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Mr Xavier Prats-Monné
Director-General
Directorate General for
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European Commission
200, rue de la Loi
B-1049 Brussels

Subject: The European Commission's request for scientific assistance on the publication by Kruse-Plass *et al.* (2017) in relation to the environmental risk assessment of *Bt*-maize MON810, Bt11 and 1507 for cultivation

Dear Mr Prats-Monné,

In the context of your urgent request for scientific assistance on the publication by Kruse-Plass *et al.* (2017)[1] dated 17 March 2017 (Reference: Ares(2017)1436052 – 17/03/2017), I consider it useful to summarise EFSA's work on the potential exposure of non-target (NT) lepidopteran larvae to *Bt*-maize MON810, Bt11 and 1507 pollen deposited on their host plants in or near *Bt*-maize fields conducted by the GMO Panel, and to give you an overview of scientific outputs on these events delivered by EFSA and its Panel, before analysing this new publication. This letter is therefore structured in two parts.

Overview on EFSA's work on quantifying the risk to NT Lepidoptera by Bt-maize MON810, Bt11 and 1507 pollen

The GMO Panel has quantified the risk to NT Lepidoptera associated with the ingestion of *Bt*-maize pollen deposited on their host plants through estimates of larval mortality based on mathematical models developed by Perry *et al.* (2010[2], 2011[3], 2012[4], 2013[5]). Since 2009, EFSA and its GMO Panel have published seven scientific outputs on this topic, either on their own initiative or on request of the European Commission, applying and further refining the model in a stepwise approach, whilst taking into account new information. The main findings of these EFSA outputs are presented in a chronological overview below.

In its 2009 Scientific Opinion[6], the GMO Panel has quantified the risk to NT Lepidoptera for maize MON810 pollen using the Perry *et al.* (2010, 2011) model. The model integrates a relationship between mortality and pollen dose based on laboratory bioassays (dose-mortality relationship), with a relationship between dose and distance from a maize crop based on field measurements (dose-distance relationship). Predictions of mortality were made within a *Bt*-maize field and at

1 http://enveurope.springeropen.com/articles/10.1186/s12302-017-0106-0
2 http://rspb.royalsocietypublishing.org/content/277/1686/1417
3 http://rspb.royalsocietypublishing.org/content/early/2011/01/04/rspb.2010.2667
4 http://onlinelibrary.wiley.com/wol1/doi/10.1111/j.1365-2664.2011.02083.x/abstract
5 http://www.sciencedirect.com/science/article/pii/S0304380013003979
6 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.1149/epdf

various distances from it. The model structure distinguishes between parameters relating to worst-case local exposure at small spatial and temporal scales to large-scale effects. The model generated realistic data for three widespread European species (*Vanessa atalanta*, *Inachis io* and *Plutella xylostella*) in 11 representative maize ecosystems in four European countries.

Based on the model predictions, the GMO Panel advised risk managers to mitigate the possible exposure of NT Lepidoptera to maize MON810 pollen, e.g., by planting border rows of conventional maize around maize MON810 fields, especially in areas of high abundance of NT lepidopteran populations.

In its 2011 Scientific Opinion[7], the GMO Panel recalibrated the aforementioned model on its own initiative, in order to simulate and assess potential adverse effects resulting from the exposure of NT Lepidoptera to maize 1507 pollen under representative EU cultivation conditions, and extended it to estimate the efficacy of certain risk mitigation measures (Perry *et al.*, 2012). The initial model was extended to: (i) differentiate between small-scale, local, worst-case mortality and global mortality allowing for exposure; (ii) allow for the between-species variability in lepidopteran sensitivity to *Bt*-proteins; (iii) assess the efficacy of various mitigation measures for risk management; and (iv) study different host-plant densities in crops and field margins (see also Perry *et al.*, 2013). A similar exercise was conducted for maize MON810/Bt11 upon request of the European Commission[8].

The GMO Panel concluded that certain lepidopteran species (i.e., those in the 'very highly' to 'extremely' sensitive categories) can be at risk when ingesting a certain amount of *Bt*-maize pollen, whilst emphasising that no actual species had yet been recorded with that degree of sensitivity and that the species at risk were therefore hypothetical. Despite this, the GMO Panel took this worst-case approach to ensure inclusion of all potential species sensitivities within the modelling exercise, in order to study the possible implications for all lepidopteran species of exposure to *Bt*-maize pollen.

Moreover, the GMO Panel recommended risk managers to implement isolation distances between the protected habitats, where sensitive NT Lepidoptera can be found, and the nearest *Bt*-maize field (i.e., 20 and 30 meters for maize MON810/Bt11 and 1507, respectively).

In its 2012 Scientific Opinions on MON810/Bt11[9] and 1507[10], following a request of the European Commission, the GMO Panel re-applied the Perry *et al.* (2012) model to consider additional hypothetical agricultural conditions for maize MON810, Bt11 and 1507. Previous risk mitigation recommendations remained unchanged.

In its 2015 Scientific Opinion[11], the GMO Panel refined its model predictions, accounting for new information on maize pollen deposition over long distances reported by Hofmann *et al.* (2014)[12]. An analysis of various sources of uncertainties affecting the exposure of NT Lepidoptera to *Bt*-maize pollen was conducted, in order to provide updated quantitative estimates of exposure levels. For the calculation of those estimates, EFSA considered three exposure scenarios at a range of isolation distances (i.e., a 'direct comparison' scenario, a 'most realistic' scenario and a 'conservative' scenario), at two protection levels and for a range of lepidopteran species, including hypothetical ones, with a wide spectrum of

7 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2429/epdf
8 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2478/epdf
9 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.3016/epdf
10 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2934/epdf
11 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4127/epdf
12 https://enveurope.springeropen.com/articles/10.1186/s12302-014-0024-3

sensitivities to *Bt*-proteins, to allow risk managers to select appropriate risk management measures.

The GMO Panel concluded that its previous recommendation for a 20 meters isolation distance around protected habitats, within which maize MON810/Bt11 should not be cultivated, remains valid for species of all sensitivity levels, including notional ones. New calculations showed that the previously recommended isolation distance of 30 meters from the nearest maize 1507 field would still protect all NT Lepidoptera with known levels of sensitivity, up to and including that of the 'highly sensitive' pest species *P. xylostella*. Should hypothetical species with greater sensitivities exist, larger isolation distances would be needed to ensure the desired level of protection.

In a 2016 Technical Report[13], EFSA considered the implications of new relevant scientific publications by Hofmann *et al.* (2016)[14] and Lang *et al.* (2015)[15] on the environmental risk assessment conclusions and risk management recommendations previously made by the GMO Panel. EFSA considered that the Lang *et al.* (2015) publication provides confirmation of the robustness of exposure factors previously estimated by the GMO Panel, and gives reassurance that the 'most realistic' scenario is a reliable basis for risk management recommendations based on the sensitivities of the notional species modelled. Since there were no data, either in Lang *et al.* (2015) or Hofmann *et al.* (2016), that indicated the necessity to revise the previous environmental risk assessment conclusions and risk management recommendations on maize MON810, Bt11 and 1507 for cultivation, EFSA concluded that the previous GMO Panel risk assessment conclusions and risk management recommendations remain valid and applicable.

Analysis of the publication by Kruse-Plass et al. (2017)[16] in relation to EFSA's work on quantifying the risk to NT Lepidoptera by Bt-maize MON810, Bt11 and 1507 pollen

In their recent publication, Kruse-Plass *et al.* (2017) commented EFSA's 2016 Technical Report[17] and former GMO Panel Scientific Opinions. The authors raise a number of arguments in relation to the Perry *et al.* (2010, 2012) models and the use of their data by EFSA and its GMO Panel.

EFSA notes that the Kruse-Plass *et al.* (2017) publication is a commentary that presents no new data of which EFSA and its GMO Panel are unaware, and that the data reported by Kruse-Plass *et al.* (2017) have been previously presented in Hofmann *et al.* (2014, 2016). These previously reported data have already been assessed by EFSA and its GMO Panel[18,19], in line with EFSA's commitment to continuously review all available scientific information.

The approach for quantifying the risk to NT Lepidoptera followed by EFSA and its GMO Panel has been to estimate larval mortality for different exposure scenarios of which the 'most realistic scenario' represents actual exposure of a NT lepidopteran larva to *Bt*-proteins contained in that maize pollen, as this scenario has integrated an analysis of the various sources of uncertainty affecting exposure. Hofmann *et al.* (2014, 2016) and Kruse-Plass *et al.* (2017) focused largely on the density of pollen grains *per se*, without allowing for reduction of exposure. Although the authors have attempted to estimate the ratio between pollen dispersal and deposition on host plants, EFSA and its GMO Panel did not consider these estimates sufficiently

[13] http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1070/pdf
[14] https://enveurope.springeropen.com/articles/10.1186/s12302-016-0082-9
[15] http://www.sciencedirect.com/science/article/pii/S0006320715301300
[16] http://enveurope.springeropen.com/articles/10.1186/s12302-017-0106-0
[17] http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1070/pdf
[18] http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4127.pdf
[19] http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1070/pdf

robust for several reasons outlined in their former scientific outputs. In addition, EFSA is of the opinion that it was correct to state in its 2016 Technical Report that the Lang *et al.* (2015) data provided support for the implementation of the 'most realistic' scenario referred to above.

Within the frame of this analysis, EFSA has not identified an argument raised by Kruse-Plass *et al.* (2017) that would invalidate EFSA's approach, including derived risk management recommendations made previously by its GMO Panel.

In summary, I consider that EFSA and its GMO Panel, through their substantial and continued contribution, have strived to maintain scientific rigour in the quantification of the risk to NT Lepidoptera, and consistently provided risk managers with the most up-to-date scientific advice accounting for new relevant scientific publications and developments in the field, and remaining scientific uncertainties.

Please do not hesitate to contact me if you desire further clarifications. I remain available for any further enquiry you may have on this matter.

Yours sincerely,

Bernhard Url

Cc: Mr L. Miko, Mr T. Brégeon, Ms S. Jülicher, Ms B. Benault, Mr L. Terzi, Ms C. Bruetschy, Ms M. Kammenou, Ms A. Pagida – EC
Mr G. De Seze, Ms E. Waigmann, Mr Y. Devos, Mr F. Alvarez – EFSA