SCIENTIFIC OPINION

Statement supplementing the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize Bt11 for cultivation[1]

EFSA Panel on Genetically Modified Organisms (GMO)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

This Statement, published on 24th February 2012, replaces the earlier version published on 8th December 2011.[4]

Abstract

In this Statement, the EFSA GMO Panel supplements its previous evaluations of the potential impact of maize Bt11 cultivation on a range of non-target lepidopteran species using existing data on species sensitivity and considering various scenarios of exposure which may occur across Europe. The mathematical model, initially developed for maize MON 810 and recently recalibrated for maize 1507, was used to estimate the efficacy of risk mitigation measures. In situations where 'extremely sensitive' non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that risk mitigation measures are adopted to reduce exposure. Risk managers are provided with tools to estimate global and, where needed local, mortality of exposed non-target Lepidoptera, both before and after different risk mitigation measures are put in place, and for different host-plant densities. Risk mitigation measures are only needed when the proportion of maize and uptake of maize Bt11 (and/or maize MON 810) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area, then risk mitigation measures are not required. In addition, the EFSA GMO Panel recommends that appropriate insect resistance management (IRM) strategies for maize Bt11, which should be integrated with those of other Cry1Ab-expressing maize events currently grown commercially in the EU, are implemented in order to delay the possible resistance evolution to the Cry1Ab protein in target pests. The EFSA GMO Panel also considers that post-market environmental monitoring and IRM need to be revised. The EFSA GMO Panel concludes that, subject to appropriate management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize. The EFSA GMO Panel considers that the conclusions on the risk to non-target Lepidoptera from maize Bt11 apply equally to maize MON 810.

[1] On request from the European Commission, Question No EFSA-Q-2011-00005, adopted on 30 November 2011.

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[4] Editorial changes have been made on pages 1, 4, 17, 29 and 38. These changes do not affect the overall conclusions of this Statement. To avoid confusion the original version has been removed from the website.

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KEY WORDS

GMO, maize (*Zea mays*), Bt11, Cry1Ab, insect resistance, non-target organisms, Lepidoptera, environmental safety, post-market environmental monitoring, mathematical modelling

SUMMARY

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) was asked to further analyse some aspects of the environmental risk assessment (ERA) of genetically modified (GM) maize event Bt11 in light of the scientific data and methodology currently available and to clarify its previous recommendations to risk managers. In addition, the EFSA GMO Panel was asked to reconsider the plan for post-market environmental monitoring (PMEM) of maize Bt11 in light of its 2011 Scientific Opinion providing guidance on PMEM of GM plants.

In delivering this Statement, the EFSA GMO Panel considered the initial notification C/F/96/05.10 for cultivation of maize Bt11, the additional information supplied by the applicant upon request of the EFSA GMO Panel, as well as relevant scientific publications. The EFSA GMO Panel also utilised material from its previous 2009 evaluation of the ERA of the similar Lepidoptera-resistant maize event MON 810 and from recent work on the risk mitigation and monitoring of maize MON 810.

The possible resistance evolution to the Cry1Ab protein in lepidopteran target pests continues to be a concern associated with the cultivation of maize Bt11, as resistance evolution may lead to altered pest control practices that may cause adverse environmental effects.

The EFSA GMO Panel reiterates its earlier recommendation that appropriate insect resistance management (IRM) strategies relying on the ‘high dose/refuge’ strategy should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests. The EFSA GMO Panel also recommends the applicant to consider integrating the IRM and CSM for maize Bt11 with that of other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU. In addition, the applicant should consider the recommendations to improve the IRM and CSM made in the 2009 EFSA GMO Panel Scientific Opinion for the renewal of maize MON 810 for cultivation and the 2011 EFSA GMO Panel Scientific Opinion on the annual 2009 PMEM report on maize MON 810.

In areas where other lepidopteran pests than the European and Mediterranean corn borer occur, they might also be subject to resistance evolution due to exposure to the Cry1Ab protein expressed in maize Bt11. Therefore, the EFSA GMO Panel recommends that these species are also considered by the applicant in the context of IRM and CSM to monitor resistance evolution to the Cry1Ab protein in these species, as well as in general surveillance (GS) through farmer questionnaires.

Data on the biological activity of the Cry1Ab protein variant of maize Bt11 and maize MON 810 against sensitive lepidopteran species confirm that both variants are biologically equivalent. In addition, the reported ranges in the levels of the Cry1Ab protein expressed in maize Bt11 pollen were shown to be similar to those in maize MON 810 pollen. Based on the sensitivity and protein expression data, the EFSA GMO Panel considers that the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply equally to maize Bt11. Therefore, the amounts of maize Bt11 pollen grains found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae, except for local populations of lepidopteran species with such hypothetical high sensitivities to the Cry1Ab protein that they comprise just 1% of the total species at risk. The degree of this mortality may be estimated quantitatively from the levels of exposure. The EFSA GMO Panel supplements its evaluation of the ERA of maize Bt11 in line with the environmental safety evaluations of other Lepidoptera-resistant maize events (such as maize 1507 and MON 810). The range of sensitivities explored within the modelling exercise applied to maize 1507

and risk mitigation measures for any 'highly sensitive' species that might be exposed and hence at risk were also considered.

The EFSA GMO Panel concludes that locally exposed non-target Lepidoptera that are 'extremely sensitive' to the Cry1Ab protein may be at risk if exposed to harmful amounts of maize Bt11 pollen. Therefore, the EFSA GMO Panel considers that the risks identified during the ERA require management and recommends that appropriate risk mitigation measures be adopted, wherever it is necessary. As an example, if considered proportionate, the planting of border rows of non-*Bt*-maize adjacent to uncultivated margins of maize Bt11 fields, would limit the exposure of those larvae feeding on host-plants present within maize field marings and also would contribute to the required percentage of non-*Bt*-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of IRM. Another example is the establishment of isolation distance to lepidopteran species of conservation concern in protected habitats according to Directive 2004/35/EC.

The EFSA GMO Panel provides risk managers with tools to estimate global and, where needed local, mortality of exposed non-target Lepidoptera, both before and after different risk mitigation measures are put in place, and for different host-plant densities. This enables risk managers to choose risk mitigation measures proportionate to the level of identified risk and to the protection goals pertaining to their region. Special attention should be paid to the degree of large-scale exposure as risk mitigation measures are only needed when the proportion and uptake of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area[5,6], the global mortality is predicted to remain below 1%, even for 'extremely sensitive' species, and then risk mitigation measures using non-*Bt*-maize border rows are not required.

The EFSA GMO Panel considers that lepidopteran species of conservation concern with unknown sensitivity to the Cry1Ab protein occurring in protected habitats according to Directive 2004/35/EC require additional protection and, in these cases, recommends that maize Bt11 is not cultivated within 20 m of the boundary of these habitats, in order to minimise exposure and hence risks to these Lepidoptera.

The EFSA GMO Panel concludes that risk mitigation measures are only required in situations where 'extremely sensitive' non-target Lepidoptera populations might be at risk; for example, when 'extremely sensitive' non-target Lepidoptera and their host-plants are present in *Bt*-maize fields and margins in areas where there is a high proportion of maize in arable fields and a high rate of adoption of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU). Similarly, resistance evolution to target species is only expected when the selection pressure is high due to high adoption of maize Bt11 (and/or other Cry1Ab-expressing maize events) in a region.

The EFSA GMO Panel concludes that, subject to the proper implementation of the risk mitigation measures, the effect on non-target Lepidoptera is reduced to a level of no concern. Therefore, there is no formal requirement for CSM of non-target Lepidoptera. However, in many cases, e.g., if 'extremely sensitive' species do not exist or are not present where maize Bt11 might be cultivated, the recommended risk mitigation measures may be disproportionate to the level of risk or uncertainty and put unnecessary burdens on farmers. If applicants, in agreement with risk managers, wish to reduce the proposed risk mitigation measures because they are considered too conservative, then monitoring studies may be required. The EFSA GMO Panel suggests that, in these latter cases, further studies could be conducted to confirm the estimates of the ERA on the sensitivity of non-target Lepidoptera

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5 For example, a maximum uptake of 25% of maize Bt11 (and/or maize MON 810) in a region where maize represents 30% or less of the arable land

6 I.e., zv = 0.075, and with conservative assumptions for the other parameters y=a=x=0.5, yielding $R = 0.009375$

and whether non-target Lepidoptera larvae, with an ‘extremely high’ sensitivity to the Cry1Ab protein, are present and feeding on host-plants occurring in and adjacent to maize fields at the time of pollen shed.

The EFSA GMO Panel also considers that the current plan for GS, and in particular the methodology, needs further details according to the requirements laid down in its 2011 Scientific Opinion providing guidance on PMEM of GM plants as well as its Scientific Opinion on the annual 2009 PMEM report on maize MON 810.

The EFSA GMO Panel concludes that, subject to appropriate risk management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize.

The EFSA GMO Panel considers that the conclusions drawn regarding the risk to non-target Lepidoptera from maize Bt11, listed above, and the recommendations on risk management measures, apply equally to maize MON 810.

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BACKGROUND AS PROVIDED BY EFSA

On 20 April 2005, the Panel on Genetically Modified Organisms (GMO Panel) of the European Food Safety Authority (EFSA) issued a Scientific Opinion for the placing on the market of the insect resistant genetically modified (GM) maize Bt11 for feed uses, import, processing and cultivation under Part C of Directive 2001/18/EC (notification reference C/F/96/05.10) (EFSA, 2005a). Based on the evaluation of the environmental risk assessment (ERA), the EFSA GMO Panel concluded that there was no evidence indicating that placing maize Bt11 on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed uses. At the time, the EFSA GMO Panel also recommended that maize Bt11 cultivation should be accompanied by appropriate risk management strategies to delay the potential evolution of resistance to the Cry1Ab protein in target insects and to minimise exposure of non-target Lepidoptera (EFSA, 2005a).

In 2006 and 2008, the European Commission successively requested the EFSA GMO Panel to consider whether new scientific evidence published in the scientific literature may require a revision of the conclusions of its previous Scientific Opinion on maize Bt11. Following these requests, the EFSA GMO Panel evaluated the available new scientific information, and found no new evidence for adverse environmental effects caused by the cultivation of maize Bt11 (EFSA, 2006, 2008). Therefore, the EFSA GMO Panel concluded that no new scientific information had been made available that would invalidate its previous Scientific Opinion.

In 2009, during its evaluation of the application for renewal of authorisation of the similar Lepidoptera-resistant maize event MON 810 for cultivation (EFSA, 2009), the EFSA GMO Panel developed and used a new risk assessment methodology. This new approach utilised a mathematical model to simulate and assess potential adverse effects resulting from the exposure of non-target lepidopteran species to Cry1Ab-containing maize pollen deposited on their host-plants under representative cultivation conditions (for further details, see Perry *et al.*, 2010). On the basis of the data provided by the applicant and obtained from a literature survey and the modelling exercise, the EFSA GMO Panel concluded that the amounts of maize MON 810 pollen found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae. However, considering the uncertainties inherent in all modelling exercises, the EFSA GMO Panel considered it advisable that, especially in areas of abundance of protected non-target Lepidoptera populations, the adoption of maize MON 810 cultivation be accompanied by management measures, in order to mitigate the possible exposure of larvae of these species to maize MON 810 pollen.

In August 2010, as part of the updating of its evaluation of the ERA of the Lepidoptera-resistant maize event 1507 that expresses the Cry1F protein, the EFSA GMO Panel recalibrated the model to perform a similar analysis for maize 1507. Further work was done to extend the model to derive estimates of mortality that allow for: (1) between-species variability in acute sensitivity to the Cry1F protein by considering a range of sensitivities of five hypothetical non-target lepidopteran species; (2) the effect of two different within-crop host-plant densities; and (3) the effect of various risk mitigation measures. This enabled the EFSA GMO Panel to further detail its previous evaluation of maize 1507 in terms of possible risks for non-target lepidopteran species, as well as to clarify its past recommendations to risk managers (EFSA, 2011c; and see also Perry, 2011a,b; Perry *et al.*, 2010, 2011a,b).

To ensure consistency of the environmental safety evaluation among Lepidoptera-resistant maize events (such as maize events 1507, MON 810 and Bt11), the European Commission requested the EFSA GMO Panel to further analyse the ERA of maize Bt11 and to clarify its recommendations to risk managers on 8 December 2010. In addition, on 5 July 2011, the European Commission requested the EFSA GMO Panel to reconsider the plan for post-market environmental monitoring (PMEM) of maize Bt11 in light of its 2011 Scientific Opinion providing guidance on PMEM of GM plants (EFSA, 2011a).

Terms of reference as provided by the European Commission and EFSA

On 8 December 2010, the EFSA GMO Panel received a request from the European Commission to further analyse some aspects of the ERA of maize Bt11 in light of the scientific data and methodology currently available, as well as to clarify its recommendations to risk managers.

On 5 July 2011, the EFSA GMO Panel received a supplementary request from the European Commission to reconsider the PMEM of maize Bt11 according to its 2011 Scientific Opinion providing guidance on PMEM of GM plants.

EVALUATION

1. INTRODUCTION

Maize Bt11 was developed by the applicant, Syngenta Seeds, to express a Cry1Ab protein variant, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against the lepidopteran target pests European corn borer (ECB, *Ostrinia nubilalis* Hübner) and Mediterranean corn borer (MCB, *Sesamia nonagrioides* Lefebvre).

2. ENVIRONMENTAL RISK ASSESSMENT

2.1. Interactions of maize Bt11 with target organisms

The potential of maize Bt11 to cause adverse effects through direct or indirect interactions between the GM plant and target organisms was previously evaluated by the EFSA GMO Panel (EFSA, 2005a, 2006). In its 2005 Scientific Opinion on maize Bt11 (EFSA, 2005a), the EFSA GMO Panel identified the possible resistance evolution of target Lepidoptera to the Cry1Ab protein as a potential risk. The large-scale cultivation of maize Bt11 over several years was expected to increase the selection pressure on European populations of corn borers such as the European corn borer (*Ostrinia nubilalis*) and the Mediterranean corn borer (*Sesamia nonagrioides*), which might result in the evolution of resistance.

Instances of field resistance to *Bt*-maize have been reported outside Europe for two lepidopteran target pests in maize that are not present in the European fauna (Tabashnik *et al.*, 2009; Huang *et al*., 2011): *Busseola fusca* (Van Rensburg, 2007; Kruger *et al.*, 2009, 2011b) and *Spodoptera frugiperda* (Matten *et al.*, 2008; Moar *et al.*, 2008; Tabashnik, 2008; Tabashnik *et al.*, 2008a; Storer *et al.*, 2010).

Resistance evolution in populations of target pest(s) to Cry1 proteins found in Lepidoptera-resistant maize events is not considered a direct environmental harm, but the consequences of the establishment of lepidopteran target pests with resistance to Cry1 proteins could be that farmers would use other target pest control methods (e.g., insecticides) resulting in higher environmental load or the displacement of biocontrol programmes at a larger scale (Andow, 2008). Other regionally important lepidopteran pests (e.g., *Sesamia cretica*, *Helicoverpa armigera*, *Mythimna unipuncta*) exposed to Lepidoptera-resistant maize events may also have the potential to evolve resistance to Cry1 proteins.

In line with its previous evaluations of the cultivation of Lepidoptera-resistant maize events (EFSA, 2005a,b, 2006, 2009, 2011c), the possible evolution of resistance to the Cry1Ab protein in lepidopteran target pests is considered by the EFSA GMO Panel as a relevant environmental and agronomic concern associated with the cultivation of maize Bt11, as the consequences of resistance evolution may lead to altered pest control practices that may cause adverse environmental effects.

In addition, the EFSA GMO Panel has recognised that other Lepidoptera-resistant maize events (i.e., maize event MON 810) may also be present in areas where maize Bt11 is likely to be cultivated and that the area of Cry1Ab-expressing maize will be the sum of the areas of these maize types. Therefore, in these areas, the probability of evolution of resistance to the Cry1Ab protein should consider the effects of maize Bt11 cultivation be it in combination or in rotation with other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU, both spatially and temporarily.

2.2. Interactions of maize Bt11 with non-target organisms

2.2.1. Literature review (hazard identification)

In the course of its evaluation, the EFSA GMO Panel requested the applicant to provide any new data on non-target organisms (NTOs) generated with maize Bt11 in lower- and higher-tier studies, that would have been issued after the adoption of the 2005 Scientific Opinion on maize Bt11 (EFSA, 2005a).

The applicant reviewed scientific publications[7] in which potential adverse effects of Lepidoptera-resistant maize events expressing the Cry1Ab protein on NTOs were assessed in lower- and higher-tier studies. The literature search focused on publications in peer-reviewed journals and was conducted using the Ovid platform. BIOSIS previews, CAB Abstracts, Embase, Ovid MEDLINE, and PASCAL databases were accessed via Ovid. Only publications issued after the adoption of the 2005 EFSA GMO Panel Scientific Opinion on maize Bt11 were considered (EFSA, 2005a).

The EFSA GMO Panel evaluated the applicant's literature review. From the 144 provided literature citations, 23 studies related specifically to maize Bt11. No evidence was found that would invalidate previous EFSA GMO Panel conclusions on the environmental safety of maize Bt11. The applicant's literature review did not identify new safety concerns that have not been considered in previous EFSA GMO Panel Scientific Opinions (EFSA, 2008, 2009, 2011c). Moreover, an additional literature analysis performed by the EFSA GMO Panel did not reveal new evidence that Cry1Ab-expressing maize events, including maize Bt11, would raise environmental safety concerns to non-lepidopteran NTOs.

However, available scientific evidence confirms that a potential risk to the larvae of non-target Lepidoptera is the ingestion of potentially harmful amounts of pollen arising from Lepidoptera-resistant maize and deposited on their host-plants in or near Bt-maize fields (e.g., reviewed by EFSA, 2006, 2008, 2009, 2011c; Lang and Otto, 2010; Perry *et al*., 2010, 2011b).

2.2.2. Non-target Lepidoptera

Maize plants are not an important resource of food for the larvae of indigenous Lepidoptera with the exception of a few pest species. Therefore, the main potential risk to non-target Lepidoptera, particularly endangered species or species of conservation concern, is exposure of larvae of non-target Lepidoptera to potentially harmful amounts of pollen deposited on host-plants in or near maize Bt11 fields (EFSA, 2005a,b, 2009, 2011c).

To be in a position to evaluate whether the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply to maize Bt11, the applicant was asked:

a) to provide data on the susceptibility (sensitivity) of relevant lepidopteran species to the Cry1Ab protein variant expressed in maize Bt11, and to assess whether there is a significant difference in susceptibility of those species to the Cry1Ab protein variant expressed in maize MON 810 (see section 2.2.2.1, below);

b) to provide data on the Cry1Ab protein content in maize Bt11 pollen and its variability, and to compare this range with that reported in the scientific literature for maize MON 810 pollen (see section 2.2.2.2, below).

If no significant differences in susceptibility (sensitivity) and protein expression data between both maize events (see a & b, above) were found, the applicant was requested to discuss whether the

[7] Additional information dated 26 May 2011 / Appendix 2

mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply to maize Bt11 (see section 2.2.2.3, below).

If significant differences in susceptibility (sensitivity) and protein expression data were found in the applicant's comparative assessment (see a & b, above), then the applicant was requested to provide a comprehensive exposure assessment, either by feeding the Perry *et al.* (2010) model with the newly collected susceptibility (sensitivity) and protein expression data, or by performing a similar exercise with any other model the applicant would consider applicable.

The additional information described above was requested by the EFSA GMO Panel on 6 January 2011, and provided by the applicant on 30 May 2011. The EFSA GMO Panel evaluated the additional information in accordance with its Scientific Opinion delivering guidance on the ERA of GM plants (EFSA, 2010a). Where relevant, newly available data published in the scientific literature were also taken into account (see section 2.2.1).

2.2.2.1. Biological activity of the Cry1Ab protein variants of maize Bt11 and MON 810 (hazard assessment)

Using available scientific information, the applicant compared the biological activity of the Cry1Ab protein variants in maize Bt11 and MON 810 (in pollen) against the Monarch butterfly (*Danaus plexippus*), and concluded that: "s*ince the active core is common between all [Cry1Ab protein] variants, the range of species that are susceptible to Cry1Ab is anticipated to be the same*". According to Pleasants *et al.* (2001), the sensitivity of *D. plexippus* to pollen of maize Bt11 and MON 810 is similar. For other species, there is little data demonstrating that their individual sensitivity to maize Bt11 is similar to their sensitivity to maize MON 810.

Erasmus *et al.* (2010) studied the effect of maize Bt11 and MON 810 on the non-target pest species *Agrotis segetum*. Although some significant differences in effects on larval mass and fecundity of this moth were reported under laboratory conditions, the EFSA GMO Panel concludes that meaningful differences in population effects are unlikely under field conditions. Moreover, Li *et al.* (2007) have shown that the efficacy for controlling *O. nubilalis* was similar between maize Bt11 and MON 810.

The EFSA GMO Panel also evaluated the amino acid sequence present in the core of the Cry1Ab protein variants of maize Bt11[8] and MON 810[9], and confirmed their sequence identity.

Therefore, the EFSA GMO Panel considers that there is sufficient evidence to confirm that the biological activity of the Cry1Ab protein variants of maize Bt11 and maize MON 810 against sensitive lepidopteran species is similar.

2.2.2.2. Expression levels of the Cry1Ab protein in maize Bt11 and MON 810 pollen (exposure assessment)

Upon request of the EFSA GMO Panel, the applicant reported on ranges in the levels of the Cry1Ab protein expressed in pollen from maize Bt11. These data were collected for maize Bt11 itself, or for stacked transformation events containing maize Bt11 from nine independent studies (i.e., seven studies in the USA, two studies in the EU)[10].

The EFSA GMO Panel assessed the provided dataset. The protein expression data indicate that the reported range in the levels of the Cry1Ab protein expressed in pollen from maize Bt11 (ranging from 0.008 to 0.100 µg/g dry weight) overlaps with that of maize MON 810 (ranging from 0.001 to

[8] Application EFSA-GMO-RX-Bt11 / Technical dossier / Section C3
[9] Application EFSA-GMO-RX-MON810 / Technical dossier / Section C3
[10] Additional information dated 26 May 2011 / Appendix 3

0.097 µg/g dry weight). Based on available data from the US Environmental Protection Agency and the Canadian Food Inspection Agency, Dutton *et al.* (2003) also reported similar Cry1Ab protein contents in maize pollen from maize Bt11 and MON 810. Evidence on protein expression levels confirms that the Cry1Ab protein content in maize Bt11 pollen is similar to that in maize MON 810 pollen.

Therefore, the EFSA GMO Panel concludes that the environmental exposure of non-target Lepidoptera to maize Bt11 pollen is expected to be similar to that of maize MON 810 pollen.

2.2.2.3. Applicability of mortality estimates calculated for maize MON 810 to maize Bt11 (risk characterisation)

Since the biological activity of the Cry1Ab protein variants of maize Bt11 and MON 810 and the Cry1Ab expression levels in pollen were considered similar, the applicant argued that the same conversion factor used by Perry *et al.* (2010) to convert reported LC_{50} values from maize Bt176 pollen (pollen grains cm^{-2}) to maize MON 810 pollen could be utilised to convert reported LC_{50} values from maize Bt176 pollen grains cm^{-2} to maize Bt11 pollen grains cm^{-2}.

Based on the additional information provided by the applicant and data obtained from a literature survey, the EFSA GMO Panel concludes that the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply equally to maize Bt11. Therefore, the amounts of maize Bt11 pollen grains in and around maize fields are unlikely to adversely affect a significant proportion of non-target Lepidoptera larvae (but see section 2.2.3 below; and see also Perry *et al.*, 2010, 2011a,b).

The EFSA GMO Panel accepts the applicant's conclusion that there is no need to provide a comprehensive exposure assessment, either by feeding the Perry *et al.* (2010) model with a range of sensitivities and with protein expression data, or by performing a similar exercise with any other model.

2.2.3. Risk characterisation using an extended model of exposure

To ensure consistency among environmental safety evaluations of similar Lepidoptera-resistant maize events (such as maize events 1507, MON 810 and Bt11), the EFSA GMO Panel decided to supplement its evaluation of the ERA of maize Bt11 (and by analogy of maize MON 810), in line with the range of sensitivities, within-crop host-plant densities and risk mitigation measures explored within the modelling exercise applied to maize 1507 (EFSA, 2011c; Perry *et al*., 2011b). This also enabled the EFSA GMO Panel to quantify the effect of reducing non-target Lepidoptera exposure to maize Bt11 pollen and consequently to revisit in further details its previous recommendations to risk managers (EFSA, 2005a).

2.2.3.1. Model description

The EFSA GMO Panel concludes that the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply equally to maize Bt11. Therefore, the basis for the model was largely as described in Perry *et al*. (2010) and reiterated with minor differences in Perry *et al.* (2011b) and appendices, so only brief details are given here, focussing on those differences between the two model versions. The model simulates two scenarios with a square maize Bt11 (or maize MON 810) field of area C = 15 ha, firstly surrounded on all four sides by an uncultivated margin of width *D* = 2 m and secondly with no margins at all. The model estimated mortality for five hypothetical non-target lepidopteran species; in this case, sublethal effects were not modelled (see Perry *et al*., 2010, 2011a). The host-plant density of each hypothetical species within the margin was assumed to be f = 0.75 plants m^{-2}.

2.2.3.2. Sensitivity of larvae of lepidopteran species to maize Bt11 pollen

The purpose of modelling five hypothetical species was to allow for the variability in estimated mortality due to the fact that species differ in their sensitivity to pollen from maize Bt11 (equally applicable to maize MON 810). The degree of sensitivity was considered to be expressed by the parameter *m*, representing the LC_{50} in units of pollen grains cm^{-2} (see Perry *et al.*, 2011b). The sensitivities modelled for maize 1507 (see also Table 2 in section 2.3.5.1 of EFSA, 2011c) ranged from:

- 'below-average' (*m* = 21057, a value very close to the LC_{50} for the moth pest *Spodoptera litura*);
- 'above-average' (*m* = 1853, a value very close to the LC_{50} for the moth pest *Trichoplusia ni* and near to the 25^{th} percentile of the ranked species sensitivity frequency distribution, see EFSA, 2011c and Wolt *et al*., 2005);
- 'highly sensitive' (*m* = 163.2, somewhat less sensitive than the moth pest *Plutella xylostella* and near to the 8^{th} percentile of the distribution);
- 'very-highly sensitive' (*m* = 14.36, very close to the 1^{st} percentile and more sensitive than any lepidopteran species tested thus far);
- to 'extremely sensitive' (*m* = 1.265, very close to the 0.2 percentile).

These five LC_{50} values form a geometric series with 11.4-fold increments.

Note that in a random sample of 500 lepidopteran species only one species would be expected to be as sensitive as the 'extremely-sensitive' category. Perry (2011b) discussed how the usefulness or otherwise of this categorisation depends on the number of non-target species thought to be at risk through their utilisation of habitats within the maize ecosystem. Consideration of this hypothetical 'extremely sensitive' (and arguably 'very-highly sensitive') category is likely to be disproportionate because in practice there may well be no species that approach that degree of sensitivity. Despite this, the EFSA GMO Panel has assumed this 'worst-case' category of extreme sensitivity to ensure inclusion of all potential species sensitivities within the modelling exercise, in order to study the possible implications for all Lepidoptera species of exposure to maize Bt11 (or maize MON 810) pollen.

For maize Bt11 (or maize MON 810), the LC_{50} value for the fourth (most exposed) instar of the moth *P. xylostella* was assumed by Perry *et al.* (2010) to be 3,626 *Bt*-maize pollen grains cm^{-2} (Felke and Langenbruch, 2005), whereas for maize 1507 the LC_{50} value reported by Wolt *et al.* (2005) for first instars of *P. xylostella* was 54 *Bt*-maize pollen grains cm^{-2}. Since *P. xylostella* is regarded as the most sensitive of those species tested for maize 1507 and Bt11 (or maize MON 810), the EFSA GMO Panel assumed an identical relative sensitivity for those maize events and used the ratio 3626/54 = 67.15 to derive the following corresponding series of five values of *m* for maize Bt11 (or maize MON 810), again with 11.4-fold increments as: *m* = 1,413,939 ('below-average sensitivity'); 124,425 ('above-average sensitivity'); 10,959 ('highly sensitive'); 964 ('very-highly sensitive') and 85 ('extremely sensitive').

Whereas LC_{50} values have been established for seventeen species for maize 1507, many fewer have been determined for maize Bt11 and MON 810. The species *Vanessa atalanta* and *Inachis io* were assumed by Perry *et al.* (2010) to have an LC_{50} value of *m* = 5,800 *Bt*-maize pollen grains cm^{-2}, just greater than the 'highly sensitive' categorisation. For a Cry1-resistant strain of *Ostrinia furnicalis*, Xu *et al.* (2010) found an approximate value of *m* of at least 576,000 (approximately average sensitivity) and for *D. plexippus*, Hellmich *et al.* (2001) found a value ten-fold greater (well below average sensitivity).

2.2.3.3. Risk mitigation measures for maize Bt11

The EFSA GMO Panel noted that the Cry1F protein content in maize 1507 pollen is about 350 times the Cry1Ab protein content found in maize MON 810 pollen (EFSA, 2011c), and that, as expected, estimated mortality of non-target lepidoptera exposed to maize 1507 pollen was generally greater than found previously for maize MON 810 (EFSA, 2009). Because of this, for maize 1507, it seemed sensible to quantify the effect of the risk mitigation measures recommended previously by the EFSA GMO Panel (EFSA, 2005b). In this case, and also for maize Bt11 (EFSA, 2005a) and MON 810 (EFSA, 2009), the measures recommended were the planting of border rows of non-Lepidoptera-resistant maize (hereafter abbreviated as non-*Bt*-maize) at the edges of the crop, adjacent to uncultivated margins of the *Bt*-maize fields, which could limit the exposure to those individuals feeding on host-plants occurring within maize fields and their margins and also could contribute to the required percentage of non-*Bt*-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of IRM.

In addition, for lepidopteran species of conservation concern in protected habitats according to Directive 2004/35/EC (EC, 2004), the EFSA GMO Panel recommended that maize 1507 is not cultivated within 30 m of the boundary of these habitats, so that exposure and hence the risks to larvae of these lepidopteran populations are minimised in these areas. In its recent Scientific Opinion on maize 1507 (EFSA, 2011c), the EFSA GMO Panel provided a range of separation distances from the maize 1507 field to reduce the exposure of non-target lepidopteran species of conservation concern within those protected habitats (section 3.1.2.3 in EFSA, 2011c). This Statement considers applying the use of similar methodology to reduce exposure of these species to maize Bt11 (or maize MON 810) pollen.

For non-target lepidopteran larvae within field margins, mitigation by border rows of non-*Bt*-maize works by increasing the effective distance of these larvae from the source of *Bt*-maize pollen (see EFSA, 2011c; Perry 2011a,b for further details). Similarly, larvae in the non-*Bt*-maize rows at the edge of the field suffer correspondingly less mortality the further they are located from the *Bt*-maize field interior. Mortality of non-target Lepidoptera within the *Bt*-maize field interior is assumed to be unaffected by the presence or absence of the non-*Bt*-maize borders. For the field size (15 ha) studied, border widths of $w = 21$ m and $w = 24$ m would result in a percentage of non-*Bt*-maize in the assumed field of, respectively, 20.5% and 23%, both close to the 20% recommended by many authorities, such as the US EPA (EPA, 1998), as non-*Bt*-maize refuge to delay the possible evolution of resistance to Cry proteins amongst target pest species (e.g., MacIntosh *et al*., 2010). In this Statement, the EFSA GMO Panel considers no mitigation ($w = 0$) and mitigation using a border of width $w = 24$ m.

As in EFSA (2011c), in this Statement, the EFSA GMO Panel tabulated estimated local mortality (see section 2.2.3.5, below for definition) for the five different categories of sensitivity to maize Bt11 (equally applicable to maize MON 810), at increasing distances from the nearest maize Bt11 or MON 810 field (Table 2). This information is used to suggest a separation distance beyond which the local mortality is reduced to a level of no concern below 0.5%, even for 'extremely sensitive' species.

2.2.3.4. Within-crop host-plant density

Perry *et al*. (2011b) noted that the efficacy of mitigation was 'highly sensitive' to the parameter e that represented the within-crop host-plant density. Following their approach, in this Statement, the EFSA GMO Panel considers the two scenarios: no host-plants within the crop ($e = 0$) and a within-crop host-plant density of $e = 0.01$ plants m^{-2}.

2.2.3.5. Reduction in estimated mortality due to large-scale exposure

Mortality is estimated in two phases: firstly locally, using the 'small-scale' parameters (see Perry *et al*., 2010, 2011a,b; Perry, 2011b) and then globally, using the 'large-scale' parameters. In this

Statement and these publications, the term 'locally' means spatially within the crop and/or its immediate vicinity, and temporally within the period of pollen shed; the term 'globally' means after averaging over an entire landscape or regional scale and over a whole growing season.

The five 'large-scale' parameters are:

- *y*, the proportion of the lepidopteran host-plant that is found within arable crops and in their margins (as opposed to other habitats);

- *z*, the proportion of arable fields that are cropped with maize (as opposed to other crops) in any year in the region;

- *v*, the proportion of all maize sown within the defined region that is cropped with the *Bt*-maize;

- *x*, the proportion of larvae that remains exposed, after allowance for a set of physical and behavioural effects that tend to reduce exposure;

- *a*, the proportion by which exposure is reduced owing to lack of temporal coincidence between the sensitive larval stage concerned and the period over which pollen from the *Bt*-maize is shed.

Estimates of global estimated mortality, after allowing for these effects of large-scale exposure, are calculated by multiplying each estimated local mortality rate by the product of the five parameters *yzvxa* which is denoted in this Statement as the parameter *R* (Table 1).

The average expected global mortality is always reduced from the expected local mortality because the latter represents an absolute 'worst-case' which would never occur in practice, since it takes no account of large-scale processes. However, in contrast to the estimates of global mortality displayed by Perry *et al.* (2010) and by EFSA (2009) for maize MON 810, here the EFSA GMO Panel provides estimates of mortality at the local, small-scale and gives a range of values of *R* that will enable risk managers to translate these local estimates to global estimates of mortality appropriate to the region(s) modelled (see also Perry *et al*., 2011b).

There is considerable scientific uncertainty concerning the estimated values of the large-scale parameters, and therefore considerable uncertainty in the value of *R*. However, EFSA (2011c) justified the consideration of four values of *R* as follows:

- *R* = 0.08 ('conservative', in the sense of values of *y, z, v, x* and *a* that lead to relatively greater mortality);

- *R* = 0.02 (from the precautionary values of *y*, *z*, *v*, *x* and *a* adopted by Perry *et al*. (2010));

- *R* = 0.0049 (from values of *y, z, v, x* and *a* considered typical by the EFSA GMO Panel);

- *R* = 0.00024 ('non-conservative', in the sense of values of *y, z, v, x* and *a* leading to relatively smaller mortality).

Of course, for display purposes the value *R* = 1 may be used to indicate local mortality only. In practice, risk managers should calculate the value(s) of the key parameter *R* that pertains to their region(s).

2.2.3.6. Results from the model

Results of the quantified risk of mortality, prior to mitigation, are summarised in Figure X(a) for a 15 ha field cropped with maize Bt11 (or maize MON 810) and with 2 m margins, and a within-crop host-plant density of 0.01 plants m^{-2}; and in Figure X(b) for a within-crop host-plant density of zero; and in Figure X(c) for a 15 ha field with no margins and a within-crop host-plant density of 0.01 plants m^{-2}.

The estimated local and global percentage mortality for the range of five hypothetical species, together with estimates for *P. xylostella* and *I. io* - *V. atalanta* are also given in numeric form in Table 1, for the two combinations of each of the factors host-plant density, margin and mitigation. Note that when host-plant density is zero and there is no margin, local mortality is zero since there are no host-plants in the field and therefore no non-target Lepidoptera exposed.

Table 2 gives estimates of distances from the nearest field cropped with maize Bt11 (or maize MON 810) that would be necessary to decrease the estimated local mortality below a certain level.

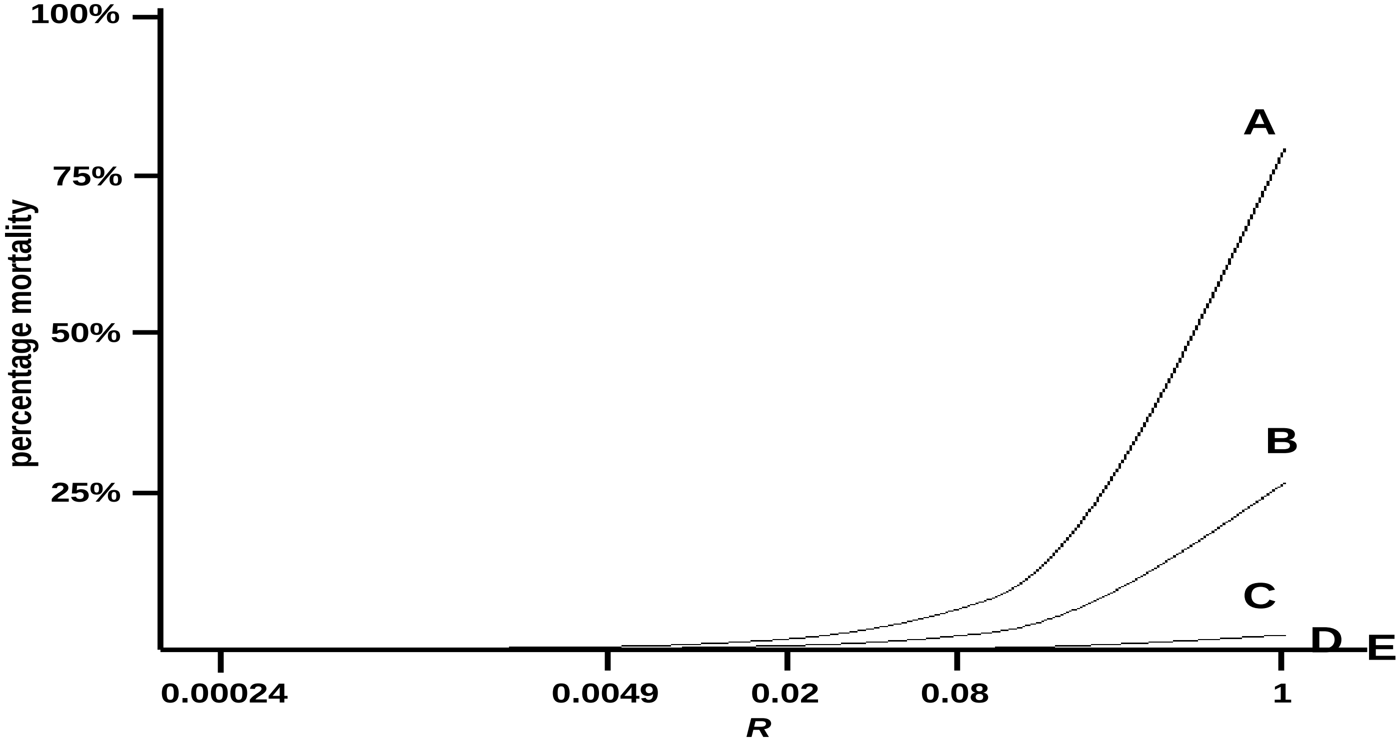

Figure X(*a*) Local estimated percentage mortality (at *R* = 1) and global estimated percentage mortality (at *R* < 1) for a 15 ha field cropped with maize Bt11 (or maize MON 810), with 2 m margins and a within-crop host-plant density of 0.01 plants m^{-2}. Mortality increases monotonically with species sensitivity: line A indicates 'extreme' sensitivity; line B indicates 'very-high'; line C 'high'; line D 'above-average'; and line E 'below-average'. Mortality (*y*-axis) is plotted against *R* (*x*-axis), the parameter that measures the degree of large-scale exposure. Local mortality is given by the values corresponding to *R* = 1 (see right hand end of *x*-axis). Global estimated mortality allows for the effects of large-scale exposure and is calculated by multiplying the estimate of local mortality by *R*, where *R* is a proportion between zero and unity. Values shown on the x-axis are: *R* = 0.08 ('conservative'); *R* = 0.02 ('precautionary Perry *et al*., 2010'); *R* = 0.0049 ('typical'); and *R* = 0.00024 ('non-conservative'). A logarithmic scale is used for the *x*-axis to aid visibility

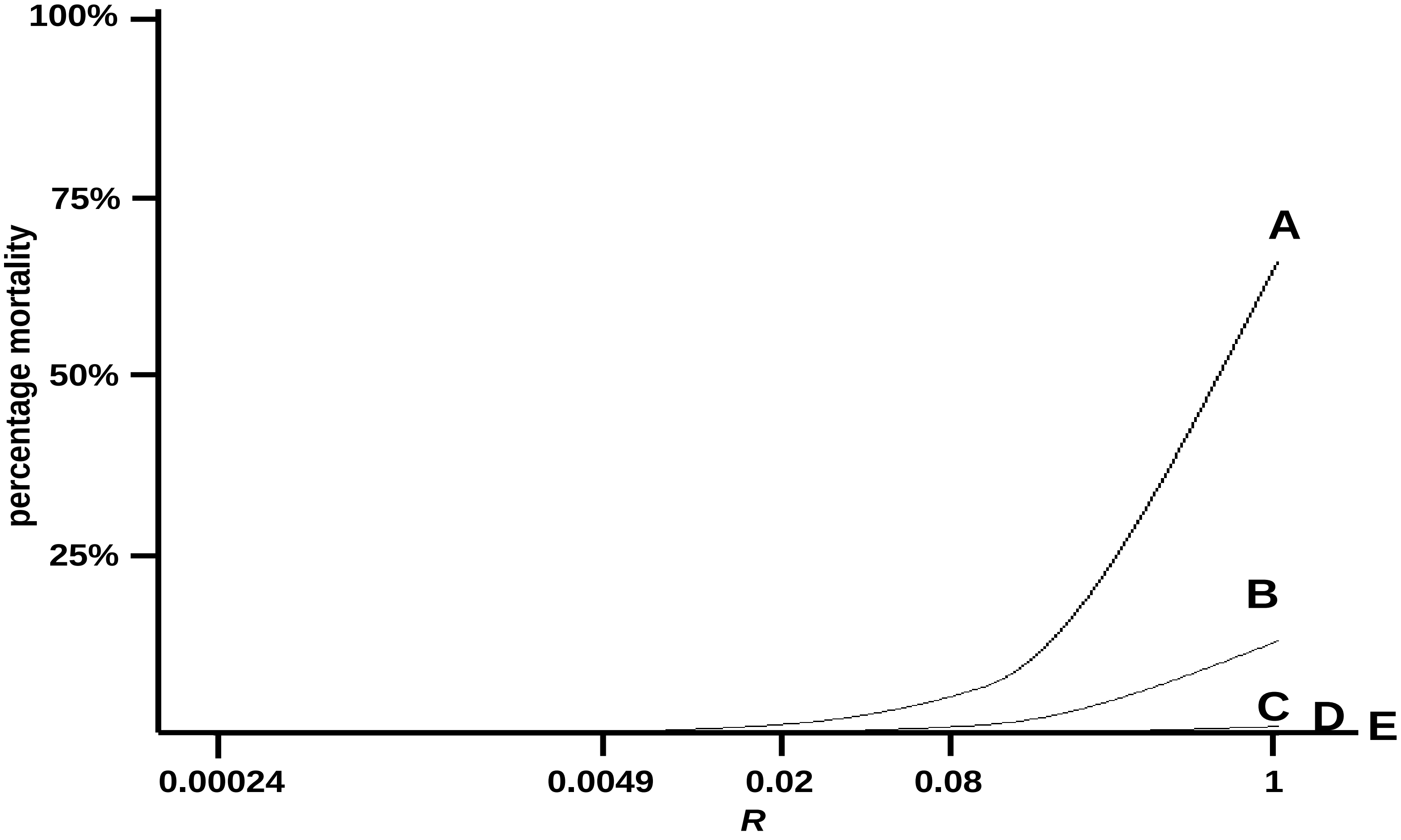

Figure X(*b*) Local and global estimated percentage mortality for a 15 ha field cropped with maize Bt11 (or maize MON 810), with 2 m margins and no host-plants within the crop (within-crop host-plant density of 0.00 plants m^{-2}). For other details see the legend to Figure X(*a*), above. A logarithmic scale is used for the *x*-axis to aid visibility

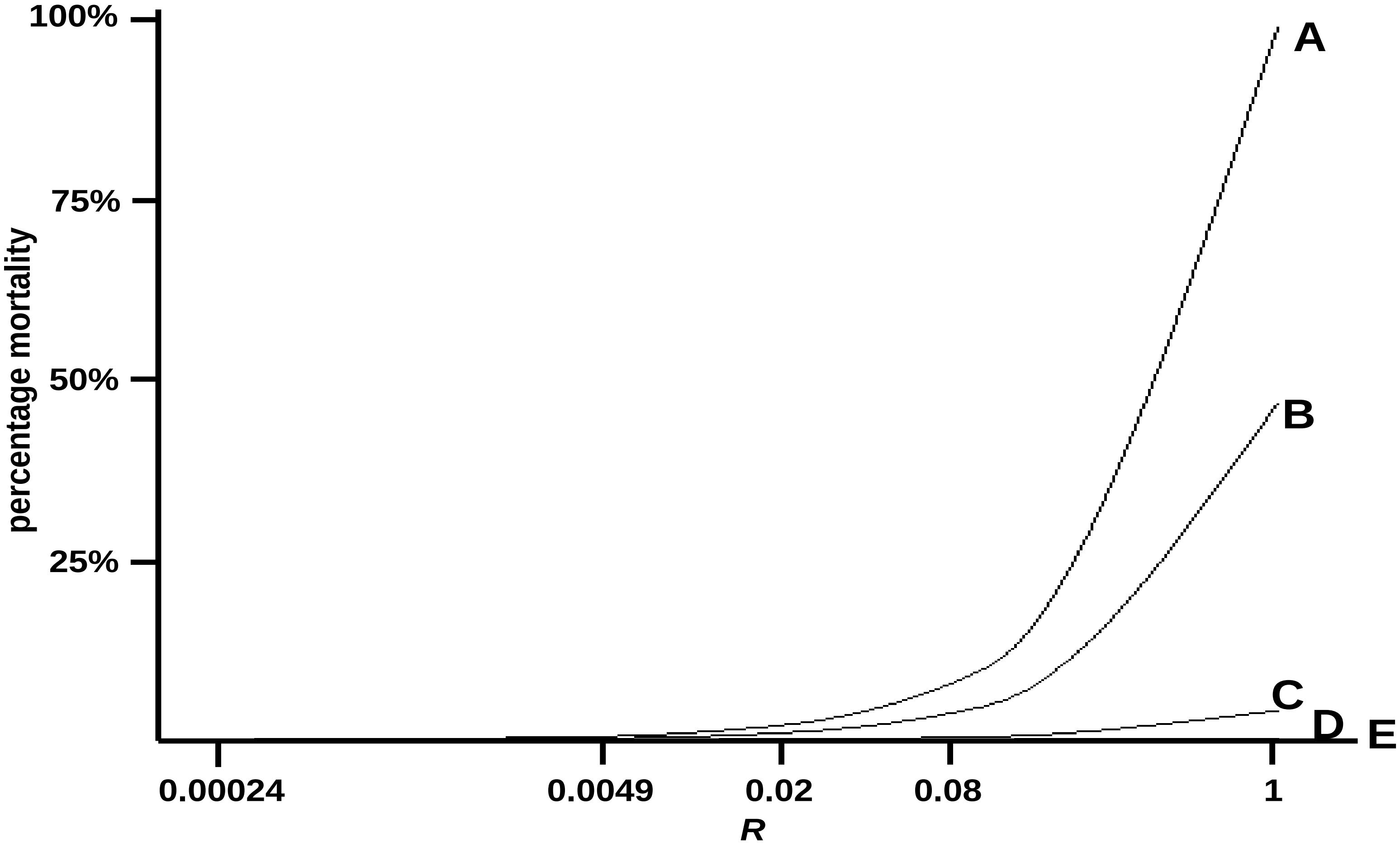

Figure X(*c*) Local and global estimated percentage mortality for a 15 ha field cropped with maize Bt11 (or maize MON 810), with no margins and a within-crop host-plant density of 0.01 plants m^{-2}). For other details see the legend to Figure X(*a*), above. A logarithmic scale is used for the *x*-axis to aid visibility

Table 1: Estimates of local and global percentage mortality of non-target Lepidoptera larvae in maize Bt11 fields (equally applicable to maize MON 810)

Sensitivity	Mortality ▸		Local mortality		Global mortality							
	R ▸		1.0		0.08 'Conservative'		0.02 'Perry et al. (2010)'		0.0049 'Typical'		0.00024 'Non-conservative'	
	Mitigation ▸		None	Full (24 m)	None	Full (24 m)	None	Full (24 m)	None	Full (24 m)	None	Full (24 m)
	Host-plant density within the crop	Margin										
below average	zero	2 m	6.0×10^{-3}	$< 10^{-5}$	4.8×10^{-4}	$< 10^{-5}$	1.2×10^{-4}	$< 10^{-5}$	$< 10^{-5}$	$< 10^{-5}$	$< 10^{-5}$	$< 10^{-5}$
below average	0.01	2 m	0.0125	6.9×10^{-3}	1.0×10^{-3}	5.5×10^{-4}	2.5×10^{-4}	1.4×10^{-4}	6.1×10^{-5}	$< 10^{-5}$	$< 10^{-5}$	$< 10^{-5}$
below average	0.01	none	0.023	0.0177	1.8×10^{-3}	1.4×10^{-3}	4.5×10^{-4}	3.5×10^{-4}	1.1×10^{-4}	8.7×10^{-5}	$< 10^{-5}$	$< 10^{-5}$
above average	zero	2 m	0.081	1.5×10^{-5}	6.5×10^{-3}	$< 10^{-5}$	1.6×10^{-3}	$< 10^{-5}$	4.0×10^{-4}	$< 10^{-5}$	$< 10^{-5}$	$< 10^{-5}$
above average	0.01	2 m	0.17	0.094	0.014	7.5×10^{-3}	3.4×10^{-3}	1.9×10^{-3}	8.3×10^{-4}	4.6×10^{-4}	4.1×10^{-5}	2.3×10^{-5}
above average	0.01	none	0.31	0.24	0.025	0.019	6.2×10^{-3}	4.8×10^{-3}	1.5×10^{-3}	1.2×10^{-3}	7.4×10^{-5}	5.8×10^{-5}
high	zero	2 m	1.1	2.0×10^{-4}	0.088	1.6×10^{-5}	0.022	$< 10^{-5}$	5.4×10^{-3}	$< 10^{-5}$	2.6×10^{-4}	$< 10^{-5}$
high	0.01	2 m	2.3	1.3	0.18	0.10	0.046	0.025	0.011	6.2×10^{-3}	5.5×10^{-4}	3.0×10^{-4}
high	0.01	none	4.2	3.2	0.33	0.26	0.083	0.064	0.020	0.016	9.9×10^{-4}	7.7×10^{-4}
Inachis io & *Vanessa atalanta*	zero	2 m	2.1	4.0×10^{-4}	0.17	3.2×10^{-5}	0.043	$< 10^{-5}$	0.011	$< 10^{-5}$	5.1×10^{-4}	$< 10^{-5}$
Inachis io & *Vanessa atalanta*	0.01	2 m	4.5	2.5	0.36	0.20	0.089	0.049	0.022	0.012	1.1×10^{-3}	5.9×10^{-4}
Inachis io & *Vanessa atalanta*	0.01	none	8.1	6.3	0.64	0.50	0.16	0.13	0.040	0.031	1.9×10^{-3}	1.5×10^{-3}
Plutella xylostella	zero	2 m	3.5	6.7×10^{-4}	0.28	5.3×10^{-5}	0.070	1.3×10^{-5}	0.017	$< 10^{-5}$	8.4×10^{-4}	$< 10^{-5}$
Plutella xylostella	0.01	2 m	7.2	4.0	0.58	0.32	0.14	0.080	0.036	0.020	1.7×10^{-4}	9.6×10^{-4}
Plutella xylostella	0.01	none	13.1	10.2	1.05	0.82	0.27	0.20	0.064	0.050	3.1×10^{-3}	2.4×10^{-3}
very high	zero	2 m	13.0	2.8×10^{-3}	1.0	2.2×10^{-4}	0.26	5.5×10^{-5}	0.064	1.4×10^{-5}	3.1×10^{-3}	$< 10^{-5}$
very high	0.01	2 m	26.4	14.4	2.1	1.2	0.53	0.29	0.13	0.071	6.3×10^{-3}	3.5×10^{-3}
very high	0.01	none	47.2	36.8	3.8	2.9	0.94	0.74	0.23	0.18	0.011	8.8×10^{-3}
extreme	zero	2 m	65.9	0.038	5.3	3.0×10^{-3}	1.4	7.5×10^{-4}	0.32	1.8×10^{-4}	0.016	$< 10^{-5}$
extreme	0.01	2 m	79.2	32.0	6.3	2.5	1.6	0.63	0.39	0.15	0.019	7.6×10^{-3}
extreme	0.01	none	100	80.6	8.0	6.4	2.0	1.6	0.49	0.40	0.024	0.019

Table 2: Estimated local mortality (%) for the five categories of hypothetical sensitivities, together with estimates for *Plutella xylostella* and *Inachis io* - *Vanessa atalanta*, with increasing distances from the nearest crop of maize Bt11 (or maize MON 810)

Distance from *Bt*-maize crop (m)	Sensitivity						
	'below-average'	'above-average'	'high'	***I. io* - *V. atalanta***	***P. xylostella***	'very high'	'extreme, worst-case'
2	0.0	0.1	0.7	1.4	2.4	9.2	57.8
5	0.0	0.0	0.3	0.5	0.8	3.3	31.8
10	0.0	0.0	0.0	0.1	0.1	0.6	7.2
15	0.0	0.0	0.0	0.0	0.0	0.1	1.3
20	0.0	0.0	0.0	0.0	0.0	0.0	0.2
25	0.0	0.0	0.0	0.0	0.0	0.0	0.0

2.2.4. Conclusions

For maize Bt11 (or maize MON 810), the model predicts that in general, estimated mortality of non-target Lepidoptera: (1) increases with species sensitivity; (2) is greater when there is no margin; (3) is greater when the host-plant density in the crop is greater; and (4) decreases greatly with mitigation when there are no host-plants in the crop, but to a lesser degree when the host-plant density in the crop is above zero. This is in line with findings for maize 1507 (see for further details, EFSA, 2011c; Perry *et al*., 2011b).

2.2.4.1. Global mortality

In particular, for maize Bt11 (equally applicable to maize MON 810):

- estimated global mortality never exceeds 1% for typical values of the large-scale exposure level (R = 0.0049), even for 'extremely sensitive' species;

- estimated global mortality never exceeds 1% under conservative assumptions for parameters y,x,a, when maize represents 30% (or less) of arable land (z = 0.3) and the uptake of *Bt*-maize does not exceed 25% (v = 0.25), thus yielding a value of R = 0.009375;

- estimated global mortality never exceeds 1%, even for 'extremely sensitive' species and under conservative assumptions for parameters y, x, a, when maize represents 30% or less of arable land and the proportion of *Bt*-maize remains only moderate (uptake below 30%), yielding a value of R = 0.012, as long as there is a margin and, in addition, there is full mitigation (i.e., non-*Bt*-maize border rows of 24 m width for a 15 ha field and pro-rata for fields of different sizes);

- estimated global mortality never exceeds 1%, even for 'extremely sensitive' species in intensive maize production areas with a conservative assumption of the exposure level (R = 0.08), as long as there is a margin, with no host-plants within the crop, and, in addition, there is full mitigation;

- for the two butterfly species for which there are data, *I. io* and *V. atalanta*, estimated global mortality never exceeds 1%, even under a conservative assumption for large-scale exposure (R = 0.08), and for any combination of margin and host-plant density.

For hypothetical species (based on the full range of species covered by the species sensitivity distribution), with the same conservative assumption of large-scale exposure (R = 0.08), Table 3 gives the expected percent of hypothetical species that would be likely to suffer > 1% mortality.

Table 3: Expected percent of all hypothetical species that would be likely to suffer > 1% mortality

Host-plant density	Width of margin	Mitigation employed	Expected percent of hypothetical species suffering > 1% global mortality
zero	2 m	full	< 0.2%
zero	2 m	none	1%
0.01	2 m	full	2%
0.01	2 m	none	5%
0.01	zero	full	6%
0.01	zero	none	6%

2.2.4.2. Local mortality

For local mortality, as long as there is a margin and full mitigation (i.e., non-*Bt*-maize border rows of 24 m width for a 15 ha field and pro-rata for fields of different sizes), and if host-plant density can be assumed to be zero, then local mortality is negligible (< 0.05%). However, even if there is a margin and full mitigation, if host-plant density is assumed to be 0.01 plants m^{-2}, then local mortality exceeds 30% for (hypothetical) 'extremely sensitive' species and exceeds 10% for very 'highly sensitive' species such as *P. xylostella*.

Small declines in lepidopteran populations are difficult to detect in practice (Aviron *et al.*, 2009) because of the natural fluctuations and trends in lepidopteran populations (Conrad *et al.*, 2006). Regarding local mortality rates, it should be noted that, by comparison, abiotic mortality factors analysed in field studies for some lepidopteran species can reduce the larval population by more than 50% (Annamalai *et al.*, 1988) in one season. Also, biotic mortality factors such as the impact of larval and pupal parasitoids can be high, since parasitisation rates as high as 80% are often found in field conditions (e.g., Telekar and Shelton, 1993; Liu *et al.*, 2000).

Nevertheless, the EFSA GMO Panel concludes that there is a risk to certain 'extremely sensitive' non-target lepidopteran species[11] where high proportions of their populations are exposed over successive years to high levels of maize Bt11 (and/or maize MON 810) pollen deposited on their host-plants.

2.3. Impacts of the specific cultivation, management and harvesting techniques

The PAT protein expressed in maize Bt11 has been used as a selectable marker during the transformation process. The scope of the application for maize Bt11 cultivation does not cover the use of glufosinate-ammonium-containing herbicides on maize Bt11. Therefore, potential environmental adverse effects due to the applications of glufosinate-ammonium-containing herbicides and possible changes in weed management are not considered by the EFSA GMO Panel in this Statement.

Bt-crops, such as maize Bt11, may reduce the use of insecticides and may cause changes in crop rotations in response to reduced pest pressure (Gómez-Barbero *et al.*, 2008a; Brookes and Barfoot, 2010). However, this reduction in pesticide use and the narrow spectrum of activity of Cry proteins may provide an opportunity for secondary pests, previously controlled by insecticides used against key target pests, to reach damaging levels (Wang *et al.*, 2008, Lu *et al.*, 2010). Natural enemies failing to fully control secondary pests, and reduced competition with target pests might also play a role in secondary pest outbreaks (Catangui and Berg, 2006; Sanvido *et al.*, 2007; Eichenseer *et al.* 2008; Romeis *et al.*, 2008; Fitt, 2008; Kennedy, 2008; Naranjo *et al.*, 2008; Dorhout and Rice, 2010; Lu *et al.*, 2010; Virla *et al.*, 2010). During the last decade *Striacosta albicosta* (the western bean cutworm) expanded across the cornbelt in the USA due to the decrease of competition from other lepidopteran target pests as a consequence of *Bt*-maize cultivation (Michel *et al.*, 2010). The western bean cutworm is not affected by the Cry1Ab protein expressed in *Bt*-maize, and was therefore able to occupy the ecological niche of the more susceptible *Helicoverpa zea* (corn earworm) and European corn borer (Catangui and Berg, 2006; Dorhout and Rice, 2010). However, *S. albicosta* is not present in European maize cultivation.

Where secondary pests remain uncontrolled, they can build up higher populations, affecting other crops in the agricultural landscape (Meissle *et al.*, 2011). Such a situation has been recently reported for mirid bugs in *Bt*-cotton in China: mirid bug infestation levels increased in alternative host crops (Chinese date, grapes, apple, peach and pear), and were significantly correlated with regional proportion of *Bt*-cotton planted (Lu et *al.*, 2010). However, it is considered unlikely that a similar

[11] Here, an 'extremely sensitive' species means a species in the highest sensitivity category as defined in Table 2 of EFSA (2011c).

situation occurs in *Bt*-maize in Europe, as it has a smaller pest spectrum than cotton, and the insecticide input in conventional maize is generally lower than in conventional cotton (Meissle *et al.*, 2011). It should also be noted that the emergence of secondary pests is not specific to *Bt*-crop cultivations only, or maize Bt11 in particular. Arthropod assemblages in agricultural fields are in a continuous fluctuation in terms of their species number, composition and individual densities over time and space. Human interventions, including pest control, influence these parameters. Whenever pest management of crops changes, the abundance of some pest species may decline and other pest species may increase.

If secondary pests reached damaging levels, additional pest control measures might be necessary and some changes in management could result in adverse environmental effects. In general, it is recommended to adhere to integrated pest management (IPM) principles to manage secondary pests and minimise environmental impacts (Meissle et *al.*, 2011). Predicting the incidence of secondary pests and the environmental consequences of changes in management measures is highly dependent upon cultivation practices, farming systems and regional environmental factors.

The EFSA GMO Panel concludes that, apart from changes in insecticide regimes, there are no anticipated changes in management that will occur with the cultivation of maize Bt11. The EFSA GMO Panel notes that the incidence of secondary pests and the environmental consequences of changes in management measures is highly dependent upon farming systems and regional environmental factors, and is therefore difficult to predict. Risk managers should be aware that, whenever pest management measures change, species assemblages will change accordingly and the environmental consequences should be considered in the framework of IPM in National Action Plans according to Directive 2009/128/EC.

2.4. Conclusion on the environmental risk assessment

The possible resistance evolution to the Cry1Ab protein in lepidopteran target pests is identified by the EFSA GMO Panel as a concern associated with the cultivation of maize Bt11. Resistance evolution may lead to altered pest control practices that may cause adverse environmental effects. Since other Cry1Ab-expressing maize events (e.g., maize MON 810) may also be present in areas where maize Bt11 is likely to be cultivated in the EU, the probability of resistance evolution to the Cry1Ab protein should consider the effects of maize Bt11 cultivation be it in combination or in rotation with other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU, both spatially and temporarily. In addition to the European and Mediterranean corn borers, which are the major target pests, other regionally important lepidopteran pests exposed to maize Bt11 alone or in combination with maize MON 810 may also have the potential to evolve resistance to the Cry1Ab protein.

Data on the biological activity of the Cry1Ab protein variant of maize Bt11 and MON 810 against sensitive lepidopteran species confirm that both variants are biologically equivalent. In addition, the reported ranges in the levels of the Cry1Ab protein expressed in maize Bt11 pollen were shown to be similar to those in maize MON 810 pollen. Based on the sensitivity and protein expression data, the EFSA GMO Panel considers that the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply equally to maize Bt11. Therefore, the amounts of maize Bt11 pollen grains found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae, except for regional populations of lepidopteran species in the hypothetical ‘extremely sensitive’ category.

The EFSA GMO Panel also concludes that, apart from changes in insecticide regimes, no other changes in management are anticipated with the cultivation of maize Bt11. The reduction in pesticide use and the narrow spectrum of activity of Cry proteins may permit populations of herbivore arthropods to develop that are no longer controlled by insecticides previously applied. Thus, reduced or no insecticide applications in maize Bt11 may provide an opportunity for secondary pests, previously controlled by insecticides used against key target pests, to reach damaging levels. The incidence of such dynamics will depend upon a series of factors, including cultivation management applied at the farm level, the crop rotation and the receiving environments.

The EFSA GMO Panel concludes that the cultivation of maize Bt11 could have the following adverse effects on the environment in the context of its intended uses: (1) the adoption of altered pest control practices with higher environmental load due to potential evolution of resistance to the Cry1Ab protein in populations of exposed lepidopteran target pests; and (2) reductions in populations of certain 'extremely sensitive' non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize Bt11 pollen deposited on their host-plants.

3. RISK MANAGEMENT STRATEGIES (INCLUDING POST-MARKET ENVIRONMENTAL MONITORING)

3.1. Risk mitigation measures

3.1.1. General aspects of mitigation

According to the EFSA GMO Panel Scientific Opinion delivering guidance on the ERA of GM plants (EFSA, 2010a) and in line with Annex II of Directive 2001/18/EC (EC, 2001), the risk assessment can identify risks that require management and propose risk mitigation measures to reduce the levels of risk. In order to reduce the identified risks associated with the GM plant deployment to a level of no concern, the EFSA GMO Panel evaluated the scientific quality of the management and risk mitigation measures, as well as their adequacy and efficacy. Risk mitigation should be proportionate to the results of the different risk scenarios studied, the specific protection goals in the receiving environments, and to the levels of scientific uncertainty and risk identified in the ERA (EFSA, 2011a).

3.1.2. Interplay between environmental risk assessment and mitigation

The ERA of maize Bt11 concluded that:

(1) the potential consequences of resistance evolution to the Cry1Ab protein in populations of exposed lepidopteran target pests may cause adverse environmental effects. Resistance to the Cry1Ab protein is likely to evolve in exposed populations of target lepidopteran pest species, particularly those subjected to the highest selection pressures, such as in areas of continuous and/or high adoption of maize Bt11 cultivation be it in combination or in rotation with other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU. While this is not considered a direct environmental harm, the consequences of resistance evolution may require altered pest control practices with higher environmental load. Considering that lepidopteran target pests may evolve resistance to the Cry1Ab protein under conditions of continuous exposure to maize Bt11, the applicant proposed to put in place risk mitigation measures to delay the possible evolution of resistance;

(2) exposed non-target Lepidoptera that are 'extremely sensitive' to the Cry1Ab protein may be at risk if exposed to harmful amounts of maize Bt11 pollen.

The EFSA GMO Panel considers that the risks identified during the ERA require management and, in the following sections, recommends that risk mitigation measures be adopted, wherever it is necessary. The suggested risk mitigation measures take into consideration the level of scientific uncertainty associated with the conclusions of the ERA (e.g., by considering hypothetical 'extremely high' levels of sensitivity and exposure of local non-target Lepidoptera). In order to reduce the identified risks and remaining scientific uncertainty associated with the cultivation of maize Bt11 to a level of no concern, the scientific quality of several risk mitigation measures, as well as their reliability and efficacy were evaluated by the EFSA GMO Panel. These aspects are described below.

3.1.3. Risk mitigation measures to delay resistance evolution to the Cry1Ab protein in maize Bt11

In line with the applicants' EU working group on IRM (as referred to by Alcalde *et al.* (2007)), the applicant proposed to put risk management measures in place to delay the possible resistance evolution in the target insect pests. According to the IRM plan proposed by the applicant, farmers growing more than 5 ha of *Bt*-maize in the EU shall establish refuge areas with non-*Bt*-maize, corresponding to at least 20% of the surface planted with *Bt*-maize. The applicant's reasoning for implementing the *refugia* only on farms where the total area of *Bt*-maize is greater than 5 ha is based on: (1) the high fragmentation of the European agricultural landscape; (2) the lack of economic feasibility for providing *refugia* on farms with less than 5 ha *Bt*-maize; and (3) the negligible risk of resistance evolution in areas with *Bt*-maize fields smaller than 5 ha (Alcalde *et al.*, 2007). In addition to maintaining an adequate level of refuge areas with non-*Bt*-maize, the IRM plan proposed by the applicant covers the following elements: (1) monitoring target pests for any potential evolution of resistance to maize Bt11; (2) the implementation of a comprehensive education programme to aid farmers in understanding the importance of IRM to delay the resistance evolution by planting refuge areas; and (3) the application of a remedial action plan addressing any contingency if resistance should occur.

The EFSA GMO Panel agrees with the applicant that appropriate IRM strategies are capable of delaying possible evolution of resistance under field conditions (Alstad and Andow, 1995; Andow, 2008; Tabashnik *et al.*, 2008a, 2009; Huang *et al.*, 2011). Resistance management strategies, relying on a 'high dose/refuge' strategy, have been endorsed for several Cry-expressing crops in several countries (Bates *et al.*, 2005; Andow, 2008; MacIntosh, 2010; Gaspers *et al.*, 2010; Huang *et al.*, 2011). The 'high dose/refuge' strategy proscribes planting *Bt*-maize that produces a very high concentration of the insecticidal Cry protein (25 times the amount needed to kill > 99% of susceptible individuals), so that nearly all target insects that are heterozygous for resistance do not survive on it. In addition, a nearby refuge of non-*Bt*-maize is required where the target insect pests do not encounter the Cry protein (Ives and Andow, 2002). (Note that in this Statement, a refuge is intended to mean a refuge area with maize that does not express Cry proteins which are active against Lepidoptera). Under these conditions, most of the rare resistant individuals surviving on *Bt*-maize will mate with abundant susceptible individuals emerging from nearby refuges to produce heterozygous progeny that is phenotypically susceptible. If inheritance of resistance is recessive, the hybrid progeny from such matings will die on *Bt*-maize.

Available evidence suggests that most of the underlying assumptions contributing to the success of the 'high dose/refuge' strategy in delaying resistance evolution are fulfilled for maize Bt11 and corn borers.

According to the IRM plan proposed by the applicant, only farmers growing more than a total area of 5 ha of *Bt*-maize in the EU shall establish refuge areas with non-*Bt*-maize, corresponding to at least 20% of the surface planted with *Bt*-maize. In practice, this would mean that non-*Bt*-maize *refugia* would not be implemented on a considerable proportion of farms in certain EU countries, as the area planted to *Bt*-maize on these farms would cover less than 5 ha. Considering experiences in Spain and other EU countries, this would not pose a risk, as *Bt*-maize would not be widely adopted in a given region. The Spanish experience illustrates that only in regions where pest infestation is high (e.g., Cataluña), does the adoption rate of *Bt*-maize reach approximately 60% (Gómez-Barbero *et al.*, 2008b). Therefore, it is likely that sufficiently large areas of non-*Bt*-maize will remain providing widely distributed mosaics of both non-*Bt*- and *Bt*-maize at regional scales. However, if maize Bt11 alone or in combination or in rotation with other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU, were adopted on a larger scale in a region, the risk of resistance evolution is likely to increase requiring more specific refuge mitigation measures. In the case of a cluster of fields with an aggregate area greater than 5 ha of Cry1Ab-expressing maize, the EFSA GMO Panel advises that there shall be *refugia* equivalent to 20% of this aggregate area, irrespective of individual field and farm size.

The EFSA GMO Panel is not aware of new information that would invalidate its previous evaluations on Cry1Ab-expressing maize events (EFSA, 2005a,b, 2006, 2009, 2011c) and therefore agrees with the applicant to implement an IRM plan that relies on the 'high dose/refuge' strategy, in order to delay resistance evolution in corn borers. Based on field data on inter-field dispersal flight characteristics of Mediterranean corn borer adults (Eizaguirre *et al*., 2004, 2006), the implementation of appropriate refuges in terms of size, location and configuration will enable successful management of the potential resistance evolvement for this species as well.

Considering that other regionally important lepidopteran pests exposed to maize Bt11 may also have the potential to evolve resistance to the Cry1Ab protein (e.g., *Sesamia cretica*, *Helicoverpa armigera*, *Mythimna unipuncta*), the EFSA GMO Panel advises the applicant to consider regionally important lepidopteran pests (other than the European and Mediterranean corn borers) of maize Bt11 in the context of IRM. However, the Cry1Ab protein might not be expressed in relevant plant parts at high toxicity dose for some of these lepidopteran pest species, meaning that one of the underlying assumptions contributing to the success of the 'high dose/refuge' strategy in delaying resistance evolution would not be fulfilled.

Appropriate adaptation of IRM to local and/or regional conditions (e.g., IPM, farming system) is a key element of its success (Tyutyunov *et al.*, 2008; MacIntosh, 2010). Therefore, the EFSA GMO Panel recommends that stewardship agreements pertaining to IRM, as proposed by the applicant, consider the following factors:

- the biology and ecology of target pest(s) (e.g., number of generations, alternative host-plants, dispersal behaviour, pest density level);

- the management of maize Bt11 fields (e.g., cultivation practices and IPM measures, configuration of non-*Bt*-maize *refugia*);

- the local characteristics (e.g., adoption rate of Cry1Ab-expressing maize events (maize Bt11 and MON 810), farming systems, landscape structure and heterogeneity);

- stakeholders/growers (e.g., communication, socio-economic background, education/training);

- integration of IRM (including resistance monitoring) strategies for maize Bt11 with those of other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU.

3.1.4. Risk mitigation measures to reduce exposure of non-target lepidopteran species occurring within maize fields and their margins to maize Bt11 pollen

Previously, in 2005, the EFSA GMO Panel recommended that appropriate management options for the cultivation of maize Bt11 are put in place, in order to reduce exposure of non-target Lepidoptera and to delay the potential evolution of resistance to the Cry1Ab protein in target lepidopteran pests (EFSA, 2005a).

In this Statement, the EFSA GMO Panel concludes that the risks identified during the ERA require management and recommends that appropriate risk mitigation measures be adopted, wherever it is necessary. In order to reduce the identified risks and the remaining scientific uncertainty associated with the cultivation of maize Bt11 to a level of no concern, the scientific quality of the several risk mitigation measures, as well as their adequacy and efficacy, was evaluated by the EFSA GMO Panel.

Considering the wide range and variability of agro-ecosystems, the EFSA GMO Panel is of the opinion that a set of risk mitigation measures (e.g., non-*Bt*-maize border rows) should be considered if these are appropriate for local protection goals of particular receiving environments and proportionate to the level of scientific uncertainty and risk identified in the ERA (EFSA, 2011a).

As an example, if considered proportionate, the planting of border rows of non-*Bt*-maize adjacent to uncultivated margins of maize Bt11 fields, could limit the exposure to those individuals feeding on host-plants present within maize field margins and also could contribute to the required percentage of non-*Bt*-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of IRM.

3.1.5. Risk mitigation measures to reduce the exposure of non-target lepidopteran species of conservation concern in protected habitats to maize Bt11 pollen

Bt-maize pollen might be hazardous to the larvae of lepidopteran species of conservation concern (Darvas *et al.*, 2004; Lang, 2004; Traxler *et al.*, 2005; Lang and Otto, 2010), and should therefore be the focus of specific risk management (Hofmann *et al.*, 2010). The purpose of the risk mitigation measures described here is to avoid harm to non-target lepidopteran species of conservation concern and occurring in protected habitats, as defined under Directive 2004/35/EC (EC, 2004). Emphasis is taken of any harm that has significant adverse effects on reaching or maintaining the favourable conservation status of such species in their protected habitats. The significance of such effects is to be assessed locally with reference to the baseline condition, taking account of the criteria set out in Annex I of Directive 2004/35/EC. The recommendations of the EFSA GMO Panel are to avoid cultivation of maize Bt11 within these habitats and to establish isolation distances to all relevant habitats as defined in Directive 2004/35/EC. Table 2 gives estimates of distances from the nearest maize Bt11 field that would be necessary to decrease the estimated mortality (before any allowance for large-scale exposure effects) below a certain level. The EFSA GMO Panel considers that a distance of 20 m is sufficient to reduce the mortality to a negligible level below 0.2% in the margins of the protected areas, even for ‘extremely sensitive’ species.

3.1.6. Conclusion on risk mitigation measures

The EFSA GMO Panel considered that the risks identified during the ERA require management and made recommendations for appropriate risk mitigation measures, wherever it is necessary. The suggested risk mitigation measures take into consideration the level of scientific uncertainty associated with the conclusions of the ERA (e.g., by considering hypothetical ‘extremely high’ levels of sensitivity and exposure of non-target Lepidoptera). In order to reduce the identified risks and remaining scientific uncertainty associated with the cultivation of maize Bt11 to a level of no concern, the scientific quality of several risk mitigation measures, as well as their reliability and efficacy, were evaluated by the EFSA GMO Panel.

The EFSA GMO Panel reiterates its earlier recommendation that appropriate IRM strategies (i.e., ‘high dose/refuge’ strategy) should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in target pests, taking into consideration the presence of all Cry1Ab-expressing maize events. In the case of a cluster of fields with an aggregate area greater than 5 ha of Cry1Ab-expressing maize, the EFSA GMO Panel advises that there shall be *refugia* equivalent to 20% of this aggregate area, irrespective of individual field and farm size.

Possible resistance evolution by other regionally important lepidopteran pests should also be considered. Therefore, the EFSA GMO Panel advises the applicant to consider regionally important lepidopteran pests (other than the European and Mediterranean corn borers) of maize Bt11 in the context of IRM. However, the Cry1Ab protein might not be expressed in relevant plant parts at high toxicity dose for some of these lepidopteran pest species, meaning that one of the underlying assumptions contributing to the success of the 'high dose/refuge' strategy in delaying resistance evolution would not be fulfilled for maize Bt11.

The EFSA GMO Panel recommends caution when predicting future responses of the European and Mediterranean corn borer in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors. Therefore, the EFSA GMO Panel, while agreeing with the 'high dose/refuge' strategy, recommends the periodic re-evaluation of the adequacy and efficacy of this IRM strategy.

The EFSA GMO Panel considers that, subject to the implementation of appropriate risk mitigation measures, the identified risks of maize Bt11 cultivation on non-target Lepidoptera can be reduced to a level of no concern. Special attention should be paid to the degree of large-scale exposure as risk mitigation measures are only needed when the proportion and uptake of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area[12,13] (see www.oecd.org/), the global mortality is predicted to remain below 1%, even for 'extremely sensitive' species, and then risk mitigation measures using non-*Bt*-maize border rows are not required.

However, the EFSA GMO Panel considers that lepidopteran species of conservation concern with unknown sensitivity to the Cry1Ab protein occurring in protected habitats according to Directive 2004/35/EC require additional protection and, in these cases recommend that maize Bt11 is not cultivated within 20 m of the boundary of these habitats, so that exposure and hence the risks to larvae of these lepidopteran populations are minimised in these habitats.

The EFSA GMO Panel concludes that risk mitigation measures are only required in situations where 'extremely sensitive' non-target Lepidoptera populations might be present and subject to sufficiently high exposure; for example, when 'extremely sensitive' non-target Lepidoptera and their host plants are present in *Bt*-maize fields and margins in areas where there is a high proportion of maize in arable fields and a high rate of adoption of maize Bt11 (and/or maize MON 810). Similarly, resistance evolution to target species is only expected when the selection pressure is high due to high adoption of maize Bt11 (and/or other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU).

3.2. Post-market environmental monitoring

3.2.1. General aspects of post-market environmental monitoring

Directive 2001/18/EC (EC, 2001) introduces an obligation for applicants to implement monitoring plans in order to trace and identify any direct or indirect, immediate, delayed or unanticipated effects on human health or the environment of GMOs as or in products after they have been placed on the market. Monitoring plans should be designed according to Annex VII of the aforementioned Directive. According to Annex VII, the objectives of PMEM are: (1) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the ERA are

[12] For example, a maximum uptake of 25% of maize Bt11 (and/or maize MON 810) in a region where maize represents 30% or less of the arable land

[13] I.e., zv = 0.075, and with conservative assumptions for the other parameters y=a=x=0.5, yielding $R = 0.009375$

correct via case-specific monitoring (CSM); and (2) to identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the ERA via general surveillance (GS) (EFSA, 2011a).

3.2.2. Interplay between environmental risk assessment, mitigation and post-market environmental monitoring

The EFSA GMO Panel concluded that the risk for certain 'extremely sensitive' non-target Lepidoptera identified during the ERA of maize Bt11 may require management and recommends that appropriate risk mitigation measures be adopted wherever it is necessary. As an example, if considered proportionate, the planting of border rows of non-*Bt*-maize adjacent to uncultivated margins of maize Bt11 fields, could limit the exposure to those non-target Lepidoptera feeding on host-plants present within maize field margins and also could contribute to the required percentage of non-*Bt*-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of IRM.

3.2.3. Case-specific monitoring

The EFSA GMO Panel reiterates its earlier recommendation that appropriate IRM strategies relying on the 'high dose/refuge' strategy should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests (EFSA, 2005a). In the case of a cluster of fields with an aggregate area greater than 5 ha of Cry1Ab-expressing maize (i.e., both maize Bt11 and maize MON 810), the EFSA GMO Panel advises that there shall be *refugia* equivalent to 20% of this aggregate area, irrespective of individual field and farm size (for further details, see EFSA, 2009). In addition, the EFSA GMO Panel makes additional recommendations to the applicant: (1) to focus the sampling of lepidopteran target pests in 'hotspot areas[14]' over time; (2) to include in the samplings surviving lepidopteran target pests within fields of maize Bt11, in order to detect potentially resistant individuals; (3) to consider regionally important lepidopteran pests (other than corn borers) of maize Bt11; and (4) to revise the monitoring protocol aiming at a detecting resistance allele frequency below 5% in 'hotspot areas.

The EFSA GMO Panel recommends that there is coordination and integration of IRM and monitoring of maize Bt11 with those of other Cry1Ab-expressing maize events currently grown commercially in the EU and caution when predicting future responses of the European and Mediterranean corn borer in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors. Therefore, the EFSA GMO Panel, while agreeing with the 'high dose/refuge' strategy, recommends the periodic re-evaluation of the adequacy and efficacy of this IRM strategy (for further details, see EFSA, 2011b).

The EFSA GMO Panel concluded that only under certain exposure scenarios would cultivation of maize Bt11 present a risk to non-target Lepidoptera that are 'extremely sensitive' to the Cry1Ab protein. In such situations, risk mitigation measures covering worst-case scenarios are recommended. This allows an overall conclusion that, subject to the proper implementation of these management measures, the effect to non-target Lepidoptera is reduced to a level of no concern. Therefore, there is no formal requirement for CSM of non-target Lepidoptera. In addition, small declines in lepidopteran populations as estimated in this Statement are difficult to detect in practice because of the natural fluctuations and trends in lepidopteran populations.

However, in many cases, e.g., if 'extremely sensitive' species do not exist or are not present where maize Bt11 might be cultivated, the recommended risk mitigation measures may be disproportionate

[14] In the present document, '*hotspot area*' is defined by an area of high adoption rate of maize Bt11 and the presence of multivoltine types of target pests

to the level of risk or uncertainty and put unnecessary burdens on farmers. If applicants, in agreement with risk managers, wish to reduce the proposed risk mitigation measures because they are considered too conservative, then monitoring studies may be required. The EFSA GMO Panel suggests that, in these latter cases, further studies could be conducted to confirm the estimates of the ERA on the sensitivity of non-target Lepidoptera and whether non-target Lepidoptera larvae, with an extremely high sensitivity to the Cry1Ab protein, are present and feeding on host-plants occurring in and adjacent to maize fields at the time of pollen shed (EFSA, 2011c).

Large-scale monitoring of commercial cropping areas would at best be able to measure only large population effects if they occurred in locally common lepidopteran species and therefore is unlikely to achieve the level of sensitivity commensurate with the effects that are anticipated by the EFSA GMO Panel, even if extensive and repeated sampling was conducted over many seasons (Aviron *et al*., 2009). Indeed, the estimated global mortality for all hypothetical species has been estimated to be considerably less than 10%, the effect size considered by Lang and Bühler (2012), provided that the proposed risk mitigation measures proposed by the EFSA GMO Panel are implemented.

3.2.4. General surveillance

According to Directive 2001/18/EC, the objective of GS is to detect any unanticipated adverse effects on protected and valued entities of the environment that may be due to the cultivation of GM plants, including biodiversity and ecosystem services (EFSA, 2011a).

The applicant proposed to conduct GS for maize Bt11 throughout the period of validity of the authorisation. The applicant proposed to build its GS plan on four approaches: (1) the use of annual farmer questionnaires; (2) the review of scientific information provided by existing monitoring networks; (3) the monitoring and review of ongoing research and development, as well as scientific literature; and (4) the implementation of industry stewardship programs, in order to identify potential adverse effects associated with the intended uses of maize Bt11.

3.2.4.1. Farmer questionnaires

The EFSA GMO Panel agrees with the approach of the applicant to establish farmer questionnaires as a reporting format that provides relevant information. The questionnaires to farmers exposed to or using GM plants are regarded by the EFSA GMO Panel as an adequate tool for addressing several aspects of GS (EFSA, 2011a). The EFSA GMO Panel is of the opinion that farmer questionnaires enable the reporting of any on-farm observations of effects associated with the cultivation of maize Bt11 as this approach uses first-hand observations and rely on farmers' knowledge and experience of their local agricultural environments, comparative crop performance and other factors that may influence events on their land (Schmidt *et al*., 2008; Wilhelm *et al*., 2010). Some of the questions link directly to assessment endpoints or give indirect indications of effects on assessment endpoints (EFSA, 2011a).

Farmer questionnaires should be designed to determine whether the farmer/manager/worker has noticed any differences between the GM plant and its management and that of similar non-GM plants growing on the farm, nearby or previously (EFSA, 2011a). The applicant and risk managers are advised to consider the EFSA GMO Panel Guidance Document on PMEM of GM plants (EFSA, 2011a) and the specific recommendations on the annual PMEM report of maize MON 810 cultivation in 2009 (EFSA, 2011b) when finalising their or evaluating monitoring plans.

The EFSA GMO Panel considers the format and contents of the farmer questionnaire, as provided by the applicant, and proposes the following modifications:

- to add questions on the possible occurrence and observation of (GM) volunteer maize from previous crops (whenever relevant) and feral maize plants in field margins for the consideration of unanticipated effects on the persistence and invasiveness potential of maize Bt11;

- to add question on weed occurrence in maize Bt11 fields to inform on the possible presence of host-plants for non-target Lepidoptera;

- to consider the occurrence of regionally important lepidopteran pests other than corn borers in maize Bt11 fields and surrounding areas;

- in addition to the questions on pest and disease incidences on maize Bt11, the farmer questionnaire should specifically request information on the occurrence of possible unexpected field damaged maize Bt11 plants which might be associated with corn borer control failures, as this information will complement the CSM of resistance evolution to the Cry1Ab protein in target pests;

- to add questions on the proportion of non-*Bt*-maize compared with maize Bt11 on the farm, the distance between the refuge area and the monitored maize Bt11 field in case the refuge is planted as a separate field adjacent to the Bt-maize field, the differences in pest management practices of the refuge.

In line with the general recommendations on the farmer questionnaire set in its 2011 Scientific Opinion on PMEM of GM plants (EFSA, 2011a), the EFSA GMO Panel advises farmer questionnaires:

- are designed to ensure the appropriate statistical validity and representativeness of the collected data, including the proportion of fields growing maize Bt11 in a region and a minimum percentage or number of questionnaires required to achieve statistical power in the data collected;

- are designed to generate data on the agronomic management of maize Bt11, as well as data on impacts on farming systems and the farm environment;

- use a field or group of fields growing maize Bt11 as the basic unit for monitoring in representative farming regions and for representative cropping systems within the country. The precise fields should be identified, so that their locations can be subsequently retrieved from registers of GM plant sites;

- clearly identify the comparator (e.g., variety, location) and whether it is being grown adjacent to maize Bt11, on the same farm or in another location. If no comparators are being grown spatially or temporally close to maize Bt11, then the rationale for selecting another comparator (e.g., historical data) should be fully described;

- where appropriate, observe the field/fields in subsequent years for any unusual residual effects;

- provide information on other GM plant events being grown at the same sites and farms;

- are user friendly but also information rich;

- are constructed to encourage independent and objective responses from farmers, land managers and others involved with maize Bt11 or its transgene products;

- are audited to ensure the independence and integrity of all monitoring data.

In addition to the general recommendations on the farmer questionnaire (EFSA, 2011a) and in line with its 2011 Scientific Opinion on the annual PMEM report on maize MON 810 cultivation in 2009 (EFSA, 2011b), the EFSA GMO Panel advises the applicant to take into account the following points:

- the sampling frame should be comprehensive and a stratification should be applied consistently in each country. Adequate sampling should be carried out from the previous stratification exercise;

- the cultivation areas, with high uptake of maize Bt11 and where maize Bt11 has been continuously grown in previous years, should be over-represented in the sampling scheme;

- the number of farmers not participating in the survey and the reasons thereof should be documented;

- impartial and standardised interviews should be carried out by independent parties and effective quality and auditing procedures should be considered;

- additional questions to the farmer questionnaire should be considered to better describe the cultivation of maize Bt11 and other Lepidoptera-resistant maize events in the local area and/or the previous years, the receiving environments and the management systems in which maize Bt11 is being grown;

- relevant data as from other sources of information (e.g., official statistics on crop management practices) should/could be considered for validity check of the questionnaires (e.g., consistency, representativeness);

- the raw data, programmes, logs and output files related to the statistical analysis of the farmer questionnaires should be provided. Confidence intervals for the analysis of the monitoring characteristics should be included in the statistical report;

- appropriate statistical procedures should be used based on using a distribution for appropriate outcomes;

- the use of a standard default effect size of 5% is not relevant for all assessment endpoints and, where scientifically justified, different default effect sizes should be considered for some assessment endpoints;

- data should be pooled and statistically analysed over years. At the end of the ten years of GS, the applicant should conduct a statistical analysis with all pooled data;

- a codification for farmers repeatedly surveyed over years should be set up. These farmers should be particularly monitored;

- the number of years the surveyed farmer has grown maize Bt11, and other GM plants, especially other Cry1Ab-expressing maize events, should be indicated.

3.2.4.2. Existing monitoring networks

Since farmer questionnaires focus mainly on the cultivation area of the GM plant and its surroundings, the EFSA GMO Panel supports the consideration of additional information sources for GS (EFSA, 2011a). In this respect, Directive 2001/18/EC proposed to make use of established routine surveillance networks, in order to obtain data on environmental impacts in the landscape where GMOs are cultivated from a range of existing monitoring networks which observe changes in biota and production practices from farm up to regional level. EU Member States have various networks in place – some of which have a long history of data collection – that may be helpful in the context of

GS of GM plant cultivations. Existing monitoring networks involved in routine surveillance offer recognised expertise in a specific domain and have the tools to capture information on important environmental aspects over a large geographical area. However, the EFSA GMO Panel recognises that existing monitoring networks fully meeting all the needs of the monitoring of GM plant cultivations can be limited (Bühler, 2006; Mönkemeyer *et al*., 2006; Schmidtke and Schmidt, 2007; Graef *et al*., 2008). The development of harmonised criteria for the systematic identification, specification and analysis of existing surveillance networks across the EU is therefore considered important (EFSA, 2011a).

The EFSA GMO Panel agrees with the proposal of the applicant to describe the generic approaches for using existing monitoring networks. The applicant has also given consideration to the use of any future surveys of conservation goals as defined in the Directive 2004/35/EC on environmental liability (EC, 2004) in farming regions where maize Bt11 will be cultivated and intends to investigate their suitability for providing data on potential changes in biota.

Knowing the limitations of existing monitoring networks, it is important to describe the processes and criteria that will be used for selecting and evaluating existing monitoring networks for supplying data related to the unanticipated adverse effects of GM plants in GS. Therefore, the applicant, in consultation with Member States, should:

- consider the protection goals, the assessment endpoints and their indicators that could be monitored through existing monitoring programmes;
- identify the type of existing monitoring networks that would be appropriate to survey the protection goals considered to be at risk in the countries where maize Bt11 will be grown;
- describe the generic approach and develop more detailed criteria to evaluate existing monitoring networks and how appropriate networks will be selected (considering the hereunder list of points);
- identify what changes need to be made to these monitoring networks and describe how these might be implemented, and identify gaps in information that could be filled by additional surveys;
- encourage these networks to adopt the proposed modifications and describe how data from these networks will be integrated and assessed.

In addition, when selecting existing monitoring networks to be part of GS, the applicant is recommended to consider the following points for assessing the suitability of these existing networks to supply relevant GS data:

- the relevance of protection goals and their indicators monitored through existing monitoring networks;
- the type (e.g., raw data) and quality of the data recorded;
- the statistical power and the effect sizes detected by monitoring networks, where appropriate;
- the ease of access to the data collected by existing monitoring networks (e.g., availability of data via Internet, free access to data or access subject to a fee, protected data of ongoing research projects);
- the track record and past performance of existing monitoring networks;

- the methodology used by existing monitoring networks (e.g., sampling and statistical approach) including: (1) the spatial scale of data collection (e.g., local, regional, national, zonal): existing monitoring networks focusing on agricultural areas cultivated with GM plants or with conventional plants like maize, potato (for which GM are also available and grown) should be preferred; (2) temporal scale of data collection: appropriate frequency of data collection and reporting (e.g., short-term vs. long-term data sets, regularity of data collection); and (3) other parameters such as the language of the reports, impartiality.

Furthermore, the EFSA GMO Panel recommends that the applicant describes arrangements with any third parties participating in its GS plan. It is recommended to consider how arrangements for collecting, collating and analysing data will be made, and to describe how formal agreements, procedures and communication will be established with the European Commission and Member States or other third parties, although detailed arrangements may not have been agreed at the time of the application.

The EFSA GMO Panel also recommends to include in the sources of information that support GS of maize Bt11, existing monitoring networks that monitor herbicide usage, botanical diversity on farms and weed resistance evolution, so that the scientific requirements for the detection of any unforeseen environmental effects due to altered farm management practices associated with maize Bt11 cultivation are met.

3.2.4.3. Monitoring and review of ongoing research and development, as well as scientific literature

An additional approach to support GS is to review all new scientific, technical and other information pertaining to maize Bt11, including information on GM plants with similar traits or characteristics, which has emerged during the reporting period. This will include reviewing of results from ongoing research and development studies (e.g., variety registration trials) and all publications including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the cultivation of the plant/trait combination for which the report is being drafted (EFSA, 2011a).

The EFSA GMO Panel recommends that the applicant:

- to cover all relevant peer-reviewed publications, including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the cultivation of the plant/trait combination for which the report is being drafted;
- to describe the criteria for selecting and evaluating the scientific reliability of publications;
- to adhere to systematic literature review methodology to select relevant papers (EFSA, 2010b).

3.2.4.4. Industry stewardship programs

The EFSA GMO Panel welcomes the applicant's proposal to develop stewardship programs for the introduction, marketing, and management of maize Bt11, but advises that these programmes should be made available well in advance of the time of commercialisation so as to allow risk managers to validate the implementation of risk management measures and detailed monitoring plans.

3.2.4.5. Reporting results of post-market environmental monitoring

The applicant will submit a report on an annual basis covering CSM and GS. In case of adverse effects altering the conclusions of the ERA, the applicant will immediately inform the European Commission and Member States. The EFSA GMO Panel agrees with the proposal made by the applicant on reporting intervals. The EFSA GMO Panel recommends that effective reporting procedures are established with the Competent Authorities of Member States and the European Commission as required under the Council Decision 2002/811/EC on monitoring.

The results of PMEM should be presented in accordance with the standard reporting formats established by the 2009/770/EC Commission Decision on standard reporting formats (EC, 2009). In addition, the applicant is recommended to provide raw data, in order to allow different analyses and interrogation of the data and to allow scientific exchange and co-operation between Member States, the European Commission and EFSA. The EFSA GMO Panel recommends that the applicant describes whether the PMEM reports contain cumulative analyses of data with previous years' results.

3.2.5. Conclusions on post-market environmental monitoring

In 2005, the EFSA GMO Panel gave its opinion and made recommendations on the scientific quality of the PMEM plan proposed by the applicant (EFSA, 2005a).

The EFSA GMO Panel reiterates its earlier recommendation that appropriate IRM strategies relying on the 'high dose/refuge' strategy should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests. The EFSA GMO Panel also reiterates its recommendations for CSM for resistance evolution in target pests and recommends that the applicant should consider integrating the IRM and CSM for maize Bt11 with that of other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU. In addition, the applicant should consider the recommendations to improve the IRM and CSM made in the 2009 EFSA GMO Panel Scientific Opinion for the renewal of maize MON 810 for cultivation (EFSA, 2009) and the 2011 EFSA GMO Panel Scientific Opinion on the annual 2009 PMEM report on maize MON 810 (EFSA, 2011b).

The EFSA GMO Panel concludes that risk mitigation measures are only required in situations where 'extremely sensitive' non-target Lepidoptera populations might be at risk; for example, when 'extremely sensitive' non-target Lepidoptera and their host-plants are present in *Bt*-maize fields and margins in areas where there is a high proportion of maize in arable fields and a high rate of adoption of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU). The EFSA GMO Panel concludes that, subject to the proper implementation of these risk mitigation measures, the effect on non-target Lepidoptera is reduced to a level of no concern. Therefore, there is no formal requirement for CSM of non-target Lepidoptera. However, in many cases, e.g., if 'extremely sensitive' species do not exist or are not present where maize Bt11 might be cultivated, the recommended management measures may be disproportionate to the level of risk or uncertainty and put unnecessary burdens on farmers. If applicants, in agreement with risk managers, wish to reduce the proposed risk mitigation measures because they are considered too conservative, then monitoring studies may be required. The EFSA GMO Panel suggests that, in these latter cases, further studies could be conducted to confirm the estimates of the ERA on the sensitivity of non-target Lepidoptera and whether non-target Lepidoptera larvae, with an 'extremely high' sensitivity to the Cry1Ab protein, are present and feeding on host-plants occurring in and adjacent to maize fields at the time of pollen shed (EFSA, 2011c).

The EFSA GMO Panel agrees with the GS approach of the applicant: (1) to establish farmer questionnaires as a reporting format of any on-farm observations of effects associated with the cultivation of maize Bt11; (2) to use existing monitoring networks which observe changes in biota and production practices from farm up to regional level to obtain data on environmental impacts in the landscape where maize Bt11 is cultivated; (3) to review all new scientific, technical and other information pertaining to maize Bt11; and (4) to develop stewardship programs for the introduction, marketing, management and stewardship of maize Bt11, but requests that its proposals to strengthen GS are implemented. The EFSA GMO Panel considers that the current plan for GS, and in particular the methodology, needs further details according to the requirements laid down in its 2011 Scientific Opinion providing guidance on PMEM of GM plants and its Scientific Opinion on the annual 2009 PMEM report on maize MON 810 (EFSA, 2011a,b). The EFSA GMO Panel agrees with the reporting intervals and modalities proposed by the applicant.

CONCLUSIONS AND RECOMMENDATIONS

Following a request from the European Commission, the EFSA GMO Panel was asked to further analyse some aspects of the ERA of GM maize event Bt11 in light of the scientific data and methodology currently available and to clarify its previous recommendations to risk managers. In addition, the EFSA GMO Panel was asked to reconsider the plan for PMEM of maize Bt11 in light of its 2011 Scientific Opinion providing guidance on PMEM of GM plants.

In delivering this Statement, the EFSA GMO Panel considered the initial notification C/F/96/05.10 for cultivation of maize Bt11, the additional information supplied by the applicant upon request of the EFSA GMO Panel, as well as relevant scientific publications. The EFSA GMO Panel also utilised material from its previous 2009 evaluation of the ERA of the similar Lepidoptera-resistant maize event MON 810 and from recent work on the risk mitigation and monitoring of maize MON 810.

The possible resistance evolution to the Cry1Ab protein in lepidopteran target pests continues to be a concern associated with the cultivation of maize Bt11, as resistance evolution may lead to altered pest control practices that may cause adverse environmental effects.

The EFSA GMO Panel reiterates its earlier recommendation that appropriate IRM strategies relying on the 'high dose/refuge' strategy should be employed, in order to delay the potential evolution of resistance to the Cry1Ab protein in lepidopteran target pests. The EFSA GMO Panel also recommends the applicant to consider integrating the IRM and CSM for maize Bt11 with that of other Cry1Ab-expressing maize events such as maize MON 810 currently grown in the EU. In addition, the applicant should consider the recommendations to improve the IRM and CSM made in the 2009 EFSA GMO Panel Scientific Opinion for the renewal of maize MON 810 for cultivation and the 2011 EFSA GMO Panel Scientific Opinion on the annual 2009 PMEM report on maize MON 810.

In areas where other lepidopteran pests than the European and Mediterranean corn borer occur, they might also be subject to resistance evolution due to exposure to the Cry1Ab protein expressed in maize Bt11. Therefore, the EFSA GMO Panel recommends that these species are also considered by the applicant in the context of IRM and CSM to monitor resistance evolution to the Cry1Ab protein in these species, as well as in GS through farmer questionnaires.

Data on the biological activity of the Cry1Ab protein variant of maize Bt11 and maize MON 810 against sensitive lepidopteran species confirm that both variants are biologically equivalent. In addition, the reported ranges in the levels of the Cry1Ab protein expressed in maize Bt11 pollen were shown to be similar to those in maize MON 810 pollen. Based on the sensitivity and protein expression data, the EFSA GMO Panel considers that the mortality estimates calculated by Perry *et al.* (2010) for maize MON 810 apply equally to maize Bt11. Therefore, the amounts of maize Bt11 pollen grains found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae, except for local populations of lepidopteran species with such hypothetical high sensitivities to the Cry1Ab protein that they comprise just 1% of the total species at risk. The degree of this mortality may be estimated quantitatively from the levels of exposure. The EFSA GMO Panel supplements its evaluation of the ERA of maize Bt11 in line with the environmental safety evaluations of other Lepidoptera-resistant maize events (such as maize 1507 and MON 810). The range of sensitivities explored within the modelling exercise applied to maize 1507 and risk mitigation measures for any 'highly sensitive' species that might be exposed and hence at risk were also considered.

The EFSA GMO Panel concludes that locally exposed non-target Lepidoptera that are ‘extremely sensitive’ to the Cry1Ab protein may be at risk if exposed to harmful amounts of maize Bt11 pollen. Therefore, the EFSA GMO Panel considers that the risks identified during the ERA require management and recommends that appropriate risk mitigation measures be adopted, wherever it is necessary. As an example, if considered proportionate, the planting of border rows of non-*Bt*-maize adjacent to uncultivated margins of maize Bt11 fields, would limit the exposure of those larvae feeding on host-plants present within maize field margins and also would contribute to the required percentage of non-*Bt*-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of IRM. Another example is the establishment of isolation distance to lepidopteran species of conservation concern in protected habitats according to Directive 2004/35/EC.

The EFSA GMO Panel provides risk managers with tools to estimate global and, where needed local, mortality of exposed non-target Lepidoptera, both before and after different risk mitigation measures are put in place, and for different host-plant densities. This enables risk managers to choose risk mitigation measures proportionate to the level of identified risk and to the protection goals pertaining to their region. Special attention should be paid to the degree of large-scale exposure as risk mitigation measures are only needed when the proportion and uptake of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU) are sufficiently high, regardless of the other parameters. If maize Bt11 (and/or maize MON 810) cultivation remains below 7.5% of the regional Utilized Agricultural Area[15,16], the global mortality is predicted to remain below 1%, even for ‘extremely sensitive’ species, and then risk mitigation measures using non-*Bt*-maize border rows are not required.

The EFSA GMO Panel considers that lepidopteran species of conservation concern with unknown sensitivity to the Cry1Ab protein occurring in protected habitats according to Directive 2004/35/EC require additional protection and, in these cases, recommends that maize Bt11 is not cultivated within 20 m of the boundary of these habitats, in order to minimise exposure and hence risks to these Lepidoptera.

The EFSA GMO Panel concludes that risk mitigation measures are only required in situations where ‘extremely sensitive’ non-target Lepidoptera populations might be at risk; for example, when ‘extremely sensitive’ non-target Lepidoptera and their host-plants are present in *Bt*-maize fields and margins in areas where there is a high proportion of maize in arable fields and a high rate of adoption of maize Bt11 (and/or other Lepidoptera-resistant maize events such as maize MON 810 currently grown in the EU). Similarly, resistance evolution to target species is only expected when the selection pressure is high due to high adoption of maize Bt11 (and/or other Cry1Ab-expressing maize events) in a region.

The EFSA GMO Panel concludes that, subject to the proper implementation of the risk mitigation measures, the effect on non-target Lepidoptera is reduced to a level of no concern. Therefore, there is no formal requirement for CSM of non-target Lepidoptera. However, in many cases, e.g., if ‘extremely sensitive’ species do not exist or are not present where maize Bt11 might be cultivated, the recommended risk mitigation measures may be disproportionate to the level of risk or uncertainty and put unnecessary burdens on farmers. If applicants, in agreement with risk managers, wish to reduce the proposed risk mitigation measures because they are considered too conservative, then monitoring studies may be required. The EFSA GMO Panel suggests that, in these latter cases, further studies could be conducted to confirm the estimates of the ERA on the sensitivity of non-target Lepidoptera and whether non-target Lepidoptera larvae, with an ‘extremely high’ sensitivity to the Cry1Ab protein, are present and feeding on host-plants occurring in and adjacent to maize fields at the time of pollen shed.

[15] For example, a maximum uptake of 25% of maize Bt11 (and/or maize MON 810) in a region where maize represents 30% or less of the arable land

[16] I.e., zv = 0.075, and with conservative assumptions for the other parameters y=a=x=0.5, yielding R = 0.009375

The EFSA GMO Panel also considers that the current plan for GS, and in particular the methodology, needs further details according to the requirements laid down in its 2011 Scientific Opinion providing guidance on PMEM of GM plants as well as its Scientific Opinion on the annual 2009 PMEM report on maize MON 810.

The EFSA GMO Panel concludes that, subject to appropriate risk management measures, maize Bt11 cultivation is unlikely to raise additional safety concerns for the environment compared to conventional maize.

The EFSA GMO Panel considers that the conclusions drawn regarding the risk to non-target Lepidoptera from maize Bt11, listed above, and the recommendations on risk management measures, apply equally to maize MON 810.

Documentation provided to EFSA

1. Letter from the European Commission, dated 8 December 2010, to the EFSA Executive Director concerning a complementary environmental risk assessment of GM maize Bt11 in light of a new modelling exercise.
2. Acknowledgement letter, dated 6 January 2011, from the EFSA Executive Director to the European Commission.
3. Letter from EFSA to the applicant, dated 6 January 2011, requesting additional information.
4. Letter from the applicant to EFSA, dated 26 May 2011, providing the additional information requested by EFSA.
5. Letter from the European Commission, dated 5 July 2011, regarding an extension of deadline in order to consider the 2011 Scientific Opinion providing guidance on PMEM of GM plants.
6. Letter from EFSA to the European Commission, dated 20 September 2011, concerning the evaluation of the PMEM plan for maize Bt11.
7. Letter from EFSA to the European Commission, dated 3 November 2011, concerning an extension of deadline for a comprehensive evaluation of the PMEM plan for maize Bt11.

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