Import approval for genetically engineered maize: Did Monsanto benefit from unlawful exploitation of transitional provisions?

Authorities ‘unable to find’ original dossier as filed by Monsanto

20 April 2020 / Testbiotech is concerned that Monsanto (Bayer) unlawfully obtained an import authorisation for genetically engineered maize without a proper risk assessment as required by EU regulations. The reason: officially, Monsanto filed its application for market approval just before a more rigorous EU regulatory framework for risk assessment came into force. However, there are doubts that the application was actually filed in time.

In December 2018, the Commission granted market authorisation for a genetically engineered maize (MON87427 x MON89034 x 1507 x MON88017 x 59122) following an application by Monsanto. This is a so-called ‘stacked event’ in which several gene constructs are combined to increase resistance to insects and herbicides.

Monsanto sent an ‘application letter’ to the Belgian authorities on 15 November 2013 to notify them of the application. From here, the documents were forwarded to the European Food Safety Authority (EFSA). However, the full suite of supporting scientific dossiers required to complete the application only appear to have been finalized and submitted in February 2014. This was after the deadline when the more rigorous standards (Implementing Regulation (EU) No 503/2013) came into force. Nevertheless, the European Food Safety Authority (EFSA) conducted its risk assessment of the application on the basis of the previous regulation, and the Commission subsequently granted market authorisation.

Testbiotech therefore suspects that Monsanto unlawfully obtained market authorisation from the authorities for its maize. After an in-depth examination, Testbiotech filed a case (T-534/19) at the General Court of the EU in July 2019. At the same time, Testbiotech requested both the Belgian authorities and EFSA for access to the originally filed dossiers. The surprising response: the authorities in Belgium declared that they were not able to find the original dossier, and the only documents that Testbiotech was able to obtain from EFSA (other than the application letter) are all dated 2014.

Based on this information, Testbiotech is assuming that Monsanto did not file a full dossier before the deadline. Therefore, the EU Commission should not have granted market approval. However, since Testbiotech could not get hold of the original Monsanto application, it was impossible to prove precisely what had been submitted in November 2013. Therefore, Testbiotech had no option but to withdraw its legal challenge. However, it remains deeply concerned that the EU authorities have failed to follow a fair and transparent procedure in this case.

“This case leaves us with a very bad feeling, and the EU authorities have done nothing to alleviate our concerns. The EU Commission and EFSA appear to have neither exercised due diligence prior to granting approval, nor subsequently,” Christoph Then comments for Testbiotech. “At the same time, some in the Commission are prepared to speed up the approval processes for genetically engineered plants to accommodate the US government. However, there cannot be a deal that does not respect the safety of human health and the environment. The Commission now has to make it very clear that it will unconditionally uphold the high standards based on the precautionary principle set out in EU regulations.”

The genetically engineered maize at issue raises several complex questions in regard to health risks: it was genetically engineered multiple times and has an especially high resistance to glyphosate.

Furthermore, it is also resistant to other herbicides and produces several insecticides. However, the combinatorial effects of the toxins and herbicidal residues were never thoroughly tested. Indeed, the risks associated with such 'stacked' crop plants have recently been highlighted in the outcome of the RAGES project in Switzerland. In addition, the European Parliament has repeatedly voted against such import approvals.

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Further information: Testbiotech's legal challenge [2]
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