

## MEMO FROM THE FRENCH AUTHORITIES TO THE MEMBER STATES

==--==--==

**Re: Draft Commission decision on the emergency measures taken by France concerning the placing on the market of genetically modified maize line MON810, pursuant to Article 34 of Regulation 1829/2003/EC, to be submitted to the vote of the Member States at the SCFCAH meeting on 16 February 2009**

The Commission has placed on the SCFCAH meeting agenda for 16 February 2009 a discussion with a view to a Committee vote on a draft decision to reject the emergency measure taken by France in February 2008 regarding the cultivation of genetically modified maize line MON810. This draft decision follows the opinion adopted by the European Food Safety Authority on 29 October 2008. In this opinion, the EFSA GMO Panel considers that France has provided no new evidence to justify these emergency measures.

The French authorities would like to inform the Member States of the exact evidence that led them to invoke these emergency measures and would like to draw their attention to the particular circumstances surrounding the Commission's draft decision when the reassessment of this GMO is not yet complete at Community level.

### **1- Background information on the authorisation to place MON810 on the market**

The placing on the market of genetically modified maize line MON810 was authorised a) for animal feed and cultivation by Commission Decision 98/294/EC of 22 April 1998, pursuant to Directive 90/220/EEC, and b) in the form of derivatives for human consumption pursuant to Regulation 258/97.

In keeping with the procedure defined by Regulation (EC) No. 1829/2003 (articles 8 and 20) and Regulation (EC) No. 641/2004 (Article 11), Monsanto notified the Commission in July 2004 of this maize as an existing product placed on the market before the entry into force of this regulation, pursuant to articles 8(1)(a), 8(1)(b), 20(1)(a) and 20 (1)(b) of Regulation (EC) No. 1829/2003. This maize is now listed on the Community register of genetically modified food and feed, thereby authorising its use for human and animal consumption as well as its cultivation. With renewal applications having been filed for the different uses of MON810 maize, including its cultivation, in April and May 2007, this maize remains authorised to be placed on the market until a decision is made on these applications.

### **2- Assessment of the Committee for the Formation of a High Authority on GMOs (Comité de Préfiguration)**

Following the work conducted by the Grenelle Environment Forum in autumn 2007, it was decided to set up a High Authority on GMOs (renamed High Council on Biotechnologies by the act on GMOs in France adopted by French Parliament in June 2008). In late 2007, a Committee for the Formation of this High Authority (Comité de Préfiguration) was set up to propose an optimal organisational structure for the High

Authority. The President of the French Republic also tasked this committee with a reassessment of the genetically modified maize line MON810 in the light of new evidence published since its authorisation.

The conclusions of this assessment were submitted on 9 January 2008. They presented new scientific evidence on the environmental impact of this maize. The new scientific information is as follows:

- Dissemination: New evidence since 1998 concerns the characterisation of pollen dispersal (*Klein et al., 2003; Rosi-Marshall et al., 2007; Brunet 2006; Quist and Chapela, 2001*) over large distances (kilometres) (*A. Messéan, 2006*) related in particular to climatic conditions and events and to different environments. These results show that it is not possible to exclude cross-pollination between GMO fields and GMO-free fields at the local scale (small agricultural region) (*A. Messéan, 2006*). Dispersal of the Bt toxin and its persistence have been demonstrated and are governed by edaphic, climatic and environmental factors (*Icoz and Stotsky, 2007*).
- Appearance of resistance in target pests: Selection of a resistant strain in two secondary target lepidoptera (*Huang et al., 2007; Van Rensburg, 2007*).
- Effects on non-target fauna: New evidence confirms the possibility of long-term toxic effects in earthworms (*Zwahlen et al., 2003*), isopods, nematodes and monarch butterflies (Rhopalocera) (*Hardwood et al., 2005; Prasifka et al., 2007; Dutton et al., 2005*). Exposure among natural populations of monarchs remains very low (less than 1%), notably for these latter via harmful effects on behaviour. (*Marvier et al, 2007*). Published articles have shown that Bt toxin may be present in the food chain (*Obrist et al, 2006*) and persistence of insecticide molecules has been reported in water (*Douville et al, 2006; Rosi-Marshall et al, 2007*) and in sediment draining from a plot (more than 20–40 days) (*Icoz, Stotzky, 2007*), in contact with roots and in the soil (*Saxena and Stotzky, 2005; Mulder et al. 2006; Castaldini et al, 2005*) with exposure of insect populations (*Griffith et al, 2006; Johnson et al, 2006*) higher up the food chain. A global analysis of nontarget entomofauna (*Marvier et al., 2007*) demonstrated that Bt maize cultivation does have an effect on some families of invertebrates.

Given this new scientific evidence, the French authorities considered that the cultivation of MON810 maize was liable to present a serious threat to the environment.

Pursuant to Article 34 of Regulation (EC) No. 1829/2003 and in keeping with the procedure stipulated by articles 53 and 54 of Regulation (EC) No. 178/2002, the French authorities hence informed the European Commission of the need to take emergency measures to suspend the cultivation of genetically modified maize MON810. At the same time, they provisionally prohibited the cultivation of this maize on their territory pending a decision on the application for the renewal of authorisation to place this GMO on the market.

Moreover, the Committee for the Formation of a High Authority on GMOs (Comité de Préfiguration) underscored the need for a more thorough assessment of the biological and microbiological effects of the observed dispersal and persistence of Bt molecules and the transgene in the soil (more than 200 days) (*Crecchio and Stotzky, 2001*). It also stressed the importance of real-time, long-term monitoring of the effects of MON810 field crops on fauna, flora, fungi and ecosystems as part of a “biovigilance” programme.

### **3- The Commission's response to the French measure**

The Commission informed the Member States of the French measure at an extraordinary SCFCAH meeting on 5 March 2008. At France's request, the Commission referred the matter to EFSA for its opinion on the evidence put forward by France to invoke this emergency measure. This opinion was published on 29 October 2008. In this regard, the Commission asked EFSA to contact French scientists so that the members of the EFSA GMO Panel and the French scientists who were on the Committee for the Formation of a High Authority on GMOs (Comité de Préfiguration) could discuss the matter in depth. This meeting was held on 9 October 2008.

The French authorities feel that the content of these discussions could have been given greater publicity, especially the points of agreement and the persistent sticking points between the EFSA GMO Panel members and the French scientists who attended this meeting.

Furthermore, EFSA has not yet given its opinion on the reassessment of MON810 in the authorisation renewal procedure. Yet the Commission has wasted no time proposing draft decisions on both the emergency measure taken by France and the safeguard clauses invoked by Hungary and Greece, which will be submitted to the SCFCAH for its consideration on 16 February 2009 and to the Working Group on Environment on 6 February 2009 (in the case of the Hungarian safeguard clause).

In view of the above, the French authorities believe it is ill advised to separate out the MON810 authorisation renewal decisions from the decisions on the safeguard clauses and the emergency measure. These clauses and measure should therefore be able to be upheld until a decision has been made on the renewal of this GMO.

The French authorities believe this subject is particularly important and sensitive. It merits adequate analysis, especially since the conclusions of the Environment Council meeting of 4 December refer to a consensus on the need to improve environmental risk assessments of GMOs.