GREENPEACE

Regulatory systems for GE crops a failure: the case of MON863.

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New peer-reviewed evaluation[i] of Monsanto's data shows MON863 should not have been approved in EU or elsewhere

MON863 is a genetically engineered (GE) insect resistant maize (corn) that expresses a Bt-toxin (Cry3Bb1). This toxin, which stems from a micro-organism (*Bacillus thuringiensis*), is meant to protect the maize against the corn rootworm pest. This GE maize is different from other GE maize plants (Mon 810, Bt11, Bt 176) already placed on the market, as they produce another toxin (Cry1Ab), which is toxic to the European corn borer. Further, GE maize MON863 contains an antibiotic resistance marker gene (ntpII conferring resistance to kanamycin).

Greenpeace and others have previously stated several times (see Chronology of MON863) that the data submitted in support of market approval for this GE maize gives rise to serious concerns regarding the food safety of MON863. However, significant findings found in a 90 day rat feeding study are generally dismissed by the regulatory authorities, e.g. by the European Food Safety Authority (EFSA)[ii], as *"not considered as biologically relevant"*, or *"incidental findings".*

This new evaluation is the first independent evaluation of data submitted by a biotech company for regulatory approval of a GMO for food/feed published in a peer-reviewed scientific journal. The new evaluation shows that, far from being not of biologically relevance, the statistical differences found should be grounds for a recall of the GE crop. This GE maize should not have been approved, for cultivation or food/feed, in the EU or anywhere else in the world.

New evaluation highlights MON863 poses risk to human and animal health

Scientists from CRIIGEN (Committee for Independent Research and Genetic Engineering, based at the University of Caen, France), have analysed the data obtained from a feeding trial submitted by Monsanto in support of its application to the EU to market MON863.

The independent scientists found that after the consumption of MON863:

- **There were *"signs of toxicity"* in the liver and kidney of the test animals**. Analysis of blood, urine, liver and kidneys showed signs of disruption to kidney/liver function. The researchers conclude that *"the two main organs of detoxification, liver and kidney, have been disturbed".*
- **Weight gain was different.** Rats showed slight but dose related significant variations in growth for both sexes, resulting in 3.3. % decrease in weight for males and 3.7 % increase for females.

1. Chemical data indicate disruption of liver/kidney function

Although some chemical differences did show up in the original Monsanto data, the European Food safety Authority (EFSA) stated "*Whilst some statistically significant differences were observed, these differences were not considered as biologically relevant since they fall within normal variation ranges.*"[iii] However, a closer examination of the data in this new study shows differences in blood and urine chemistry between rats fed MON863 and rats fed non GE maize (including blood sugar and fats, urine phosphorus and sodium) that were either discounted or not recognised. The authors of this new evaluation state: *"It appears that the statistical methods used by Monsanto were not detailed enough to see disruptions in biochemical parameters"*

The new evaluation suggests that these results are of biological relevance as they suggest disruption to liver/kidneys, which indicate that MON863 is causing toxicity in rats.

2. **Differences in weight gain between rats fed GE and non GE maize**

The authors analysed the weight gain growth curves - something that Monsanto failed to do, even with their published data[iv]. The authors proved there were significant differences in the weight gains, with differences between male and females. Together with the indications of liver/kidney function, the authors suggest that this could be due to *"endocrine disruption and/or hormonal metabolism differences"*. Although Monsanto did find some differences in weight gain, they simply discarded them by comparing to historical or population data, rather than the control (fed non GE maize), which is the normal and valid comparison. The cause of the differences in weight gain was never investigated by Monsanto. However, Seralini and colleagues (the authors of this new study) suggest that a further investigation into sexual hormones could explain some of the observations.

Cause of toxicity not known

It is not known whether the signs of toxicity are caused by the Bt protein, or from some changes in the plant's own DNA caused by the genetic engineering event.

MON863 cannot be considered safe for food/feed

The authors of this new evaluation have shown that there are serious concerns over the food and feed safety of MON863. These concerns have simply been dismissed where they should have been ground for the rejection of the GM crop. At the very least, the differences should have been investigated further.

The authors of this evaluation state ***"it cannot be concluded that GM corn MON863 is a safe product".*** This conclusion of the independent scientists is in stark contrast to those from regulatory authorities who have approved MON863 who deemed it is as safe as its non GE counterpart. In countries where MON863 is approved (Australia, Canada, China, the EU Japan, Korea, Mexico, Philippines, Taiwan, United States), the regulatory authorities have failed to recognise the warning signs in a GE crop. They have recommended a GE crop that has potential to cause adverse effects on health for approval.

Greenpeace demands an immediate and complete recall of MON863 from the global market. We also call upon governments to undertake an urgent reassessment of all other authorised GE products and a strict review of current testing methods.

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[i] Séralini, G-E, Cellier, D. & Spiroux de Vendomois, J. 2007. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Archives of Environmental Contamination and Toxicology DOI: 10.1007/s00244-006-0149-5. Hepatorenal = of or pertaining to the liver and kidneys.

[ii] EFSA 2004. Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto (Question No EFSA-Q-2003-121).Opinion adopted on 2 April 2004. The EFSA Journal 50: 1-25

[iii] Statement of the scientific panel on genetically modified organisms on an evaluation of the 13-week rat feeding study on MON 863 maize, submitted by the German authorities to the European Commission adopted on 20 October 2004. http://www.efsa.eu.int

[iv] Hammond, B., Lemen, J., Dudek, R., Ward, D., Jiang, C., Nemeth, M. & Burns, J. 2006. Results of a 90-day safety assurance study with rats fed grain from corn rootworm-protected corn. Food and Chemical Toxicology 44: 147-160.