

Parma,  
Ref. BU/JK/EW/YD/AF/SM/shv(2014)

**Subject: Proposal from the GMO Panel for a self-task activity to supplement its previous risk mitigation measures reducing exposure of non-target Lepidoptera to maize MON810, Bt11 or 1507 pollen**

Dear Bernhard,

Over the last three years, EFSA and its GMO Panel issued several scientific outputs on the environmental risk assessment of the genetically modified (GM) maize events (MON810, Bt11 and 1507) for cultivation in the European Union, and recommended the implementation of specific risk mitigation measures to delay resistance evolution in target Lepidoptera and reduce exposure of non-target Lepidoptera that may be at risk through the ingestion of harmful amounts of *Bt*-maize pollen deposited on host-plants in and nearby maize MON810, Bt11 or 1507 fields.

In its continuous striving to screen the scientific literature and other relevant sources, EFSA and its GMO Panel recently identified a new scientific publication that would require the revision of the previous risk mitigation measures that aimed at reducing exposure of non-target Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen.

I, on behalf of the GMO Panel, would therefore like to revise the previous risk mitigation measures for non-target Lepidoptera potentially occurring in European protected habitats. The GMO Panel will deliver a statement supplementing its previous scientific outputs on this topic.


For the completion of this assignment, no interactions with other EFSA Units are foreseen.

The proposed deadline for the adoption of a statement by the GMO Panel is 31 May 2015.

Thank you very much for considering this request.

On behalf of the EFSA GMO Panel.

Yours sincerely,

*and with my very best wishes,  
as ay* 

Prof. Joe Perry  
Chair of the EFSA GMO Panel

**Annex: Proposal from the GMO Panel for a self-task activity to supplement its previous risk mitigation measures to reduce exposure of non-target Lepidoptera to maize MON810, Bt11 or 1507 pollen**

**GMO Unit**

Cc: Juliane Kleiner, Elisabeth Waigmann, Zoltán Divéki, Yann Devos, Fernando Alvarez, Sylvie Mestdagh – EFSA

## Annex

-

### Proposal from the GMO Panel for a self-task activity to supplement its previous risk mitigation measures reducing exposure of non-target Lepidoptera to maize MON810, Bt11 or 1507 pollen

#### I. BACKGROUND

In 2005, the GMO Panel issued positive scientific opinions on both genetically modified (GM) maize 1507 and Bt11 for cultivation in the European Union. In 2009, the GMO Panel gave its positive scientific advice on the renewal of the authorisation for the continued marketing of maize MON 810, including cultivation, subjected to specific recommendations to risk managers (e.g., resistance management of target pests).

Over the last three years, EFSA and its GMO Panel delivered, upon requests of the European Commission and on their own initiative, scientific outputs supplementing the initial environmental risk assessment (ERA) conclusions of these maize events, and, when needed, clarifying the initial set of risk management recommendations. Overall, EFSA and its GMO Panel were aiming at completing a comprehensive and up-to-date ERA of these maize events in the light of the most recent and relevant scientific literature.

The assessment of possible adverse effects that the cultivation of maize MON810, Bt11 or 1507 might have on non-target Lepidoptera constituted a prominent part of the update and led to the development of a mathematical model. The model was designed to simulate and predict potential adverse effects resulting from the exposure of non-target Lepidoptera to pollen from maize MON810, Bt11 or 1507 under representative EU cultivation conditions. Depending on their sensitivity and the amount of ingested pollen, non-target Lepidoptera may be at risk following the ingestion of *Bt*-maize pollen deposited on host-plants in and nearby maize MON810, Bt11 or 1507 fields. To reduce exposure of non-target Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen, the EFSA GMO Panel recommended isolation distances between GM maize fields and protected habitats.

EFSA recently identified a new scientific publication<sup>1</sup> by Hofmann et al. (2014), which provides a comprehensive dataset on the long-distance dispersal of maize pollen. These data are likely to influence the level of exposure of non-target lepidopteran larvae to GM maize pollen deposited on their host-plants nearby maize fields, and hence the outcomes of the modelling exercise.

The GMO Panel is therefore of the opinion that its previous risk mitigation measures to reduce exposure of non-target Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen need to be revised in the light of the recent findings reported by Hofmann et al. (2014).

---

<sup>1</sup> Hofmann F, Otto M and Wosniok W, 2014. Maize pollen deposition in relation to the distance from the nearest pollen source under common cultivation - Results of 10 years of monitoring (2001 - 2010). Environmental Sciences Europe 2014, 26:24 doi:10.1186/s12302-014-0024-3

## **II. PROPOSAL**

To revise the previous risk mitigation measures that aimed at reducing exposure of non-target Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen in the light of recent and relevant scientific literature (e.g., publication by Hofmann et al. (2014)).

## **III. TIMELINE & DELIVERABLE**

The duration of this self-task activity is of five months, so as to ensure proper discussion within the relevant standing Working Group of the GMO Panel.

Starting date: beginning of January 2015

Closure date: end of May 2015

Deliverable: Statement of the GMO Panel

## **IV. TERMS OF REFERENCE**

The GMO Panel, assisted by its standing Working Group on ERA, is requested to revise the risk mitigation measures recommended to reduce exposure of non-target Lepidoptera potentially occurring in European protected habitats to maize MON810, Bt11 or 1507 pollen.