European Food Safety Authority

**GMO UNIT**

Parma, 10 October 2008

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

**FRENCH SAFEGUARD CLAUSE ON GM MAIZE MON810**

## EFSA Meeting report of the meeting of 9 October 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

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| French delegation of 4 scientists: | Denis Bourguet | INRA. Centre de biologie et de gestion des populations. Centre de Biologie et de Gestion des Populations (CBGP) |
| | Pierre-Henri Gouyon | Laboratoire d'écologie, systématique et évolution. Muséum National d'Histoire Naturelle Systématique & Evolution |
| | Yvon Le Maho | CNRS. Institut Pluridisciplinaire Hubert Curien |
| | Marc Lavielle | INRA. Université Paris-Sud, Equipe de Probabilités, Statistique et Modélisation |
| EFSA GMO Panel: | Salvatore Arpaia, Detlef Bartsch, Niels Hendriksen, Jozsef Kiss, Gijs Kleter, Joe Perry, Jeremy Sweet | |
| EFSA GMO Unit: | Karine Lheureux, Sylvie Mestdagh, Elisabeth Waigmann (Chair) | |
| EFSA Legal & Policy Affairs Unit: | Dirk Detken | |
| European Commission: | Bernadette Murray, Yannis Karamitsios (DG ENV) | |

### 1. Welcome

The Chair of the meeting welcomed the French scientists, 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 French safeguard clause

The European Commission introduced the historical and legal background of the French safeguard clause, and its request to EFSA, to provide a scientific opinion on the documents submitted by France. The safeguard clause at stake was invoked by the French authorities under Article 23 of Directive 2001/18/EC as well as under Article 34 of Regulation (EC) No 1829/2003. According to the mandate of the European Commission, EFSA was requested under Art. 29(1) of Regulation (EC) No 178/2002 to assess four specific types of information[1]. The initial data package accompanying the mandate of the European Commission, forwarded to EFSA on 27 February 2008, was supplemented with an additional report of the French scientist Yvon Le Maho in the course of the evaluation by the GMO Panel, on 12 June 2008.

Following a common agreement, the deadline for the EFSA GMO Panel to issue a scientific opinion was fixed for October 2008. In order to reinforce the scientific co-operation with national institutions, and in order to ensure a more effective mode of collaboration on scientific issues, EFSA and its GMO Panel contacted national experts to clarify, where appropriate, outstanding points that had been identified by the GMO Panel during its risk assessment of the information provided by the French authorities in support to their safeguard clause.

## 4. Background & procedural aspects

EFSA clarified that this bilateral meeting is in the frame of the above formal mandate where EFSA is expected to assess the documents provided by France and to deliver a scientific opinion of the GMO Panel under Art 29 of Regulation (EC) No 178/2002. This meeting is therefore meant to listen to the arguments provided by the French authorities in support of their safeguard clause, to engage into an interactive technical discussion and in this context to clarify, where appropriate, outstanding issues related to the supporting documents.

It was 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. In second instance, 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 expressed by the experts were personal views and would not pre-empt the final opinion of the GMO Panel.

## 5. Technical aspects related to the French safeguard clause

With regard to the **environmental risk assessment** of maize MON810 and in line with the submitted data package to support the safeguard clause, the French scientists and the experts of the GMO Panel discussed the following points:

- Pollen dispersal:
  French scientists considered pollen dispersal as such as an environmental concern due to the potential cross-pollination of adjacent non-GM maize fields. Such

[1] 1. The opinion of the "comité de préfiguration" of the High Authority for GMOs; 2. The French position that the justifications presented by Monsanto on 30 January 2008 are not sufficient to invalidate the data of the French Order; 3. The scientific evidence which is presented in the accompanying note of the Order and in the note forwarded to the European Commission under Regulation (EC) No 1829/2003; 4. The scientific justification of the duration of the measure, which is linked to the ongoing procedure on the notification for the renewal of MON810, as referred to in Article 1 in the Decree."

pollination would lead to economic losses to farmers of specific farming sectors (e.g. organic farmers, farmers producing their own seeds (concept of '*semences fermières*')). The participating GMO Panel experts made clear that pollen dispersal as such is not considered as a hazard in itself but relates to co-existence and economic issues, which fall outside the Panel's mandate.

- Appearance of resistance in lepidopteran target insects:
  French scientists agreed that so far, no resistance has been detected to Cry1Ab protein in MON810 maize hybrids in primary target pest (e.g. ECB) in Europe and in France and therefore also agreed with the efficacy of the insect resistance management plans implemented on Bt crops (and in particular on maize MON810). However, recent publications (e.g. Tabashnik et al., 2008) demonstrated the appearance of resistance to a different protein (Cry1Ac) in a different crop (cotton) and in another target pest outside Europe (*Helicoverpa zea* in cotton in the US). Subsequently in this case, the potential inadequacy of the 'high dose/refuge' strategy to limit the development of resistance was postulated by the French scientists. Through the mentioning of two related publications (Huang et al., 2007; Van Rensburg, 2007) listed in the opinion of the '*Comité de préfiguration de la Haute autorité*', the French scientists wanted to increase the consideration of possible resistance development in target organisms in the future, although no such adverse effect has been identified so far. The GMO Panel experts agreed that the potential development of resistance to Cry toxins constitutively expressed in Bt crops is a relevant issue, and that it can be managed on a case-by-case basis. In this respect resistance management and post-market monitoring for resistance is and will be in place for Bt maize cultivation.

- Effects on non-target organisms (NTO):
  The French scientists claimed that the occurrence of potential adverse effects in a longer term is not always possible to predict. Experts from the GMO Panel reiterated the fact that hazards of Cry proteins on non-target lepidopteran pests are well known but that the level of environmental exposure in the field is required to translate these known hazards into risks for non-target organisms. The French scientists were not convinced that it is only a matter of exposure, and they considered that European regulations foresee monitoring as an adequate tool to address such long term (unanticipated) effects.

- Biovigilance (and post-market monitoring plan):
  The participating experts of the GMO Panel referred to the post-market monitoring activities foreseen by the European legislative framework in order to cover uncertainties (e.g. potential long-term effects, see above for NTO) remaining at the end of the environmental risk assessment. EFSA was involved in developing guidelines for post-market monitoring activities, including general surveillance. Post-market monitoring falls under the responsibilities of the national Competent Authorities. French scientists repeated the importance of monitoring GM crops as well as developing predictive models for potential long-term effects. It was agreed by the GMO Panel members that predictive models can be valuable in the context of risk assessment.

The following **food and feed-related aspects** were also addressed:

- Some assumptions of risks made by French scientists did not specifically relate to maize MON810, though the French ban at stake applies to maize MON810 only.

- The French scientists pointed towards the need for verifying the equivalence of the bacteria-produced protein – generally used in safety tests – with the GM plant-produced protein. Data showing the equivalence between the microbial and plant-produced proteins must be part of GMO applications for market authorisation. The participating experts of the GMO Panel noted that this is indeed addressed in the guidance provided to applicants and commonly considered in the evaluation of new applications and renewal applications by the GMO Panel.

- It was asserted by the French scientists, that there is the need for prolonged and repeated-dose toxicity testing. Long-term toxicity studies on animals, including second generation, should be a compulsory requirement. The experts of the GMO Panel noted that in line with the case-by-case approach as outlined in internationally harmonized guidelines of Codex Alimentarius and the EFSA Guidance, the requirement for animal tests for each GMO depends on the outcome of prior steps of its risk assessment including the comparative analysis between that GMO and its counterpart with a history of safe use and the safety assessment of the newly expressed protein(s). 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.

- The need for robust statistical analysis with clear hypothesis and respective endpoints was raised by the French scientists. This opinion was shared by the participating experts of the GMO Panel. Reference was made to the ongoing work of the EFSA self-tasking Working Group on Statistical analysis and experimental design for compositional field trials embodied in the newly updated food/feed sections of the Guidance Document of the GMO Panel, as well as more recent work just begun on updating the environmental risk assessment sections of Guidance Document of the GMO Panel. Both parties supported the use of empirical data to underpin risk assessment, and the use of commercial varieties with a history of safe use within field trials to provide credible estimates of natural variability and to quantify equivalence testing methodology.

- There is a lack of evidence to prove the possible toxicity of maize MON810. This point was shared by both parties;

- The issue of oncogens and the possibility of horizontal transfer from genes in food to consumers was also raised by the French scientists, who further noted that this falls under the more general issue of genetic stability of the transgenes within the GMO. The experts of the GMO Panel added that testing for genetic stability is a standard requirement under the EFSA guidance for risk assessment of GMOs and is part of the comprehensive molecular characterisation of a GMO.

## 6. General remarks of the French scientists

For the French scientists, the current scientific knowledge is not satisfactory and has not allowed them to identify specific risks of GM maize MON810 on biodiversity. However,

few tests/methods are currently available to predict possible long-term effects of GM crops on biodiversity. French scientists are therefore not in a position to conclude on the MON810 risk assessment but are of the opinion that present uncertainties about possible long-term effects have to be reported to risk managers, leaving in their hands any type of decision (e.g. monitoring/management measures, prohibition, refusal of marketing) as regards the GM crop in question.

The position of the French scientists was that risk managers should decide on what risk certainty would be acceptable e.g. in terms of adverse effects of GMOs on the environment/biodiversity. A relative quantification (definition of thresholds in the risk assessment) of the risks would be paramount for the French scientists to come to any recommendation for risk managers.

## 7. Closing of the meeting

A discussion was held on the data package as provided by the European Commission to EFSA in order to issue a scientific opinion on the information package used by the French authorities to support their national safeguard clause on maize MON810. With regard to the overall risk assessment of maize MON810, French scientists did not present new research data in support of the safeguard clause.

It was made clear that, following this meeting, a scientific opinion will be delivered by the EFSA GMO Panel in order to comply with the terms of reference of the European Commission mandate.

EFSA thanked the French scientists, the EFSA GMO Panel members and the European Commission for attending the meeting.