

**Comité de préfiguration
d'une haute autorité
sur les organismes génétiquement modifiés
institué par le décret n°2007-1719 du 5 décembre 2007**

**Opion on the dissemination of MON 810
on the French territory**

The committee for the formation of a high authority on GMOs met in December 07 and in January 08. Its mission statement charges it with the “reevaluation of the risks and benefits for the environment and public health of the voluntary dissemination of MON 810 maize”

The committee has established the relevant areas to be evaluated, inspired by the expressed desire of the GMO group of the Grenelles de l'Environnement to expand.

The Committee put together thematic summaries for each of these areas, where in some cases only little scientific literature is available. The entire body of scientific literature could not be taken into account.

In accordance with its mission statement, questions regarding the justification for growing GM crops in the environment and questions regarding all GMOs were not investigated.

During the discussion of each of the scientific summaries, the Committee outlined the status of the impact evaluation by indicating which results were already available at the moment of first authorisation, what data is new, and which new questions are considered to be important.

In view of these actions,

1/ The committee underlines the publication of several new scientific facts related to the impact of MON 810 on the environment, human health, economy and agronomy.

- **Dissemination:** The new fact since 1998 concerns the characterisation of pollen dispersal (Klein et al, 2003 ; Rosi-Marshall et al, 2007 ; Brunet 2006) (Kuest ; Chapela 2001) over large distances (kilometers) (A. MESSEAN, 2006) linked mainly to climatic conditions and events and to the environment. These results prove the impossibility of zero cross-pollinisation between GM and non-GM fields at local level (small agricultural region) (A. MESSEAN, 2006). The discussion centered on the importance of these results when it comes to the impact on seed purity, “respect” of adventitious presence thresholds and coexistence rules. The dissemination of Bt toxin and its persistence were proven and are dependent on soil, climatic and environmental factors (Icoz et Stostky ; 2007).

- Appearance of resistance in target insects: no new facts on the main target insects (no shown resistance) but selection of resistant strains for two lepidopteran secondary pests (Huang et al, 2007 ; Van Rensburg, 2007).
- Effect on non-target organisms: new facts confirm possible toxicological adverse effects on earthworms (Zwahlen et al. 2003), isopods, nematods and the monarch butterfly (rhopalocera) (Hardwood et al. 2005, Prasifka et al. 2007 ; Dutton et al, 2005). The exposure of natural Monarch populations remains very limited (less than 1%), in particular via harmful behavioural effects (Marvier et al., 2007)¹. Publications show the presence of possible Bt toxins in the trophic chain (Obriest et al, 2006) as well as a persistence of the insecticides in water (Douville et al, 2006 ; Rosi-Marshall et al, 2007) or in sediments drained from fields (more than 20 to 40 days) (Icoz, Stotsky, 2007), in contact with roots and soil (Saxena et Stotsky, 2005 ; Mulder et al. 2006 ; Castaldini et al, 2005) with an exposure of insect populations (Griffith et al., 2006 ; Johnson et al, 2006) higher up in the trophic chain. A global analysis of the non target entomofauna (Marvier et al 2007) shows an effect of Bt maize on certain invertebrate families, effects which are however less important than those caused by insecticides. Finally the study by Marvier et al showed no direct toxic effects.
- Human health: new facts have shown the impact of Bt maize on mycotoxin levels, which can be reduced by 90% to 95% (AFSSA ; 2004) compared to untreated conventional hybrids. Insecticide treatment does not lead to similar decreases. The levels of fumonisins (classified as possibly carcinogenic for humans, 2B group CIRC), in conventional hybrids regularly exceed 2000 ppb depending on insect attacks in the regions of Midi-Pyrénées and Aquitaine.

2/ The committee lists the points which have not sufficiently been taken into account or are new, as having to be taken into account in the evaluation of impact of all GMOs.

- Molecular and biochemical characterisation: the protein which is produced by the transgene is not identical to the one produced by *Bacillus thuringiensis*. Its characteristics in terms of replication, post-translational modifications, biodegradability, persistence and presentation may be different from those of the natural Cry1Ab toxin. Only the studies using MON 810 maize are relevant for an evaluation of toxicity to humans and the environment. It would be interesting to know the interaction between the transgene and different genetic backgrounds. The question of the production by MON 810 of peptides with unexpected sequences was brought up, as well as their impact on the development of insects and vertebrate and the weakness of the evaluation dossier on that point; there was however no consensus on this subject. The question of the possible production and “creation” of metabolites coming from the degradation of Bt toxin was also raised but remains unanswered.
- Impact on pollinating insects: studies on the impact on bees have to be conducted in hives under real-life operational conditions, to take into account cumulative effects. No consensus was reached on this point.
- Toxicological elements: no new facts other than the toxic impact as described above, but a large majority of members underlined the insufficiency of the 90-day rat study, which has insufficient power. Indeed, the methodology used (validated

¹ **Translation note :** this sentence is strange also in the original text

by the OECD) on rats does not allow to conclude on the absence or presence of significant differences between the test group and the comparator, and on the biological interpretation of the observed differences (Lavielle, 2007). It is necessary to rethink the protocol. The committee considers it necessary to perform long-term studies, on material with appropriate genetic backgrounds, on other varieties and especially on larger samples. The committee underlines the absence of evaluation of endocrine, teratogenics and transgenerational effects.

- Biological and microbiological effects : the biological and microbiological effects resulting from the dissemination or the persistence of Bt molecules or of the transgene in soil (for over 200 days) are to be examined (Crecchio, Stotzky, 2001)
- Epidemiological elements: The committee underlines the importance of conducting epidemiological studies. It notes that the experience of countries with high consumption of GMO cannot be used to that effect because no studies were conducted with regard to epidemiology, due to lack of traceability.
- Economic elements : the currently available information concerns only the micro-economic dimension (for the farm) and seems to show in France a positive effect on the margin (yield) per hectare, as of infestation levels of 0.3 larvae/stem (for 600,000 to 700,000 hectares of grain corn on average), of about 40 to 110€ per hectare, compared to conventional hybrids. Moreover field experience show advantages in terms of ease of use (later harvest, savings on drying cost). Nevertheless, some important factors of variation (climate, parasites,) make it difficult to analyse at this level. The potential price difference between the GM product and the conventional one has not been taken into account. The economic impact of contamination on the conventional, specific or biological chains were raised, without a solution being found in economic literature. The same goes for the costs incurred by coexistence (isolation, analysis, transport, separation of lots, economical and ecological circumstances) on which studies are currently ongoing. The more global economic effects have not been taken into account because they are not specific to MON 810 but they should be taken into account by the High Authority. In a more general way, the committee notes the insufficient economical analysis at farm level, the food and feed chains and the international market.
- Biovigilance: the committee underlines the importance of a real time, long-term follow-up of the effects of planting on fauna; flora, fungi, the ecosystem, in an overall framework programme of biovigilance.
- Pesticide use : quantitative pesticide reduction linked to the use of MON 810 should be better studied
- Analysis of the economical, sociological and political conditions of coexistence between agriculture, biologicals, conventional, GM and others.

3/ Based on these elements, the committee is of the opinion that:

- The following new facts have arisen since 1998:
 - Characterisation of dissemination over long distances
 - Identification of resistance in certain secondary target insects
 - New elements on the effects on non-target fauna and flora

- Reduction of mycotoxin levels
- Furthermore, the following aspects have to be studied further:
 - Molecular and biochemical characterisation
 - Methodology the toxicological and ecotoxicological studies
 - Epidemiological surveillance tool
 - Biological surveillance tool
 - Economical analysis at farm and food/feed chain levels, taking into account externalities.
- These facts and questions reflect questions regarding the environmental, human health and economical consequences possibly resulting from planting and commercialisation MON 810

The points brought up by the Committee related to safety are also applicable to the transformation products authorised for import into the EU. On the longer term, it will be important to take into account the ecological impact of authorised products for import.