

## Testbiotech publishes data from industry

Risk assessment of genetically engineered plants undermined by industry and EFSA

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Munich

In a new report, Testbiotech examines and publishes data from industry. The data were prepared by industry and presented to the European Food Safety Authority (EFSA) for the risk assessment of a genetically engineered maize. The material was leaked to Testbiotech at beginning of 2011. It concerns a type of maize called SmartStax. Monsanto and Dow AgroSciences developed the plants, which are derived from crosses between several genetically engineered plants. SmartStax produces six different insecticidal toxins and is tolerant to two herbicides. EFSA published its risk assessment in 2010, and declared this maize safe for human and animal consumption. However, the analysis performed by Testbiotech shows that the investigations carried out by industry are unsuitable for examining health risks for human and animals. Further necessary independent quality control is missing.

“There are indications that some data were 'streamlined' to be consistent with expectations of industry,” says Christoph Then of Testbiotech. “In any case, the documents reveal insufficient risk assessment of human and animal health. For example, the combinatorial effects of the toxins as produced in the plants were only explored in pest insects. Further, the maize was fed to poultry to test nutritional efficiency, but there was no investigation of potential health risks to humans and animals.”

In several cases the data show a tenfold or even twentyfold variation in the content of the insecticidal toxins. The exact range of variation under changing environmental conditions has not been determined, thus open questions remain concerning the genetic stability of the genetically engineered plants. There are no evaluated protocols to enable independent measurements of the content of the toxins.

EFSA bases its risk assessment to large extent on data derived from the parental plants originally used to produce SmartStax. But this approach is highly complicated since these plants produce a much lower number of insecticidal toxins, thus less interactions can to be expected. Further the results of the risk assessment of these parental plants show a wide range of uncertainties. In one case even kidney damage is under discussion. Experts from several member states have been urging EFSA for more detailed investigations. This was rejected by EFSA – EFSA simply referred to their own Guidance which does not require feeding studies to exclude health risks for humans and animals.

Testbiotech concludes that the documents show alarming deficiencies in risk assessment as performed by industry and EFSA. These deficiencies should not be hidden behind confidentiality issues. On that account, Testbiotech makes these documents available to the broader public. There is no infringement by Testbiotech of obligations concerning data confidentiality, as the leaked dossiers were made available to Testbiotech without any restrictions.

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**Further information:** [Link to the report and the documents](#) [2]

Attachment

Size



[PR Testbiotech-SmartStax\\_2.pdf](#) [3]

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