

EFSA caught up in massive conflicts of interest whilst at the same time dismissing scientific findings

European Food Safety Authority and EU Commission suspected of abusing their power to bolster their position at the EU Court of Justice
Thursday, 29 September 2016

Testbiotech has raised serious allegations against the European Food Safety Authority (EFSA), asserting that it is deeply entangled in conflicts of interest in its assessment of recent scientific findings. In July 2016, upon request of the EU Commission, EFSA claimed that a new scientific paper published by Norwegian scientists on the risks of genetically modified (GM) plants could not be used as a basis for drawing final conclusions, and would therefore not be relevant for risk assessment. At the same time, the Norwegian publication is one of the key documents in the court case at the EU Court of Justice (T177/13), in which both the EU Commission and EFSA are joint parties.

The court case concerns accusations made by Testbiotech that the risks associated with genetically engineered plants are not sufficiently assessed before they are allowed on the market. The Norwegian publication was filed by Testbiotech to prove that relevant risks were indeed set aside by EFSA and the EU Commission. Testbiotech is concerned that the EU Commission and the EFSA are following their own interests to bolster their position in the court case by dismissing the new study.

Testbiotech initiated the case at the EU Court of Justice in 2013, when the EU Commission allowed a genetically engineered soybean produced by Monsanto and known as Intacta, for import and use in food and feed without sufficient risk assessment. In response, EFSA, Monsanto and the UK government joined forces on the side of the EU Commission in an attempt to influence the outcome of the case. The Monsanto soybean, Intacta, is engineered to be resistant to the herbicide glyphosate and also expresses an insecticidal Bt toxin. Testbiotech substantiated their case by arguing there is a pressing need to assess the combinatorial effects of residues from spraying with those of the insecticide before any decision can be taken on the safety of the soybeans.

The hearing at the court in Luxembourg took place in May 2016. At the time, Testbiotech filed the recent Norwegian publication as a key document because it deals with the combinatorial effects of Bt toxins and glyphosate. The peer-reviewed publication (Bøhn et al. 2016) documents unexpected negative effects in the model organism *Daphnia magna*, and recommends further investigations to exclude risks for the environment. After the hearing, upon request of the EU Commission, EFSA published its opinion on the publication, and issued a general statement saying that "limitations associated with the design and reporting of the study, EFSA considers that several uncertainties remain, which do not allow a proper interpretation of the effects observed".

The position of EFSA is highly questionable since: i) EFSA only takes one small part of the publication into account, and all the findings are dismissed due to the design of the study. ii) EFSA did not approach the Norwegian scientists in regard to the uncertainties in methodology. iii) EFSA, despite conceding there were remaining uncertainties, did not recommend any further investigations. They simply came to the conclusion that the publication would not bring new evidence to light. From a scientific point of view, this is quite astonishing since the accumulated and combinatorial effects of Cry toxins, and combinatorial effects of Cry toxins with herbicides are a well-recognised knowledge gap in scientific literature. This is particularly serious as most of the currently available genetically engineered plants (maize, cotton and soybeans) incorporate several of these traits. Combinations of Bt toxins and residues from spraying have never been properly assessed. In this regard, the relevance of the publication goes far beyond the current court case.

Upon request, one of the scientists from Norway, Thomas Bøhn told Testbiotech: "Our peer-reviewed publication show interesting results that warrant further investigations. *Daphnia magna* was not expected to be harmed by these Bt toxins at all, and not in a dose-response manner, but it does.

Two toxins made double harm. This is for example relevant to the 'stacking' of multiple Bt toxins in the same genetically modified plants. In addition, we found that Bt toxins and glyphosate interact, meaning that we need to better understand 'cocktails' of polluting chemicals. I find it surprising that the responsible food safety authority in Europe is not initiating and inspiring further research on these topics."

Testbiotech is also concerned that the expert from EFSA, who is named as first author, Yann Devos, is known to be active in an organisation called the International Society for Biosafety Research (ISBR). This organisation is largely financed by companies which profit from marketing genetically engineered seeds. Concerns about Yann Devos were recently raised in a letter to EFSA, but any conflicts of interest were denied by the authority's executive director, Bernhard Url.

"EFSA should withdraw its opinion. The EU Commission should never have asked EFSA to selectively assess this publication, and EFSA should have refused this request from the Commission. Instead an assessment of all findings should have been performed by independent experts in cooperation with the Norwegian scientists," says Christoph Then for Testbiotech.

Testbiotech demands that the EU Commission put further authorisations on hold for as long as safety of the relevant products is not proven. If uncertainties remain, the precautionary principle has to be applied to protect health and the environment; and further investigations have to be carried out.

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