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Relevance of a new scientific publication (Hofmann et al., 2016) for previous environmental risk assessment conclusions and risk management recommendations on the cultivation of *Bt*-maize events MON810, Bt11 and 1507

European Food Safety Authority

Abstract

Following a request from the European Commission, the European Food Safety Authority (EFSA) assessed the relevance of the Hofmann et al. (2016) publication for the environmental risk assessment and risk management of the *Bt*-maize events MON810, Bt11 and 1507 for cultivation. Hofmann et al. (2016) reported data on pollen deposition on maize and weed species in maize fields obtained from a 3 year study in Germany. Data on pollen deposition on host plant leaves in relation to distance from the nearest maize field are informative, as they can be used to develop mathematical models applied to estimate the risk to non-target Lepidoptera associated with the ingestion of *Bt*-maize pollen deposited on their host plants. EFSA considers that there are no data in Hofmann et al. (2016) that indicate the necessity to revise the previous environmental risk assessment conclusions and risk management recommendations for *Bt*-maize made in EFSA (2015). EFSA is of the opinion that the publication provides new data that confirm the robustness of exposure factors estimated by EFSA (2015), and give reassurance that the 'Most Realistic' scenario proposed by EFSA (2015) is a reliable basis for risk management recommendations based on the sensitivities of the notional species modelled. Therefore, EFSA considers that the previous risk assessment conclusions and risk management recommendations on maize MON810, Bt11 and 1507 for cultivation made by the Panel on Genetically Modified Organisms remain valid and applicable.

Key words: *Bt*-maize, butterflies and moths, environmental risk assessment, host plants, non-target Lepidoptera, pollen deposition

Requestor: The European Commission

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Summary

Following a request of the European Commission, the European Food Safety Authority (EFSA) assessed the scientific publication by Hofmann et al. (2016) and its relevance for the environmental risk assessment (ERA) and management of *Bt*-maize events MON810, Bt11 and 1507 for cultivation. EFSA assessed whether the publication contains new information that would change or invalidate its previous risk management recommendations on limiting the exposure of non-target (NT) Lepidoptera of conservation concern, potentially occurring in protected habitats, as defined under Directive 2004/35/EC, to maize MON810, Bt11 and 1507 pollen.

In their publication, Hofmann et al. (2016) reported concentrations of maize pollen deposited on leaves of host plants (maize, nettle, goosefoot, sorrel and blackberry) of NT Lepidoptera measured in and at the edges of maize fields between 2009-2012 in Germany. The authors concluded that "*daily means and variation of single values ... are considerably higher than previously assumed*", and thus "*underestimated*" by European risk assessors. Hofmann et al. (2016) therefore recommended isolation distances "*in the kilometre range ... rather than the 20-30 m distance*" as suggested by EFSA (2015) under common cultivation conditions of *Bt*-maize.

Data on pollen deposition on host plant leaves in relation to distance from the nearest maize field are informative. When gathered and presented appropriately, these data may be used to develop mathematical models applied to estimate the risk to NT Lepidoptera associated with the ingestion of *Bt*-maize pollen deposited on their host plants. In particular, such data enable tests of the assumptions made in EFSA (2015), upon which recommendations for risk management were based.

Hofmann et al. (2016) reported no data on pollen deposition outside maize fields; in particular, no data are presented that would enable verification of pollen deposition assumptions on host plants found in protected habitats. Further, two technical issues invalidate the applicability of the Hofmann et al. (2016) data to ERA and risk management. The first concerns the method adopted by Hofmann et al. (2016) for estimating the density of pollen on individual leaves. The second concerns the method used by Hofmann et al. (2016) to standardise all the data from within the crop and at field edges relative to the same distance from the pollen source. The conclusions that may be drawn from Hofmann et al. (2016) are therefore very limited. However, EFSA notes that the order of magnitude of the mean within-crop accumulated pollen deposition on nettle leaves and the mean within-crop accumulated pollen deposition in mechanical samplers, and the ratio between them are not inconsistent with the corresponding values in EFSA (2015) and with data reported by Lang et al. (2015).

Regarding the order of magnitude of the mean pollen deposition on nettle leaves reported by Hofmann et al. (2016), the publication does not contain any data to warrant reassessment of values reported in the review by Perry et al. (2013) and used as the basis for assumptions in the 'Most Realistic' (MR) scenario of EFSA (2015).

In conclusion, there are no data in Hofmann et al. (2016) that indicate the necessity to revise the previous ERA conclusions and risk management recommendations for *Bt*-maize made in EFSA (2015). The data presented in Hoffmann et al. (2016) provide confirmation of the robustness of exposure factors estimated by EFSA (2015), and give reassurance that the MR scenario in EFSA (2015) is a reliable basis for risk management recommendations based on the sensitivities of the notional species modelled. Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on maize MON810, Bt11 and 1507 for cultivation remain valid and applicable.

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1. Introduction

Following a request of the European Commission, the European Food Safety Authority (EFSA) assessed the publication by Hofmann et al. (2016) and its relevance for the environmental risk assessment (ERA) and management of *Bt*-maize events MON810, Bt11 and 1507 for cultivation. EFSA assessed whether the publication contains new information that would change or invalidate its previous risk management recommendations on limiting the exposure of non-target (NT) Lepidoptera of conservation concern potentially occurring in protected habitats, as defined under Directive 2004/35/EC, to maize MON810, Bt11 and 1507 pollen.

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Since 2009, the EFSA Panel on Genetically Modified Organisms (referred to hereafter as 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 (EFSA, 2009, 2011a,b, 2012a,b, 2015) based on mathematical models developed by Perry et al. (2010, 2011, 2012, 2013). Based on these model predictions, the GMO Panel provided risk managers with a set of risk mitigation measures (e.g., non-*Bt*-maize border rows around a *Bt*-maize crop, isolation distances from protected habitats to nearest *Bt*-maize field) to limit the exposure of NT lepidopteran larvae to *Bt*-maize pollen.

Following new information reported by Hofmann et al. (2014) concerning pollen deposition measured in mechanical, standardised passive, samplers, the GMO Panel assessed the consequences for its previous risk assessment conclusions and risk management recommendations for *Bt*-maize (EFSA, 2015). In particular, isolation distances to protected habitats were reviewed. For NT lepidopteran larvae of conservation concern potentially occurring in protected habitats, isolation distances of 20 m and 30 m were recommended between protected habitats and the nearest fields of maize MON810/Bt11 and 1507, respectively. The GMO Panel concluded that its previous recommendation for a 20 m isolation distance around protected habitats, within which maize MON810/Bt11 should not be cultivated, remains valid. New calculations showed that the previously recommended isolation distance of 30 m 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 *Plutella xylostella*. Should hypothetical species with greater sensitivities exist, larger isolation distances would be needed to ensure the desired level of protection.

Following the publication of EFSA (2015), two further scientific publications have presented new data relevant to this issue: Lang et al. (2015) and Hofmann et al. (2016). Data on pollen deposition on host plant leaves in relation to distance from the nearest maize field are informative, as they may be used to develop mathematical models applied to estimate the risk to NT Lepidoptera associated with the ingestion of *Bt*-maize pollen deposited on their host plants. In particular, such data enable tests of the assumptions made in EFSA (2015), upon which recommendations for risk management were based. This Technical Report examines the consequences of the findings reported in these two publications for the previous GMO Panel risk management recommendations.

1.1.2. Terms of Reference as provided by the requestor

EFSA is requested to analyse the publication by Hofmann et al. (2016) and to provide the European Commission with a response indicating whether "*the new scientific information contains elements that could lead the GMO Panel to reconsider the outcome of its previous opinions on GM Bt crops*".

2. Data and Methodologies

2.1. Data

In delivering this technical report, EFSA took into account data and findings reported in the publication by Hofmann et al. (2016).

2.2. Methodologies

EFSA took into account the appropriate principles described in the guidelines of the GMO Panel for the ERA of GM plants (EFSA, 2010), and relevant scientific publications (i.e., Perry et al., 2010, 2011, 2012, 2013; EFSA, 2015; Lang et al., 2015).

3. Assessment

The EFSA assessment described below is structured into two parts. In the first part of the assessment, the EFSA Scientific Opinion updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to *Bt*-maize pollen (EFSA, 2015) is described, followed by a summary of the findings of the two scientific publications that have presented new data relevant to this issue (i.e., Lang et al., 2015 and Hofmann et al., 2016). In the second part, the relevance of these publications for the ERA and risk management of maize MON810, Bt11 and 1507 is considered.

3.1. Summary of recent relevant scientific publications

3.1.1. EFSA (2015)

Scientific background

Maize is not an important resource of food for indigenous Lepidoptera with the exception of few pest species; therefore, exposure to potentially harmful amounts of pollen deposited on host plants in or near *Bt*-maize fields is expected to be the main hazard to the larvae of non-target Lepidoptera feeding on these host plants during maize pollen dehiscence (EFSA, 2011a). The estimated risk of NT lepidopteran larval mortality due to ingestion of *Bt*-maize pollen depends, *inter alia*, on three quantities: the toxicity of the *Bt*-maize pollen; the sensitivity of the lepidopteran species and its life stage concerned; and exposure (the dose ingested).

Regarding toxicity, the GMO Panel (EFSA, 2011b) considers that the biological activity of the Cry1Ab protein variants of maize Bt11 and MON810 against sensitive lepidopteran species is similar. Mortality estimates for maize MON810 apply equally to maize Bt11 (EFSA, 2015). The content of the Cry1F protein in maize 1507 pollen was estimated to be 32 ng/mg dry weight (EFSA, 2011a), which is about 350 times higher than the Cry1Ab protein content in maize MON810 pollen. It is well-documented that larvae of a range of Lepidoptera can be affected by Cry1F protein with a spectrum of sensitivity which is quantitatively considerably greater than Cry1Ab protein (EFSA, 2011a). Sensitivity is estimated through bioassay data which yield an LC_{50} value for the mortality-dose relationship; these data are variable and therefore the determination of LC_{50} values and sensitivities are subject to uncertainty, which may be quantified through confidence limits. Furthermore, there are few datasets available for estimating the sensitivity of Lepidoptera for most assessed *Bt*-maize events, and almost all of those available were obtained using pest species (EFSA, 2011a). For maize 1507, none of the 16 studied species has been identified as being more sensitive than the pest species *P. xylostella* (at just less than the 6^{th} percentile of the estimated sensitivity distribution, see Wolt et al. (2005) and Table 2 in EFSA, 2011a).

According to the available literature, the dose potentially ingested by larvae is assumed to be linearly related to the number of pollen grains present per unit area of leaves of their host plant. Previous risk management recommendations (EFSA, 2009, 2011a,b, 2012a,b) have focussed on the nettle (*Urtica dioica*) since it is the host plant of some iconic species of butterflies such as the Peacock (*Inachis io*) and the Red Admiral (*Vanessa atalanta*).

It is generally agreed that pollen deposition declines with increasing distance from the nearest pollen source, but proposed relationships governing this decline differ (see review by Perry et al., 2013). In particular, for the GMO Panel Scientific Opinions published prior to 2014 (EFSA, 2009, 2011a,b, 2012a,b) the assumed dose of pollen on host plants within the *Bt*-maize source crop was almost seven times greater than that assumed under the relationship for mechanical samplers published by Hofmann et al. (2014). Furthermore, outside the source crop, the assumed dose was greater than that assumed by Hofmann et al. (2014) up to 9 m from the crop edge. In contrast, beyond 9 m from the edge of the crop, and in particular at distances greater than 30 m, the dose assumed by Hofmann et al. (2014) was much larger than that assumed in GMO Panel Scientific Opinions. Since within and close to the *Bt*-maize field the estimates of mortality made by the GMO Panel (EFSA, 2009, 2011a,b, 2012a,b) exceed those that would be derived assuming the Hofmann et al. (2014) relationship, there was no need to revise the consequences for the previous EFSA risk assessment conclusions and risk management recommendations for *Bt*-maize for NT larvae within the field and its margins. Therefore, EFSA (2015) focussed on the isolation distances previously recommended by the GMO Panel to reduce exposure of sensitive NT lepidopteran larvae of conservation concern potentially occurring in protected habitats, further than 10 m from the nearest maize field and often in remote areas relatively far from the nearest source of maize pollen.

The most important gap in the information in Hofmann et al. (2014) is that there are no data to enable any calibration between pollen density measured by the mechanical sampler and the pollen density per cm^2 leaf surface as encountered on a host plant by a NT lepidopteran larva at the same spatial location. Regarding exposure, the data published in Hofmann et al. (2014) recorded the distance to the nearest maize crop, but gave no information regarding the number of maize fields in the area contributing to pollen deposition, or their location, or maize variety. In addition, no information was available on the freshness of the pollen recorded or wind directions.

The dose-distance relationship, derived by Hofmann et al. (2014) from regression on logarithmic scales, should have been based on their data from samplers placed at distances from the nearest maize crop ranging from 0.8 m to 4.4 km. However, Hofmann et al. (2014) also included samples taken from within the crop which, in the context of their regression analysis, were assigned, a negative value as distance from the crop edge. Consequently, because logarithms of negative numbers do not exist, such data cannot validly be used to contribute towards the calculation of the regression relationship on logarithmic scales. Hofmann et al. (2014) wrongly included these within-crop data in their regression calculations. EFSA (2015) did not highlight this limitation, because for protected habitats, at distances of the order of more than tens of metres from a maize field, the inclusion or exclusion of a few data points from within the maize crop would make little difference to the relationship derived. However, it must be emphasised that in the Hofmann et al. (2014) publication there is no valid published information concerning the relationship between pollen deposition and distance from within the *Bt*-maize crop or at any distance up to 0.8 m from the edge of the crop. This issue is returned to below, as it has relevance for the interpretation of data in Hofmann et al. (2016).

Scientific Opinion

In EFSA (2015), the GMO Panel ran new simulations with exactly the same *Bt*-related mortality model as used by Perry et al. (2010, 2011, 2012, 2013), but assuming the dose-distance relationship defined by Hofmann et al. (2014). These were termed the 'Direct Comparison' (DC) scenario. This scenario is unrealistic because it takes no account of other factors associated with exposure.

The pollen density on the surface of the leaf of a host plant available for potential ingestion by a NT lepidopteran larva will in general be considerably less than that measured in a mechanical sampler at the same distance from the source field because of a range of exposure factors. An uncertainty analysis identified eight exposure factors that need to be accounted for in deriving estimates of actual exposure from data derived from mechanical samplers: (1) the proportion of total recorded pollen from *Bt*-maize, dependent on the mixture of GM and non-GM maize fields in the landscape, as well as on the ratio of non-*Bt*-maize to *Bt*-maize plants within fields; (2) the effect of the three-dimensional structure of leaves compared to the flat surface of a mechanical sampler; (3) the effect of wind and rain removing pollen from leaves; (4) the displacement and accumulation of pollen on areas such as leaf veins and axils, affecting ingestion; (5) the loss of pollen due to consumption of pollen by non-lepidopteran species unaffected by *Bt*-protein; (6) the degradation of the *Bt*-protein in pollen; (7) the effect of potential changes in feeding behaviour of NT lepidopteran larvae; (8) the potential lack of temporal coincidence between the sensitive larval development stage under consideration and maize pollen deposition. The GMO Panel employed an expert elicitation process to estimate the magnitude of the proportional impact of each of these exposure factors. These values were multiplied together and the product (0.0396) was used as a multiplicative factor to adjust the Hofmann et al. (2014) recorded dose to a value that reflected more realistic levels of exposure. These new simulations (as above, but with doses reduced to 0.0396 of the Hofmann et al. (2014) values) were termed the 'Most Realistic' (MR) scenario.

A further set of simulations were run, termed the 'Conservative' (CO) scenario, obtained by multiplying doses in the MR scenario by 9.0, to study *Bt*-related mortality for the 2.5 % of occasions when the dose as measured in the mechanical samplers was at the upper 95 % confidence interval. However, the GMO Panel emphasised that "*caution is required in the interpretation of this CO scenario, because for every site-occasion for which exposure is nine-fold higher than the expected value, there will be a site-occasion for which exposure is nine-fold lower than expected, and that the overall average exposure remains as in scenario MR, above*". Indeed, the GMO Panel has always taken a deterministic approach, basing their recommendations on estimates of mortality averaged over populations of NT Lepidoptera with appropriate exposure, as in the MR scenario.

The GMO Panel (EFSA, 2015) recommendations for risk management based on the MR scenario are as follows: "*The GMO Panel concluded that the new information provided by Hofmann et al. (2014) does not impact greatly on the Bt-related mortality estimates for NT Lepidoptera of conservation concern, occurring within protected habitats and potentially exposed to maize MON810/Bt11 pollen. Under the MR scenario, the estimated mortality for all species considered is always less than 0.5 % for the previously recommended isolation distance of 20 m. Therefore, the previous GMO Panel recommendation for isolation distances around protected habitats, within which maize MON810/Bt11 should not be cultivated, remains valid*".

Under the MR scenario, the "*new calculations show that the previously recommended isolation distance of 30 m from the nearest field of maize 1507 would still protect NT Lepidoptera with known levels of sensitivity, including the most sensitive species yet recorded, P. xylostella. However, should hypothetical species with greater sensitivities exist, larger isolation distances would be needed to ensure the desired level of protection*". Purely as an example, from Table 5 of EFSA (2015), for hypothetical species up to 10 times more sensitive than *P. xylostella*, the previously recommended isolation distance of 30 m would ensure an estimated percentage mortality of less than 1 %. For hypothetical NT species 25 times more sensitive than *P. xylostella*, an isolation distance of 200 m would be required to ensure an estimated percentage mortality of less than 1 %. In EFSA (2015), risk managers were provided with a tool to estimate and mitigate the risk for NT Lepidoptera of conservation concern, at a range of isolation distances, at two protection levels and for a range of lepidopteran species with a wide spectrum of sensitivities to *Bt*-proteins, including hypothetical species not yet assessed. The aim was to allow risk managers to select the most appropriate risk management measures (i.e., isolation distances) that are proportionate to the level of risk identified according to appropriate protection goals.

3.1.2. Lang et al. (2015)

Lang et al. (2015) investigated the butterfly community of protected habitats and their potential exposure to possible cultivation of *Bt*-maize in a heterogeneous, agricultural landscape in Switzerland. They recorded densities of maize pollen deposited on nettles (*U. dioica*), simulated the effect of different pollen dispersal ranges and *Bt*-maize adoption rates on the exposure of protected habitats, and explored the consequences of different buffer zones around protected habitats.

On average, the 49 recorded butterfly species showed a temporal overlap of 50±30 % of their larval stage with the maize pollen shedding period. Mean maize pollen density on nettles was 6.5±13.6 pollen grains/cm^2 (range: 0–100). Most of the pollen was deposited close to maize fields at distances less than 30 m away, but pollen also drifted onto host plants as far as 500 m away. The authors argued that maize pollen may be distributed over large distances of the order of kilometres, and performed simulations in which exposure to *Bt*-maize pollen deposition occurred within protected habitats at various adoption rates of *Bt*-maize.

Based on these results and the known sensitivities of lepidopteran larvae to *Bt*-proteins, the authors concluded that isolation distances of at least 50–100 m, or more in specific cases, would be required around protected habitats to minimise the conflict between species conservation and *Bt*-maize cultivation.

3.1.3. Hofmann et al. (2016)

Hofmann et al. (2016) reported concentrations of maize pollen deposited on host plant leaves of NT Lepidoptera (maize, nettle, goosefoot, sorrel and blackberry) measured under field conditions, within maize crops and at crop edges, between 2009-2012 in Germany. The plant-specific pollen deposition data were supplemented by standardised measurements of pollen release rates, and deposition obtained by volumetric pollen monitors and passive samplers.

The daily leaf deposition value (=mean value of observed pollen density on a leaf surface for a given day, averaged over measurements from one day per site) was 2,710 pollen grains/cm^2 for maize and 1,665 pollen grains/cm^2 for nettle. The maximum single leaf-deposition values were 103,000 pollen grains/cm^2 on maize and 13,802 pollen grains/cm^2 on nettle. The mean of pollen deposition onto leaves over all sites and days (during the flowering period) ranged from 54 to 478 pollen grains/cm^2 depending on plant species and site.

The authors concluded that "*daily means and variation of single values ... are considerably higher than previously assumed*", and thus "*underestimated*" by European risk assessors. Hofmann et al. therefore recommended isolation distances "*in the kilometre range ... rather than the 20-30 m distance*" as suggested by EFSA (2015) under common cultivation conditions of *Bt*-maize.

3.2. Relevance of Lang et al. (2015) and Hofmann et al. (2016) for the ERA conclusion and risk management recommendations on *Bt*-maize events MON810, Bt11 and 1507 for cultivation

3.2.1. Lang et al. (2015)

Lang et al. (2015) measured actual pollen density on nettle leaves at various distances from a source maize field. Their data enabled the GMO Panel to test some of the assumptions regarding the second and third exposure factors in EFSA (2015), namely the effect of 3-D structure of leaves and the effect of wind and rain removing pollen. The estimated values for these factors (see Table 2 and Appendix A of EFSA, 2015) were, respectively, 0.61 and 0.65, so their product is 0.396. Under the EFSA (2015) DC scenario, the Lang et al. (2015) data would be expected to follow the Hofmann et al. (2014) dose-distance relationship. Under the EFSA (2015) MR scenario, the Lang et al. (2015) data would be expected to follow the Hofmann et al. (2014) dose-distance relationship, reduced by this multiplicative factor of 0.396.

Although the raw data of Lang et al. (2015) were not published, it is possible to digitise the data from their Figure 3 relating maize pollen on nettle leaves to distance from the nearest maize crop, so that it can be placed on comparable logarithmic scales to the Hofmann et al. (2014) data. Figure 1, below, shows the relationship for the data of Lang et al. (2015) between dose, d, in units of pollen grains/cm^2, and distance, E, in units of metres from the edge of the nearest maize crop. For these data, linear regression (line AB) yields the following relationship:

$$\log_{10} d = 1.27 - 0.763 \log_{10} E$$

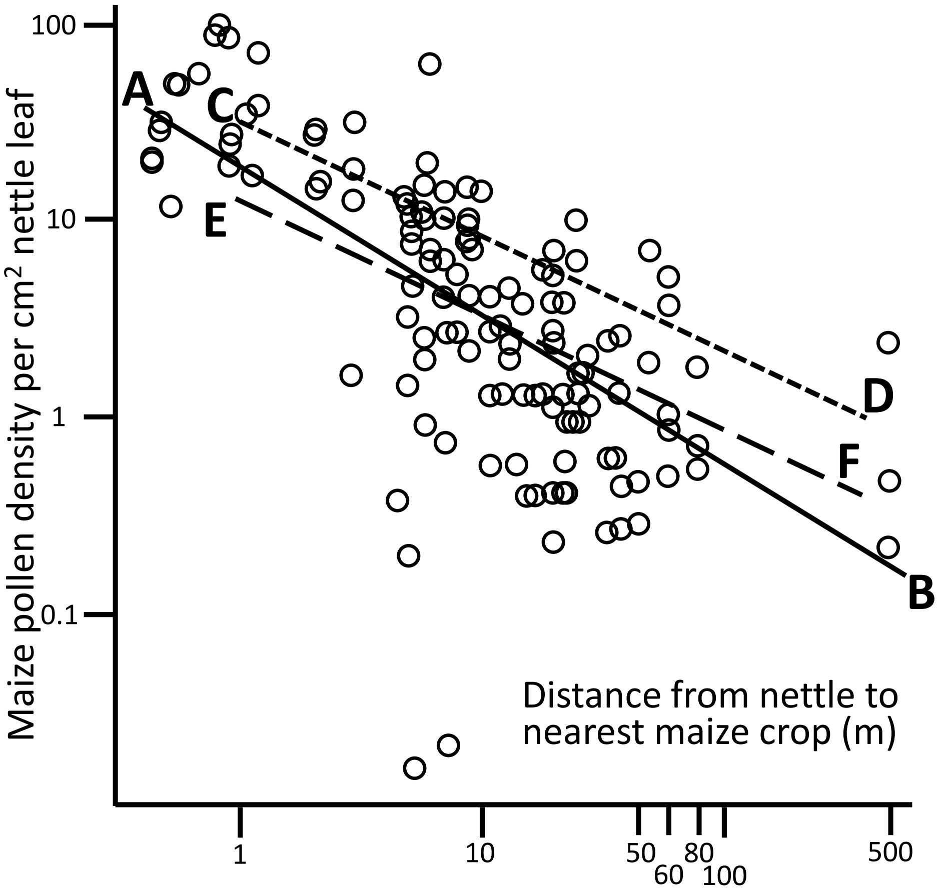
The Hofmann et al. (2014) dose-distance relationship (line CD), as in the EFSA (2015) DC scenario is:

$$\log_{10} d = 1.502 - 0.585 \log_{10} E$$

The EFSA (2015) MR scenario dose-distance relationship (line EF) is:

$$\log_{10} d = 1.100 - 0.585 \log_{10} E$$

Clearly, the line AB shows an adequate fit to these variable data. By contrast, the Lang et al. (2015) data confirm that the Hofmann et al. (2014) dose-distance relationship overestimates pollen deposition, that all exposure factors should be accounted for, and therefore that the EFSA (2015) DC scenario is unrealistic. The line EF is fairly close to the regression line AB, and provides a good approximation to the data, thus confirming the robustness of the two exposure factors estimated by EFSA (2015). This provides reassurance that estimates from the EFSA (2015) MR scenario are a reliable basis for risk management recommendations based on the sensitivities of the notional species modelled.



Maize pollen densities per cm^2 of nettle leaf area with increasing distance from the nearest maize crop

Figure 1: Digitised data from Figure 3 of Lang et al. (2015) relating dose of pollen counted per cm^2 of nettle leaf to the distance of the nettle plant from the edge of the nearest maize crop. Data plotted on double logarithmic axes to match scaling adopted by Hofmann et al. (2014). Lines shown on figure are AB: regression line of best fit; CD: dose-distance relationship of Hofmann et al. (2014) as used in scenario DC of EFSA (2015); EF: dose-distance relationship of Hofmann et al. (2014) reduced by multiplicative product, 0.396, of two exposure factors estimated in EFSA (2015), corresponding to scenario MR.

3.2.2. Hofmann et al. (2016)

Hofmann et al. (2016) measured actual pollen density on the leaves of plants of various species, including nettles, within maize crops and at field edges. Unlike Lang et al. (2015), no data were presented that would enable verification of pollen deposition assumptions on host plants in protected habitats, outside maize fields.

Two aspects of the data in Hofmann et al. (2016) invalidate their applicability to ERA and risk management. Most seriously, the method for estimating the density of pollen on individual leaves does not employ random sampling, but is designed to deliberately include areas of high pollen density on leaves, resulting in statistically biased, overestimates of pollen deposition. Hofmann et al. (2011) found that their chosen method gave estimates that were on average over two times greater than the true mean. Secondly, all the data from within the *Bt*-maize crop and at crop edges were standardised to relate to the same distance from the pollen source. The relationship used for the standardisation was the Hofmann et al. (2014) dose-distance relationship for distances from 0.8 m to 4.45 km, but, as explained in Section 3.1.2, above, this cannot be used for data within the maize crop and at crop edges. Hence, all data have been standardised, involving potential multiplication or division by five-fold or more, using a relationship with no evidential basis for the data on which it is used. The standardisation is unnecessary; information should be given which facilitates identification of the relationship between pollen deposition dose and distance, as in Perry et al. (2013), Hofmann et al.

(2014) and Lang et al. (2015). EFSA notes that recorded pollen deposition within the crop may be very sensitive to the height of the mechanical samplers relative to the maize plant parts within the canopy. Further information would be required to resolve this source of uncertainty.

The conclusions that may be drawn from Hofmann et al. (2016) are therefore very limited. However, EFSA notes that the order of magnitude of the mean within-crop accumulated pollen deposition on nettle leaves and the mean within-crop accumulated pollen deposition in mechanical samplers, and the ratio between them are not inconsistent with the corresponding values in EFSA (2015) and with data reported by Lang et al. (2015).

Regarding the order of magnitude of the mean pollen deposition on nettle leaves reported by both Lang et al. (2015) and Hofmann et al. (2016), neither publication contains any data to warrant reassessment of values reported in the review by Perry et al. (2013) and used as the basis for assumptions in the MR scenario of EFSA (2015).

4. Conclusions

There are no data either in Lang et al. (2015) or Hofmann et al. (2016) that indicate the necessity to revise the previous ERA conclusions and risk management recommendations for *Bt*-maize made in EFSA (2015). Both publications provide confirmation of the robustness of exposure factors estimated by EFSA (2015), and give reassurance that the EFSA (2015) MR scenario is a reliable basis for risk management recommendations based on the sensitivities of the notional species modelled. Therefore, EFSA considers that the previous GMO Panel risk assessment conclusions and risk management recommendations on maize MON810, Bt11 and 1507 for cultivation remain valid and applicable.

Documentation provided to EFSA

1. Letter from the European Commission, dated 1 June 2016, to the EFSA Executive Director requesting scientific assistance on new scientific information (Hofmann et al., 2016) in relation to their risk assessment of genetically modified *Bt*-crops.

2. Acknowledgement letter, dated 1 July 2016, from the EFSA Executive Director to the European Commission.

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