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Evidence to ban 1507 maize

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I. Summary

Pioneer Hi-Bred and Mycogen Seeds developed Bt toxin-producing and herbicide tolerant GM maize 1507, and asked for authorisation for cultivation in 2001. After a decade in which the European Food Safety Authority (EFSA) undertook several assessments, it published new opinions in November 2011 and November 2012. This paper considers these opinions and assesses the gaps and unanswered questions in the EFSA assessments published to date, with regards to GM law and mandates from the European Commission (EC).

With regard to the updated opinion about the potential impacts on non-target organisms from November 2011, this paper concludes that the opinion does not deliver sufficient information to duly assess the risks of maize 1507, and that EFSA has not fulfilled the various mandates it has received from the EC that have a bearing on 1507. There are substantial weaknesses in its assessment. Even though EFSA acknowledges that information is lacking, and that 1507 poses a risks to some butterflies and moths (Lepidoptera), it still considers it safe to cultivate the maize. While assessing the effect on non-target organisms it focuses on Lepidoptera and excludes effects on other arthropods, aquatic and soil organisms. Where it becomes obvious that 1507 cultivation can have adverse effects on the environment, EFSA suggests an inadequate and impracticable risk mitigation strategy to allow cultivation nonetheless.

In the opinion from November 2012, EFSA assesses 36 scientific articles that it had previously not considered, but does not come to conclusions that would change their previous assessments. The lack of sufficient consideration of peer-reviewed scientific literature raises additional concerns regarding the scientific standard EFSA applied in its previous opinions of the GM maize dating from 2005.

In the new assessments, EFSA fails to assess 1507's herbicide tolerance by claiming that the herbicide tolerance was only intended as a marker. This is in contradiction to the original notification from 2001 and to EFSA's own, earlier opinions.

Herbicide tolerance is not assessed at all

Glufosinate tolerance has still not been assessed, even though this has been requested by DG Sanco and DG Environment, and the EU's Environment Council in 2008. The applicant itself promotes maize 1507 as a glufosinate-tolerant crop in the USA. Thus EFSA's argument that the glufosinate tolerance trait was simply added as a marker gene is not only not valid in the current situation – it is also a contradiction to the original notification from 2001. In it the notifier clearly states that the glufosinate tolerance is intended for weed management, gives the herbicide concentrations that can be used in the field, and

analyses plant material from 1507 plants treated with glufosinate. An environmental risk assessment however is lacking in the notification and has not been requested by EFSA.

Adverse effects on non-target organisms not properly assessed

Risks for butterflies and moths, but which ones?

The EFSA GMO Panel (2011) states that 1507 maize and its Cry1F toxin forms a risk for at least some butterfly and moth species, and that there is a lack of knowledge concerning which of these species are at risk and where they are in an agricultural landscape. But instead of asking for basic data *before* granting the cultivation approval, the EFSA panel proposes that the applicant should collect such data as part of the post-market monitoring. At the same time, EFSA proposes its own strategy to reduce the risk for non-target Lepidoptera. However, even this risk mitigation strategy is untested, not workable and suffers from the same lack of information.

Conduct studies with the actual toxin

In general, most studies of the effects of Bt toxins have been undertaken with Cry1Ab and Cry1Ac, including a number of studies to which the EFSA refers in its risk assessment of 1507 maize. However, 1507 produces a different toxin: Cry1F. Results of risk assessment studies with Cry1Ab/Ac cannot simply be transferred to crops producing a different Bt toxin, because the adverse effects on non-target organisms can differ between these toxins. This is already the case with non-target Lepidoptera, where some butterfly species react more sensitively to Cry1Ab than to Cry1F, while others are more sensitive to Cry1F. It can therefore not be concluded that if Cry1Ab does not cause adverse effects on a non-target organism, there will also be no affect caused by Cry1F.

With regard to potential effects caused by 1507 pollen, it also needs to be taken into account that not only the Bt toxin is different but also that the concentration can be much higher. EFSA (2011) states "*Cry1F protein in pollen of maize 1507 is about 350 times the Cry1Ab protein content expressed in maize MON 810 pollen.*" This means that information about the amount of pollen from two different Bt maize plants (e.g. 1057 and MON810) does not correlate with the amount of the respective Bt toxin that a butterfly larvae might take up; it could be considerably more in the case of Cry1F. In general, several of the studies referred to in EFSA 2011 are about the effects of other Bt toxins on non-target organisms (such as bees, soil organisms, and aquatic organisms, see below).

There is insufficient evidence to assess impacts on bee health

According to the EFSA, there is only one peer-reviewed scientific study about the effect of Cry1F toxin on honey bees, conducted nine years ago in the US, in which Bt maize pollen was fed to bee larvae in the laboratory (Hanley et al. 2003). Other studies did not use the Bt toxin Cry1F. There are therefore *no* studies in the field, *no* studies in Europe, and *no* study that has been undertaken any more recently than nine years ago. This is not a sufficient basis to assess the safety of 1507 cultivation for bees or other pollinators in the EU.

There are no studies assessing the impact of 1507 on soil organisms

To assess possible adverse effects on soil organisms we need to know how much Bt toxin is released into the soil and how long it stays there, as well as studying effects on a range of soil organisms such as earthworms and mycorrhiza. It appears that no studies on soil organisms have been undertaken with 1507 plant material or Cry1F toxin.

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There is insufficient evidence to assess aquatic impacts

To assess the possible adverse effects on soil organisms we need to know whether 1507 cultivation will have adverse effects on aquatic organisms in the EU. Such studies still need to be undertaken; simply referring to lab studies undertaken with Cry1Ab is insufficient, since the results could be quite different in the field with Cry1F.

Introduction

1507 maize was developed in a technical collaboration between Dow AgroSciences and Pioneer Hi-Bred. It has been genetically modified to produce the *Bacillus thuringiensis* (Bt) toxin Cry1F that protects the plant against the *Ostrinia nubilalis* moth (the European Corn Borer, ECB) and to be herbicide tolerant, specifically against glufosinate ammonium. 1507 maize is also known by its Unique Identifier DAS-Ø15Ø7-1 or as TC1507, and is sold in the USA under the brand name Herculex I (Cera Database).

So-called “stacked traits” - GM plants with the traits of two or more GM plants - have been developed as well and are currently grown in field trials in the EU. These include GM maize varieties with several Bt toxins and/or with an additional tolerance to the herbicide glyphosate (Roundup). EFSA assesses stacked traits as a simple 'sum' of the original GMOs and therefore a positive decision on GM maize 1507 will be a relevant step towards a future approval of 1507 hybrids.

Bt-Toxin Cry1F

Bt toxin Cry1F is toxic to a number of Lepidoptera (moths and butterflies), including several maize pests. The Cry1F gene from *B. thuringiensis* var. *aizawai* used in 1507 expresses a genetically modified version of the original bacterial Cry1F toxin. This toxin is different to the toxin found in other Bt plants, such as Cry1Ab, which is produced by MON810 maize. Nevertheless, most of the EFSA 2011 risk assessment refers to studies concerning the Cry1Ab and Cry1Ac toxins. However some butterfly and moth species react more sensitively to Bt toxins Cry1Ab/Ac, whilst others are more sensitive to Cry1F (EFSA 2011:15). Therefore even data concerning individual species cannot be assumed to apply to maize containing Cry1F, just because they are applied to crops producing Cry1Ab or Cry1Ac.

So far, there is no explanation as to *why* there are these differing sensitivities, and the mode of action of Bt toxins is not completely understood either (see for example Broderick et al. 2006 or Soberon et al. 2009).

Differences also exist with respect to the amount of Bt toxin produced in different parts of the plant and between different GM plants.

“ *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 MON 810 pollen.*” (EFSA 2011:15)

This means that information about the amount of *pollen* of two different Bt maize plants (e.g. 1057 and MON810) does not correlate with the amount of Bt toxin that a butterfly larvae might take up.

Herbicide tolerance

1507 is also herbicide tolerant to glufosinate-ammonium (short: glufosinate, also known as phosphinothricin)¹ sold under the brand names *Liberty*, *Basta*, *Kaspar* and *Ignite*.

Herbicide-tolerance allows the field plants to be sprayed herbicides in order to kill off weeds. This practice can leave residues on the plant material after harvest. Environmental effects can not only include the direct impacts of the herbicide but also impacts of the changes in weed management, for example if plants are reduced that provide feed and habitat.

¹EC number 278-636-5, CAS number: 82785-28-2, Index number 015-155-00-X. EINECS (European Inventory of Existing Commercial chemical Substances): http://esis.jrc.ec.europa.eu/lib/esis_pgm.php?GENRE=ECNO&ENTREE=278-636-5.

Pioneer-Hi Bred and Mycogen grew 1507 in field trials for the notification with and without the application of glufosinate, stating an “improved weed management”. They assessed the tolerance level “at field application rates of 1600 g a.i./ha of glufosinate-ammonium herbicide without showing any phytotoxicity symptoms” (C/ES/01/01 SNIF, 2001)

Herbicide tolerance against glyphosate (Roundup) is the GM trait used the most at present, and experiences from North and South America show a drastic increase in glyphosate-resistant weeds and the severity of infestations with these weeds. By 2012, at least 24 glyphosate-resistant weed species had been documented worldwide (Weed Science: Glycines). In this situation, agrochemical companies as well as farmers can turn to glufosinate as an alternative herbicide - either individually or in combination with glyphosate. For this, stacked GMOs that are glyphosate and glufosinate tolerant are developed: for example several 1507 hybrids that are currently being field-tested.

But glufosinate-resistant weeds are already appearing as well. In 2010, the glufosinate resistant Italian Rye Grass (*Lolium multiflorum*), was discovered in Oregon in the USA,² which is also resistant to glyphosate (Wilson et al. 2011; Weed Science: Glutamine Synthase Inhibitor). In addition to these weeds causing massive problems, a study from the USA also shows that the introduction of herbicide tolerant crops led to the application of an additional 174 million kg of herbicides between 1996 and 2009 in the US (Benbrook 2009).

Glufosinate

At the time that Pioneer and Mycogen applied for approval to cultivate 1507 in the EU, the herbicide glufosinate was here only used in apple orchards;³ it was not approved for the use in growing field crops such as maize. Nonetheless, it was already used in 1507 field trials in 1999/2000 in France, Italy and Bulgaria (EFSA 2005b:7). At the same time - in 2000 - Aventis Crop Science (which later became part of Bayer CropScience) asked the EU Commission to include glufosinate as a herbicide in the Pesticide Directive 91/414/EEC - a process that was not finalised until 2007 (DG Sanco 2007).

As part of the herbicide approval process, EFSA's pesticides panel assessed glufosinate's environmental and health effects, using three different scenarios: weed control in apple orchards, pre-emergence weed control on potato fields, and the use of glufosinate as a “selective herbicide” in the cultivation of “transgenic maize”⁴ (EFSA 2005a). In its conclusions, EFSA not only gave details about the toxicity of glufosinate, but also stated that the expected exposure of farmers to glufosinate in GM maize cultivation would be too high to be acceptable (EFSA 2005a).

“The review [by EFSA] has identified one acceptable exposure scenario for operators in orchards, but the exposure scenarios in maize and potato were not acceptable.” (DG Sanco 2007)

Despite this negative assessment, glufosinate was approved as an active substance in the EU in October 2007, under Pesticide Directive 91/414/EEC (EU Pesticide Database), but was classified as having acute and reproductive toxicity (Reproductive toxicity 1B). This approval will run out in 2017. Because of its classification it will not be eligible for a renewed approval under the new Pesticide Regulation 1107/2009. However, industry

² Wilson V. Avila-Garcia and Carol Mallory-Smith. 2011. Glyphosate-Resistant Rye-Grass (*Lolium perenne*) Populations also Exhibit Resistance to Glufosinate. *Weed Science*, 59 (3): 305 – 309.
<http://www.bioone.org/doi/abs/10.1614/WS-D-11-00012.1>

³ Glufosinate was developed in the 1980s, but fail to get approval in European countries in the 1990s. It was has been registered in the USA since 1993.

⁴ The GM maize variety is not specified.

appears to be pushing hard to change this classification in the EU. At the same time, industry is trying to establish glufosinate as the alternative to glyphosate (Roundup) in the USA, in order to deal with glyphosate-resistant weeds (see above).

II. Herbicide tolerance

Herbicide tolerance as an agricultural trait

1507 maize is tolerant to the herbicide glufosinate-ammonium and intended to be used as such - not only in other parts of the world, but also according the original notification in the EU in 2001.

Question 18: The function of the PAT protein in 1507 maize is to tolerate the application of glufosinate-ammonium herbicide.

Question 19: The pat gene is also expressed constitutively by the CaMV35S promoter. Expression of PAT protein confers tolerance to application of glufosinate-ammonium. Field trials show that 1507 maize will tolerate field application rates of 1600 g a.i./ha of glufosinate-ammonium herbicide without showing any phytotoxicity symptoms. Tolerance to glufosinate-ammonium herbicide provides for improved weed management. (C/ES/01/01 SNIF, 2001)

The notifiers determined the herbicide concentration that could be used, and undertook the compositional analysis of untreated 1507 plant material, 1507 treated with herbicides and controls (EFSA 2005b, 2005c).⁵ However, the notifiers did not undertake any studies on environmental effects of the herbicide tolerance (for example through changes of agricultural practices).

EFSA GMO Panel agreed with this on the basis that such an assessment would be too difficult to do.

The environmental risk assessment made no comparisons of the environmental profile of the use of glufosinate on maize in comparison with other herbicides. Indeed, this would be difficult to do because of the range of other herbicides used and the range of agricultural systems and environments in which maize is grown and the wide diversity of weed species and associated flora and fauna that will be found in maize fields. (EFSA 2005b)

Instead EFSA replies to comments by member states by referring to Perry *et al.* (2004) that indicated that regimes applying glufosinate either had a better or similar biodiversity impact compared with these herbicides. This article doesn't actually mention glufosinate, but predicts changes in weeds abundance after the then up-coming ban of the herbicide atrazine.

*The Panel considers that the presence of the pat gene and the **use of glufosinate** is not likely to give an increased impact on biodiversity in most situations. The Panel therefore comes to the conclusion that case specific monitoring regarding any consequences due to the application of glufosinate in combination with the cultivation of 1507 maize is not required. The Panel, however, recommends that*

⁵ See for example EFSA (2005b): “Maize plants in Chilean field trials were all treated with glufosinate, while those in the European field trials were split into treated and untreated groups.

” (p.7) or “In summary, the analysis of nutrient composition of kernels from maize line 1507 (glufosinate-treated and non-treated) occasionally revealed statistically significant differences in some compounds.” (p.8).

observation of general weed abundance and diversity should be included in the general surveillance plan. (EFSA 2005b, emphasis added by the authors)

The Panel also points out that the issue of glufosinate residues and of the approval of glufosinate herbicides does do fall under its remit, but under a different directive.⁶

No risk assessment was done for the herbicide tolerance, but it is the glufosinate tolerance that is treated as an agricultural trait: to be used and monitored in the field - and not just as a marker.

A history of two application processes: 1507 and glufosinate

The notification to cultivate 1507 in the EU, and the application to extend the use of glufosinate herbicides started very much at the same time in 2000/01.

1507 was already grown in field trials with glufosinate applications in 1999/2000, and the so-called Farm Scale Evaluations (1999-2003) which included a glufosinate-tolerant GM maize, were under-way in the UK, when Aventis (later Bayer) applied to include glufosinate as herbicide for field crops. The two processes have run in parallel since then.⁷

As described in the introduction, glufosinate was only approved as an herbicide in 2007, but with a classification that, in 2009, already put it on the list of herbicides of which no new permit will be given, once the current period runs out in 2017.

Meanwhile, it took also several years for the initial assessment of GM maize 1507 to take place. In 2005, after member states had repeatedly commented on the notification, the EFSA GMO Panel gave its first positive opinion in which it concluded that the herbicide tolerance would not lead to problems - even though there were no studies done (see above) - and that the assessment of the herbicide itself needed to be done by others.

The Panel is aware that glufosinate containing herbicides are currently being evaluated within the framework of the above mentioned Directive [91/414/EEC]. (EFSA 2005b)

In 2008, after first proposing not to approve 1507 for cultivation, the EU Commission referred 1507 back to EFSA with questions concerning new studies on non-target organisms (see above). In addition, in September 2008, the Heads of DG Environment and DG Health and Consumer also asked EFSA to clarify the interplay between GM directive 2001/18 and Pesticide Directive 91/414. In their letter to the Executive Director of EFSA they state that, "the consequences of the change in agricultural practices due to herbicide use of GM HT plants have to be duly considered within the environmental risk assessment under Directive 2001/18" (European Commission 2008, emphasis in the original). In essence, EFSA is not only required to assess the herbicide tolerance of 1507 maize as a genetic modification of the plant itself, but is also requested by the EC to assess the additional environmental effects that may be caused by consequent changes in the use of herbicides. This mandate to assess the effects of herbicide tolerance is not only relevant for 1507 maize, but for all other herbicide tolerant GM crops as well.

However, this general demand to assess the herbicide tolerance of the 1507 (and Bt11) maize varieties was not reflected in EFSA's second opinion, published in October 2008 (EFSA 2008b). The GMO Panel confined itself to assessing the eleven studies listed by the EU Commission and came to the overall conclusion that they did not contain any

⁶ "The safety of residues of glufosinate applied to 1507 maize and of any metabolites has to be evaluated under a different Directive (EC, 1991) before market approval, and is therefore not within the remits of this opinion. The Panel is aware that glufosinate containing herbicides are currently being evaluated within the framework of the above mentioned Directive (EC, 1991)." (EFSA 2005b); Council Directive 91/414/EEC

⁷ For a detailed time line see Annex 3.

information that would change their previous positive opinion.

In its specific assessment of Butler et al. (2007) - one of the eleven listed articles - the EFSA GMO Panel called for EU member states to establish management systems for herbicide tolerant GM crops (even though it still did not assess the herbicide tolerance of 1507):

“... the GMO Panel encourages that both applicants and appropriate competent authorities in Member States establish and implement herbicide management systems for GMHT crops that do no more environmental harm than conventional systems and which are consistent with the environmental protection goals and biodiversity action plans in each Member State.”
(EFSA, 2008b)

In December 2008, the Environment Council of the European Union adopted detailed conclusions on genetically modified plants (GMPs) in which it considers

“with particular importance”:

“(i) Strengthening of environmental assessment and of monitoring arrangements” and

“4. NOTES WITH SATISFACTION that [the EU Commission’s mandate to EFSA to develop and update its guidelines] includes examination of the criteria and requirements for assessing all GMPs, including GMPs that produce active substances covered by directive 91/414/EEC and herbicide-tolerant GMPs with a view to reviewing them if necessary; UNDERLINES in particular the need to study the potential consequences for the environment of changes in the use of herbicides caused by herbicide-tolerant GMPs [...]” (Council of the European Union 2008).

How did the change from 'trait' to 'marker' happen?

In their initial comments some member states had already pointed out that glufosinate did not have the necessary approval to be used in 1507 cultivation. The understanding appears to have been that 1507 would not be grown with glufosinate until the herbicide would be approved, but neither the comments by member states nor the first EFSA opinions question that the herbicide tolerance is an agricultural trait not just a marker. The lack of environmental risk assessment studies of this trait only shows the low quality of the assessment and the EFSA opinion as such. In the period between 2007 and 2009, at least three developments run parallel:

- a general discussion on how to assess herbicide tolerant GM crops, in which the EU Commission requests that this issues is assessed.
- glufosinate gets approved in 2007, but already in 2009 it is on a new list of herbicides that will be phased out again.
- DG Environment first proposes not to approve of 1507 cultivation, but refers 1507 back to the EFSA in 2008, since there was no majority for this decision.

In this period, the notifiers apparently also changed their understanding of what 1507 is and what not - turning the herbicide tolerance as an agricultural trait into a simple marker that would not need to be assessed further.

A new draft decision from 2009, in which DG Environment proposes to permit the cultivation of 1507 maize, refers to a letter from February 2007 in which the notifiers claim that the herbicide tolerance has never been meant as anything else than a marker. DG Environment therefore proposed to allow the cultivation with glufosinate - but in a way as if

1507 would not be tolerant to it.

The scope of the notification, as confirmed by the consent-holder on 23 February 2007, does not cover the commercial use of the product as a plant tolerant to glufosinate in the EU, since the pat gene for glufosinate tolerance was only to be used as a marker gene. Therefore without prejudice to Directive 91/414/EEC, the product should not be used with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to such herbicides. (EU Commission 2009, draft).

Instead of addressing the lacking environmental risk assessment of the herbicide-tolerance, the European Commission simply tried to avoid the issue. (So far there has been no vote on this draft, it was withdrawn from the original agenda in 2009.)

Since then, in the EU application process, both the applicants and the operators of 1507 field trials continue to state that the herbicide tolerance is only intended as a marker, and both the EFSA GMO Panel and the EU Commission seem to have taken up this line of argumentation, claiming that with such an intended use there was no need to assess the herbicide tolerance.

“Since the scope of the application does not cover the use of glufosinate-ammonium containing herbicides on maize 1507, potential effects due to the use of such herbicides on maize 1507 are not considered by the EFSA GMO Panel.” (EFSA 2011:8)

Meanwhile, 1507 is still marketed as glufosinate tolerant in the US.

Field trials to study the herbicide tolerance

Without doubt, 1507 is grown in field trials with herbicide applications. The field trials that were conducted 1998-2000 to provide material for the comparative analysis were sprayed with glufosinate. In 2002, Pioneer provided sprayed plant material for a feeding study (Sindt et al. 2007). As late as 2009, two field trials took place in Spain to study the effectiveness of the herbicide tolerance (see Annex 2).

By 2012, most field trials with 1507 in the EU are trials for variety registration without environmental assessments, but a number of 1507 hybrids have pending cultivation applications and/or are being field tested in the EU. (See Annex 1 and 2 for detailed lists.)

According to the EC's Joint Research Centre (JRC) database of *Deliberate release into the environment of GMOs [...] field trials with 1507 and its hybrids with glufosinate were to be found at several locations in the EU in recent years. These include for example:*

- field trials between 2005 and 2008 in Spain and Portugal in which herbicide residues were recorded;
- field trials between 2006 and 2009 in Hungary in which glufosinate *and* glyphosate were applied;
- field trials between 2009 and 2010 in Spain.

Unfortunately the information in the JRC database is not very consistent and the actual trials are not well described. Sometimes only the applications of “herbicides” are mentioned; at other times glufosinate applications are explicitly mentioned. (See Annex 2 for a list of more field trials and more details.)

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All of this indicates that even though the application for 1507 maize cultivation now states that herbicide tolerance was only included as a marker, it is likely that - at least in the long run - the use of glufosinate with 1507 and its hybrids is probable.

Dow and Bayer promote the use of glufosinate

In 2007, the year when glufosinate was authorised for agricultural use in the EU, Dow AgroSciences published a Technical Bulletin to promote 1507 under the trade name *Herculex I*. It states quite prominently that 1507 is intended for use with glufosinate:

“Corn plants possessing this tolerance can be directly sprayed after emergence with glufosinate-ammonium herbicides, allowing for broad spectrum weed control without herbicide damage to the maize plant. Benefits to the farmer include convenient and effective weed control that ultimately enhances yield potential for the maize.” (Dow AgroSciences 2007:2)

And further on:

“Expression of the PAT protein was found in leaf tissue samples at detectable levels up to approximately 40.8 ng/mg total protein. These levels are sufficient to confer tolerance to glufosinate-ammonium herbicide at the level of the whole plant.” (Dow AgroSciences 2007:5)

“Maize containing HERCULEX I can be sprayed with this herbicide to control targeted weeds with no crop loss.” (Dow AgroScience 2007:6)

Furthermore - with the dramatic increase of glyphosate-resistant weeds in the USA - Bayer is promoting the use of glufosinate-tolerant crops in rotation with RoundupReady crops under the heading “Respect the Rotation”. (Bayer CropScience 2011). If the European Union authorises glufosinate and glyphosate-tolerant GM plants for cultivation, then promoting the rotation between two different herbicide tolerant crops seems to be the obvious next step in the EU as well.

Does this mean that 1507 maize can be grown with glufosinate?

According to current argumentation, the herbicide tolerance is ‘just’ a marker gene and 1507 is not intended to be sprayed with glufosinate - even though the plants are capable to tolerate such treatment. The draft decision of the EU Commission from 2009 keeps the question sufficiently vague, stating that glufosinate can be used just as with conventional maize cultivation, but it does not give any actual details or impose restrictions on when it can be used or how much glufosinate would be acceptable in their view.

“Article 3 - Conditions for placing on the market.

The product may be placed on the market and cultivated as any other maize that is not tolerant to glufosinate, subject to the following conditions: [...]

(f) it shall also be indicated on the label, or in an accompanying document for non-prepackaged products, that: [...]

- [...] the product shall not be used with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to glufosinate;” (EU Commission 2009)

1507 is tolerant to glufosinate, and glufosinate herbicides are available to farmers, for example as a pre-emergence herbicide to kill off weeds on a field before the maize plants germinate.

Reports from the USA show that farmers are experimenting with the application of different broad-spectrum herbicides such as glufosinate, when they are advised to do so, but also when they are explicitly advised *not* to do so.⁸ Similar behaviour can be expected from farmers in the EU as well if a herbicide-tolerant crop and the corresponding herbicide are available on the market.

III. Bt toxin Cry1F and its effect on non-target organisms

Bt crops are genetically modified to produce a protein that is toxic to pests feeding on these crops. Naturally these proteins are produced by the soil bacterium *Bacillus thuringiensis* (Bt); they only become toxic when they are activated by enzymes and other interactions in the gut of Lepidoptera (the insect order of butterflies and moths). However, even though the names of the Bt toxins produced by Bt plants (e.g. Cry1F or Cry1Ab in MON810 for example) are the same, the proteins are actually different from those produced by the soil organisms: usually they are smaller and toxic to Lepidoptera without further activation in the gut. This can increase the range of their toxic effects on other organisms that are not affected by the naturally produced protein.⁹

In contrast to the Bt toxin Cry1Ab, there are only a few GM crop varieties that produce Cry1F. In general, there are also very few studies involving the Cry1F toxin, and those that do exist are nearly all conducted by/with scientists from Dow, Pioneer Hi-Bred and Monsanto. However, EFSA does not question this lack of studies; it only states that, “no new scientific information has been made available.” (EFSA 2011: p.3, 28 and 51). In 2007, Environment Commissioner Dimas, responsible for GMOs at that time, proposed not to allow the cultivation of the two GM maize varieties 1507 and Bt11 (DG Environment 2007a and 2007b).¹⁰

However, a few other Commissioners disagreed with his proposal and the European Commission eventually referred both cases back to EFSA again, in July 2008. In its mandate the European Commission asked EFSA to assess whether eleven scientific articles that had been published since the first opinion or any other new studies “would lead the EFSA to alter its conclusions or refine it” (European Commission 2008).¹¹

Assessing these eleven studies, the GMO Panel did not come to a different conclusion. In 2012, the EU Commission asked again - this time for the GMO Panel to generally take “recent scientific” literature into account. The GMO Panel replied to this request with a database research with a few keywords specific for 1507 and Cry1F. While this research yielded 36 studies that EFSA had not previously assessed, it only brought four additional non-target organisms (NTO) studies up. Other studies with under-represented NTOs, but different Bt toxins that could give an indication which effects should be studied for 1507 and Cry1F as well are systematically excluded by this approach.

⁸ Several (agricultural) newspaper articles underline this, such as “Weed Control for Liberty Link vx glyphosate-resistant corn”, C.O.R.N Newsletter 2008-04, Ohio State University; “Raising the red flag over Ignite, WideStrike Combo”, <http://www.cotton247.com/production/cropprotection/?storyid=1952>, January 2011; “Resistant giant ragweed”, <http://deltafarmpress.com/management/resistant-giant-ragweed>, May 2010; or “Growers swing at pigweed with Ignite on WideStrike” <http://farmprogress.com/southern-farmer/library.aspx/growers-swing-pigweed-using-ignite-widestrike-41/48/189>, January 2010;

⁹ Besides the natural Cry1F protein produced by *Bacillus thuringiensis* and the Cry1F toxin produced by 1507 maize, there is also a third variation from GM *E.coli* bacteria. These bacteria are used to produce larger amounts of Bt toxin for testing purposes. In contrast to Cry1F toxin in 1507 plant material, this is used as purified toxin, and often referred to as “bacterial protein”.

¹⁰ The title of this draft decision still identifies 1507 as herbicide tolerant: “... a maize product [...] genetically modified for resistance to certain trepidation pests and for tolerance to the herbicide glufosinate-ammonium“ (DG Env. 2007).

¹¹ Nearly all of these studies concern Bt toxins, but one of them (Butler et al. 2007) deals with the environmental aspects of herbicide tolerance of GM plants.

Non-target organisms are more than just arthropods

In the light of on-going discussion to reform the guidance for the environmental risk assessment of GMOs¹² and seemingly in order to try out their mathematical model on another Bt maize, the EFSA GMO panel requested a self-task from the head of EFSA in November 2010, seeking to update the previous environmental risk assessment of GM maize 1507; this was granted. The Panel proposed to:

- focus on possible adverse effects on non-target organisms (e.g. Lepidoptera),
- investigate what additional data would be needed from the applicants, and
- clarify additional recommendations to risk managers.

But in the EFSA 2011 opinion, EFSA only focuses on non-target *arthropods*,¹³ only one group of non-target organisms. Within the non-target arthropods they focus only on insects and on a mathematical model of possible effects on groups of Lepidoptera.¹⁴ This is a very narrow focus and makes it impossible to guarantee it will not have an impact on other non-target organisms. Other non-target organisms are not considered by EFSA. They are only briefly mentioned in an overview table referring to data from the US Environmental Protection Agency (EPA) and the Organisation for Economic Cooperation and Development (OECD) from 2005 to 2007. Possible effects on other groups of organisms such as earthworms have been raised before, but the GMO Panel gives no explanation as to why it simply equates “non-target organisms” with “non-target arthropods”. Yet in the last decade discussions about the impacts of Bt-producing GM crops on non-target organisms has been broadened to include effects on a much wider range of non-target organisms, as well as differences in the effects of different Bt toxins.

In this context it is necessary to underline the fact that barely any studies have been undertaken with the Bt toxin Cry1F, even though its differences to Cry1Ab have been recognised. The EFSA GMO Panel should have required additional studies on this issue from the applicant - especially since the question about whether additional data might be needed was already formulated in the outline of the self-task.

Functional groups

EFSA acknowledges that there are up to 1,000 non-target arthropod species on fields in the EU, but in their opinion they only group them by their ecosystem function, e.g. as pollinators, with just a few studies covering these groupings. Furthermore, most of these studies are undertaken with Cry1Ab and Cry1Ac, not Cry1F (EFSA 2011). It might be useful to group non-target species by the way in which they come into contact with 1507 plants (e.g. as pollinators), but it is questionable whether such functional groups are sufficiently representative of all the species contained within them. The differing sensitivities of Lepidoptera species, as listed by EFSA (2011) itself in detail, means that the adverse effects of Cry1F can vary between species that fall into the same functional group.

In addition to this, the species for which there are scientific articles available have been chosen by the respective authors for their own research objectives, and not necessarily as

¹² EFSA started drafting a new guidance for environmental risk assessments which was finalised and published in 2010 (EFSA 2010b).

¹³ The phylum of arthropods consists of invertebrates with an exoskeleton and a segmented body, e.g. insects, crustacea, spiders, and millipedes.

¹⁴ In the 2012 opinion this restriction basically remains. EFSA identified four additional studies: three on arthropods (one species of lacewing, aphid and ladybird beetle each) as well as one on a symbiotic mycorrhizal fungi.

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representatives for larger functional groups. In the case of the functional group of pollinators, EFSA simply refers to a single existing study with bees (Hanley et al. 2003, see below). Other groups, such as decomposers in the soil, are not studied at all.

There is only one new field study with non-target arthropods quoted by EFSA (2011) to prove the safety of 1507 cultivation (Higgins et al. 2009). This study was conducted for three years on four locations in the US corn belt - a landscape that is very different from agricultural landscapes in the EU, which have, for example, many more and smaller fields and different types of field margins. This study only investigated changes in the abundance of whole (functional) groups of arthropods, and - as the authors state themselves - it could only have detected reductions of these groups by 50%. Any smaller reductions in numbers, any effects that did not result in reduced numbers, and any effect on individual species could not have been detected by this study design.

Thus this study, conducted by a scientist from Pioneer HiBred (DuPont), is incapable of properly assessing the safety of 1507 cultivation in the EU, both because of its design and its location.

One single lab study with bee larvae

According to EFSA, there is only *one* peer-reviewed scientific study (Hanley et al. 2003) about the effect of Cry1F toxin on honey bees, conducted nine years ago in the US, feeding Bt maize pollen to bee larvae in the lab.

In addition there are two meta-studies that summarise the results of different studies with different Bt toxins (Duan et al. 2008; Malone & Burgess 2009). For one of these meta-studies (Duan et al. 2008), it is worth noting that two of the five authors work for Monsanto, and that a third is one of the co-authors of the 2003 study and was thereby assessing his own work.

Duan et al. (2008) and EFSA (2009) acknowledge that under stress situations in the fields, bees might be more susceptible than in the lab - but EFSA still doesn't request any other study; instead it just considers 1507 safe enough.

“ However, Duan et al. (2008) considered that in field settings, honeybees might face additional stresses, which could theoretically affect their susceptibility to Cry proteins and generate indirect effects.” (EFSA 2009: 11)

So there are *no* studies in the field, *no* studies in Europe, and *no* study that has been conducted within the last nine years. This is not a sufficient basis to assess the safety of 1507 cultivation for honey bees and other pollinators in the EU. This has not changed with the latest EFSA opinion where no such studies were found in the scientific literature. Pollinators are crucial for protection various ecosystems as well as for the farming sector.

Aquatic organisms

In 2007, Rosi-Marshall et al. published a study that showed that Bt toxins can be found in surface waters - a part of the agricultural landscape that is rarely studied in environmental risk assessments - and that Bt toxin Cry1Ab can have adverse effects on caddis flies, a water insect closely related to butterflies. Interestingly, it also showed yet another way in which non-target organisms can come into contact with Bt toxin: in this case by using Bt-containing plant material to build their cases. The EFSA GMO Panel refers to two studies (Chambers et al. 2010, Jensen et al. 2010) with aquatic leaf-chewing species but - just as with Rosi-Marshall et al. (2007) - these were done with Cry1Ab; there are no studies examining the impact of Cry1F or 1507 on aquatic species.

Nevertheless, Rosi-Marshall et al.'s study is an indicator for possible effects with respect to Cry1F. However, although this *is* acknowledged by EFSA, the study is also dismissed on the basis that it used Bt maize pollen concentration at a rate that is “*two to three times higher than the maximum observed input rate of pollen in the field*” (EFSA 2011: 14).

This is short-sighted from a scientific perspective. First of all, it is a legitimate approach to start a study with high concentrations in lab experiments to see whether there are any effects and then continue with lower concentrations and/or field studies to see whether the effects persist. But more importantly, as EFSA states on the next page of its opinion: 1507 has 350 times more Bt toxin in its pollen than MON810 (EFSA 2011: 15). So Rosi-Marshall's study is likely to have used *lower* Bt concentrations than those that one would expect to find in 1507 pollen. This also contributes to the argument that the results of risk assessment studies cannot be transferred between events with different Bt toxins.

Besides Rosi-Marshall et al.'s article and follow-up publications there are two other articles that show that an environmental risk assessment of Bt crops also needs to include aquatic systems. Bøhn et al. (2008) observed reduced fitness of *Daphnia* feeding on MON810, and Douville et al. (2009) found that *Elliptio companata* mussels from an intensive maize-growing area were significantly contaminated with Cry1A and Cry1Ab genes in their gills, digestive glands, and gonads, as well as finding the transgene in surface water and sediment samples.

All these studies were done with Cry1Ab toxin, and none of them looked at the circumstances in European agricultural landscapes. However, they do indicate that it is important to find out whether 1507 cultivation would have similar adverse effects on aquatic organisms in the EU. Such studies need to be undertaken with Cry1F in the field; it is not sufficient to simply refer to lab studies investigating Cry1Ab.

In the 2012 opinion of EFSA, the database search parameters did not allow to find further scientific literature about how aquatic organisms might be affected by Bt toxins in general - even though for example the articles by Rosi-Marshall and her co-authors could give valuable insight into the kind of studies that are still missing for 1507 maize.

Soil organisms

To assess possible adverse effects on soil organisms we need to (1) know how much Bt toxin is released into the soil and how long it stays there, and (2) study its effects on a range of soil organisms including earthworms and mycorrhiza, for example, as well as arthropods.

In its third opinion (2011), the EFSA GMO Panel refers to three studies about the fate of Cry1F released into the soil by 1507 plants. All three were carried out by scientists from Dow AgroSciences. Two of them (Herman et al. 2001, 2002) are ten-year old studies that show rapid degradation of Cry1F proteins under defined conditions in the lab. However, these studies did not use plant material from 1507 maize, but Cry1F proteins produced by GM bacteria. Such a study design excludes delays caused by the rate of decomposition of the plant material as well as effects on soil organisms. In the other study (Shan et al. 2008), 1507 maize was grown for three years in the field, but effects on soil organisms were not directly assessed. The authors could not measure Bt toxin in the soil. They then used soil and root samples in the lab to test effects on the tobacco bud worm (*Heliothis virescens*) which is not a soil organism.

It appears that no studies on soil organisms have been undertaken using 1507 plant material or Cry1F toxin, and this has not changed with the latest EFSA opinions.

Non-target Lepidoptera

In 2006, the EU Commission requested EFSA to clarify its opinion about non-target butterflies. EFSA reaffirmed its prior position:

“[...] GMO Panel is of the opinion that the risk of Bt11 and 1507 pollen to non-target Lepidopteran species is negligible due to the low bioactive CRY content and the low levels of exposure of wild species to maize pollen [...] that there is no evidence to indicate that placing of maize line 1507 and derived products on the market is likely to cause adverse effects on human or animal health or the environment in the context of its proposed use.” (EFSA 2006b)

By 2011, the possibility that Bt toxins have adverse effects on non-target Lepidoptera has been generally accepted, but there is still insufficient data to make specific risk assessments. Unanswered questions include: which species are affected by what quantities or concentrations of the Bt toxin; what sub-lethal effects, such as reduced weight or longer development times, might be caused by Cry1F; and when and how do the feeding periods of the various caterpillars coincide with the flowering of the maize plants. However, even without answers to these questions, EFSA acknowledges, in its opinion (EFSA 2011), that Cry1F can have adverse effects on Lepidoptera.

Yet instead of concluding that it would not be safe to cultivate 1507, or asking the applicant for more data to come to a more informed conclusion, the EFSA GMO Panel applies its own mathematical model to estimate what percentage of Lepidoptera would die if 1507 is cultivated, and then proposes a “risk mitigation plan” by which this percentage could be reduced.

Missing data to be collected during cultivation

The EFSA GMO Panel (2011) states that 1507 maize and its Cry1F toxin form a risk for at least some butterfly and moth species, and that there is a lack of knowledge as to which of these species are at risk and where they are in an agricultural landscape.

“ The 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)¹⁵ 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.” (EFSA 2011:38)

Where there is data available and the applicant concluded that there was no relevant risk, the EFSA GMO Panel even disagrees with the applicant:

*“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.” (EFSA 2011:26)*

¹⁵Note by the author: About half of the authors of the Perry et al. articles are members of the EFSA GMO Panel.

In contradiction to its previous opinions about the same maize, EFSA now states that there is a risk. This statement should lead to a final recommendation that maize 1507 cannot be assessed as being safe for cultivation without further information demonstrating its safety. But instead of asking for basic data to be provided *before* granting the cultivation approval, EFSA proposes that the applicant should collect such data as part of post-market monitoring.

“The EFSA GMO Panel recommends carrying out further field studies on non-target Lepidoptera” (EFSA 2011: 43)

“In this respect, data are required on the sensitivity of non-target Lepidoptera which are estimated to have a high or greater sensitivity for the Cry1F protein, and where such species are present in different regions of Europe where maize 1507 will be grown. It is therefore recommended that applicants and Member States cooperate in determining which focal non-target Lepidopteran species should be examined, and where such Lepidopteran larvae and their host-plants might be found during flowering of maize in maize 1507 growing regions. Such observations could trigger further investigation on the sensitivity of these non-target Lepidopteran species to the Cry1F protein.” (EFSA 2011: 44)

Just to emphasize this: this recommendation to collect further data is not made as part of the environmental risk assessment undertaken *before* a cultivation approval is granted, but as part of the monitoring that should take place *during* commercial cultivation of 1507.

This turns the concept of monitoring on its head. Post-market environmental monitoring is meant *“to trace and identify any direct or indirect, immediate, delayed or unanticipated effects”* (EFSA 2011: 40). The collection of basic data about the sensitivity of non-target Lepidoptera is something that needs to be done as part of the risk assessment *before* starting cultivation.

Modelling to develop a risk mitigation strategy

In spring 2010, a group (half of whose members also sat on the EFSA GMO Panel) published a mathematical model concerning the exposure of non-target Lepidoptera species to Bt maize expressing Cry1Ab, using MON810 maize, which is authorised for cultivation in the EU (Perry et al. 2010). Shortly after this, in November 2010, the EFSA GMO Panel proposed that it should *“update the evaluation of the environmental risk assessment and risk management recommendations on insect-resistant genetically modified maize 1507 for cultivation”* (EFSA-Q-2010-01470). In November 2011 this resulted in the publication of another scientific article (Perry et al. 2011), as well as in the publication of EFSA’s third opinion on 1507 in which *“the mathematical model, developed for maize MON 810, was recalibrated and extended to estimate the efficacy of certain mitigation measures.”* (EFSA 2011) The 2011 opinion relies heavily on the work of a significant group of EFSA members, and is based on their own mathematical model and resulting scientific article, as well as on so-called “risk mitigation” strategies to minimise the impact of 1507 maize on non-target butterflies. Together with claims that there are no new studies showing negative effects on other non-target insects, and still ignoring the need to assess 1507’s herbicide tolerance, EFSA gives a positive opinion yet again.

Seemingly in an attempt to deal with this lack of data, members of the EFSA GMO Panel have in recent years developed a mathematical model to assess the effect of MON810 cultivation on non-target Lepidoptera. They used the assessment of 1507 to “recalibrate”¹⁶

¹⁶“the mathematical model, developed for maize MON 810, was recalibrated and extended to estimate the efficacy of certain mitigation measures.” (EFSA 2011)

this model. The results of this mathematical model were published as Perry et al. 2011 in November 2011, coinciding with the publication of the EFSA opinion on 1507.

However, such a model has serious limitations. First of all, risk assessment studies for the assessment of non-target organisms are generally studies conducted to observe and measure effects of the GM crop on actual organisms in the field or in the lab. These studies generally reveal the degree to which basic data is still lacking, about, for example, which organisms there are on and around the fields, and what direct and indirect adverse effects could occur. Any model is restricted by the availability of such data, and the EFSA admits that there is a lack of data.

In its 2011 opinion, the EFSA GMO Panel proposes a number of actions for risk mitigation, in order to reduce adverse effects on non-target Lepidoptera. Because the studies and the model are almost exclusively based on “global mortality” and mortality rates based on LD50 and LC50,¹⁷ the whole model lacks relevant information on sub-lethal effects, even though the potential importance of these are acknowledged.

“Sublethal 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 sublethal effects other than those of larval weight. Sublethality is also beyond the scope of this EFSA GMO Panel Scientific Opinion.” (EFSA 2011:38)

Such sub-lethal effects include, for example, growth inhibition on neonate monarch butterflies, which has been shown to occur in response to higher Bt toxin concentrations in an earlier study. GM Freeze (2011) published an analysis of the EFSA opinion with more details on this issue (see below).

Even with these shortcomings, however, the EFSA GMO Panel still comes to the conclusion that there *is* a risk to moths and butterflies:

“Nevertheless, the EFSA GMO Panel concludes that there 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.” (EFSA 2011:2)

In its second opinion in 2012, EFSA answered specific questions raised about this model and the proposed risk mitigation strategy, but did not come to different conclusions. The criticisms on the model and the risk mitigation is therefore still valid.

“Don’t grow too much 1507 maize”

While the EFSA GMO Panel acknowledges that there are risks to sensitive non-target Lepidoptera its response is to develop a plan to mitigate these risks so that less than 1% of them would die.

This mitigation plan is mainly based on not cultivating too much 1507 maize in any one area. But if there *is* a higher rate of cultivation then ‘mitigation measures’ - mainly planting non-Bt rows - would be required to reduce the risk for Lepidoptera.

“If maize 1507 cultivation remains below 5% of the Agricultural Unit of Account, the global mortality is predicted to remain below 1% even for extremely sensitive species, and then risk assessment measures are not required.” (EFSA 2011)

According to the EFSA 5% AUA equals 20% 1507 maize in an area where maize is grown on 25% of the arable land. However, this approach does not take the cultivation of any

¹⁷LD50/LC50: Lethal doses/concentration at which 50% of the test organisms die.

other Bt crops into account. In an area where MON810 is also being cultivated, for example, the Lepidoptera would be subject to the impacts of both Bt maize varieties. Future approvals of any other Bt crop - either maize or any other crop - would again increase the amount of Bt toxin in the Lepidoptera habitats.

And even with the cultivation of 1507 on its own, practical questions arise: how would areas be defined in order to determine whether a farmer could or could not grow 1507, or when 'mitigation measures' are required? How large should such an area be, and how evenly mixed should the distribution of 1507 and non-1507 maize be?

The proposed risk mitigation measures

For areas where 1507 maize is cultivated on more than 5% AUA, the EFSA GMO Panel also proposes a "risk mitigation strategy". This includes, as summarised by GM Freeze (2011):

- "Planting buffer strips of non-GM maize around the edge of 1507 GM 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.
- Increasing distances between 1507 maize and larval food plants for at risk species.
- Spraying the 1507 maize to remove larval food plants.
- Detassling the border rows of 1507 maize crops (i.e. removing the male pollen-producing flowers).
- Establishing and maintaining additional habitats for vulnerable species at distances greater than 30 meters from the crop.
- Changing cropping systems (i.e. employing rotations)."

As GM Freeze (2011) explains in more detail:

"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 doubts remain as to whether they are effective, practicable 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 destasseling male [flowers] along crop edges, are clearly impractical." (GM Freeze 2011)

In particular, the proposal to spray 1507 maize fields with herbicides to kill off weeds that could act as food plants for non-target butterflies sounds counterproductive. Removing feeding plants for non-target butterflies from a 1507 field would put even more pressure on Lepidoptera in agricultural landscapes instead of protecting them.

To conclude: even the EFSA GMO Panel admits that cultivating 1507 poses a risk for Lepidoptera, and that there is a lack of data. Based on its own model, EFSA then sets a threshold for 1507 cultivation, estimating limits to cultivation that should ensure that no more than 1% of non-target Lepidoptera are killed; it does this without taking the potential presence of other Bt crops such as MON810 into account. If the cultivation rate of 1507 is

higher than the suggested 5% AUA, EFSA develops so-called risk mitigation measures intended to reduce the risks, but there are doubts as to whether these measures would be effective, practicable or enforceable. Instead of proposing such thresholds and measures and asking the applicant to provide more basic data for a risk assessment during cultivation, EFSA should have concluded that it is not safe to cultivate 1507.

Reviewing the model

The scientific articles Perry et al. 2010 and 2011 used as the basis for EFSA's risk mitigation as well as the broader issues of modelling risks in this way, are still under scientific debate.¹⁸

An article (Holst et al. 2013) uses a different model that comes to different conclusions when taking spatial and temporal overlaps between the presence of butterfly larvae and Bt pollen into account. Modelling the Peacock butterfly feeding on stinging nettles (*Inachis io*) and MON810 cultivation in Germany, the authors come to the conclusion that in the North of Germany there won't be an overlap and therefore little risk for this butterfly species - but in the South there is, because in the South of Germany this butterfly species has two generations per year. In the North it only has one generation.

The authors comment also on Perry et al.'s use of generic parameters for the models, their subsuming of several mechanisms and informal estimations, instead of using existing data.

We contend that such an assessment is best carried out using empirical data, which invites scientific review and integration of knowledge, rather than on expert opinion, on which a qualified assessment is not possible. (Holst et al 2013)

Not only come the two different models to different conclusions - they also show the need for a scientific discussion about whether or to which degree modelling can be used to replace other studies.

The EFSA GMO Panel however will not be in the position to assess this scientific debate and draw conclusions for the risk assessment of 1507 from it, because it is now in a conflict of interest. A prominent number of the GMO Panel members are co-authors of one of the models by Perry et al., to the point that the GMO Panel describes the model as its own in the latest EFSA opinion.¹⁹

In 2012, the EFSA now provides its own scientific work to answer questions posed to them by the EU Commission. The role of the EFSA GMO Panel has clearly changed into that of a stakeholder.

Reviewing the scientific literature

In June 2012, just half a year after the 2011 opinion was published, the EU Commission requested that the EFSA prepares a new opinion "gathering all available information related to the environmental risk assessment of maize 1507 for cultivation."

EFSA replied to that request by searching the scientific literature database for the period 2005-2012 for a number of specific keywords. This resulted in a list of 61 peer-reviewed articles of which 25 had already been considered. In the remaining 36 articles the EFSA did not find information that changed their previous opinion. The 25 articles is not the result

¹⁸ See for example Lang et al 2011 and Holst 2013.

¹⁹ "The EFSA GMO Panel was asked by the European Commission to apply its mathematical model [...] and to provide information on the factors affecting the insect resistance management plan, additional to that in its 2011 Scientific Opinion." (EFSA 2012b).

of EFSA's pro-active approach: in 2008, the EU Commission had already requested that the EFSA would consider a list of 11 articles.

For the first time EFSA states the use of an external scientific database and a systematic research for relevant literature for its scientific opinion of maize 1507.

The worrying issue here is less the content of these articles but the need for such a request. Since 2005, the EFSA has repeatedly re-assessed its opinions on 1507 including with a self-task, but apparently without actively including recent peer-reviewed articles on the issue. The lack of considering comprehensively peer-reviewed scientific literature raises additional concerns which scientific standard EFSA applies in its opinions of the GM maize.

IV. Conclusions

Even though it is more than 10 years since the first application for authorisation of 1507 maize was made, there has been remarkably little environmental risk assessment undertaken for 1507 and its Bt toxin Cry1F. For some important groups such as bees and other pollinators, there is only one lab study and two meta-studies assessing adverse effects available in the peer-reviewed literature.

However, adverse effects on Lepidoptera are acknowledged by EFSA, although the assessment of these effects is based primarily on EFSA's own mathematical model and its risk mitigation plans.

1507 is herbicide tolerant and sold as such in the USA. The original notification from 2001 clearly states the herbicide tolerance as a trait. 1507 hybrids are also being field-tested in the EU with herbicide applications. While the GMO is still the same as it was in 2001, the words to describe it have changed. In the first years of the process, EFSA did not request studies to assess potential environmental effects of the herbicide tolerance because the GMO Panel agreed with the notifiers that there wouldn't be an adverse effect - now it does not assess them because it is claimed that the herbicide tolerance was never meant to be used anyway. In the end it comes down to the fact that the herbicide tolerance of a GMO for which the herbicide is available is simply not assessed - even though this has been requested by, for example, the EU Council.

There may well be an additional reason why such an 'old' GM maize is still being pushed for cultivation approval, even when there are such obvious gaps in the risk assessment: the EFSA GMO Panel considers stacked GM hybrids mainly as a combination of separate GM events that have previously been declared safe on an individual basis. A cultivation approval for 1507 would not only be relevant for 1507 itself, but also for any of the 1507 hybrids for which applications are also pending.

However, we see substantial gaps in the EFSA opinion:

1. The glufosinate tolerance of 1507 is not assessed by EFSA. This is surprising, considering that both DG Environment and DG Health and Consumers, as well as all the environment ministers in their Council conclusions of December 2008, have explicitly demanded such an assessment.
2. EFSA's opinion asserts that a potential risk for butterflies and moths exists. But instead of concluding that 1507 cannot be assessed as safe, EFSA suggests conducting further studies *after* authorisation for commercial cultivation.

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3. EFSA's proposed risk mitigation measures intended to reduce the risks, are doubtful as to whether they would be effective, practicable or enforceable.
4. There is a long list of possible adverse effects on non-target organisms that have not been assessed in the different EFSA opinions on 1507.

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VI. Annex

Annex 1: Additional 1507 applications

Year	Approval	GM events	goal	applicant
2001		1507	placing on the market	Pioneer / Mycogen
	2006	1507	food and feed	Pioneer & Dow
		1507	cultivation	
2004	2007	1507 x NK603	food and feed	Pioneer & Dow
2005	2010	1507 x 59122	food and feed	Dow AgroSciences
		1507 x 59122	cultivation	Dow AgroSciences
	2010	59122 x 1507 x NK603	food & feed	Pioneer
2006		59122 x 1507 x NK603	food and feed; cultivation	Pioneer
2007	2011	1507	feed renewal	Pioneer
2008		MON89034 x 1507 x MON88017 x 59122	food and feed	Dow & Monsanto
2009		MON89034 x 1507 x NK603	food and feed	Dow & Monsanto
2010		1507 x MON88017 x 59122	food and feed	Dow & Monsanto
		MON 89034 x 1507 x NK603	food and feed	Dow & Monsanto
		Bt11 x MIR162 x 1507 x GA21	food and feed	Syngenta
2011		1507 x 59122 x MON810 x NK603	food and feed	Pioneer
		Bt11 x 59122 x MIR604 x 1507 x GA21	food and feed	Syngenta
		Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21	food and feed	Syngenta

Table 1: Applications for 1507 stacked events in the EU. Source: EFSA Register of Questions.

The hybrids combine additional herbicide tolerance - mainly glyphosate (Roundup) tolerance from NK603 - and additional Bt toxins Cry1Ab and Cry1Ac against European corn borer

Annex 2: Field trials with glufosinate applications

Number	Period	Country	Operator	GMO	Trial description
B/DE/10/207	2010-14	Germany	Pioneer	59122 x 1507 x NK603, 1507 x NK603, 59122, 1507, NK603	“agronomic performances [...] with and without applications of herbicides.”
B/ES/10/39	2010	Spain	Pioneer	1507 x NK603	“agronomic performances [...] with and without applications of herbicides.”
B/ES/10/41	2010	Spain	Pioneer	59122 x 1507 x NK603	“agronomic performances [...] with and without applications of herbicides.”
B/ES/10/03	2010	Spain	Procasa Semillas	1507	“to assess [...] PAT protein conferring tolerance against glufosinate ammonium herbicide”
B/ES/09/54-CON	2009	Spain	Pioneer	98140 x 1507	“with and without applications of herbicides (glyphosate, ALS-inhibiting herbicides such as sulfonyleureas, glufosinate).”
B/ES/09/56-CON	2009	Spain	Pioneer	98140 x 1507 x 59122	“with and without applications of herbicides (glyphosate, ALS-inhibiting herbicides such as sulfonyleureas, glufosinate).”
B/ES/09/27	2009	Spain	Dow	1507	“to assess the efficacy of [...] PAT protein conferring tolerance against glufosinate ammonium herbicide”
B/HU/05/12/1	2006-09	Hungary	Dow	1507 x NK603	“under European conditions, the evaluation of the selectivity of glyphosate and glufosinate herbicides”
B/HU/05/12/2	2006-09	Hungary	Dow	1507 x 59122 x	“under European conditions, the evaluation of the selectivity of glyphosate and glufosinate herbicides”
B/PT/05/02	2005-08	Portugal	Pioneer	1507 x NK603	“to evaluate the residual behaviour of glufosinate and glyphosate”
B/PT/05/04	2005-08	Portugal	Pioneer	59122 x 1507 x NK603	“to evaluate the residual behaviour of glufosinate and glyphosate”
B/ES/05/17	2005-08	Spain	Pioneer	59122 x 1507 x NK603	“to control maize volunteers with different herbicides, to evaluate the residual behaviour of glufosinate and glyphosate”
B/ES/05/12-CON	2004-07	Spain	Dow	confidential but most likely a 1507 hybrid	“to collect data on the composition, protein expression and herbicide” “residues of the different plant parts”

Number	Period	Country	Operator	GMO	Trial description
B/ES/05/10	2005-07	Spain	Pioneer	1507 x NK603	“to control maize volunteers with different herbicides, to evaluate the residual behaviour of glufosinate and glyphosate”

Table 2: Examples of field trials of 1507 and 1507 hybrids with glufosinate applications.

This list is incomplete due to the inconsistency of data provided in the JRC Database GMO Register.



Annex 3: Time line of the 1507 maize cultivation application in the EU

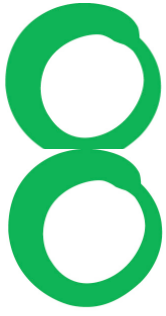
Just as 1507 maize, the maize Bt11 carries a tolerance to glufosinate herbicides, but produces a different Bt toxin (Cry1Ab). In recent years both GM maize events have often been discussed together.²⁰

1998-2000	Field trials with 1507 are conducted in Chile, France, Italy and Bulgaria. These include the application of glufosinate-ammonium as herbicide; either on all plants (Chile) or on part of the fields for comparative analysis.
2000	Aventis Crop Science notifies the EU Commission of its wish to include glufosinate in the Annex of the Pesticide Directive 91/414/EEC. At this moment 'existing data' for the EU only refers to its use in apple orchards (DG Sanco 2007).
2001	Pioneer Hi-Bred International/Mycogen Seeds submit an application to place 1507 maize on the market in the EU (C/ES/01/01). A notification for the use of 1507 maize as food is submitted separately (C/NL/00/01). In both applications 1507 is explicitly described as 'herbicide-tolerant' and a concentration of glufosinate-ammonium as herbicide application is determined in field trials. The cultivation notification clearly states: "Tolerance to glufosinate-ammonium herbicide provides for improved weed management."
2003/2004	EU member states comment on the notification and point out that glufosinate is at that moment not authorised for maize cultivation. In communication with the authorities the notifiers apparently adjust their application: "In the further information provided, the notifier states that the scope of the notification C/ES/01/01 is limited to the cultivation of 1507 maize without the application of glufosinate-ammonium until the herbicide is licensed for its use."
2005	EFSA (2005a) publishes a peer review on the toxicity of glufosinate as part of the process to include it into the Pesticide Directive, using GM maize as one of the application types besides the use in apple orchards.
June 2005	EFSA GMO Panel publishes two positive opinions on 1507 maize: one for use as food and feed, and one for 1507 cultivation. In the comparative assessment, differences are made between plant material from untreated 1507 plants and from 1507 plants treated with herbicides. EFSA claims that it studied the effect of the herbicide tolerance, but only looked at effects of the PAT protein that causes the tolerance, not at the safety of glufosinate residues on the plants, nor at effects of changes in agricultural practices of applying glufosinate on fields of herbicide-tolerant crops (EFSA 2005b). Effects of changed agricultural practices are mentioned and dismissed. It is clear that the GMO Panel considers the herbicide tolerance as a trait – not just as a marker. The Panel just isn't thorough in its assessment. Glufosinate does not have an approval for agricultural use at this point, and the GMO Panel points out that others have to undertake the pesticide assessment.

2005-2008	In field-trials in Spain and Portugal, 1507 hybrids are grown with herbicide applications of glufosinate and glyphosate to evaluate pesticide residues.
March 2006	The EU Commission grants approval to use 1507 as food, valid until 2016.
June 2006	Several member states raise objections to the EFSA opinion, especially with respect to effects on non-target organisms in general and Lepidoptera specifically, as well as on monitoring measures. (DG Environment 2006).
July 2006	The EU Commission requests EFSA to review its opinions, asking whether specific risk management measures should be undertaken, such as monitoring with specific scientific studies with respect to non-target organisms and geographical differences (EFSA 2006).
November 2006	EFSA (2006) reaffirms its opinion that negative effects on animal and human health and the environment are unlikely.
2007	Dow AgroSciences (2007) publishes product information about 1507 (Herculex) emphasising the benefit of the glufosinate tolerance.
2007	Glufosinate gets approved in the EU for agricultural use, classified as <i>Reproductive Toxicity 1B</i>
October 2007	The Environment Commissioner Dimas (2007a,b) proposes not to authorise the cultivation of the two GM maize events 1507 and Bt11. The draft decision explicitly mentions scientific studies concerning the effects of Bt toxins on non-target organisms and emphasises that due to unknown reasons the production of Bt toxin in the plants vary greatly and that long-term effects of Bt toxins in the environment are unknown. This draft does not get approved by the EU Commission.
January 2008	DG Environment requests the EFSA GMO Panel to provide 4 guidelines: “1. A precise definition of the tests to be carried out on non-target organisms [...]. 2. The establishment of a complete list of non-target organisms to be tested in Europe, representing the different European regions, the different food chains and the different trophic levels [...] 3. A clear definition of tests to be carried out in order to assess the potential long term effects on the environment, this includes in particular the modification of cultivation practices, toxin accumulation in soils and waters, the effects on food chains, etc. 4. A precise and detailed description of field trials for a complete assessment of the effects of GMOs on the environment [...]” (DG Environment 2008)
March 2008	The EFSA GMO Panel proposes revised <i>Terms of Reference</i> for the <i>Guidance on environmental risk assessment</i> (EFSA 2008a). These do not mention the modification of cultivation practices or toxin accumulations that explicitly anymore, but contain a “section related to GM herbicide tolerant crops” (Mandate M-2008-0100, EFSA 2010).
July 2008	DG Environment requests EFSA to “review [eleven] recent scientific studies relating to the impact on the environment of the cultivation of two genetically modified maizes: 1507 and Bt11.” (Mandate M-2008-0708)
September 2008	DGs Environment and Health and Consumer Protection send a joint letter to EFSA to clarify the interplay between the GMO Directive (2001/18) and the Pesticide Directive (91/14/EC) focussing on how herbicide tolerant crops should be assessed. The European Commission clarifies that “the consequences of <i>the change in agricultural practices</i> due to herbicide use on GM HT plants have to be duly considered within the environmental risk assessment under Directive 2001/18” (European Commission 2008).
October 2008	EFSA (2008b) published its second opinion concluding that none of these studies contradict its earlier opinions, and disregarding the letter on herbicide tolerance.

December 2008	The Environment Council unanimously adopts its conclusions which “underline in particular the need to study the potential consequences for the environment of changes in the use of herbicides caused by herbicide tolerant GMPs and to ensure coherence between risk assessments of GMPs which produce active substances covered by directive 91/14/EEC and those of the corresponding plant protection products” (Council of the European Union 2008).
January 2009	The EU adopts new regulation for pesticides 2009/1107, incl. criteria for the (re-)authorisation of pesticides classified as toxic for reproduction, carcinogenic and/or mutagenic. Under these criteria, glufosinate is one of 22 pesticides that cannot have their marketing licence extended.
January 2009	The EU Commission (2009) issues authorisation proposals to allow the cultivation of 1507 and Bt11. The issue of glufosinate tolerance is only addressed by demanding that the label or accompanying document states “the product shall not be used with glufosinate herbicide in any manner differing from conventional practice with maize not tolerant to glufosinate.” In the reasoning for it DG Environment states: “The scope of the notification, as confirmed by the consent-holder on 23 February 2007, does not cover the commercial use of the product as a plant tolerant to glufosinate in the EU, since the pat gene for glufosinate was only to be used as a marker gene.” This is in clear contradiction to the initial notifications.
2010	Confirmatory data evaluation of glufosinate, based on additional data that Bayer provided.
January 2010	A group of authors, of which half are members of the EFSA GMO Panel, publishes a scientific article (Perry et al. 2010) about a mathematical model to assess the risk of MON810 cultivation for non-target Lepidoptera.
June 2011	The EU Commission renews the feed approval for 1507. The combined food-and-feed approval is valid until 2016.
November 2010	The EFSA GMO Panel requests permission from the Director of EFSA to undertake “a self task on an update of the Environmental Risk Assessment of the GMO Panel on the GM maize 1507 for cultivation.” (EFSA 2010a)
November 2010	The EFSA GMO Panel publishes its “Guidance on the environmental risk assessment of genetically modified plants” (EFSA 2010b)
November 2011	Perry et al. (2011) publish a second scientific article about using their model for the assessment of 1507 maize.
December 2011	The EFSA GMO Panel publishes its third opinion on 1597, focusing on non-target butterflies and on its own proposals for risk management (EFSA 2011).
2017	The licence for glufosinate will run out.

Table 3: Time line of the 1507 maize cultivation application and the permit for use of glufosinate-ammonium herbicides for agricultural use in the EU.



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Luxembourg	Dvizhenje na Ekologistite na Makedonija
Macedonia	Moviment ghall-Ambjent
Malta	Vereniging Milieudefensie
The Netherlands	Norges Naturvernforbund
Norway	Polski Klub Ekologiczny
Poland	Friends of the Earth Scotland
Scotland	Priatelja Zeme - Slovensko
Slovakia	Amigos de la Tierra
Spain	Jordens Vänner
Sweden	Pro Natura
Switzerland	Zelenyi Svit
Ukraine	

Friends of the Earth Europe campaigns for sustainable and just societies and for the protection of the environment, unites 30 national organisations with thousands of local groups and is part of the world's largest grassroots environmental network, Friends of the Earth International.