TESTBIOTECH Background 2 - 6 - 2014

Testbiotech e. V.
Institute for Independent
Impact Assessment in
Biotechnology

Genetically engineered Maize 1507: EFSA cannot invalidate evidence of substantial gaps in risk assessment

Christoph Then & Andreas Bauer-Panskus

This project was realised with support of the Grassroots Foundation

Content

Summary

Testbiotech published three reports on genetically engineered maize 1507 at the end of 2013 and the beginning of 2014. Two of them were assessed by EFSA following a request by the EU Commission.

Testbiotech presented detailed evidence in the reports that EFSA risk assessment is not based on sufficient data and leaves too much room for uncertainties. This is crucial since there is no doubt that sufficiently reliable data is a prerequisite for adequate risk assessment, which fulfils the requirements of EU legislation on consumer and environmental protection.

The response from EFSA in no way invalidates the evidence provided by Testbiotech, which shows that the data currently used to exclude risks to the environment and human health are insufficient. Further, the authority failed to address uncertainties and knowledge gaps from a precautionary point of view as foreseen by EU regulations. In the light of these findings, the EU Commission should reject the EFSA statement and suspend market authorisation of maize 1507.

What kind of evidence did Testbiotech provide?

Testbiotech published three reports on genetically engineered maize 1507 at the end of 2013 and beginning of 2014 (Then & Bauer-Panskus, 2013 und 2014, Bauer-Panskus & Then, 2014). Maize 1507 is genetically engineered to produce an insecticidal toxin (Cry1F) and was made resistant to a herbicide (glufosinate). The EU Commission announced that market authorisation for cultivation will be given soon.

EFSA assessed two of the reports prepared by Testbiotech (Then & Bauer-Panskus, 2013 and 2014) following a request by the EU Commission. EFSA came to the conclusion that the reports “do not reveal any new information that would invalidate the previous risk assessment conclusions“. This suggests that Testbiotech tried to give (but could not provide) evidence that maize 1507 is causing harm to the environment and human health. However, in order to provide such evidence, much more data would have been needed which could only have been generated by further investigations and research. Whilst Testbiotech is demanding that such investigations and research should be conducted, the organisation is not claiming that results are already available. Thus the answer of

EFSA is based on a misinterpretation of the evidence provided by Testbiotech in the reports.

The Testbiotech reports in fact do provide evidence that EFSA risk assessment is not based on sufficient data and leaves too much room for uncertainties. This is decisive, since there is no room for doubt that sufficiently reliable data are a prerequisite for carrying out adequate risk assessment to fulfill the requirements of EU legislation on consumer and environmental protection. A substantial lack of sufficiently reliable data means that no proper risk assessment can be carried out, and therefore no market authorisation can be given.

In the reports, Testbiotech provides precise evidence of the serious lack of sufficiently reliable data for specific relevant areas of risk assessment, but EFSA screened the reports mostly for new data giving evidence of harm caused by maize 1507. Naturally, they did not find any such data (which were indeed not presented by Testbiotech) so, of course, EFSA reiterated their own conclusion that maize 1507 is safe.

EFSA's approach is not adequate to tackle the issues raised by Testbiotech. Their response suffers considerably from a (deliberate?) misinterpretation of the aims and purposes of the Testbiotech reports. Moreover, it highlights a more general and very substantial problem: If there is no independent risk research, we do not have sufficient data on potential harm to human health and the environment. Nevertheless, such products are currently authorised. This problem is especially relevant for maize 1507 for which there are hardly any independent studies available (Bauer-Panskus & Then, 2014).

Why the absence of reliable data is a huge problem

The following example shows the deficiencies in the EFSA argumentation. The evidence in the Testbiotech reports identifies the fact that EFSA failed to assess the content of the Bt toxin in the plants sufficiently:

- by overlooking data from industry showing a much higher range of variations in the concentration of the Bt toxin than previously assumed by EFSA. This is confirmed in the EFSA response.
- by not requesting additional investigations. There are no data available on the maximum range of variations of the Bt content under environmental conditions that are likely to

influence the concentration of the toxin in the plants. EFSA is now saying that those variations have to be expected, but would not matter in risk assessment. Yet, how exactly does EFSA come to such a conclusion without systematic investigation of the real range of variations?

- by not requesting sufficiently reliable protocols for testing the Bt content in the plants to enable validation of the data. In its response, EFSA does not even mention this issue.

Consequently, none of the concerns raised by Testbiotech have been invalidated by the EFSA response.

That the existing data are insufficient to conduct proper risk assessment can be shown in more detail by looking at the EFSA approach in a computer modeling of the risks for protected butterflies. This modeling on which the EFSA response is focused is based on
a) the dispersal of pollen on plants that butterfly larvae feed on
b) the susceptibility of butterfly larvae (given as LC 50 dosage which can be understood as the dosage of toxin that is sufficient to kill 50 percent of the exposed population) and
c) the concentration of Bt toxins in the pollen.

Of course, such a model cannot be applied without programming reliable data into the computer. But, as already pointed out there is a serious lack of crucial data:

- EFSA does not have any specific data on the susceptibility of European butterflies to Bt toxin as expressed in the pollen. Rather, EFSA is operating with dosages that are mostly hypothetical and are not derived from experimental investigations on European butterflies. EFSA even agrees with Testbiotech that the only data on European butterflies, which were provided by industry, are not of sufficient scientific value (!). It is evident there is a need to gather sufficiently reliable data on protected European butterflies before any modeling can be applied.
- EFSA bases its modeling on a maximum variation of 25% percent of the Bt content in pollen. However, as Testbiotech shows, the Bt content in some parts of the plant can vary about tenfold and more, while at the same time very few data on pollen from 1507 are available. A lot more data on the Bt content in the pollen would be needed to show that the EFSA calculation covers the relevant concentrations.
- The EFSA model leaves aside other impact factors and stressors that can affect the survival

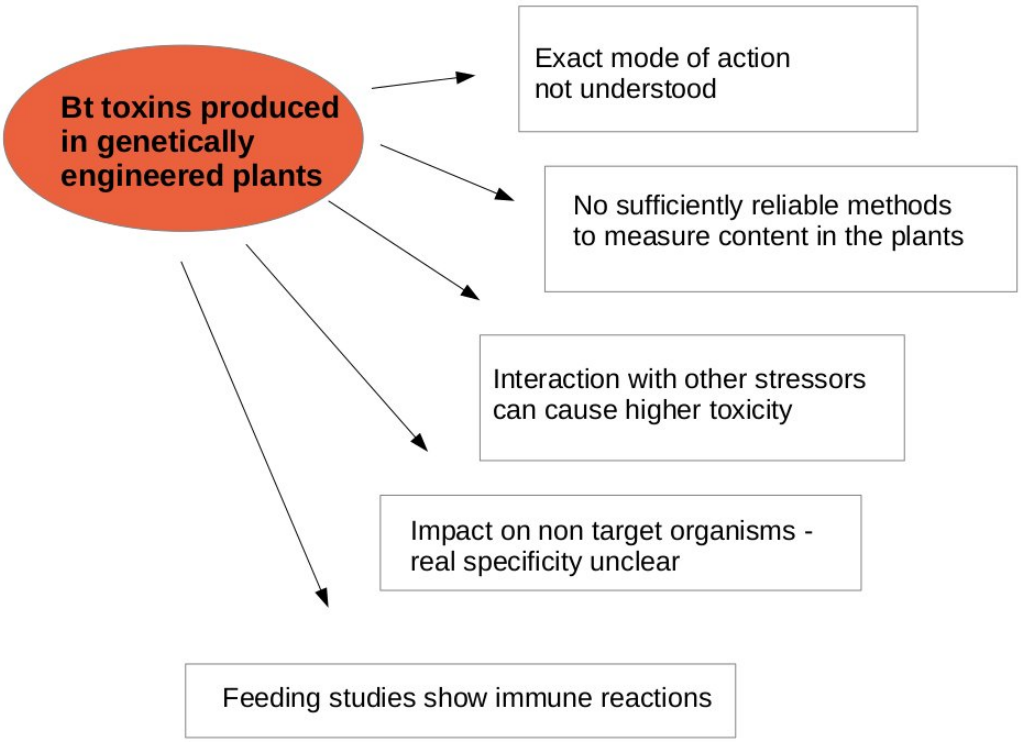
rate of butterfly larvae under real conditions. Even if the impact of Bt toxin alone were minor, any interaction with other stressors can have a huge effect on the real populations of butterflies. Thus, synergies with other stressors need to be taken into account, and there is a need for some real data on abundance in particular regions and population dynamics of the relevant species. Currently these data are largely missing.

In conclusion, the EFSA modeling used to assess risks for European butterflies is not based on real data but mostly on hypothetical assumptions. EFSA claims that its model even takes 'worst-case scenarios' into account. However, without reliable data, how can the worst-case scenario ever be determined?

So how about the real toxicity of Bt proteins?

Testbiotech provides evidence of knowledge gaps and a substantial lack of data needed to assess the real specificity of the toxin. EFSA has now vaguely confirmed that “the knowledge on the activity spectrum of Bt proteins is growing continuously” and that “some Bt proteins are not as specific as initially reported”. Nevertheless, EFSA did not sufficiently address this problem in its opinions on maize 1507. No systematic testing with the proteins as produced in the plants was required to test true specificity and interactions with other compounds that are known to enhance toxicity. As cited by Testbiotech, there are several publications available on various Bt toxins which indicate negative effects on the health of mammalian species, but there has been no in-depth testing with Cry1F to exclude such risks. The Onose et al., 2008 publication, which was incorrectly cited by EFSA, does not deal with toxin Cry1F produced in the maize, but with another Bt toxin.

To show the current range of uncertainties in risks assessment, Testbiotech has produced the diagram below to illustrate some of the areas identified as knowledge gaps for Bt toxins in genetically engineered plants. It includes risks to health such as immune reactions observed in several studies. None of these issues have been addressed in EFSA's risk assessment so far.



Overview: Some unanswered questions that are relevant for the risk assessment of Bt toxins in genetically engineered plants

Conclusions

The evidence provided by Testbiotech that current data are not sufficient to exclude risks for the environment and human health is not invalidated by the EFSA response. The authority did not deal with uncertainties and knowledge gaps from a precautionary perspective as foreseen by EU regulations, but simply rejected the findings of Testbiotech because they found no final evidence for actual harm caused by maize 1507.

Given that the regulatory framework of the EU gives much weight to the precautionary principle, the EU Commission has to reject the statement of EFSA and suspend market authorisation of maize 1507.

References

EFSA (2014) Request to review the scientific basis of two Testbiotech reports on maize 1507, EFSA (2014): Request to review the scientific basis of two Testbiotech reports on maize 1507, www.testbiotech.org/node/1055

Bauer-Panskus & Then, C. (2014) Case study: Industry influence in the risk assessment of genetically engineered maize 1507, Testbiotech Background, www.testbiotech.org/node/1030

Then, C., & Bauer-Panskus, A. (2014) Genetically engineered maize 1507: Industry and EFSA disguise true content of Bt toxin in the plants - data insufficient to conclude on the safety of the plants. Testbiotech Background. www.testbiotech.org/node/1015

Then, C., & Bauer-Panskus, A. (2013) High-Level-Risk-Maize 1507: Shortcomings at the European Food Safety Authority (EFSA) and in EU Commission decision making should prompt reassessment of genetically engineered maize 1507. Testbiotech Background . www.testbiotech.org/node/981