

In Two Minds

EFSA GMO Panel concedes Bt crop risks to non-target moths and butterflies, but hangs hopes on unproven mitigation

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Summary

Genetically modified (GM) 1507 maize was developed by Pioneer Hybrid/Mycogen Seeds to control European corn borer (*Ostrinia nubilalis*) and corn stalk borer (*Sesamia* species) larvae using a Bt CryF1 toxin (see explanation below).

The European Food Safety Authority (EFSA) GMO Panel has issued two scientific opinions on 1507 maize. The first opinion, produced in 2005, found there was no risk to non-target species. The second, produced in 2011, concluded a number of sensitive moth and butterfly species could be harmed by exposure to the CryF1 toxin in the pollen of 1507 maize.

There are also conflicts between the 2005 and 2011 opinions over the toxicity of the Cry1F toxin.

The EFSA GMO Panel concedes a lack of data about which species may be exposed to the toxin via pollen and that data on sub-lethal impacts are very limited.

Despite the acknowledged scientific uncertainty surrounding potential environmental impact, the EFSA GMO Panel recommends 1507 maize be approved for cultivation provided mitigation measures are taken. Other maize varieties with the 1507 GM traits are awaiting approval, so the risk assessment should have considered exposure via these crops as well.

There is considerable scientific doubt about the effectiveness of the proposed mitigation measures, including:

- Confusion over basic information needed to determine separation distances, like the distance maize pollen will move from the crop and quantities found at different distances.
- The practicality, enforceability and impact of the proposed measures are not known.
- The effectiveness of measure to prevent target pest species developing resistance to the CryF1 toxin, particularly important as any breakdown in resistance could lead to further environmental harm from the need to use additional chemical controls.

Given the scientific uncertainty about the impacts of GM 1507 maize and lack of clarity that the proposed mitigation measures will work, the precautionary principle should apply and the application should be rejected.

It is unacceptable to rely on post market monitoring (PMM) to try and fill gaps in data and to demonstrate the effectiveness of mitigation measures, as by the time any problems are observable they will already be causing damage, which could be irreversible.

The case of 1507 maize is an excellent example of how scientific understanding develops over time. In the six years between EFSA's two opinions evidence of harm emerged where the agency originally said there was no risk, nevermind harm. Genetics is an imperfectly understood discipline, which is why we must take a precautionary approach to all GM food and crops – what we do not know now may emerge as problems later.

Introduction

The introduction of GM insect resistant crops in the 1990s led to concern that toxins intended to kill pests in maize and cotton could also harm non-target organisms in the same families as the target

insects. Non-target species could also include insect predators, soil organisms, aquatic insects and other non-pest species. As some of these are already under considerable pressure from industrial agriculture it is important to ensure all safety considerations of GM crops are thorough and careful.

This briefing examines the 2005 and 2011 EFSA GMO Panel opinions about the impact on non-target species of GM maize 1507.

The GMO Panel's opinion changed significantly between 2005 and 2011 in the light of new information available about potential harm to some sensitive species.

Yet despite this change in opinion, and despite supporting the view that insect resistance could develop if preventative measures are not strictly followed, the EFSA GMO Panel still supports the approval of this GM maize because it believes the harmful effects can be mitigated. The Panel also warns that secondary pest species not controlled by the GM crops may increase as primary pests are displaced by the Bt toxins. Both breakdown of resistance and increases in secondary pests could lead to increased use of chemical pesticides, in addition to the Bt toxins in the GM maize, resulting in more environmental harm.

The changes between the two EFSA GMO Panel opinions suggest the precautionary approach adopted by some Member States over cultivation approval for GM crops is correct. However the European Commission has continued to approve the import of GMOs for food and feed (including 1507 maize) without any regard for the impact cultivating those crops has on the environment, biodiversity or local communities in producer countries. It is not acceptable for Europe to export our environmental damage in this way. If cultivating GM crops is damaging it should not be permitted anywhere.

Biodiversity on farmland

The past 50 years has seen a steep decline in the numbers and diversity of farmland wildlife species, for example farmland birds.ⁱ The numbers and diversity soil dwelling micro- and macroorganisms have also altered as a result of changes in farming practices.ⁱⁱ

The arrival of GM insect resistant and herbicide tolerant crops introduced new threats to farmland biodiversity, from direct toxicityⁱⁱⁱ to reductions in food supply arising from reduced numbers of weeds and weed seeds.^{iv} Past attempts to restore farmland wildlife through the Common Agriculture Policy using financial incentives paid to farmers to improve habitats have only been moderately successful in arresting the long-term declines.^v

Mitigation measures applied to GM crops must therefore be viewed in the context of an overall policy seeking to reverse the decline in farmland biodiversity, rather than merely preventing further losses from what is already a severely degraded ecosystem.

GM 1507 maize

GM 1507 maize was developed by Pioneer Hi Bred/Mycogen Seeds to control European corn borer (*Ostrinia nubilalis*) and corn stalk borer (*Sesamia* species) larvae, which can cause serious damage to crops if populations are high enough. The modification of a gene in 1507 maize enables it to produce a Bt toxin called Cry1F, which targets *Lepidopteran* (moth) pests. 1507 maize is also tolerant to Bayer CropScience's herbicide glufosinate ammonium, which is used as a marker gene in the GM process (ie, it is not intended to use it for weed control on commercial crops at present).

Pioneer Hybrid and Mycogen/Dow Agro Sciences have filed EU cultivation applications for three other GM maize varieties containing the 1507 Bt gene in combination with traits conferring tolerance to the herbicide glyphosate and other Bt toxins.¹ Crops with several "stacked" GM traits for insect resistance and herbicide tolerance dominate new applications for approval in the EU and the US as weed and insect resistance to current GM crops become problematic. Smartstax maize,

¹ 1507 x NK603 (Pioneer Hi-Bred and Mycogen Seeds), 1507 x 59122 (Mycogen Seeds) and 59122 x 1507 x NK603 (Pioneer Hi-Bred)

containing six insect resistance genes and two herbicide tolerance genes, has been approved in the US and Canada.^{vi} Stacked GM traits are mainly aimed at delaying the development of insect and weed resistance, a growing problem in single trait GM crops in the US, by adding more GM toxins and allowing several herbicides to be sprayed on the crops to avoid dependence on just one Bt toxin and/or one herbicide.

Bt toxins

Bt is a generic name given to a group of naturally occurring toxins produced by the soil bacterium *Bacillus thuringiensis*. Cry1Ac is one such toxin, there are many more. Bt toxins are sometimes used as agricultural insecticides without the application of GM. When sprayed on crops Bt toxins are classed as insecticides, yet the large amounts constantly produced by GM Bt plants and released into the soil are not.

Individual Bt toxins are most effective against one group of insects – either *Lepidoptera* (moths and butterflies) or *Coleoptera* (beetles). The CryF1 toxin in 1507 targets *lepidopteran* pests in maize.

Although these toxins are not sufficiently broad spectrum to kill all insects, they may impact on non-target species in the same group who come into contact with the toxin via their food supply.^{vii and viii} In some cases the toxins may also affect unrelated species.^{ix and x} Of particular concern is the presence of Bt pollen on the food plants of non-target *Lepidopteran* species, such as the Monarch butterfly.

Basing a risk assessment on the impact of 1507 maize alone may therefore seriously underestimate future production of the Cry1F toxin in maize crops as biotech companies push stacked crops as insurance against pest and weed resistance developing. All Bt maize producing CryF1 Bt toxin should be considered when carrying out an environmental risk assessment for this particular toxin, as the full environmental exposure may be higher and more widespread. Its effect when present with other Bt toxins should also form part of the assessment.

Food and feed safety

The safety of 1507 maize is not covered by this briefing. However the recommendation of EFSA's GMO Panel to approve it has been questioned because Monsanto's own data shows reductions in white and red blood cells in mice fed 1507 maize, as well as significant differences in the composition of 1507 maize compared with other maize varieties (including its non-GM parent) and inadequate feeding trials.^{xi}

EFSA's change of opinion

2005 – All's well

EFSA produced its first opinion on 1507 maize in March 2005. This gave 1507 the all clear for cultivation in the EU^{xii}:

“Therefore no unintended environmental effects due to the establishment and spread are anticipated. The likelihood of adverse effects on non-target organisms or on soil functions due to the expression of the cry gene or the pat gene is considered to be very low. The possible development of resistance of target organisms to Bt toxin has been identified as a potential risk due to large scale cultivation and/or long term exposure. Thus, an appropriate case-specific monitoring plan to record the development of resistance has been provided. In addition, the GMO Panel agrees in principle with the approach proposed by the applicant in the general surveillance plan.”

2011 – Or maybe not

A number of scientific papers on the impacts of Bt crops on non-target organisms led to pressure on the European Commission from EU Member States, and the GMO Panel was eventually asked to look afresh at the impact of 1507 maize on non-target organisms.

EFSA's second opinion was published in November 2011. It now cast doubt on the safety of 1507^{xiii}:

“The EFSA GMO Panel concludes that the cultivation of maize 1507 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 Cry1F protein in populations of exposed lepidopteran target pests, and (2) reductions in populations of certain highly sensitive non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants. In situations where highly sensitive non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that mitigation measures are adopted to reduce exposure.”

In other words EFSA now accepts that Cry1F from 1507 maize could be toxic to certain sensitive moth and butterfly species inhabiting field margins of arable farms across the EU.

Importantly the EFSA GMO Panel also acknowledged that:

- The development of resistance in the target pest species cannot be ruled out, and this could lead to greater use of chemical pesticides if the Bt resistant type individuals became dominant.
- Secondary insect pests on maize may become a problem because of reduced spraying of the Bt crops and reduced competition from the pests targeted by the 1507 Bt toxin. Ultimately secondary pests may require control with chemical insecticides as well.

Secondary pests

In some areas where Bt crops are widely grown, like China^{xiv}, some farmers wrongly assume Bt toxins control all insects and therefore drop all other pest control measures. This has led to crops being threatened by increased numbers of pests not controlled by Bt, for example mirid bugs. In sub-tropical regions this occurs with leaf hopper species (a maize pest because it is a vector of diseases).^{xv}

The EFSA GMO Panel accepts that this may lead to more pesticide use to control pests, saying, *“If secondary pests reached damaging levels, additional pest control measures might be necessary and some changes in management could result in adverse environmental effects.”*^{xvi}

What species might be affected and where

The EFSA GMO Panel identifies the main threat from 1507 maize to non-target butterflies and moths as ingestion by larvae of GM pollen landing on plants they feed on, saying, *“[C]ertain highly sensitive non-target lepidopteran species are at risk where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants.”*^{xvii}

The GMO Panel uses a computer model developed by its members to attempt to predict *Lepidopteran* larvae exposure to Bt pollen. This model only deals with lethal effects on non-target species, and the Panel concedes the method is not entirely satisfactory, saying, *“A full exposure assessment was done but it required many factors to be taken into account, some of which had to be modelled with little available data,”*^{xviii} and adding:

“The EFSA GMO Panel acknowledges that predicting the effects of maize 1507 pollen on populations of non-target Lepidoptera in any location is problematic particularly when information on the sensitivity of many Lepidoptera species is not available and there will be fluxes in populations of both exposed larvae and host-plants.”^{xix}

And

“[T]he incomplete availability of Cry1 sensitivity data concerning EU Lepidoptera of conservation concern has been remarked upon by many authors; recently Perry et al. (2010, 2011a) and Lang et al. (2010) have both emphasized that further information is required. Gaspers et al. (2010) emphasised that lack of standardised experimental methodology may induce variability and/or bias into estimates of LC50s from laboratory bioassays; future international standardisation of methodology might be desirable to ensure consistency between studies.”^{xx}

The Panel is also frank about the difficulties in assessing sub-lethal impacts on non-target species, which the model makes no attempt to address:

“Sub-lethal effects are an important issue that can lead to adverse effects on a population over and above those of mortality. Little information exists in the literature concerning sub-lethal effects other than those on larval weight. Sub-lethality is also beyond the scope of this EFSA GMO Panel Scientific Opinion.”^{xxxi}

Regular exposure to low sub-lethal levels of Bt toxins could, for example, affect immune systems, fecundity or life expectancy, which could reduce populations over time but may be difficult to attribute to Bt toxicity without further long-term studies.

EFSA does not specify which *Lepidopteran* species it considers to be at risk, but correctly says the impact on individual *Lepidopteran* species depends on a wide range of factors including:

- The presence of host plants in the vicinity of 1507 crops.
- Whether pollen emissions from 1507 maize coincides with caterpillar hatching and feeding.
- The sensitivity of each species to Cry1F toxin.
- The amount of pollen falling on each plant.
- The proximity of those plants to the pollen source.

Many species lay their eggs on a single specific plant species, which hatched caterpillars then feed on until they pupate before emerging as adults. Others use several host plant species for egg laying. It is therefore important to understand these complex interactions in order to determine the risks to any given species. Table 1 gives examples of European moth and butterfly species found on farmland and along field boundaries/hedgerows, along with their larval food plants (all of which are common farmland plants), illustrating the potential for widespread harm.

The EFSA GMO Panel identifies evidence of sensitive non-target species receiving lethal doses of Bt toxin from 1507 maize pollen. The Panel reports a number of moth species are recorded feeding on common weed species in maize fields across Europe. For example the Pale Shining Brown (*Polia bombycina*), a priority species in the UK Biodiversity Action Plan, feeds on Sow thistle (*Sonchus*) species, which are present in over 80% of all fodder maize fields. In Germany larvae of the moth *Schiffermuelleria schaefferella* feeds frequently on Fat Hen (*Chenopodium album*), a common weed in maize crops, and larvae of *Bedellia somnulentella* and the common Plume Moth (*Emmelina monodactyla*) feed frequently on common bindweed (*Calystegia sepium*)^{xxii}, also frequently found in arable fields and margins.

The Panel took issue with some of the evidence on non-target species submitted by Pioneer Hybrid/Mycogen Seeds regarding risk to non-target species:

*“However, the EFSA GMO Panel does not agree with the applicant’s conclusion that this study provided adequate evidence that there is a negligible risk of maize 1507 to non-target Lepidoptera in the EU. Firstly, as stated above, there is no evidence that the average sensitivity found for the single species *V. cardui* will be typical of other species of Lepidoptera or even of other Nymphalids. Secondly, the exposure assessment used by the applicant assumes that the host-plant is exclusively the nettle *Urtica dioica* when it is known that some populations of *V. cardui* are known to prefer thistles (*Cirsium* spp. and *Carduus**

spp.) (Janz, 2005). Finally, the use of the data of Gathmann et al. (2006) on densities of *Urtica* in maize fields in the exposure assessment was incorrect.^{xxiii}

Table 1 EU butterfly and moth species reliant on common farmland and hedgerow plants to feed larvae

Common name	Scientific name	Larvae food plant
Orange tip (B)	<i>Antocharis cardamines</i>	Garlic mustard (<i>Alliari petiole</i>) and Cuckoo flower (<i>Cardamine pratensis</i>)
Gatekeeper (B)	<i>Pyronoa tithonus</i>	Coarse grasses including cock's food (<i>Dactylis glomerate</i>) and annual meadow grass (<i>Poa annua</i>)
Peacock (B)	<i>Inachis oi</i>	Stinging nettle (<i>Urtica dioica</i>)
Comma (B)	<i>Polygonia c-album</i>	Stinging nettle (<i>Urtica dioica</i>)
Painted lady (B)	<i>Vanessa cardui</i>	Stinging nettle (<i>Urtica dioica</i>) and burdock (<i>Arctium</i> spp.)
Common blue (B)	<i>Polyommatus icarus</i>	Legumes including trefoils and clovers
Small tortoiseshell (B)	<i>Aglais urtica</i>	Stinging nettle (<i>Urtica dioica</i>)
Red admiral (B)	<i>Vanessa atalanta</i>	Stinging nettle (<i>Urtica dioica</i>)
Dark spinach (M)	<i>Peluga comitata</i>	Orache (<i>Atriplex</i> spp.) and goosefoot (<i>Chenopodium</i> spp.)
Figure of Eight (M)	<i>Diloba caeruleocephala</i>	Hawthorn (<i>Crataegus</i>), blackthorn (<i>Prunus spinosa</i>) and apple (<i>Malus</i>)
Least carpet (M)	<i>Idaea rusticata</i>	Ivy (<i>Hedera</i>) and traveller's joy (<i>Clematis vitalba</i>)

Key: B = butterfly species M = moth species

The EFSA GMO Panel goes on to discuss the risk management of the impacts on non-target species:

“It is possible to base the risk management decisions on global mortality, or on local mortality rates. For example, in case of a 60% local mortality rate and a typical value of $R = 0.0049$, the global mortality rate would then be $0.0049 \times 60\% = 0.3\%$ and thus categorised as $< 1\%$ and ‘low’. However, regardless of global, large-scale estimates, this degree (60%) of local mortality may be unacceptable (e.g., if protected non-target Lepidoptera occur directly in maize 1507 fields or in their margins). Risk managers may then require alternative strategies to the mitigation measure modelled, particularly for species of conservation concern.”^{xxiv}

The Panel also highlighted the difficulties in monitoring *Lepidopteran* populations, especially as they can be dramatically affected by both abiotic factors (eg, the weather) and biotic factors (eg, diseases, predators and parasites). This serves to underline the difficulties in predicting the outcomes of Bt pollen falling on the food plants of the many different species found in the farmed landscape and that local populations could be at risk.

Pest problems in maize crops are worsened by intensive growing methods and monocultures. These could be altered to use an agroecological approach aimed at keeping pest pressure below the threshold at which economic losses occur.

As farmland populations of many *Lepidoptera* are declining due to factors such as habitat loss and pesticide use, further losses due to 1507 maize should be prevented by not approving the application for commercial cultivation. The lack of toxicity data for many potentially vulnerable species reinforces the need for a precautionary approach.

Confusion over Cry1F's toxicology

EFSA's GMO Panel is not at all clear about the relative toxicity of the Cry1F Bt toxin present in 1507 pollen between their 2005 and 2011 opinions. In 2005 they reported:

“[A] >10.000 times lower toxicity of the Cry1F toxin (as produced in 1507 maize) on monarch butterfly first instars as compared with other Cry toxins (e.g. CryIAb). On the other hand, according to the data presented in the respective dossiers, Cry1F concentration in 1507 maize pollen is higher in comparison with CryIAb concentration in Bt11 pollen (1.3 ng Crytoxin mg⁻¹ plant protein in Bt11 pollen compared with 160 ng Cry protein mg⁻¹ plant protein in 1507 maize pollen).”^{xxv}

This statement is in itself confusing – on one hand the Panel says Cry1F is much less toxic than other Cry toxins, but then on the other says 1507 pollen contain 123 times more toxin than another Bt maize pollen. Unfortunately the Panel’s 2011 assessment of the toxicity of Cry1F only adds to the confusion:

“It is well-documented that larvae of a range of Lepidoptera can be affected by the Cry1F protein with a spectrum of sensitivity which is quantitatively different from the Cry1Ab protein. The content of the Cry1F protein in maize 1507 pollen was estimated to be 32 ng/mg dry weight (EPA, 2001, 2005). The 32 ng/mg dry weight of Cry1F protein in pollen of maize 1507 is about 350 times the Cry1Ab protein content expressed in maize MON810 pollen.”^{xxvi}

Between 2005 and 2011 the EFSA GMO Panel uses different concentrations for Cry1F toxin in 1507 pollen, which vary by a factor of 5. One explanation might be that this is due to the difference between wet and dry weight concentrations, but this is not clear from the text and does not increase understanding of toxic loads present.

The 2011 opinion also highlights the uncertainties surrounding the toxicology of Cry1F, which is variable depending of the precise nature of the toxin used in toxicity tests (ie, toxin or protoxin), the origins of the test insects, the batch of toxin used and the method used administer the toxin to the test species (eg, in food or by surface application). There is also considerable variability in sensitivity between different species to different Bt toxins. Tests on non-target species were often carried out using toxins derived from GM microbes rather than 1507 maize. Although the EFSA GMO Panel claims “equivalence of the Cry1F protein produced by *E. coli* and maize 1507”^{xxvii}, other commentators have raised concerns that the toxins produced by plants may differ from those generated by bacteria.^{xxviii}

This further underlines the considerable scientific uncertainty surrounding the EFSA GMO Panel opinion on the impacts of 1507 maize on non-target species. This is precisely the sort of circumstance where the precautionary principle should be applied and approval should be rejected until the toxicology of this maize is fully understood.

How far does pollen travel?

EFSA GMO Panel says levels of 1507 pollen grains likely to harm non-target species are only found up to 30 metres from the crop.

There is considerable scientific disagreement about how far maize pollen can move. This has been a serious bone of contention in the context of GM coexistence regarding the cross-pollination of neighbouring crops. In a public consultation document on coexistence of GM, conventional and organic crops Defra^{xxix} proposed a separation distance of 80 metres. Other countries have opted for greater separation distances, for example 800 metres by Luxemburg. Several studies have shown that maize can cross pollinate at far greater distances than the 30 metres suggested by EFSA GMO Panel for deposition on larval food plants. Outcrossing has been detected in controlled studies at 800 metres (0.21% cross pollination).^{xxx} Average cross-pollination rates of 1.6% and 0.5% at 200 metres have been recorded, with a maximum of 2.47% in an individual sample. A level of 14.21% hybridisation at 25 metres and 5.79% at 75 metres was recorded in one study.^{xxxi}

Despite rapid depositing of pollen close to the source plant, the huge amounts of pollen produced (up to 25 million pollen grains per plant) results in significant amounts being airborne (125,000

grains) with concentrations dropping by 99.5 per cent at 500 metres.^{xxxii}

EFSA does not rule out local weather conditions causing large amounts of pollen to be deposited on food/feed plants in a small area, saying, *“Another source of variability occurs when pollen deposition varies spatially, especially in weather conditions ... where turbulence is largely due to vertical wind movements or gusts in thundery conditions on summer afternoons.”*^{xxxiii}

EFSA says such large deposits may be offset *“by smaller than average values elsewhere, where effects are diluted”*, but this may not be the case if the maize crop is producing large amounts of pollen at the time.

The EFSA GMO Panel seeks to play down the likely impact of 1507 maize on non-target species based on their model:

“[G]lobal estimated mortality decreases monotonically with exposure level (measured by the parameter R) determined by factors such as the proportion of the land cropping maize 1507. For typical maize production conditions where maize represents 25% or less of arable land and as long as the proportion of maize 1507 is only moderate (uptake below 20%), the global mortality is likely to be less than 1%, even for extremely sensitive non-target lepidopteran species.”^{xxxiv}

However the Panel also does acknowledge the risks, saying, *“[T]here is a risk to certain highly sensitive non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants.”*^{xxxv}

Will mitigation fix it?

Despite a significant shift in opinion on the potential adverse impacts of GM 1507 maize pollen on non-target species between 2005 and 2011, and the acknowledged gaps in data, the EFSA GMO Panel still supports the approval of the cultivation application. The Panel proposes mitigation measures to protect sensitive *Lepidopteran* species from the known risks of GM 1507 maize pollen including:

1. Planting buffer strips of non-GM maize around the edge of GM 1507 maize fields to attempt to intercept GM pollen and prevent it leaving the crop. If this corresponds to around 20% of the area planted (the recommended refuge area in US GM crops) it would also double up as a refuge to delay the development of pest resistance to the Cry1F toxin. Widths of buffer strips would be greatest in largest fields.
2. Increasing distances between 1507 maize and larval food plants for at risk species.
3. Spraying the 1507 maize crop to remove larval food plants.
4. Detasseling the border rows of 1507 maize crops (ie, removing the male pollen-producing flowers).
5. Establishing and maintaining additional habitats for vulnerable species at distances greater than 30 metres from the crop.
6. Changing cropping systems (ie, employing rotations).

To be effective mitigation measures must meet four basic requirements: they must be effective, practical, neutral in overall effect and enforceable. These proposed measures should be assessed against the basic requirements. Our analysis is given in Table 2.

None of the proposed mitigation measures put forward by the EFSA GMO Panel has been demonstrated to work in the field. Some may have some effect, but there doubts remain as to whether they are effective, practical and enforceable. Some measures, such as using herbicide to control food plants in the crops, have effectively been dismissed by the EFSA GMO Panel already. Others, such as detasseling male plants along crop edges, are clearly impractical.

Table 2 Assessment of proposed mitigation measures for GM 1507 maize

Mitigation measure	Effective?	Practical?	Neutral?	Enforceable?
Buffer strips	Use of refugia in the EU and US has been weak - 19% of large-scale maize growers did not implement refugia in Spain in 2009 ^{xxxvi} and there is good evidence of non-compliance in the US. ^{xxxvii}	Inconvenient for farmers to switch to non-GM seeds for field margins. The US is adopting a refuge policy of mixing non-GM and GM seeds into lots sold to farmers (“refuge-in-a-bag”) ^{xxxviii} to ensure better compliance, which would mean buffer zones might not be viable.	Probably	Evidence from Spain and US suggests not
Increase distance of host plants from crop	Doubtful due to distance maize pollen can move	Additional work for farmers	Yes	Probably not
Spray host weeds in crop	Only if GM crop also herbicide tolerant	Only if GM crop also herbicide tolerant	No – likely to reduce in-field biodiversity	Probably not
Detasseling on crop margins	Probably not as pollen travels greater distance than 30 metres	No due to cost	May be not – reduced yield possible	Probably not
Establishing new habitats	Probably not as similar to level entry agri-environment schemes which have had limited impact on farmland wildlife	Probably if CAP subsidised	Yes	Probably
Changing cropping system	Probably not as uptake is likely to be poor – maize is often grown on the same land in successive years and would not entirely remove the risk of exposure	Will not be popular with farmers	Probably not	Very unlikely to get universal support from farmers, so no

Pest resistance

The EFSA GMO Panel is concerned that resistance could develop to the CryF1 toxin in 1507 unless measures are taken to prevent it:

“The possible resistance evolution to the Cry1F protein in lepidopteran target pests is identified by the EFSA GMO Panel as a concern associated with the cultivation of maize 1507, as resistance evolution may lead to altered pest control practices that may cause adverse environmental effects.”^{xxxix}

However the Panel supports the mitigation measures of high Bt dose/refuge proposed by the applicants, saying, *“The EFSA GMO Panel agrees with the applicant that appropriate IRM strategies are capable of delaying possible evolution of resistance under field conditions.”*^{xli}

High dose/refuge strategies depend on the vast majority of resistant pest individuals being killed by the toxin, with survivors mating with a non-resistant type inhabiting a created refuge of non-GM crops (usually making up 20% of the crop area in fields over 5 hectares, below this refuges are not normally required).

The Panel reviews the assumptions underpinning the high dose/refuge strategy. To be effective high dose/refuge strategies must have all of the following:

- High levels of toxin are produced by the plant in the parts targeted by the pest at the time it is feeding.
- Low presence of the alleles (gene type) for resistance in the pest population.
- Resistance alleles are all recessive.
- Mating between non-resistant adults and resistant adults occurs to prevent the recessive resistance gene becoming dominant.
- There is a fitness penalty for individuals who are resistant.

The EFSA GMO Panel says, *“The evidence discussed above 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 1507 and corn borers.”*^{xlii}

However the Panel then says:

“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 Bt-maize was adopted on a larger scale in a region, the risk of resistance evolution is likely to increase requiring more specific refuge management measures. In the case of a cluster of fields with an aggregate area greater than 5 ha of Bt-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.”^{xlii}

The EFSA GMO Panel admits here that take up of 1507 by farmers is likely to be poor, so refuges might only be needed in areas where infestation is high. This would mean that many 1507 crops could end up with no refuge at all, so one of the main planks of the mitigation strategy to protect non-target species from pollen would be entirely absent. In addition this type of comment is hardly likely to encourage farmers to put in refuges when the evidence from Spain^{xliii} and the US^{xliiv} is that proper refuge use is well below 100%. Local failures to implement refuges (perhaps assuming someone else will do it) could lead to rapid, localised breakdown of resistance, which could then spread to other areas.

While it is technically a condition of the cultivation approval, it is highly unlikely that Pioneer Hybrid/Mycogen Seeds will be pursued through the courts by regulators for failing to implement the refuge strategy, any more than Monsanto have been for failure to maximise proper refuge use in Spain for Mon810 maize. The potential for three other maize varieties containing the same GM trait

as 1507 maize (see above) complicates the management and enforcement of resistance management plans because the amounts of Bt toxin produced in each variety could vary and hence the dose received by the pest could also vary.

The chances of resistance developing in other maize pests not specifically targeted by 1507 maize is also considered possible by the EFSA GMO Panel:

*“Considering that other regionally important lepidopteran pests exposed to maize 1507 may also have the potential to evolve resistance to the Cry1F protein (eg, *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 1507 in the context of the IRM strategy. However, the Cry1F protein might not be expressed in relevant plant tissues 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 1507 for those species.”*

Overall the evidence base underpinning the strategy to prevent insect resistance developing in 1507 maize relies heavily on assumptions regarding proper use of refuges and consistent expression of the toxin in the plants. Any failure to implement the former also weakens the Panel’s proposals for mitigating potential harm to non-target *Lepidopteran* species.

Reliance of post market environmental monitoring

The EFSA GMO Panel frequently concedes that data are lacking in key areas of the risk assessment and mitigation plan for GM 1507 maize. The proposed solution is not to delay approving the maize until the data are available, but to proceed with approval and rely on post market environmental monitoring (PMEM) to establish whether the assumptions currently unsupported by evidence are valid.

This is unacceptable. PMEM places far too great a burden on the environment if any of the assumptions prove inaccurate. It also places responsibility for protecting the environment and health on the company who owns the seed (ie, the very people who stand to lose most if any harm is discovered), resulting in a conflict of interest that may well reduce the chance that monitoring will be rigorous and reporting thorough.

The purpose of PMEN is, *“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.”*^{xiv}

The ineffectiveness of PMEN in detecting resistance in target pests has been highlighted recently by a US Environmental Protection Agency (US EPA) report on Monsanto’s monitoring of MON863 maize, which is showing serious breakdown of effectiveness in four US States. The US EPA says, *“After reviewing Monsanto’s monitoring plan, the BPPD IRM Team concludes that the registrant’s current resistance monitoring program (as proposed) is inadequate and likely to miss early resistance events.”*^{xvi}

The EFSA GMO panel has already identified certain non-target species as potentially at risk from the Bt toxin in 1507 maize pollen. This begs the question why the applicants are not required to fill in the gaps in data about pollen exposure before the application progresses any further.

Conclusions

GM 1507 maize is a clear potential threat to non-target species of *Lepidoptera*. Many of these species are already under pressure in the farmed landscape because of habitat loss and the use of insecticides and herbicides, so adding additional threats to that environment should not be supported.

The impact of 1507 maize on non-target species is not confined to this one GM maize as three other stacked varieties including the same Cry1F Bt toxin gene have applications pending, so the environmental risk assessments of all four must take into account exposure via any combination of these other GM maize varieties as well each individually. The presence of other Bt toxin(s) in the ecosystem, including from other varieties with the 1507 trait, must also form part of all assessments.

There is significant scientific uncertainty about which species of *Lepidoptera* are vulnerable to the Cry1F toxin for lethal and sub-lethal doses, as well as how far and in what quantity the toxic pollen will travel.

There is therefore a very strong case for invoking the precautionary principle and refusing approval for GM 1507 maize for cultivation (as well as others using similar traits) until such time that gaps in data have been filled.

The case of 1507 maize illustrates the problems of trying to maintain monocultural arable farming systems using GM. Very little research is being devoted to alternative approaches based on agroecology, in which pest numbers are managed through crop rotations, crop diversity and biological controls. This shortfall needs to be addressed urgently by diverting R&D funding away from pushing forward GM crops to shore-up an agricultural system that has been hugely damaging to the rural environment over the last half century.

Post market environmental monitoring is not an acceptable substitute for a science based risk assessment pre-release.

On the basis of the EFSA GMO Panel opinion 1507 maize in 2011 should not be approved.

The case of 1507 maize is an excellent example of how scientific understanding develops over time. In the six years between EFSA's two opinions evidence of harm emerged where the agency originally said there was no risk, nevermind harm. Genetics is an imperfectly understood discipline, which is why we must take a precautionary approach to all GM food and crops – what we don't know now may emerge as problems later.

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