European Food Safety Authority

GMO UNIT

Parma, 25 June 2008

BILATERAL TECHNICAL MEETING BETWEEN MEMBERS OF THE EFSA PANEL ON GENETICALLY MODIFIED ORGANISMS AND GREEK DELEGATION

GREEK SAFEGUARD CLAUSE ON GM MAIZE MON810

EFSA Meeting report of the meeting of 11 June 2008

***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*.**

Participants

Greek delegation of 3 experts	Nikolaos Emmanouil	Agricultural University of Athens, Department of Entomology
	Dimitra Nikolopoulou	Benaki Phytopathological Institute, Department of Pesticides control and Phytopharmacy
	Konstantinos Michos	Ministry of Rural development and food, Directorate of Inputs for crop production
EFSA GMO Panel:	Salvatore Arpaia, Detlef Bartsch, Niels Hendriksen, Jozsef Kiss, Gijs Kleter, Jeremy Sweet	
EFSA GMO Unit:	Per Bergman (Chair), Yann Devos, Karine Lheureux, Sylvie Mestdagh,	
European Commission:	Bernadette Murray, Yannis Karamitsios (DG ENV)	

1. Welcome

The Chair of the meeting welcomed the Greek delegation, present members of the EFSA GMO Panel, as well as observers from the European Commission.

2. Tour de table

Participants introduced themselves during a tour de table.

3. Historical and legal aspects related to the Greek safeguard clause

The European Commission introduced the historical and legal background of the Greek safeguard clause, and its request, directed at EFSA, to provide a scientific opinion on the

statement and documents submitted by Greece. According to the mandate of the European Commission, EFSA was requested to provide a scientific opinion on 31 July 2008. In order to reinforce scientific co-operation with national institutions, and in order to ensure a more effective mode of collaboration on scientific issues, EFSA was also invited to contact national experts to clarify all the requested information and potential sources of divergences before adopting its scientific opinion.

The Chair explained that this bilateral meeting is meant to listen to the arguments provided by the Greek authorities in support of their safeguard clause and, where appropriate, to clarify outstanding issues related to the supporting documents. The Chair also clarified that some experts of the GMO Panel were attending the meeting and representing a broad range of expertises in terms of food/feed and environmental safety. Following that meeting, a scientific opinion will be delivered by the whole GMO Panel in order to comply with the terms of reference of the European Commission mandate. Therefore, pending the agreement of the entire Panel upon its scientific opinion, the views that will be expressed by the experts during the meeting will be personal views and will not pre-empt the final opinion of the GMO Panel.

4. Technical aspects related to the Greek safeguard clause

The Greek delegation presented the scientific information used to support its invoked safeguard clause on maize MON810. Concerns were raised in two main domains: (1) the environmental and (2) the toxicological risk assessments of maize MON810.

With regard to the environmental risk assessment of maize MON810 and in line with the submitted scientific information used to support its invoked safeguard clause, the Greek delegation discussed potential adverse effects on bees (such as the Colony Collapse Disorder) possibly caused by maize MON810 through exposure to Bt-toxin. During an oral presentation supported with a written argumentation, the Greek delegation also addressed other issues than the one covered by the European Commission's mandate, namely:

- the agricultural particularities of Greece (e.g. small field size, low organic matter in agricultural soils, rich fauna and flora, high density of beehives);
- the potentially altered lignin content in maize MON810 and the potential impact thereof on the decomposition of maize residues in agricultural soils;
- the potential resistance development in target organisms and its management;
- potential adverse effects of maize MON810 on non-target organisms through exposure to Bt toxin.

It was made clear that the forthcoming scientific opinion of the EFSA GMO Panel would address environmental issues raised in the initial data package sent by the Greek authorities to the European Commission and forwarded to EFSA as part of the official mandate.

With regard to the toxicological risk assessment of maize MON810, reference was made to a rat feeding study with maize MON863 where already available raw data were re-analyzed by Séralini et al. (2007). In addition to the scientific information used to support its invoked safeguard close, the Greek delegation also presented additional information on the toxicological and allergenicity risk assessment in the form of a power point presentation, covering the following issues:

- the need for harmonised testing strategies for the toxicological and allergenicity risk assessment of GM crops;
- the need for prolonged and repeated-dose toxicity testing;

- the need for verifying the equivalence of the tested protein to that expressed in the GM crop;
- the need to follow an integrated stepwise approach in the allergenicity risk assessment;
- the need to consider inhalation routes of exposure;
- the need for testing the presence of other new constituents through animal testing.

All these concerns in relation to the toxicological and allergenicity risk assessment of maize MON810, are in fact related to how risk assessment of GM plants is conducted. Comprehensive and detailed descriptions of the risk assessment criteria in Europe are laid down in the Guidance Document of the GMO Panel for the risk assessment of GM plants and derived food and feed. This EFSA Guidance Document has been established to harmonize risk assessment in Europe. The Guidance Document is in line with international standards (e.g. OECD and Codex alimentarius) and European GMO legislation and has been laid open for wide public consultations. For toxicity testing and the need for animal feeding trials, specific reference was made to the comprehensive report of the GMO Panel on animal feeding trials published in 2007, as well as to a request that will be submitted by the European Commission to OECD for amendments of the 90-days rodent oral toxicity protocol to include whole-product testing, such as for novel foods and GMOs.

5. Closing of the meeting

The GMO Panel will issue a scientific opinion based on the scientific information provided by the Greek authorities and forwarded by the European Commission as part of its formal mandate to EFSA/GMO Panel.

EFSA thanked the Greek delegation, the EFSA GMO Panel members and the European Commission for attending the meeting.