## Risks and side effects for humans and animals: What really goes wrong in the regulation of genetically engineered plants

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At present, there is a controversy in the EU as to whether feeding trials with genetically engineered plants have to be conducted before the plants are granted market authorisation. Both the biotech industry and EFSA experts are pushing for these feeding trials not to be mandatory. They are demanding the withdrawal of a regulation requesting 90-day feeding trials that was only very recently introduced by the EU Commission. This is the background against which Testbiotech is publishing its new report providing an overview of the risks of genetically engineered plants for humans and animals, and showing that current regulations are completely inadequate.

The report is based on an analysis of EFSA opinions published within the last few years. It further takes in the outcomes of recent and ongoing EU research projects that have failed, as yet, to develop sufficiently reliable and robust methods to replace the feeding studies.

"At the moment, over 50 different genetically engineered plants have been authorised in the EU for use in food and feed. Many of them were never tested in feeding trials to investigate their impact on human or animal health. One example is the genetically engineered maize SmartStax, which produces six insecticidal toxins and is resistant to two groups of herbicides," says Christoph Then for Testbiotech, "This means that both humans and animals who consume these plants are exposed to substantial risks. And if the biotech industry and EFSA get their way, this will remain so in the future"

There are further levels of complexity that will be added to these problems in the near future. Currently, market applications for so-called stacked events such as SmartStax are clearly on the increase. In addition, there has been an increase in the number of applications being filed for plants that are changed in their nutritional quality. Moreover, as yet, none of the accumulative effects of various genetically engineered being mixed in food and feed have ever been assessed. EFSA experts as well as industry reject more detailed investigations for several reasons. Among others, they allege the proponents of feeding trials are responsible for thousands of animals being used in the studies.

"Industry and EU political decision-makers have to ask themselves if the supposed positive effects of genetically engineered plants are sufficient reason to justify animal experiments. In the light of constant consumer rejection in the EU, the answer to this question is likely to be a resounding no. But if this question is answered with yes, they must be prepared to adequately protect human and animal health as well as the environment. In this regard, there can be no compromise", says Christoph Then in a summary of the ethical dilemma. "We definitely have to raise the standards of risk assessment and make sure that many more independent studies are made available. Furthermore, there is an unquestionable need to assess and take long-term and accumulated effects into account."

Some of the changes Testbiotech is demanding:

- Broaden risk assessment to include additional methods, compounds and plant characteristics
- Apply stress tests to assess the genetic stability of the plants
- Assess the impact on the immune system and reproduction
- Take into account long-term and accumulated effects
- Assess the residues from spraying with herbicides the plants were made resistant to
- Introduce independent control during the data generation,
- Define cut-off criteria such as a prohibition of market authorisation for genetically engineered organisms able to spread into native populations.



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**Further information:** The Testbiotech report [2]

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