

## Papering Over the Cracks

*EFSA's opinion on cultivating GM MON88017 maize in Europe – Mitigation is not enough*

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### Introduction

In November 2011 the European Food Safety Authority (EFSA) GMO Panel issued a Scientific Opinion on their evaluation of the environmental risk assessment of cultivating Monsanto's insect resistant and herbicide tolerant MON88017 maize for cultivation. The opinion raises several serious concerns regarding EFSA's approach, including how it:

- Assesses risk when limited data are available.
- Interprets data.
- Approaches mitigating harm that might be caused by cultivation if these crops are ever approved in the EU.

How EFSA approaches its work is of critical importance. The main areas of concern raised in this case include the development of insect and weed resistance due to use of GM crops, the indirect impacts on farmland biodiversity of changes in weed populations due to the use of glyphosate on crops and the impacts of glyphosate on the soil and soil processes. Any of these could potentially lead to serious problems, so it is important that EFSA gets it right. This paper examines whether or not they do.

This paper will also examine if proposed "mitigation" measures in GM crops are sufficient to make GM crops acceptable. The UK Advisory Committee on Releases to the Environment (ACRE) suggests it would support mitigation measures to offset harm caused by the cultivation of GM herbicide tolerant (GMHT) maize provided mitigation:

*"[P]rovide[s] greater confidence (without a detailed analysis of all the possible herbicide regimes that could be used with the GMHT crop and their relative impact on biodiversity) that the risks posed by herbicide regimes used in association with GMHT maize would be no worse for biodiversity as compared to those associated with non-GM counterparts."*

ACRE therefore holds that mitigation is only acceptable if it is effective in ensuring GMHT crops do no more damage than conventional crops.

This, in itself, may not be enough. Farmland biodiversity has been seriously damaged by intensive farming methods. Habitat loss in the last 50 years and intensive production of non-GM maize has played a part. Using the biodiversity in current non-GM intensive maize crops as a comparator for mitigation measures in GM maize will not further the restoration of farmland biodiversity to acceptable, functional levels. What those levels should be is big question, but ACRE's "race to the bottom" approach falls well short of what is required.

### MON88017 maize

Monsanto's MON88017 maize is genetically modified with two traits. One produces the Bt toxin Cry3Bb1, which confers protection against coleopteran pests belonging to the genus *Diabrotica*, (eg, Western corn rootworm, *Diabrotica virgifera virgifera*) that infest the roots of maize. The second confers tolerance to the herbicide glyphosate, which would be applied to the crop in Monsanto's Roundup formulation. MON88017 is therefore a Roundup Ready (RR) maize "stacked" with a Bt gene to protect against Western root worm.

*Diabrotica* is a newly arrived pest in southern Europe and is already an established pest in south east Europe. It first appeared in the early 1990s in the Balkans, where it is believed it was transported in US military aircraft during the Balkans wars. It has since become established in at

least nineteen countries<sup>ii</sup>, including the UK, although in it has not established itself as a pest species in all places. For instance in the UK it was first observed in 2003 near Heathrow Airport, but no presence was recorded in 2008 or 2009<sup>iii</sup>, possibly due to the climate.

RR crops are designed to be used with glyphosate, a systemic, broad spectrum weedkiller absorbed through the green parts of plants and then transported throughout the plant, including to the tips of roots. It is possible to kill the majority of weeds that have germinated, including the roots, by spraying glyphosate, unlike some other herbicides that only kill the green parts above ground. Mounting evidence suggests glyphosate is not safe for people or the environment when used with GM crops.

The EFSA GMO panel is satisfied that there are no food safety issues associated with MON88017. This briefing does not cover food safety issues, but there are well-documented fundamental problems with the approach taken to the food safety assessment of all GM foods that raise serious concerns about EFSA's opinion for MON88017 regarding the potential impact on the health of people and farm animals.<sup>iv</sup>

### **EFSA downplays MON88017 environment impacts**

Several conclusions drawn by EFSA's GMO Panel about the environmental safety of MON88017 maize are of significant concern because they indicate the potential for long-term harm has been downplayed, or ignored, or that risks identified are capable of being dealt with by mitigation measures. These include:

1. *"The EFSA GMO Panel is of the opinion that potential adverse environmental effects of the cultivation of maize MON88017 are associated with the use of the complementary glyphosate-based herbicide regimes. These potential adverse environmental effects comprise (1) a reduction in farmland biodiversity, (2) changes in botanical diversity due to weed shifts, with the selection of weed communities mostly composed of tolerant species, and (3) the selection of glyphosate resistant weeds."*
2. *"The EFSA GMO Panel considers that the use of glyphosate-based herbicides at recommended field application rates of glyphosate on maize MON88017 is unlikely to cause adverse effects to soil microbial communities or beneficial functions mediated by them."*
3. *"The EFSA GMO Panel considers that the applicant provided conservative predictions on the duration of susceptibility of Western corn rootworm to the Cry3Bb1 protein with a 20 % refuge, though recognises that all modelling exercises are subject to scientific uncertainty, and that caution is recommended when predicting future responses of Western corn rootworm in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors."*

The impacts of glyphosate on farmland biodiversity, soil and the development of resistant weeds and insects are examined below. For a full review of the current science on the impact of glyphosate on health, the soil and the environment see "Herbicide Tolerance and GM Crops – Why the world should be ready to round up glyphosate" by GM Freeze and Greenpeace International and available at <http://www.gmfreeze.org/publications/briefings/114/>.

### **Reduction in farmland biodiversity**

The EFSA GMO panel draws a number of conclusions about MON88017 despite a lack of data:

- The GMO Panel says there are difficulties in predicting the indirect farmland biodiversity impacts of using glyphosate on MON88017 maize because of a lack of data. No large-scale trials of MON88017 using glyphosate for weed control have been carried out, and the EFSA GMO Panel says they are unlikely to take place because:

*“Large-scale experimentation to determine the impacts of all the herbicide programmes incorporating glyphosate that are likely to be adopted by farmers in the different farming regions of each Member State cultivating maize MON88017 is deemed infeasible for reasons of practicability and cost.”<sup>v</sup>*

- The GMO Panel also councils caution about extrapolating the results of the UK’s Farm Scale Evaluations (FSEs) for fodder maize, saying:

*“Caution is required when interpreting, extrapolating and scaling up the observations made under the conditions of the FSEs. First, the GMHT maize used in the FSEs was tolerant to the herbicidal active substance glufosinate-ammonium, whereas maize MON88017 will be used in association with glyphosate. Glyphosate is a very effective broad-spectrum herbicidal active substance that provides more consistent control than glufosinate-ammonium in particular cases...Glufosinate-ammonium behaves like a contact herbicide, so unlike glyphosate, it must be applied to small weeds and is not as effective on perennials that require significant translocation for complete control....Second, herbicide regimes applied in non-GMHT maize included the herbicidal active substances atrazine, simazine and cyanazine in the FSEs...Considering that these herbicidal active substances have been withdrawn from the EU market, further analysis of the FSE data was deemed necessary. The reanalysis indicated that the replacement of triazine herbicides by less efficient conventional herbicides slightly reduced the net beneficial effect of herbicide regimes in GMHT maize, but did not eliminate it....Third, the herbicide regimes used with glufosinate-ammonium tolerant maize in the FSEs might not fully reflect real agricultural practice, as the application of glufosinate-ammonium-based herbicides was limited to a single spray applied at dose rates lower than 0.800 kg/ha ai in most cases...In practice, however, it is reasonable to assume that other herbicide regimes than the one used in the FSEs will be implemented, resulting in a different impact on farmland biodiversity.”<sup>vi</sup>*

However the EFSA GMO Panel then puts forward the proposition that the FSE results for glyphosate tolerant sugar beet might provide useful data, despite the fact that this is a crop from an entirely different family of plants, with different agronomy, different biodiversity associated with it and grown in a completely different biogeographical region to MON88017:

*“Whilst the impact of glyphosate tolerant maize was not tested in the FSEs, it has been suggested that it might be similar to that which occurred in glyphosate tolerant sugar beet...Reductions in the number of weeds in glyphosate-treated sugar beet, compared with conventionally-treated sugar beet, resulted in significant reductions in weed biomass, and in subsequent weed seed production later in the season and in the following crops...”<sup>vii</sup>*

- The EFSA GMO Panel also points to the lack of field data on glyphosate tolerant crops to confirm the long-term impacts of glyphosate:

*“While long-term effects on farmland biodiversity have been predicted at the landscape level due to the continuous cultivation of GMHT crops in association with the exclusive use of glyphosate-based herbicides...such effects have not been confirmed by field data.”<sup>viii</sup>*

Yet despite an acknowledged clear lack of reliable data the EFSA GMO Panel does conclude glyphosate use could cause harm:

*“The EFSA GMO Panel concludes that indirect effects associated with the use of the complementary glyphosate-based herbicide regimes have the potential to cause adverse impacts on farmland biodiversity.”<sup>ix</sup>*

- The EFSA GMO Panel sets out the many factors that may contribute to heavy impacts of weed control crop on farmland biodiversity including:

- Crop rotation
- Tillage system used.
- Type of weed management (cultural, mechanical, chemical).
- Number of applications of the same herbicide each season.
- Timing of applications of herbicide.
- Landscape scale and field size.
- Presence or absence of uncultivated field margins and headlands.

The Panel then leaves the actual risk assessment up to others saying:

*“All of the factors above will vary from region to region, from Member State to Member State, from season to season, and from biodiversity component to biodiversity component. These factors depend not only on the nature of the particular receiving environment, but on weed pressure, soil type and climatic conditions. For these reasons, whilst meaningful conclusions can be drawn from general principles, the EFSA GMO Panel acknowledges that there are considerable challenges to making accurate predictions on the environmental consequences of the use of herbicides in GMHT cropping systems. Predictions from models would need to consider all the issues detailed above, over the full range of possible parameters that may be varied in the management of the GMHT crops, and the full range of receiving environments within Europe. The complex nature of all these dynamic effects is of course be modulated further by market forces and agricultural economics.”<sup>xk</sup>*

#### *Will Mitigation Fix It?*

Despite the clear scientific uncertainties about the impact of using glyphosate with MON88017 maize across the widely differing agri-environments of the EU, and an acknowledged risk to farmland biodiversity, the EFSA GMO Panel supports its approval provided mitigation measures are deployed:

*“Depending upon protection goals set at Member State level (e.g., EFSA, 2010c,d, e) and in situations where potential adverse herbicide effects are likely, risk managers should consider putting risk **mitigation measures in place to manage potential herbicide effects and to ensure the implementation of good agricultural practices, including integrated pest management.** Such measures should ensure that biodiversity is maintained at current levels, and that potential adverse effects on arable weeds, farmland biodiversity, food webs and the ecological functions they provide are limited to the levels currently found in non-GMHT maize.”<sup>xki</sup>*

There is very little evidence to show that mitigation measures to offset any potential harm caused to farmland biodiversity by MON88017 maize will be effective, practical, enforceable and neutral in their own effects on other parts of the agri-ecosystem. Indeed the record of existing agri-environment schemes in restoring farmland biodiversity as a result of harm caused by other intensive farming methods is poor.<sup>xii</sup> The long-term goals of agri-environment schemes funded through the Common Agricultural policy (CAP) are to reverse the decline in farmland biodiversity. The widespread monocultural cultivation of maize has made it worse, and GM maize will be no different.

The EFSA GMO Panel wants MON88017 maize managed in such a way so as to have no worse an impact on farmland biodiversity than current maize cultivation:

*“Member States may recommend using glyphosate on maize MON88017 only in regimes that have similar or reduced environmental impacts compared with conventional maize cultivation, and that do not interfere with biological functions currently supported by maize cropping systems. The EFSA GMO Panel also notes that the new legislations for the assessment and use of plant production products, introduced biodiversity more explicitly as*

*a protection goal. Regulation (EC) No 1107/2009 mentions that plant protection products shall have no unacceptable effects on the environment, especially on biodiversity and the ecosystem, whereas the use of herbicides will have to adhere to the principles of integrated pest management and be consistent with good plant protection practice in order to ensure high levels of protection of human and animal health and the environment. In addition, Member States will describe in their national action plans how they ensure that the general principles of integrated pest management as set out in Annex III of Directive 2009/128/EC on the sustainable use of pesticides are implemented by all professional users by 1 January 2014.*<sup>xiii</sup>

The EFSA GMO Panel make it very clear that delivering neutral or improved biodiversity impacts from the cultivation of MON88017 maize will be complex, and this casts serious doubt on whether the proposed mitigation measure will be effective, practical and enforceable across all the areas where maize is grown in the EU. This includes the GMO Panel recommendation saying:

*“Maize has been shown to be a poor crop for biodiversity under European conditions, having the greatest adverse effect on farmland biodiversity compared with oilseed rape and beet...Moreover, maize is frequently not grown in rotation with other crops in the EU...so the repeated use of glyphosate at recommended application rates on continuous maize MON88017 may result in reductions in botanical diversity and/or weed density in maize fields to a level that might adversely affect food chains and webs. In addition, plant communities in cropped and uncropped areas of the farm differ; it is therefore questionable whether providing plant resources on uncropped land only will be sufficient to reverse the declining trends in farmland biodiversity. Beneficial weed species adapted to the cropped area of the field can be distinct from the flora found in uncropped land, so sustaining their populations would increase the overall functional diversity of the farm ecosystem...Besides plant communities, also the scale of cropped and uncropped areas of the farm differs, with the uncropped land usually representing a small percentage of the total area of the farm. Furthermore, Roschewitz et al. (2005) established that plant species diversity in agricultural landscapes is not only affected by management of single fields, but also by the heterogeneity of the surrounding landscape. It also remains debatable whether increases in crop yield will spare land for biodiversity and hence natural habitats from conversion into arable land in European countries (i.e., Balmford et al., 2005; Mooney et al., 2005; Matson and Vitousek, 2006; Ewers et al., 2009; Godfray et al., 2010). Therefore, the EFSA GMO Panel recommends that mitigation measures are put in place that can provide considerable benefits for biodiversity at the cost of no or only small reductions in crop yield (Dewar et al., 2003; May et al., 2005; Pidgeon et al., 2007).”*

It is worth noting that all three references above refer to GMHT sugar beet and not GMHT maize, further emphasising the lack of supportive data for maize mitigation measures.

### **Impacts of glyphosate on soil**

Independent research by soil scientists and phyto-pathologists has examined the impacts of glyphosate (particularly with repeated use, as with GMHT crops) on the delicate fine area of soil around plant roots, called the rhizosphere. The rhizosphere is vital for plant health and is directly affected by root secretions and soil microorganisms. Once applied, glyphosate is exuded from plant roots into the rhizosphere, as well as entering the soil by direct spraying and via residues as plants decay, so it is important to understand if this has any impact on plant or soil health.

Independent researchers have concluded that when used on GM RR crops glyphosate can interfere with three key functions of the rhizosphere including:

- Uptake of essential micronutrients by crops.
- Nitrogen fixation.
- Protection from plant diseases.

Glyphosate is a chelating agent for metals (a chemical that combines with and deactivates metal

ions so they cannot react normally with other elements), and it changes the availability of trace elements in the soil, such as manganese. These changes in soil chemistry can be detected by soil scientists, who have recorded increases in fungal diseases like take-all root rot (a disease of wheat, barley, oats and other grasses) in both GM RR and conventional crops where glyphosate is used. Glyphosate use is increasing around the world, especially as more is being applied to combat weed resistance, resulting in an increased burden on the soil.

There is also evidence that the presence of glyphosate in the soil can have adverse effects on terrestrial and aquatic wildlife, including earthworms and amphibians.

Despite the growing body of scientific evidence of glyphosate's adverse impacts on wildlife, soil microbes and rhizosphere functions, the EFSA GMO Panel appears happy to approve MON88017 maize and dismiss all impacts as "transient and minor":

*"The EFSA GMO Panel considers that potential effects on soil microbial communities and the ecological functions they provide, due to the use of glyphosate on maize MON88017 at normal field application rates, if they occur, will be transient and minor, and are likely to be smaller or within the range currently caused by other agronomic and environmental factors. Therefore, the EFSA GMO Panel concludes that the use of glyphosate-based herbicides on maize MON88017 is unlikely to cause adverse effects to soil microbial communities or beneficial functions mediated by them at normal field application rates. The EFSA GMO Panel notes that effects of herbicidal active substances on soil microbial communities are considered through functional tests on nitrification and soil respiration under Regulation (EC) No 1107/20092."*<sup>xiv</sup>

### **Glyphosate resistant weeds**

The EFSA GMO Panel is well aware of the increasing incidence of weeds resistant to glyphosate in GM RR crops where the herbicide is the only or highly dominant means of weed control:

*"There is evidence from cultivation of GMHT crops that the repeated, continuous and exclusive use of glyphosate in no- or reduced-tillage systems causes changes in weed flora, and favours the selection of more tolerant or resistant weed communities."*<sup>xv</sup>

However the EFSA GMO Panel says, "[T]he scale of glyphosate resistant weed outbreaks has remained relatively small so far."<sup>xvi</sup> This underestimate the extent and seriousness of the weed control problem currently facing farmers growing RR crops, as well as the efforts being made by the agri-biotech corporations to provide new means of chemical weed control.<sup>xvii</sup>

Currently 13 weed species have developed resistance to glyphosate infesting an estimated 4.5 million hectares of crop land in the US alone, and a similar pattern is developing in South America.<sup>xviii</sup>

However the GMO Panel acknowledges that the situation will get worse if weed control practices on RR remain the same:

*"A concern is that glyphosate resistant weeds would become more widespread in the near future as this would represent a significant threat to the sustainability of the herbicide and trait, and perhaps to global food production (Duke and Powles, 2008a; Powles, 2010; Owen et al., 2011; Ronald, 2011)."*

*"The EFSA GMO Panel concludes that the cultivation of maize MON88017 in monoculture or in rotation with other glyphosate tolerant crops, in conjunction with the repeated and/or exclusive application of glyphosate-based herbicides will cause changes in weed flora, and will favour the evolution and spread of glyphosate resistant weeds due to the selection pressure exerted by glyphosate. This, in turn, may affect food webs, and the functional value of weed vegetation for organisms of higher trophic levels (reduced functional biodiversity)."*<sup>xix</sup>

### *Will Mitigation Fix it?*

The EFSA GMO Panel proposes several techniques to reduce the risk of glyphosate resistant weeds developing in MON88017 maize<sup>xx</sup>:

- Crop rotation (ie, rotating glyphosate tolerant crops with crops that are not tolerant to glyphosate).
- Applying a variety of herbicidal active substances each season.
- Using non-chemical weed control, including post emergence cultivation and cover crops.
- Using combinations of cultural, mechanical, chemical weed management.

This strategy is similar to the GM industry's advice for dealing with resistant weeds in RR crops in the US.<sup>xxi</sup> The US strategy is being driven by the agri-biotech companies' keenness to increase market share for herbicide tolerant seeds and the herbicides that go with them. For example Bayer uses weed management and prevention of weed resistance as the main marketing tool in launching a major campaign to promote its glufosinate ammonium tolerant crops as a rival to Monsanto's RR crops.<sup>xxii</sup>

The Monsanto approach goes further, with farmers also being asked buy into weed control "platforms" consisting of soil acting pre-emergence herbicides, herbicides mixtures to "burn-off" stubble pre-sowing and the introduction of "stacked" multiple GM HT traits in crops to allow rotation or mixture of herbicide use with glyphosate. Monsanto has already secured corporate agreements with chemical and biotech companies to jointly market herbicides and stacked GM seeds, as with the Monsanto/BASF glyphosate and dicamba tolerant stacked crops.

Clearly the agri-biotech industry has already reacted to the development of weeds resistant to glyphosate with a combination of more GM and more chemical herbicides. The environmental impacts of such a package does not appear to have been taken into account, yet the use of herbicides (and hence toxic burden on the environment) is increasing in the US and elsewhere.

The initial attractiveness of using glyphosate to control weeds on RR crops was the low cost and the simplicity of the approach. The development, or threat, of weed resistance to glyphosate means that such "simplicity" is short-lived at best, and costs spiral. This is not a sensible option for the EU. Weeds resistant to glyphosate already exist in Spain, Portugal, France, Italy and the Czech Republic because glyphosate has been overused in controlling weeds in perennial crops (eg, orchards and vineyards) and on railways lines. In Spain a small presence of resistance in Horseweed (*Coryza canadensis*) has been confirmed.<sup>xxiii</sup> This same weed is resistant to glyphosate in Brazil and is already major problem in RR maize, cotton and soya in the US.

Any farmer considering growing MON88017 maize will have to adopt complex weed management strategies in which the chemical and seed inputs will be controlled by Monsanto. This is likely to involve a package of different herbicides applied at different times to delay resistance developing to glyphosate. Data on the impact of such a pesticide packages on biodiversity and the soil is not available. Additive and synergistic effects of the herbicide applied cannot be ruled out.

Whether farmers will be persuaded to adopt mitigation measures suggested by the EFSA GMO Panel to prevent glyphosate resistant weeds developing is a matter for conjecture. Compliance problems with refuge requirements in the US, for example, have been pronounced and have contributed to the spread of herbicide resistant weeds.

Until mitigation methods have been fully developed and demonstrated to work, and until the mechanisms for enforcing compliance are fully in place and demonstrated to be effective, Members States should follow a precautionary approach and reject the application for the cultivation of MON88017 maize in the EU.

### **Bt resistant insects**

The EFSA GMO Panel clearly acknowledges the possibility that the major pest corn rootworm (*Diabrotica spp.*) could develop resistance if MON88017 is cultivated in the EU:

*“The possible resistance evolution to the Cry3Bb1 protein in coleopteran target pests is identified by the EFSA GMO Panel as a concern associated with the cultivation of maize MON88017, as resistance evolution may lead to altered pest control practices that may cause adverse environmental effects.”<sup>xxiv</sup>*

In 2011 the first cases of coleopteran species resistant to Bt toxin were confirmed in Bt maize in the US as “severe rootworm feeding injury to Bt maize contained populations of western corn rootworm that displayed significantly higher survival on Cry3Bb1 maize”.<sup>xxv</sup> In this case the maize in question was MON863, which uses exactly the same Bt toxin gene as MON88017 for Cry3Bb1 to target the same pest. MON863, like MON88017, has just a single GM trait for insect resistance.

The effectiveness of GM Bt toxins depends on the GM plant producing a lethal dose of toxin in the parts of the plant being attacked by the pest at the time of year that the pest is active. Some cases of breakdown of effectiveness in Bt crops has been associated with low (sublethal) levels of toxin being produced, allowing some individual pests to survive and breed. Some of these new generations are resistant to the Bt toxin.

To avoid such breakdowns of GM effectiveness farmers are required to sow non-GM crops as refuges for populations of non-resistant adult pests, which then mate with resistant individuals and prevent the recessive resistance gene becoming dominant. The combination of ensuring a high dose of Bt toxin through the plant and the provision of refuges is referred to as “the high dose/refuge strategy”.

The EFSA GMO Panel recommends this strategy for MON88017 maize in the EU. In common with advice in the EU and US, Monsanto proposes 20% of the crop should be refuges if fields are greater than 5 hectares. Below this no refuges are required because Monsanto considers the practice to be uneconomic in the fragmented landscapes where there is a “low chance” of resistance developing.

Yet several small GM maize fields close together on different farms (as the EFSA GMO Panel indicates would be the case in a “considerable proportion” of farms in certain unspecified EU countries<sup>xxvi</sup>) might allow resistance to develop and then spread to larger holdings. Furthermore refuge use in the EU and US is far from ideal - 19% of large-scale maize growers in Spain did not implement any refuges in 2009<sup>xxvii</sup> when cultivating MON810 Bt maize, and there is good evidence of non-compliance in the US.<sup>xxviii</sup> Further complications would arise if the current US vogue of “refuge-in-a-bag” comes to the EU.<sup>xxix</sup> These products claim to relieve farmers of the need to plant refuges by adding a percentage of non-GM seeds into seed lots. Entomologists in the US have already expressed doubts this will be effective<sup>xxx</sup> in delaying the development of resistance in target pests.

Although, “The EFSA GMO Panel considers that appropriate insect resistance management strategies are capable of delaying possible evolution of resistance under field conditions,”<sup>xxxi</sup> they are clearly not convinced that the “high dose/refuge strategy” is failsafe in MON88017 maize. While supportive of the “high dose/refuge strategy” the Panel also highlighted the many uncertainties in this approach:

*“The EFSA GMO Panel considers that the applicant provided conservative predictions on the duration of susceptibility of Western corn rootworm to the Cry3Bb1 protein with a 20 % refuge (see also EPA, 2010 for an in depth evaluation), though recognises that all modelling exercises are subject to scientific uncertainty (i.e., Perry et al., 2010), and that caution is recommended when predicting future responses of Western corn rootworm in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors (Tyutyunov et al., 2008). Moreover, scientific uncertainty related to the appropriateness of the ‘high dose/refuge strategy’ in delaying resistance evolution in Western corn rootworm remains. Therefore, the EFSA GMO Panel, while agreeing with the ‘high dose/refuge strategy’, recommends further research is conducted by the applicant to*

*confirm that the underlying assumptions of this strategy are met for the Western corn rootworm, along with the periodic re-evaluation of the adequacy and efficacy of this insect resistance management strategy.*<sup>”xxxii</sup>

The EFSA GMO Panel even challenged whether high enough doses of toxin would be produced by MON88017:

*“Maize MON88017 has been observed to reduce Western corn rootworm populations by 96 % compared with non-Cry3Bb1-expressing maize (Meihls et al., 2008). These findings confirm that (i) current Cry3Bb1-expressing maize events fail to meet the high dose criterion and do not control second or third instars, resulting in some level of adult survival, and that (ii) the expression of the Cry3Bb1 protein in these events is to be considered low-to-moderate (Siegfried et al., 2005; EPA, 2010). Meissle et al. (2009, 2011a) reported that the impact of maize MON88017 on adult Western corn rootworm is likely to be limited, as compared with first instars.*

*“The ability of heterozygous resistant progeny, resulting from the mating between individuals emerging from the refuge and Bt-maize fields, to survive on Cry3Bb1-expressing maize may diminish the efficacy of the “high dose/refuge strategy” to delay resistance evolution (Gassmann et al., 2011).*<sup>”xxxiii</sup>

The Panel also questioned the basis for Monsanto’s claim that “resistance allele frequencies to the Cry3Bb1 protein may be less than 0.01”<sup>”xxxiv</sup>. The EFSA GMO Panel says:

*“Initial resistance allele [version of the gene] frequency may be as high as 0.2, suggesting that initial resistance alleles may be present at a higher frequency under field conditions than initially assumed by the applicant”<sup>”xxxv</sup>.*

The higher the frequency of the resistant allele/version the faster resistance is likely to develop. The EFSA GMO Panel’s summary of MON88017’s ability to avoid developing resistant insects questioned whether the Monsanto’s plan would be effective:

*“The evidence discussed above suggests that not all the underlying assumptions contributing to the success of the “high dose/refuge strategy” in delaying resistance evolution are fulfilled for Western corn rootworm and maize MON88017. The Cry3Bb1 protein expressed in roots from maize MON88017 is not expressed at a high dose, and preliminary data indicate that resistance alleles may be present at a higher frequency than initially assumed, Western corn rootworm may mate in a non-random manner, the resistance trait could have non-recessive inheritance, and that fitness costs are not necessarily associated with resistance evolution.”<sup>”xxxvi</sup>*

EFSA’s GMO Panel also raised a number of other scientific uncertainties impacting upon the ability of MON88017 to prevent pest resistance developing including:

- Whether larvae surviving the exposure to the Bt toxin do so by avoiding consuming roots with high expression of the toxin.
- How maize volunteers, which may not express the toxin at a high levels, influence the number of resistant individuals.
- The role of grass species in providing an alternative host plant for western corn borer.

The EFSA GMO Panel then summed up the difficulties in assessing the effectiveness of resistance delaying strategies saying:

*“How much each of these mechanisms will contribute to the speed of resistance evolution overall is dependent upon the amount of maize MON88017 planted, the type of refuge used, and the number of maize volunteers present and the Cry3Bb1 protein expressed by those plants.”<sup>”xxxvii</sup>*

Refuge use in the EU and US is far from ideal - 19% of large-scale maize growers in Spain did not implement any refuges in 2009<sup>xxxviii</sup> when cultivating MON810 Bt maize, and there is good evidence of non-compliance in the US as noted above.<sup>xxxix</sup>

Further complications would arise if the current US vogue of “refuge-in-a-bag” comes to the EU.<sup>xl</sup> These products claim to relieve farmers of the need to plant refuges by adding a percentage of non-GM seeds into seed lots. Entomologists in the US have already expressed doubts this will be effective<sup>xli</sup> in delaying the development of resistance in target pests.

## Summary and conclusions

Given all the difficulties outlined above it is hard to understand how the EFSA GMO Panel came to support cultivation of MON88017 maize if it is following a precautionary approach.

Cultivation MON88017 maize raises serious concerns in a number of areas including:

- Impact on farmland biodiversity.
- Impacts of prolonged use of glyphosate on soil.
- Likelihood of weed resistance to glyphosate developing.
- Likelihood of insect resistance developing.

The EFSA GMO Panel raised several important concerns themselves. Yet despite the clear, acknowledged lack of full and reliable data to assess some of these risks, the EFSA GMO Panel nevertheless recommends that MON88017 should be approved for EU cultivation provided mitigating measures are used to manage the risks.

The EFSA GMO Panel assess the potential for success of such mitigation measures, including what is known about current farming practices for maize cultivation. Conventional maize cultivation is known to have a considerable environmental impact, so using it as a comparator means GM maize has only to match this poor performance to be “acceptable”. By adopting this approach both EFSA’s GMO Panel and ACRE are recommending a “race to the bottom”.

A number of the problems with GMHT crops, including MON88017, are closely linked to the use of glyphosate to control weeds. EFSA recognises that glyphosate can harm farmland biodiversity and lead to weed resistance, but appears to think mitigation measures will minimise this. Yet the data demonstrating that mitigation will be effective, practical for farmers to implement, enforceable and, at worst, neutral in overall impact are generally lacking or weak. EFSA’s reliance on mitigation appears misplaced at best.

Neither has it been demonstrated that mitigation measures will be effective and practical means to delay the development of pests resistant to Bt toxins in MON88017 (based on the creation of non-GM crop refuges to make up 20% of the crop). Experience in the EU of existing Bt maize crops suggest compliance with 20% non-GM refuges is poor and that enforcement to date has been only partially effective. In the US, where refuge compliance is also weak, the Bt maize MON863, which contains the same toxin as Mon88017, has confirmed resistance in *Diabrotica*. Once again experience suggests compliance with mitigation in the EU will be difficult and EFSA’s reliance on mitigation ill advised.

Weed and insect resistance can spread rapidly, and the end result would be greater reliance of chemical weed and insect control and an increased burden on the environment. A growing body of independent scientific evidence shows glyphosate can impair key functions of the rhizosphere, such as nutrient uptake, nitrogen fixation and protection against plant pathogens. The EFSA GMO Panel largely ignores this evidence in recommending the approval of MON88017 maize.

The lack of scientific certainty about both the impacts of MON88017 and the effectiveness of the

proposed mitigation measures should lead to the precautionary principle being invoked to reject Monsanto's application.

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