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German Risk Assessor Finds Flaws In Séralini Study

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Report Highlights:
On October 1, 2012, Germany's Federal Institute for Risk Assessment (BfR) made public its review of a controversial study on the health effects of the genetically engineered corn NK603 and the herbicide glyphosate. According to BfR, the study contains flaws and is not grounds for new safety evaluations.

German Risk Assessor's Review of the Séralini Study

A study published in the Journal Food and Chemical Toxicology (Séralini et al.) reportedly found a link between long-term health effects in rats fed the genetically engineered corn NK603 and the herbicide glyphosate. In response, the Federal Institute for Risk Assessment (BfR) and the Federal Office of Consumer Protection and Food Safety (BVL) reviewed the study.

On October 1, BfR published its findings that, in effect, the study contains flaws and is not grounds for new safety evaluations of NK603 or glyphosate.

BfR Statement

The following is an unofficial translation of the BfR press statement:

"The claim that rats, which receive genetically modified corn for their entire lifespan, die earlier than animals fed with conventional corn, is not sufficiently supported experimentally. This is the conclusion of an evaluation which the Federal Institute for Risk Evaluation (BfR) performed after the publication of „Long term toxicity of a *Roundup* herbicide and a *Roundup*-tolerant genetically modified maize" by Gilles-Eric Séralini and others in the Journal „Food and Chemical Toxicology". „The study has both weaknesses in its design as well as in statistical evaluation,[and] as a result the conclusions by the authors cannot be followed", says Professor Dr. Reiner Wittkowski, Vice President of the Federal institute. Likewise, the statement that the long term uptake of Roundup, a plant protection product containing glyphosate, leads to severe health damage and early death, is not sufficiently supported. Numerous long term studies are available for glyphosate as a herbicidal active substance. Cancer, higher mortality or impacts on the hormonal system of lab animals, as reported on by the authors in the study, have not been observed in these studies.
In mid-September 2012, a research team led by Gilles-Eric Séralini at the University of Caen in France published the results of a longitudinal study with rats which were fed genetically modified corn, which is glyphosate tolerant. A portion of the GM maize had been treated with a glyphosate pesticide (Roundup), another part was untreated. The corn was given in three doses. In addition, other animals were fed with conventional food and had Roundup in their drinking water at three dose levels. A control group was fed with genetically modified corn. The authors report that the animals in some of the test groups have earlier developed tumors and other organ damage and had died earlier than in the control group. The results could be caused by hormonal effects of Roundup, as well as ingredients of genetically modified maize.

The BfR has reviewed the study in terms of relevance to the assessment of the health risk genetically modified corn, which is glyphosate tolerant and also for the assessment of the health risk of glyphosate as the active ingredient. Based on the publication BfR comes to the conclusion that the main findings of the publication are not sufficiently documented experimentally. Moreover, essential conclusions of the authors are incomprehensible due to the shortcomings of the study design and the type of presentation and interpretation of data.

Particularly criticized in the study is that the number of animals per group is too low, which does not comply with the recommendations of internationally recognized standards for studies on carcinogenicity. The rat strain used has a relatively high spontaneous tumor rate in particular for breast and pituitary tumors, and the number of animals used is not adequate to assess the differences made by the authors between the test and control groups. The thesis of the authors, the observed effects could be due to endocrine-related harm is not covered sufficiently by the collected data. BfR complains further that the investigation was carried with the glyphosate pesticide Roundup with no determination of the administered dose. In addition, the collected data are published incompletely.

BfR has asked the authors of the study due to these shortcomings to provide the full study report, including individual animal data. BfR also asked specific questions in order to allow further evaluation of the reported effects."

(Click here for a link to the German language press release on the BfR website. BfR will reportedly release and English version of its study soon.)

Background on BfR

The Federal Institute for Risk Assessment (BfR) was established in 2002. It is responsible for preparing expert reports and opinions on food and feed safety as well as on the safety of substances and products. BfR reports to the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).