



**Friends of
the Earth
Europe**

Maize 1507: toxic and inadequately tested

Why GM maize 1507 should be banned

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I. Summary

A genetically modified maize that is tolerant to a particular herbicide and also produces its own insecticide has been developed by Pioneer Hi-Bred and Mycogen Seeds. The companies requested in 2001 for the maize, called 1507, to be authorised for cultivation in the EU. Despite a number of assessments by the European Food Safety Authority (EFSA), many questions around the crop's safety, its legal standing, and the European Commission's mandate in its authorisation, remain unanswered.

The EFSA opinions do not deliver sufficient information to duly assess the risks of the maize, nor has EFSA fulfilled the various mandates it received from the European Commission related to the crop. There are also substantial weaknesses in its assessment. In its assessment of the impacts on non-target organisms, EFSA focuses on Lepidoptera (the family of butterflies and moths) and excludes other arthropods, aquatic and soil organisms. Despite acknowledgments that information is lacking, and that the maize poses a risk to some Lepidoptera, EFSA still considers the maize safe for cultivation.ⁱ

In cases where adverse effects from the maize's cultivation are recognised, EFSA suggests inadequate and impracticable risk mitigation strategies.

In the later assessments, EFSA fails to assess the environmental impacts of the maize in relation to herbicide tolerance – by claiming that herbicide tolerance was only intended as a marker gene. This is in contradiction to the original notification from 2001 and to EFSA's own, earlier opinions.

In 2009 Pioneer Hi-Bred took the European Union to court to force it to send the GM maize for a vote in the European Council. In 2013, after the court ruled that the European Commission had failed to act, the Commission put 1507 forward for the decision for approval to Council. On 6 November 2013, the European Commission drafted a proposal with major legal gaps, asking national ministers to decide about the cultivation of the maize in Europe's fields.

If grown commercially, there is a risk that this maize will contribute to the decline in biodiversity as well as lead to the possible increase in use of a toxic and damaging herbicide.

Herbicide tolerance is not assessed at all

European GMO law requires EU institutions to assess the changes in agricultural practices caused by a GM herbicide tolerant plantⁱⁱ. EFSA still has not assessed the environmental impacts of 1507 related to herbicide tolerance, even though this has been requested by DG Sanco and DG Environment, and the EU's Environment Council in 2008.ⁱⁱⁱ Instead – in its latest opinions – EFSA claims that herbicide tolerance is only intended as a marker gene.

It is in contradiction to reports from the USA where the applicant itself promotes maize 1507 as a herbicide-tolerant crop.^{iv} Thus EFSA's argument that the herbicide tolerance trait was simply added as a marker gene is not only invalid,^v it is also in contradiction to the original notification from 2001. In it Pioneer clearly states that herbicide tolerance is intended for weed management^{vi}, gives the herbicide concentrations that can be used in the field^{vii}, and analyses plant material from 1507 plants treated with the herbicide glufosinate^{viii}. The legally required environmental risk assessment of "*changes in agricultural practises*" however is still lacking. The draft authorisation proposal explicitly refers to the original notification with the described glufosinate tolerance (Article 1).

The issue is complicated by the fact that the EU rules for the herbicide glufosinate has drastically changed in April 2013. "*Glufosinate have been restricted to uses as herbicide for band or spot*".^{ix} This means that there is no current permission to use this herbicide on 1507, but doesn't stop companies lobbying to get it permitted in the future. In addition these new rules have been implemented in only a few countries.

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^x and that there is a lack of knowledge concerning which of these species are at risk and where they are in an agricultural landscape.^{xi} But, instead of asking for basic data *before* granting the cultivation approval, EFSA proposed that the applicant should collect such data as part of the post-market monitoring. In its draft decision the EU Commission followed this advice. This seriously confuses the roles of risk assessment and monitoring. Post-market monitoring serves the purpose of observing whether the GMO and its interaction with the environment is as expected, e.g. whether a specific condition only takes place as often as expected or whether management measures work as planned. Risk assessment studies are meant for studying possible risks before the cultivation starts, so that company and farmers know what they are monitoring.

Two years ago, EFSA confirmed there was a lack of information around 1507, and proposed additional studies. Since then the applicant could have started to conduct such studies in order to have more data available.

The draft proposal of the EU Commission even fails to implement the inadequate and impracticable measures that EFSA suggested to reduce the risks for moths and butterflies.^{xii} Additionally the draft proposal fails to define the "conditions for the protection of particular ecosystems/environments and/or geographical areas;" as required by Art 19 (3) of Directive 2001/18.

Conduct studies with the actual toxin

In general, most studies of the effects of the insecticidal Bt toxins have been undertaken with the Cry1Ab and Cry1Ac toxins, 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.”*^{xiii} 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.

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.^{xiv} 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.

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. 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.

Flawed monitoring in the draft proposal

Whilst EFSA recommended several studies to determine the sensitivity and risk to exposed non-target Lepidopteran species, and to confirm the level of exposure of non-target Lepidoptera, this is not required in the draft application. There are no baselines established by the applicant that could be used for the monitoring for those non-target organisms that are at risk. Additionally the Commission doesn't require any protection or measures for highly sensitive butterflies and moths.

II. Conclusions

There are substantial gaps in the risk assessment and risk management of 1507 maize. If grown commercially, there is a risk that this maize will contribute to the decline in biodiversity as well as lead to the possible increase in use of a toxic and damaging herbicide.

The failings in the assessment and risk management include:

1. The glufosinate tolerance of 1507 is not assessed by EFSA as legally required. In the draft proposal for the authorisation the European Commission deleted any information concerning the crop's glufosinate resistance. Farmers are not informed that they should not spray the herbicide on the maize, nor will any monitoring of development of resistance amongst weeds be undertaken. Monitoring of the actual use of glufosinate on fields cultivated with maize 1507 is lacking. The Commission incorrectly assumes that new legal constraints on the use of the herbicide will dissuade farmers from using the herbicide on the maize.
2. 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.
3. 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.
4. EFSA's proposed risk mitigation measures intended to reduce the risks, are doubtful as to whether they would be effective, practicable or enforceable.
5. The monitoring plan of the draft decision of GM maize 1507 is even weaker than EFSA's mitigation plan. It requires the cooperation of existing surveillance networks without specifying them, or without any indication what happens if these networks don't agree to do so. There are no baselines established by the applicant that could be used for the monitoring for those non-target organisms that are at risk. Additionally the risk managers don't require any protection or measures for highly sensitive butterflies and moths.
6. The draft proposal fails to define the "conditions for the protection of particular ecosystems/environments and/or geographical areas;" as required by Art 19 (3) of Directive 2001/18.

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ⁱ EFSA opinion February 2012, page 2; “reductions in populations of certain highly sensitive non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants. In situations where highly sensitive non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that mitigation measures are adopted to reduce exposure.
<http://www.efsa.europa.eu/en/efsajournal/doc/2429.pdf>

ⁱⁱ Directive 2001/18 Annex II demands in its parts of steps in the environmental risk assessment to assess — “changes in management, including, where applicable, in agricultural practices.”

ⁱⁱⁱ In September 2008, Heads of DG Environment and DG SANCO 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 December 2008, the Environment Council of the European Union adopted conclusions on GMOs in which it considers

“4. NOTES WITH SATISFACTION that [the EU Commission’s mandate to EFSA includes examination of the criteria and requirements, including GMPs that produce active substances covered by directive 91/414/EEC and herbicide-tolerant GMPs; 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 [...]”.

^{iv} Dow AgroSciences (2007): *TC1507, Insect-Protected Maize (Corn), Technical Bulletin.*

http://msdssearch.dow.com/PublishedLiteratureDAS/dh_00a4/0901b803800a4d0c.pdf?filepath=herculex/pdfs/noreg/010-16438.pdf&fromPage=GetDoc

^v In 2007 the applicant informed the European Commission that the maize would not be marketed as glufosinate tolerant GM maize and is now presented by the Commission as a BT maize containing only a marker gene.

http://www.saveourseeds.org/fileadmin/files/SOS/Dossiers/Stop_the_Crop/COM_draft_approval_1507_D003697-01-00-EN.pdf

^{vi} Original application “Question 19: ... 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)

^{vii} Original application (C/ES/01/01 SNIF, 2001) 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”

^{viii} EFSA opinion 2005 page 8; “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.”

^{ix} Implementing regulation 365/2013 of constraint use of the herbicide glufosinate <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0027:0029:EN:PDF>

^x EFSA opinion February 2012, page 2; “reductions in populations of certain highly sensitive non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants. In situations where highly sensitive non-target Lepidoptera populations might be at risk, the EFSA GMO Panel recommends that mitigation measures are adopted to reduce exposure.

<http://www.efsa.europa.eu/en/efsajournal/doc/2429.pdf>

^{xi} EFSA opinion February 2012, p. 2; “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.”

(<http://www.efsa.europa.eu/en/efsajournal/doc/2429.pdf>

^{xii} 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 N, Lang A, Lövei G & Otto M (2013): Increased mortality is predicted of *Inachis io* larvae caused by Bt-maize pollen in European farmland. *Ecological Modelling* 250: 126–133

<http://www.sciencedirect.com/science/article/pii/S0304380012005315>

GM Freeze (2011): In two minds. Report. <http://www.gmfreeze.org/publications/briefings/125/>

^{xiii} EFSA opinion February 2012, page 11, <http://www.efsa.europa.eu/en/efsajournal/doc/2429.pdf>

^{xiv} Hanley AV, Huang ZY & Pett WL (2003): Effects of dietary transgenic Bt corn pollen on larvae of *Apis mellifera* and *Galleria mellonella*. *Journal of Apicultural Research* 42: 77-81. http://www.ibra.org.uk/articles/20080613_28