMO Panel. He also updated the meeting delegates on EFSA activities on RA of GMOs, in particular on past and ongoing self-tasking activities (e.g. working groups on environmental post-market monitoring, on statistics, on animal feeding trials, on allergenicity assessment, on non-target organisms, on selection of appropriate comparators). Bearing in mind the recently revised guidelines related to food and feed safety assessment of GMOs, he reminded that the EFSA guidelines are regularly updated in line with the evolution of science and expertise related to GMOs. Hence the guidelines related to the environmental impact of GMOs are currently under revision.

The Chairman of the EFSA GMO Panel reported that EFSA supports a strategy for a comprehensive risk assessment of GMOs, including assessment of possible long-term adverse effects, backed by a full set of data. EFSA guidelines go beyond current international guidelines.

A Vice-Chairman of the EFSA GMO Panel (also Chairman of the EFSA GMO panel Working Group on Environment (ENV WG)), Jeremy Sweet, reiterated the regulatory procedure for a GMO cultivation application that involves the applicant, EFSA and Member States (e.g., legal timeline for assessment of applications, including a consultation with Member States and mechanism for clarifying issues needed to be addressed by the applicant). The ERA of maize MON810 was initially assessed by the Spanish Competent Authority followed by an assessment by the EFSA GMO Panel according to the guidelines in force. In this context the applicant was requested to provide additional data in order to complete the ERA. At the end of its ERA, Spain concluded with a favourable opinion on renewal of commercialisation of maize MON810 subject to some authorisation conditions as set in their final report (e.g., case-specific monitoring and management measures to detect possible evolution of resistance in target *Lepidoptera*). It was recalled that, during the MS consultation, 11 Member States commented on the MON810 renewal application.

Although maize MON810 is cultivated in some EU Member States for a few years, the EFSA GMO Panel did not make any assumption of safe use of maize MON810 in Europe. Therefore, a comprehensive ERA of maize MON810 was carried out by the EFSA GMO Panel.

The letter signed by 18 Ministers highlighted concerns of which the EFSA GMO Panel was already aware through publications, the GMO EFSAnet and the respective safeguard clauses. These concerns were mainly the resistance development in target pests and effects on non-target organisms, in particular on non-target *Lepidoptera*. It was underlined that these concerns already have been addressed by the ENV WG in its ERA of maize MON810 and that a discussion was welcomed.

Meeting delegates were assured that the outcome of the meeting would be taken into account by the EFSA GMO Panel in its deliberations before any adoption of a scientific opinion on maize MON810 renewal.

6. PRESENTATION OF SCIENTIFIC ARGUMENTS BY MEMBER STATES

- ***Resistance development in target pests***

The Austrian delegation discussed the requirements for non-Bt maize fields as refugia.The Insect Resistance Management (IRM) plan as proposed by the applicant would only be applied on farms growing more than 5 ha of maize MON810. However as many farms particularly in Austria, but also in other Member States are small, the area planted with Bt maize on these farms might cover less than 5 ha which could result in non-Bt maize refugia not being implemented on a considerable proportion of farms in certain EU countries. The Austrian delegation considered that a cluster of several (≤ 5 ha) MON810 maize fields would require the need for a revised IRM strategy better taking into account the European agricultural landscape. Referring to the average maize field size (≤ 5 ha) on its territory, the Slovenian delegation was also concerned with the IRM strategy proposed by the applicant. The Vice-Chairman of the EFSA GMO Panel, Jeremy Sweet, recalled that this issue, even though important and addressed by the ENV WG in its discussions, is a risk management issue and should therefore best be handeled by risk managers. The Dutch delegation agreed that resistance development is not part of the risk assessment. It further pointed out that rather is an agronomical issue.

The Hungarian delegation commented on the ERA of maize MON810 and recalled previous interventions in the context of Hungarian safeguard clause on maize MON810. The Hungarian delegation was concerned by the fact that, contrary to other pesticidal active ingredient (e.g., Cry toxin formulation for spraying), MON810 has not been registered as a plant protection product. In addition a comprehensive ecotoxicity assessment of Cry1Ab protein has not been completed yet, and the full dosage of Cry1Ab toxin produced in all plant parts per hectare has not been established. Maize MON810 expressing Cry1Ab protein over the entire maize growing season triggers constant selection pressure on the environment and biodiversity increasing the risk of resistance development in target pests and exposure of NTOs. Furthermore appropriate analytical standards of the plant-produced Cry1Ab protein and quantitative analytical tests for its detection should be provided; and the plant-produced Cry1Ab protein should always be available for users in amounts adequate for testing.

The Chairman of the meeting compared the Hungarian line of reasoning to the system regulating GM plants as pesticides in the USA which is different from the European regulatory system for GM plants. The question was referred to the observers from the European Commission as EFSA operates within the given regulatory framework of the EU. The European Commission took note of the Hungarian comment in this respect.

- ***Effects on Non-Target Organisms (NTO)***

The Austrian delegation commented on possible effects of maize MON810 on NTO. In this respect, the data provided by the applicant could not be considered as sufficient to complete the ERA of maize

MON810. Many of the studies submitted by the applicant were not 'state-of-the-art' and were outdated (e.g., length of exposure data, specificity of the Bt toxin, choice of non-target organisms, experimental design). The Austrian delegation was also of the opinion that relevant scientific data should be gathered from applicant's monitoring activities and that this has not been done sufficiently during the past years of cultivation of maize MON810. Therefore, according to the Austrian delegation, it is not possible to conclude the ERA. Finally, the Austrian delegation believed that long-term effects and regional aspects of the NTO assessment were not sufficiently taken into consideration. Some data extrapolations made by the applicant should have been better explained (e.g., adequacy of data, data collection outside EU).

The Vice-Chairman of the EFSA GMO Panel reminded that maize MON810 is authorised for cultivation in Europe since 1998 under legislation not requiring monitoring. Maize MON810 has however been monitored by independent scientists in several EU member states representative of EU receiving environments. Moreover the EFSA GMO Panel is of the opinion that sufficient information is available to conclude the ERA of maize MON810, both from the application and from publications in the scientific literature.

The German delegation supported the Austrian view as regards to the low number and questionable quality of NTO studies contained in the initial MON810 renewal application. It was criticized that the applicant did not provide any new studies on non-target organisms especially ones on non-target European *Lepidoptera* (except two studies provided later as additional information on predatory mites). The ENV WG agreed as did the Spanish Competent Authority in its report that a possible impact of Cry1Ab protein on non-target *Lepidoptera* is a major concern. Therefore additional information had been requested from the applicant at several occasions. The German delegation referred to an ongoing research study on maize pollen dispersal and deposition in Germany to explain that pollen deposition sometimes occurs over longer distances and that NTO thus might be exposed to the Bt protein over longer distances. The German delegation also questioned if the genetic background of maize MON810, as authorised 10 years ago, would affect expression levels of the transgene resulting in differences between old and more recent MON810 cultivars. As to the understanding of the German delegation, each application for renewal should include new and updated data on expression and not be based on data submitted with a more than 10 year old dossier.

The Vice-Chairman of the EFSA GMO Panel underlined that the cultivated MON810 varieties used as comparators in the risk assessment fall within a restricted range of data. EFSA GMO Panel members explained that an up-to-date ERA of maize MON810 was carried out based on all available relevant scientific data (including national and international studies on maize MON810). Available national studies allowed the EFSA GMO Panel to conclude on the level of exposure and consequently on the magnitude of possible adverse effects. For instance data from Felke and Langenbruch (2002, 2005) on maize Bt176 and MON810 as well as other MON810 field studies in Europe have been considered by the ENV WG in its ERA. The EFSA GMO Panel members furthermore affirmed they were fully aware of the studies by Hoffmann and colleagues.

As already done in its past safeguard clause on maize MON810, the Hungarian delegation underlined the importance of protected non-target *Lepidoptera* and restated their zero tolerance of adverse effects on these protected NTO species in Hungary. The Vice-Chairman of the EFSA GMO Panel explained that common agricultural practices for conventional maize constitute a baseline for the ERA and pinpointed the comparative analysis of these agronomic practices for conventional maize compared to that of GM maize. As risk assessors, the EFSA GMO Panel is responsible to place into context whether impacts of common agricultural practices of GM maize are worse than these of conventional maize across all Europe. Regarding policy for farmland biodiversity, each EU MS should set its own baseline to adjust management measures to specific regions, if needed.

The German and Austrian delegations both questioned what would be an appropriate comparator and a common agricultural practice, as e.g. maize is usually not sprayed on small scale farms, i.e. no pesticides are used on maize during the growing period. The ENV WG clarified that this depends on variable farming practices. Any pesticidal (or herbicidal) treatment on cultivated crops impacts on biodiversity to a certain extent. Hence EFSA's task is to quantify the probability of adverse effects on NTO (e.g., mortality, sub-lethal effects) based on available evidence and to put that risk into context.

The Hungarian delegation mentioned that there are more than 180 protected lepidopteran species in Hungary. They described that they worked with a model weed (stinging nettle, *Urtica dioica*), two protected and one rare lepidopteran species. Each of the tested NTO species showed a different sensitivity to the Cry1 toxin-containing pollen. The Hungarian delegation reminded that the study was performed with stinging nettle dusted with GM maize pollen but that a comprehensive exposure assessment would be needed for NTO species living on a GM plant which constantly produces Cry1 toxin in the pollen.

The German delegation questioned the quality of the monitoring data provided in reports by the applicant in the past. These data are regarded to not allow any conclusion on possible effects of maize MON810. The Vice-Chairman of the EFSA GMO Panel reminded that there was no requirement for monitoring in the original approval of maize MON810 but that there will be for the renewal if consent is given. During the assessment of the maize MON810 renewal, the EFSA GMO Panel will comment only on the scientific quality of the post-market environmental monitoring plan provided by the applicant. Final implementation of the plan together with the completeness check of the reports is the responsibility of risk managers. However, the ENV WG is aware that specifically in Germany attempts are made to improve the General Surveillance of maize MON810 cultivation (e.g. cooperation between applicant and managers of existing monitoring systems) and notes that these activities are still ongoing.

The Swedish delegation pointed to the importance of deciding risk management actions in proportion to the risk level. The assessment of proportionality involves scientific assessments. Therefore it is valuable for the risk managers to receive comments on aspects of risk management options and their proportionality to the risk level from the risk assessors. The ENV WG responded positively to this suggestion.

7. EXCHANGES OF VIEWS ON

- **Resistance development**

A Panel member, Jozsef Kiss, summarised the specific points raised by Member States as regards the possible development of resistance by target pests (European Corn Borer, ECB and the Mediterranean Corn Borer, MCB) to Cry1Ab protein expressed in MON810 maize plants. Having defined the phenomenon of 'resistance', he commented that the evolution of resistance is a common response of living organisms to selection pressures and globally about 800 pests (arthropods, plant pathogens and weeds) have been identified as showing resistance to various plant protection products. He gave an overview on recently published global and European surveys that report of no observed resistance of ECB and MCB. He gave additional information on what type of data, parameters (e.g., low level of resistant alleles) and modelling studies were considered by the ENV WG during its assessment of resistance evolution as well as the absence of resistance evolution in target pests in Europe. The IRM plan provided by the applicant as well as the post-market environmental monitoring plan were mentioned as appropriate tools to detect possible resistance evolution. The Hungarian delegation referred to laboratory tests performed over 70 generations of a model species in Hungary, and in which the occurrence of cross-resistance was shown with Dipel. The ENV WG referred among others to *cry* gene stacking as one of the management tools to delay resistance development being deployed outside Europe.

- **Effects on non-target organisms (NTO)**

A Panel member, Salvatore Arpaia, presented the issues considered by the ENV WG in its assessment of possible effects of maize MON810 on NTO. He referred to the current debate of possible extended range of sensitivity (beyond *Lepidoptera*) of the Cry1Ab protein. Based on the initial application, a broad range of other available data as well as an extensive exposure analysis, the ENV WG scrutinised the relative ecotoxicity of maize MON810 to certain non-target organisms, in particular non-target *Lepidoptera*. He underlined that numerous MS comments submitted during the MS consultation period were reviewed and already considered by the ENV WG during its ERA. He outlined the main parameters important in exposure analysis.

The Austrian delegation wondered how the EFSA GMO Panel considered the extended collection of individual scientific publications in their assessment, since the meta-analysis by Marvier et al. (2007) indicated the shortcomings with regard to the information on study design and details of results as contained in many individual papers. Such deficiencies should be identified during the assessment and taken into account since they may significantly limit the conclusiveness of the results. Salvatore Arpaia commented that the added value of meta-analyses is that further statistical power is gained by pooling data from individual experiments, though the limitations of this approach is also known. However, he reminded that the ENV WG considered this meta-analysis as part of a broader range of scientific evidence.

The German delegation asked for further information on the field margins taken into account to assess non-target effects. The German delegation was not satisfied with the small margins included in the assessment and referred inter alia to the data on pollen deposition generated throughout the last years in Germany.

The Hungarian delegation underlined the effects on collembolan species at receptor level, originated outside of the known mode of action of Cry1 toxin.

A discussion ensued with delegations of Member States concerning the ENV WG ERA approach for assessing the environmental exposure of certain non-target Lepidoptera, focusing on the areas over which effects on individuals were likely to occur, and on the variability of estimates. The ENV WG clarified the difference between deterministic and stochastic approaches and the desirability of seeking average outcomes.

8. CONCLUSIONS

The Vice-Chairman of the EFSA GMO Panel, Jeremy Sweet, thanked the participants for responding to the EFSA invitation and for the fruitful discussion. A meeting report will be prepared by EFSA and circulated to all participants for comments prior to publication on the EFSA website. Today's discussion will be considered in the upcoming GMO Panel deliberations on the renewal of maize MON810.

It was mentioned that an EFSA conference on risk assessment aspects of GMOs is scheduled on 14-15 September 2009 in Brussels.

9. CLOSING OF THE MEETING BY THE HEAD OF THE EFSA GMO UNIT

The Chairman of the meeting thanked Member State delegates, experts of the EFSA GMO Panel, observers from Norway and the European Commission for their contributions to the fruitful exchange of information and views during the meeting.

ANNEX - List of participants

Country	Surname	Name	Affiliation
Austria	Heissenberger	Andreas	Umweltbundesamt GmbH - Federal Environment Agency
Austria	Eckerstorfer	Michael	Umweltbundesamt GmbH - Federal Environment Agency
Finland	Mannonen	Leena	Ministry of Agriculture and Forestry
Finland	Sarvas	Matti	Board for Gene Technology
France	Saindrenan	Patrick	Haut Conseil des Biotechnologies
Germany	Tappeser	Beatrix	Bundesamt für Naturschutz - Federal Agency for Nature Conservation
Germany	Landsmann	Jörg	Julius Kühn-Institut
Germany	Bollmann	Joachim	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz
Hungary	Darvas	Béla	Hungarian Gene Technological Authority
Hungary	Székács	András	Hungarian Gene Technological Authority
Ireland	O' Neill	John	Department of Environment, Heritage and Local Government
Italy	Morelli	Giorgio	Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione
Lithuania	Pivorienė	Odeta	Ministry of Environment
Luxembourg	Bruch	Marcel	Health Directorate
Netherlands	Glandorf	Boet	RIVM/GMO Office
Slovak Republic	Peško	Milan	Ministry of Agriculture
Slovenia	Batič	Martin	Ministry of Environment and Spatial Planning
Sweden	Eklöf	Staffan	The Swedish Board of Agriculture
Norway	Hofsvang	Trond	Norwegian Committee for Food Safety
Norway	Opsahl Sorteberg	Hilde-Gunn	Norwegian Committee for Food Safety
European Commission	Murray	Bernadette	European Commission
European Commission	Clayton	Helen	European Commission
EFSA GMO Panel	Kuiper	Harry	EFSA GMO Panel
EFSA GMO Panel	Sweet	Jeremy	EFSA GMO Panel
EFSA GMO Panel	Perry	Joe	EFSA GMO Panel
EFSA GMO Panel	Kiss	Jozsef	EFSA GMO Panel
EFSA GMO Panel	Bartsch	Detlef	EFSA GMO Panel
EFSA GMO Panel	Arpaia	Salvatore	EFSA GMO Panel
EFSA GMO Panel	Hendriksen	Niels	EFSA GMO Panel
EFSA	Geslain-Lanéelle	Catherine	EFSA

EFSA	**Bergman**	**Per**	EFSA
EFSA	**Mestdagh**	**Sylvie**	EFSA
EFSA	**Lheureux**	**Karine**	EFSA
EFSA	**Devos**	**Yann**	EFSA