Media release



EFSA favours cultivation of 'Roundup Ready Soy' within the EU

But new legal dossier shows current authorisation practice violates EU law

Munich / Brussels, 22. June 2012. The European Food Safety Authority EFSA has for the first time given a positive opinion on the cultivation of genetically engineered soy in the EU. Now the EU Commission and Member States have to make a decision on final market authorisation. The applicant, US company Monsanto, wants to sell its seeds for herbicide tolerant Roundup Ready soy to European farmers. Currently, the genetically engineered soy can be imported but not grown. But as a new legal dossier prepared on behalf of Testbiotech shows, the authorisation as planned would violate existing EU law because residues remaining in the plants from spraying with the herbicide were not taken into account during risk assessment. Furthermore, EFSA does not foresee monitoring possible health effects from these residues although required to do so by EU law.

Other authorisations already issued for the usage of genetically engineered plants in food and feed suffer from the same deficiencies. According to the legal dossier, written by the well- known EU legal expert Ludwig Kraemer, these authorisations now need to be reevaluated.

"Residues from herbicides regularly sprayed on genetically engineered plants are left out of the risk assessment of these crops. So far, this practice has been fiercely defended by EU Commissioner John Dalli. He is now not only under fire for being too close to industry, but he is also becoming a major legal problem", Christoph Then says for Testbiotech. "If the genetically engineered soy is authorised on the basis of the risk assessment as elaborated by EFSA, this should be considered a violation of existing EU law."

Professor Ludwig Kraemer worked as an official for the EU Commission (DG Environment) until 2004. Currently he is active with *Client Earth*. There are four salient points in his legal dossier:

- 1. The present practice not to monitor the potential adverse effects on human health of genetically modified plants is not in compliance with existing EU legislation.
- 2. Monitoring of potential adverse effects on human health from genetically modified plants must be performed even if such effects are unlikely to occur.
- 3. The objective of current EU legislation is to avoid *any* adverse effect on human health from genetically modified plants. Therefore, risk assessment must take the cumulative effect of herbicide residues on genetically modified plants into account.
- 4. When the monitoring plan for a genetically modified plant does not include the control of the cumulative effect of herbicide residues on human health, the authorisation must be amended.

Despite the fact that current EU legislation has been in place for more than ten years and 45 genetically engineered events have already been authorised for usage in food and feed, observation of potential adverse health effects has not been implemented as required by EU Directive 2001/18 and Regulation 1829/2003. Further residues from spraying with herbicides and emerging cumulative

effects are left out of the risk assessment of genetically engineered plants. According to a new draft regulation on the risk assessment of genetically engineered crops presented by the EU Commission, this practice will not be changed in the future. As for the residues from spraying with complementary herbicides, a lot of criticism has been voiced because pesticides like glyphosate (brand name Roundup) are increasingly used in genetically engineered crops and several scientists have warned of associated health risks.

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Link to the Ludwig Kraemer dossier: http://www.testbiotech.de/sites/default/files/Legal_Dossier_Kraemer_Pesticide_RA_PMP.pdf

Link to the recent EFSA opinion EFSA: http://www.efsa.europa.eu/en/panels/gmo.htm

Comment from Testbiotech on draft EU regulation on risk assessment: http://www.testbiotech.org/en/node/629