GREENPEACE

Background information on MON863, June 2005 (updated January 2006)

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

Monsanto's MON 863 maize is a genetically modified corn. It expresses a Bt-toxin (Cry3Bb1), intended to protect the maize against the corn rootworm pest. It differs from other Bt-plants already on the market (Mon 810, Bt11, Bt 176) as they produce another toxin (Cry1Ab), which is toxic to the European corn borer. It also contains an antibiotic resistance marker gene, which should be not used, according to recent EU law.

Battle – and victory – for transparency
On 23 April 2004, *Le Monde* reported that the French expert body in charge of GMO evaluation (CGB, Commission du Génie Biomoléculaire) had expressed doubts about the safety of GM maize MON863. Results of a rat feeding study that Monsanto delivered to EU authorities showed significant variations between rats fed conventional maize and those fed with MON863. The variations included 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 and a higher frequency of physical irregularities in the kidneys of the males, such as reduced weight and inflammation.

Monsanto requested that documents concerning the risk assessment, like rat feeding trial results, should be classified as "confidential business information". According to European law, the public has a right to full access to information concerning the risk assessment of GMOs. In particular Article 25 of Directive 2001/18/EC indicates that "in no case" should the information related to "environmental risk assessment" (defined as as "the evaluation of risks to human health and the environment, whether direct or indirect") be kept confidential. The Directive also indicates 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 prevail over Monsanto's economic interests and its policy of opacity and secrecy.

- 5 May 2004: Greenpeace writes to the German agriculture ministry, which was in charge of the initial risk assessment report, to request access to all documents concerning MON863.
- 4 August 2004: German agriculture ministry replies that the applicant, Monsanto, has refused to agree to publish the initial rat study MSL-18175, which had been classified as "confidential business information".
- 21 March 2005: the Gerrman authority decides to give access to the full document, because Monsanto cannot show that its request for confidentiality is backed by EU or national law.
- 27 April 2005: Monsanto files an appeal against the decision of German government and, in addition, takes out an injunction to prevent publication of the data.
- 9 June 2005: a German court rejects Monsanto's request, ruling that the data cannot be deemed confidential; the right of society to transparency has to be given more weight than Monsanto's economic interests. The company appealed the decision.
- 20 June, four days before EU ministers vote on the authorisation, the court rejects the appeal, and ruled that the documents be made public.

Serious safety concerns
Greenpeace's examination of the material provided by Monsanto gave rise to serious concerns.

On 22 June 2005, two new scientific opinions by renowned experts in the field are presented at a press conference in Berlin. 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 had been invited by the German government to give an opinion on MON863, both support Greenpeace in arguing that the GM maize should not gain market authorisation, given the data known so far.

Monsanto's results reveal many irregularities in the study and five significant differences between the rats fed with the GM 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 tried to negate these findings by use of “reference” and “historical” control data collected from other experiments where rats were fed non-GM maize. Inclusion of such “historical” or “reference” data is hardly valid from a scientific point of view. The direct comparison between two or more groups during a certain experiment is the critical and valid comparison in normal scientific practice. As soon as statistically significant differences appear, one should immediately check for further evidence and run further experiments. This is particularly important as this feeding trial was only conducted over 90 days. The high number of statistically significant differences raises severe doubts regarding the food and feed safety of this GM maize.

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

The above concerns give sufficient cause for concern to justify rejecting MON863. Greenpeace has commissioned independent scientists to make a new statistical analysis of the rat feeding trial performed by Monsanto. The final results should be available in early 2006.

In addition, Greenpeace considers that the EFSA has not respected the requirements of EU legislation, and that the Commission should have ordered a new toxicity study of MON863.

Timeline - EU votes

- 24 June: 14 EU member states vote against the authorisation of MON863 for use in animal feed at the Environment Council (7 vote in favour, 4 abstain).

- 8 August: the Commission authorises MON863 for import and use in animal feed. (According to comitology rules, which are used to approve GMOs, the Commission can put GMOs on the market even if a simple majority of governments is against.)

- 20 October: Greenpeace publishes a preliminary report on the toxicity study performed on rats for Monsanto. Its author, Professor Gilles-Eric Séralini, strongly criticises the method that was used in the company’s study to assess the apparent negative impacts on the health of the group of rats fed the modified maize, and the way that anomalous findings were dismissed. It concludes: “It is essential for Monsanto's entire statistical analysis to be repeated before any decision about market access is taken.” The report is sent to the Commission (DG Sanco).

- 24 October: 11 EU agriculture ministers vote against the authorisation of MON863 for use in food; 11 vote in favour; 3 abstain.

- November and December 2005: over 6,000 EU citizens send letters via email to Commissioner Kyprianou (DG Sanco), asking him not to authorise MON863 and to order a new and independent analysis of the rat study data.

- 16 December 2005: the Commission tells Greenpeace that “since the Council neither adopted the proposed measures [to authorise MON863] nor indicated its opposition to them, the

Commission is in the process of adopting the proposed measures according to Community legislation", and that they have forwarded our letter to EFSA "in order to inform the authority about [our] comments".

Greenpeace demands :

- no GMO releases in the environment ;
- more transparency and full access to company data on the risk assessment of GMOs ;
- a better implementation of the EU GMO legislation and a re-organisation of the work of the EFSA GMO panel, to make the scientific evaluation of GMOs stricter, more independent and more transparent.