

June 2005 - Background briefing: MON863

Monsanto's GM corn: Unfit for rats, unfit for humans

MON863 is a genetically modified corn which expresses a Bt-toxin (Cry3Bb1). This toxin, which stems from a micro-organism (*Bacillus thuringiensis*), is meant to protect the maize against a pest called corn rootworm. This GM maize is different from those Bt-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, the GM maize contains an antibiotic resistance marker gene, which should be not used according to recent EU law.

On 23 April 2004 the French newspaper *Le Monde* revealed that the French expert body in charge of GMO evaluation (CGB, Commission du Génie Biomoléculaire) had expressed doubts about the safety of GM maize Mon 863. By filing application for market authorisation under EU law, Monsanto had delivered the results of a rat feeding study to EU government authorities. These results show that significant variations were found between the rats fed with conventional maize and those fed with GM maize Mon863, such as an increased number of white blood cells in the males, reduced immature red blood cells in females, a significant increase in blood sugar in the females or a higher frequency of physical irregularities in the kidneys of the males, such as reduced weight and inflammation.

Victory for transparency a precedent

When it filed the application to market MON863, Monsanto requested that crucial documents concerning the risk assessment, like the results of rat feeding trials, should be classified as confidential. But according to European law the public has a right to have full access to information concerning the risk assessment of GMOs. Article 25 of Directive 2001/18/EC states that :

“2. The notifier may indicate the information in the notification submitted under this Directive, the disclosure of which might harm his competitive position and which should therefore be treated as confidential. Verifiable justification must be given in such cases.

3. The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions.”

Article 25 (4) also indicates that “in no case” should the information related to “environmental risk assessment” be kept confidential.

Article 2 (8) of Directive 2001/18/EC defines “environmental risk assessment” as “the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II.”

In Annex II of Directive 2001/18/EC the general principles declare that the risk assessment should : “be carried out in a scientifically sound and transparent manner based on available scientific and technical data”.

It took more than a year for Greenpeace to see the interests of society finally prevail over Monsanto's economic interests and its policy of opacity and secrecy.

- On 5 May 2004, Greenpeace wrote to the German agriculture ministry, which was in charge of the initial risk assessment report, to request access to the full documents concerning Mon 863.
- On 4 August 2004, the German agriculture ministry replied that the applicant, Monsanto, had refused to agree to publish the initial rat study MSL-18175, which had been classified as “confidential business information”.
- On 21 March 2005, the German authority decided to give access to the full document, because Monsanto could not show that its request for confidentiality was backed by EU or national law.

- On 27 April 2005, Monsanto filed an appeal against the decision of German government and, in addition, took out an injunction to stop the authorities publishing the data.
- On 9 June 2005, the German court decided to reject Monsanto's request; the data could not be seen as confidential, the right of society to transparency had to be given more weight than Monsanto's economic interests. The company appealed the decision.
- On 20 June, the court rejected the appeal, and ruled that the documents be made public.

Serious safety concerns

Greenpeace's ongoing examination of the material provided by Monsanto gives rise to serious concerns.

Monsanto's results reveal many irregularities in the study and five significant differences between the rats fed with the GMO maize and the control groups, which were fed conventional maize. These include statistically significant differences in white blood cells. These cells are an indicator of abnormal situations in the body such as infections and inflammations. Furthermore, there are differences in the organ weight of the kidneys and some abnormal changes in the structure of the kidneys. Monsanto tries to negate these findings by use of "reference" and "historical" control data collected from other experiments where rats were fed non-GM maize. Such inclusion of "historical" or "reference" data is hardly valid from a scientific point of view. It is the direct comparison between two or more groups during a certain experiment that is the critical and valid comparison in normal scientific practices. As soon as statistically significant differences appear, one should immediately check for further evidence, run further experiments to try to find out where those differences come from. This is particularly important as this feeding trial was only conducted over 90 days. The high number of statistically significant differences therefore raises severe doubts regarding the food and feed safety of this GMO maize.

Since the study indicates that this GM maize has the potential to negatively affect the health of rats, there are grounds for concern that it could also interfere with the metabolism of humans and other animals. This is a valid reason for rejecting the request for market permission.

Furthermore, the experiment was not well designed. Important data and parameters are missing. And, as it took only 90 days, it remains impossible to draw any conclusions regarding the effects of long-term ingestion of the maize.

Greenpeace's position has been confirmed by two new scientific opinions by renowned experts in the field, presented in Berlin on 22 June 2005: Professor Gilles-Eric Séralini, a member of two GMO evaluation committees within the French ministry of agriculture and ministry of ecology, and Professor Arpad Pusztai, who was invited some months ago by the German government to give an opinion on this GM maize. Both support Greenpeace's position that this maize should not receive market authorisation, given the data known so far.

Conclusion

The high number of statistically significant differences between rats fed MON863 and the control groups in this short feeding trial give sufficient cause for concern to justify rejecting MON863 outright.