

The MON863 case - a chronicle of systematic deception

August 13, 2002: The Monsanto company submits to the German authorities an application to import genetically engineered MON863 maize into the EU. This submission contains a 90-day rat feeding study.

MON863 is a genetically modified corn that expresses a Bt-toxin. This toxin is a modified version of the delta endotoxin Cry3Bb1 which originates from the microorganism *Bacillus thuringiensis*. The genetic manipulation is aimed at protecting maize plants against a pest called corn rootworm (*Diabrotica* spp.).

MON863 differs from other Bt-corns already placed on the market (MON810, Bt11, Bt176), which produce a modified Cry1Ab toxin conferring resistance to a pest called European corn borer (*Ostrinia nubilalis*), in that it produces an artificial Cry3Bb1 toxin. In addition to the modified Cry3Bb1 toxin gene MON863 contains an antibiotic resistance marker gene.

Outside the EU MON863 is approved for cultivation in the USA and Canada, and for food and feed in Australia, China, Japan, Korea, Mexico, the Philippines and Taiwan.

Based on the results of the 90-day rat feeding study presented in the application the Monsanto company concludes: “Toxicological parameters evaluated were survival, clinical signs, body weight changes, food consumption, clinical pathology, organ weights, and macroscopic pathology. There were no test article related changes in any of the aforementioned toxicological parameters”.

In the conclusions of the rat feeding study provided by Monsanto one can find a disturbing fact, namely that the feeding study was performed by a third company (Covance Laboratories), but the statistical analysis of the data was made by Monsanto itself.

September 2002: Experts at the French Genetic Engineering Commission (CGB, Commission du Génie Biomoléculaire) raise critical questions regarding the toxicological test data derived from the rat feeding study with MON863.

April 8, 2003: The German competent authorities publish their assessment of the MON863 application. In their report they state that the amino acid sequence of the Cry3B1 toxin produced by the MON863 maize has similarities to some other toxins. Most notably, the German authority found some “homologies to sequences from *Clostridium bifermentans*, *Caenorhabditis elegans*, *Vibrio cholerae* and *Bacillus popilliae*.” These homologies are of high relevance in respect to human and animal health. Despite the similarities to other toxins found the German authorities did not investigate the results from the 90-day rat feeding study in detail and therefore failed to find out if there might be some indices for mammalian

toxicity. Instead, the German authorities interpreted the similarities found “as being biologically irrelevant due to lack of indications of mammalian toxic activity.”

The 90 day rat feeding study which shows significant changes in the blood of the animals was mentioned in the German assessment report as follows: “From this extensive study, it can be deduced that even after long term oral exposure to MON863 maize kernels, no harmful effects are to be expected.” The German report does not mention any significant findings, but by and large repeats Monsanto's conclusion that “... no substance-specific biologically relevant effects were seen in comparison to controls ...”.

June 2003: A narrow majority of the French CGB's experts approves the results of the MON863 tests.

November 10, 2003: The French group CRIIGEN (Committee for Independent Research and Genetic Engineering) appeals to the French Commission CADA (Commission of Access to administrative Documents) in order to obtain the reports of CGB referring to significant health effects in the rat feeding study.

The French authorities had declared the CGB reports as being confidential, but CRIIGEN wins the case and presents the reports to journalists (see below).

April 2, 2004: The European Food Safety Authority (EFSA) publishes its opinion on Monsanto's MON863 application.

In their conclusion the EFSA's experts state, “The results of the 90-day sub-chronic rodent studies do not indicate adverse effects from consumption of MON863 and MON810 and the Panel concludes that there are no concerns over their safety.”

In its opinion EFSA mentions the significant findings in the rat feeding study as follows: “Some differences were observed in haematological parameters, including total white blood cell, lymphocyte and basophil counts.” But EFSA plays down these findings with a very general statement, saying that “These differences are not considered to be biologically meaningful since they fall within the standard deviation of the reference control population.”

Moreover, EFSA plays down significant findings in kidney weights observed in the rat feeding study: “The overall conclusion is that no differences in relation to feeding in MON863 maize were observed on kidney weights, kidney weights relative to body weights and kidney weights relative to brain weight.”

Finally, EFSA discusses some microscopic pathological changes in kidneys. “However, a statistically significant lower incidence of mineralized kidney tubulus was noted for rats fed

33% MON863 maize compared to those fed the control maize during histopathology after termination. These findings are not considered to pose concerns over the safety of MON863 maize.”

April 23, 2004: After CRIIGEN succeeded in accessing the report of CGB, the French newspaper *Le Monde* exposes the MON863 scandal. The newspaper covers the significant changes in the blood of rats, which were fed with MON863, and reveals that the CGB's experts had expressed safety concerns.

May 2004: Greenpeace requests the data from the rat feeding study with MON863 from the German authorities.

August 4, 2004: In a response to the German authorities Monsanto denies access to data, and only provides a short “Supplemental analysis of selected findings on the rat 90-day feeding study with MON863 maize”.

August 2004: CRIIGEN asks the French Ministry of Agriculture for access to the original toxicological data from animal feeding trials done with MON863 maize, NK603 maize, Bt11 maize and GT73 oilseed rape.

January 20, 2005: The French Ministry of Agriculture confirms that the original data from the toxicological tests should be confidential.

March 21, 2005: The German authorities announce that the data from the rat feeding study shall be given to Greenpeace. Monsanto appeals against the decision of the German authorities and submits the case to the Cologne administrative court.

June 1, 2005: Bruce Hammond (a scientist at the Monsanto company) sends in a further evaluation of the rat feeding data to the “Food and Chemical Toxicology” scientific journal . The data are published in 2006. In his conclusion the author states, “The summary prepared by the GMO Panel of the European Food Safety Authority best captures the prevailing scientific conclusions regarding the findings from this study. EFSA concluded that the results of the 90-day rodent study do not indicate adverse effects from consumption of maize line MON863”.

June 9, 2005: The Cologne administrative court decides that Monsanto has to give their rat feeding study data to Greenpeace.

June 20, 2005: The Muenster Higher administrative court (Germany) reaffirms that the data from the rat feeding study shall be given to Greenpeace. Greenpeace publishes the complete rat feeding study (more than 1000 pages) on the internet.

June 24, 2005: The Council of EU environment ministers votes on market authorisation for MON863 for animal feed. The majority of the ministers abstain or vote against the authorisation. As a qualified majority for either rejecting or approving the application fails to be reached, the final decision reverts to the European Commission.

September 15, 2005: An independent expert on biostatistics from the University of Hamburg makes a written statement to Greenpeace on the statistical design of Monsanto's rat feeding study. The expert states, "Significant differences were indeed found in the study, and afterwards were classified as irrelevant. (This is as if a marksman had shot at a wall and the rings of a target were drawn around where the shot had made a hole, and it was then maintained he had hit the target dead centre.)"

October 2005: A confidential study prepared on behalf of the Austrian government concludes that "A complete re-evaluation of the study would be indicated, but as the design and the methods are inadequate, a repetition of the study seems desirable."

October 24, 2005: The Council of EU agriculture ministers vote on market authorisation for MON863 maize for food. As a qualified majority for either rejecting or approving the application fails to be reached, the final decision reverts to the European Commission .

Just before the meeting of the EU agriculture ministers experts from the French CRIIGEN group publish a report on the first findings from the evaluation of Monsanto's rat feeding study data. In this evaluation all data from Monsanto's rat feeding study were retyped and subjected to comprehensive statistical analysis. The report states that the "findings clearly indicate major failures of statistical analysis as performed by Monsanto." CRIIGEN calls for a complete reassessment of all data from the rat feeding study.

January 13, 2006: Despite the concerns raised by EU member states, members of the EU parliament and 10,000 cyberactivists alerted by Greenpeace, the EU Commission authorises the placing on the market of foods and food ingredients derived from MON863 maize.

February 2006: Greenpeace (and other NGOs) meet with the GMO Panel of EFSA and present case studies on failures and shortcomings in risk assessment of EFSA..During the meeting the experts of EFSA reject the demand to reassess the MON863 data.

April 12, 2006: The European Commission announces that EFSA's standards should be improved. Statistical protocols and the assessment of long term effects are explicitly mentioned.

March 31, 2006: Based on the previous assessment of MON863 EFSA publishes further positive opinions on three genetically modified maize plants which were produced by the

combination of MON863 with other genetically modified maize lines - MON863 x MON810, MON863 x NK603, MON863 x MON810 x NK603). According to an analysis by Greenpeace the GE hybrid maize in animal feeding studies produced significant effects related to possible health impacts.

A summary of the application can be downloaded at
http://www.transgen.de/pdf/zulassung/Mais/MON863_Mon863xMON810_summary.pdf

http://www.greenpeace.de/fileadmin/gpd/user_upload/themen/gentechnik/Monsanto_Rattenfuetterungsstudie.pdf

<http://www.agbios.com/dbase.php?action=ShowProd&data=MON863/>
<http://www.cofepris.gob.mx/pyp/biotec/OMG.pdf>

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Assessment Report of the Robert Koch Institute in Accordance with Directive 2001/18/EC
http://www.transgen.de/pdf/zulassung/Mais/MON863_MON863xMON810_assessment.pdf

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http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gmo_opinions/381.Par.0001.File.dat/opinion_gmo_06_en1.pdf

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See page 15, footnote 11 above

L'expertise confidentielle sur un inquietant maïs transgénique. Le Monde, April 23, 2004.

Hammond, B.G., Dudek, R. Lemen, J.K. & Nemeth, M.A. (2006), Results of a 90-day safety assurance study with rats fed grain from corn borer-protected corn. Food and Chemical Toxicology 44(7): 1092 - 1099.

http://www.greenpeace.de/themen/gentechnik/anbau_genpflanzen/artikel/monsantos_gen_maiss_mon_863_studie_ueber_fuetterungsversuche_an_ratten/

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/05/793&format=HTML&aged=0&language=EN&guiLanguage=en>

Full information about the written statement is only given from Greenpeace upon request

Evaluation of the report on a Subchronic Toxicity Study with Mon863 Maize. Report for the Federal Ministry for Health and Women, 70420/0166-IB/B/12/2005. (Full information from Greenpeace only upon request.

<http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/05/258&language=en>

http://www.greenpeace.de/fileadmin/gpd/user_upload/themen/gentechnik/MON_863_French_report_statistics.pdf

http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/l_034/l_03420060207en00260028.pdf

http://www.efsa.europa.eu/de/stakeholder_stakeholder/technical_meetings.html

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/498&format=HTML&aged=1&language=EN&guiLanguage=en>

http://www.efsa.europa.eu/etc/medialib/efsa/science/gmo/gm_ff_applications/more_info/505.Par.0009.File.dat/gmo_ov_op3_en1.pdf /

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http://www.greenpeace.de/fileadmin/gpd/user_upload/themen/gentechnik/greenpeace_mon863_mon810_hybrid_03.pdf