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# GENETICALLY MODIFIED CORN STUDY REVEALS HEALTH DAMAGE & COVER-UP

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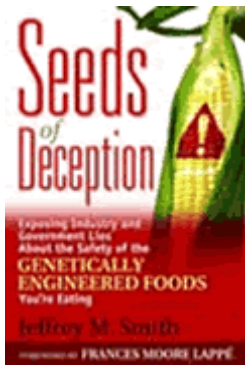
By Jeffrey Smith  
July 16, 2005  
NewsWithViews.com

When a German court ordered Monsanto to make public a controversial 90-day rat study on June 20, 2005, the data upheld claims by prominent scientists who said that animals fed the genetically modified (GM) corn developed extensive health effects in the blood, kidneys and liver and that humans eating the corn might

The United States government's support for biotech is no secret. In fact, it is the official policy in several US agencies to promote the industry, and some of them have attempted to push

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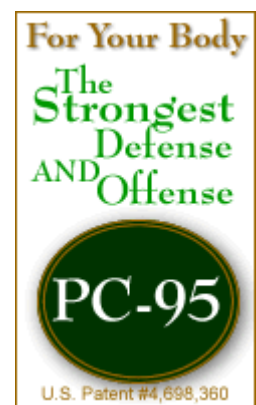
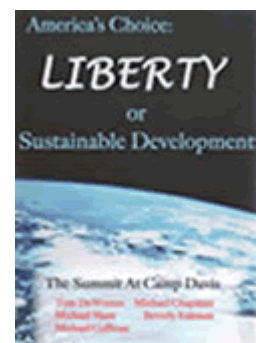
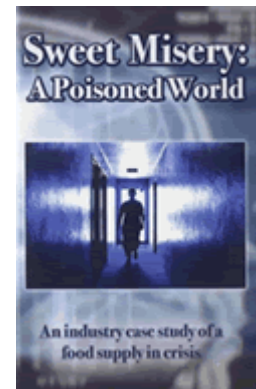
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be at risk. The 1,139 page research paper on Monsanto's "Mon 863" variety also revealed that European regulators accepted the company's assurances that their corn is safe, in spite of the unscientific and contradictory rationale that was used to dismiss significant problems. In addition, the study is so full of flaws and omissions, critics say it wouldn't qualify for publication in most journals and yet it is the primary document used to evaluate the health impacts.

Mon 863 is genetically engineered to produce a form of a pesticide called bacillus thuringiensis or Bt, designed to attack a corn pest called the root worm. Rats fed Mon 863 developed several reactions, including those typically found with allergies (increased basophils), in response to infections, toxins and various diseases including cancer (increased lymphocytes and white blood cells), and in the presence of anemia (decreased reticulocyte count) and blood pressure problems (decreased kidney weights). There were also increased blood sugar levels, kidney inflammation, liver and kidney lesions, and other changes. According to top research biologist Arpad Pusztai, who was commissioned by the German government to evaluate the study in 2004, based on the evidence no one can say that Mon 863 will cause cancer or allergies or anything specific. The results are preliminary and must be followed-up to rule these out. He warns, however, "It is almost impossible to imagine that major lesions in important organs. . . . or changes in blood parameters. . . . that occurred in GM

## acceptance of GM crops in Europe.





maize-fed rats, is incidental and due to simple biological variability."

French Professor Gilles-Eric Seralini, a molecular endocrinologist at the University of Caen, agrees that the results indicate a toxic reaction. Seralini is a member of two French government commissions that evaluate GM food, one of which originally rejected a request for approval of the corn variety in October, 2003 due to the adverse findings of the study. Seralini won a French lawsuit allowing him to express his concerns in public, and now Greenpeace has won a German court battle that makes public the data that is the source of his concerns.

Pusztai and Seralini spoke about the Mon 863 study at a June 22 press conference in Berlin organized by Greenpeace. Both scientists are uniquely qualified to evaluate the study. Seralini studies endocrine disruptors and the impact of pesticides on health. He was one of four experts appointed to respond to the WTO challenge filed by the US against the European Union's policy on GM food and crops. He has read all of the industry's GM-food submissions to Europe as well as all the commentaries on the submissions. Pusztai is the leading authority in his field of protein science (lectins) and had been commissioned by the UK government in the 1990s to develop the ideal testing protocol for all GM foods. Although his protocol was supposed to be adopted by the UK government and eventually in Europe, Pusztai's controversial finding that GM potatoes damaged the health of rats ultimately

stopped the work. Pusztai has also been commissioned to evaluate all published studies on GM foods, and has analyzed most of the confidential submissions made by industry.

Both scientists have expressed alarm about the unsupported arguments that Monsanto and some European regulators use to force product approvals. Now that the Mon 863 study is available, other scientists and the public can evaluate the industry's defense, which Pusztai and Seralini say contradict well established scientific principles. Chief among their concerns are the ways Monsanto explains away statistically significant effects.

### **Faulty Comparisons Hide Problems**

In animal feeding studies, researchers attempt to minimize differences between the test animals and the control groups, so that only the impact of the item being analyzed will stand out. In this study therefore, the test rats ate Mon 863 and the control group ate non-GM corn from the same parent line, i.e., corn whose genetics are the same except for the insertion of the genetic material and its impact. When comparing the results of these two appropriate groups, the health impacts were unambiguous and occurred at a rate that the scientific community accepts as not due to chance. But Monsanto and their supporters in the European Food Safety Authority (EFSA) appear to throw away the accepted methods of science that have been used for decades in order to

rationalize the findings.

**1.** Researchers used six additional control groups, which were fed commercial corn varieties with entirely different genetics. While such comparisons are appropriate for commercial studies, it is entirely inappropriate for a safety assessment, according to Pusztai. Monsanto claimed that when the changes in the test rats were compared to this much larger, irrelevant control group, many changes were no longer significant.

**2.** In spite of the strained logic, many results were still statistically significant when compared to these six other controls and were reported as such by the laboratory that Monsanto used to conduct the study. Monsanto therefore ignored the study's figures and claimed that since the changes in the rats were still within a wide range of reactions that are normal for the animals, they should be considered biologically irrelevant. Using this argument, for example, they declared that a 52% decrease in reticulocytes (immature blood cells) was "attributable to normal biological variability." According to Pusztai, an allowance of 5% variability is the norm in food experiments. Similarly, he says that the increase in blood sugar levels by 10% "cannot be written off as biologically insignificant, given the epidemic of diabetes."

To put Monsanto's claims into perspective, suppose that a large number of women who were fed a carefully controlled diet had a 25% increase in breast cancer compared to

matched controls on another diet. Using Monsanto's logic, the findings can be dismissed because the increase was still within the normal variability of breast cancer for the whole population.

**3.** In spite of the statistical slight-of-hand, several results could still not be dismissed since they were well beyond the range Monsanto had defined as normal. So the company claimed that the potentially dangerous health effects were not considered significant because the reaction among the rats was not consistent between males and females. "This is really ridiculous," says Seralini, because everyone studying cancer and endocrinology, for example, knows that there are differences between genders.

**4.** When even the gender defense could not be applied to a particular finding, Monsanto dismissed it since the reactions were not always dose specific. Specifically, the results observed in rats fed a diet that was 11% Mon 863 were sometimes more pronounced than results found in rats fed a 33% diet. Seralini notes that in endocrinology and toxicology research, differences are not always proportional to effects noted. A small dose of a hormone, for example, can cause a woman to ovulate, while a larger dose can make her infertile.

**5.** When all other excuses failed, Monsanto claimed that with such a large study, one would expect lots of results to fall in the statistically significant category purely by chance. Thus, no follow-up is required.

Seralini says, "It is dishonest not to do

the tests again if you have statistical significance." Pusztai similarly asks, "What is the point of doing a study if you dismiss the results you find?" He insists that you design a study specifically so that statistical significance indicates biological significance.

In spite of the fact that Monsanto's explanations were at odds with time-honored principles of science, the European Food Standards Agency (EFSA) recommended that Mon 863 be approved. In fact, the agency's justification mimics that of Monsanto, point for point. In spite of EFSA's recommendation to approve Mon 863, the majority of the countries in the EU Council of Ministers voted not to approve the corn on July 24, 2005. But EU law requires a "qualified majority" on such a vote, and so the pro-GM European Commission is now authorized to make the decision and is expected to approve Mon 863 within a few months.

Mon 863 will not be the first approved GM food in Europe to have shown significant health effects in rats. According to Seralini, an oilseed rape (GT 73), Roundup Ready corn (NK 603), and two Bt corn varieties (Bt11 and Mon 810) all showed statistically significant problems that regulators did not pursue with follow-up research. Seralini said that the effects of the GM crops were similar to that of pesticides. Some included inflammation disorders and problems in the livers and kidneys, the two major organs involved with detoxification. Seralini is part of a

research group raising money to do independent research on a GM variety he says showed more than 50 significant rat anomalies.

## **GM Food is Prone to Unpredicted Effects**

How can a GM crop create so many significant unpredicted side effects? There are several ways. The process of gene insertion, for example, typically results in hundreds or thousands of mutations throughout the genome. Insertion also changes the amount of protein that natural genes produce (5% of the genes in one study) and can destroy natural genes altogether. The protein created by the inserted gene may also create allergies or toxins. Several studies indicate, for example, that the Bt pesticide may cause allergic or immune system effects. Furthermore, according to Monsanto's submission on Mon 863 to Australia and New Zealand, some of the foreign genetic material that was added into the corn was mutated during the insertion process. This means that the composition of the Bt protein that the corn creates is actually different than the one scientists intended.

With so many ways to create side effects, many scientists and consumer groups are demanding extensive evaluations and insist that a simple 90-day rat experiment is not competent to protect the public. In the EU, pesticide approvals require research on three types of mammals, with feeding studies ranging from 90 days to two years. Seralini points out that Bt crops create

new pesticides. Mon 863, for example, is unique; it differs from the natural version of Bt pesticide in seven ways and should, according to Seralini, require at least the same level of evaluation as chemical pesticides. The same holds true for herbicide tolerant crops, which are engineered to survive large applications of weed killers such as Monsanto's Roundup. Seralini points out that these GM plants have far more herbicide residues in the edible portions and extensive toxicity tests must be performed. But the biotech industry claims that they could not afford to introduce GM crops if they had to pay for the tests normally required for pesticides in Europe. For GM crop approvals in the US, they spend even less. US authorities require only 30-day studies for the Bt plants and no safety tests whatsoever are required for herbicide tolerant varieties.

### **Flaws in the Mon 863 Study Should Have Caused It to be Rejected**

According to Pusztai, the quality of Monsanto's study was well below that normally required for a peer reviewed publication. He says, "It is odd, therefore, that it remains the central document considered by government regulatory authorities upon which to make a decision to protect the health of European citizens."

Several features of the study appear to have been rigged to avoid finding problems. Nutritional studies, for example, typically use young, fast-growing animals, which are sensitive to

toxic and nutritional effects. By using a mix of young and old animals, Monsanto's research design may have hidden serious problems. Similarly, they used rats with a huge range of starting weights. According to Pusztai, the starting weights in a rat feeding study should not vary more than 2% from the average. By contrast, the male starting weights in Monsanto's study ranged from 198.4 to 259.8 grams (or 143 to 186 grams according to the conflicting data in the study's appendix). In either case, says Pusztai, the wide range "can make it impossible to find significant differences in animal weights at the end of the experiment."

Monsanto tested the effects of two diets: in one Mon 863 constituted 33% of the rats' diet, and in the other, it was 11%. Even in the 33% group, GM corn protein comprised only about 15% of the rats' total protein. According to Pusztai, researchers should have started with the maximum amount of corn possible (while maintaining a balanced diet), and then used lower concentrations to evaluate any dose effect. (Since rats are stand-ins for humans, it is interesting to note that African aid recipients typically rely on corn for 90% of their total caloric intake.) Researchers also supplemented the corn with a commercial animal feed. Although its composition wasn't reported, it may have contained GM soy, which could have skewed the results.

The study relied on analytical methods that are half a century old and ignored powerful new methods, such as

profiling techniques, DNA chips, proteomics, and others. They relied on just two observation times (week 5 and week 14), which will not give data about the intervening periods. And the short 90-day time period will miss chronic and reproductive problems, as well as problems in the next generation.

The analysis of the findings was obscured by using six irrelevant control groups fed commercial diets, as well as data from historical databases. Such comparisons are totally unacceptable in the field of nutrition. According to Pusztai, "The study should have included a control group fed the non-GM parent line, spiked with the Bt obtained from the Mon 863. If rats reacted badly to this diet, it would show that the genetic engineering process and its unpredicted side effects, and not the Bt toxin, were responsible. Pusztai says, "A second parental line spiked with a known toxin would also be useful as a positive control," to make sure the measurements are sensitive enough to detect the expected impact of the toxin. Without this, it is difficult to know if the methods were working properly.

Monsanto also defended changes in kidney weights by comparing the values with a separate study, which used different corn genetics and a different lab. According to Pusztai, this absurd inter-experimental comparison is never done and should be disregarded.

Some of the reported weight measurements were also bizarre, suggesting possible problems with animal management or faulty data. One

rat dropped 53 grams in one week and gained 102 grams in the next. Some that were heaviest at the beginning of the experiment were the lightest at the end. And the rats hardly grew at all during the last four weeks.

Overall, the research paper was confusing, conflicting, and poorly reported. It failed to disclose, for example, the nutritional composition of the feed - backed up by chemical analysis - and the methods used to measure changes in the animals. Since these most basic requirements for a nutritional study were not provided, the research cannot be repeated and the results remain suspect.

Referring to the study as a whole, Pusztai says, "Nutritional scientists and leading journals would not accept these blatant inadequacies and misinterpretations."

### **The Politics of Science Fails to Protect the Public**

When Seralini wanted to voice his concerns about the industry's safety studies, he was told by French authorities that he was legally bound to keep even his opinions confidential. A lawsuit eventually granted him the right to speak, but until June 20, 2005, biotech companies were able to keep their feeding studies hidden by claiming that they contained confidential business information. Seralini says that "No one can understand, even among EU regulators, why the composition of the blood of rats that have eaten the GM is secret." The precedent

established by the German court may open the door for more biotech studies to be made public. Without disclosure, says Seralini, just a few toxicologists can make the decision without public evaluation. And too often, the decision-making body is heavily influenced by the applying company.

In his French Commission for Biomolecular Genetics (CBG), for example, the government nominates three candidates for the position of the very important "external referee." That referee studies the application and presents the relevant facts to the 18-member committee. For about ten years, the applicant companies such as Monsanto were able to choose which candidate of the three was to be the referee overseeing their products' approval process. Seralini says, "I had a big fight with the commission" over the conflict of interest. As a result, the government changed the rules, and for the Mon 863 application they allowed the president of the commission the right to choose the referee. The president, however, is a geneticist who works very closely with industry. He appointed the same person that the biotech industry had chosen in the past.

After the CBG failed to approve Monsanto's corn in 2003, the president asked for an outside scientist to re-evaluate just one of the significant differences - kidney weight. According to Seralini, the consultant ignored the blood and liver disorders entirely. And no additional research was actually conducted; the consultant simply re-examined the same data and declared

the results insignificant. The commission scheduled another vote, but failed to achieve a quorum. The president ruled that a quorum would not be needed in the next meeting, and only five members showed up. The president cast the deciding vote that approved Mon 863, 3 votes to 2. The other votes in favor came from the commission's vice-president, who works at an organization that conducts agricultural research, and a scientist. According to Seralini, the scientist is a toxicologist who, oddly enough, is "always against long animal toxicity tests." In fact, he had been part of the French committee that approved Novartis (now Syngenta) E 176 corn after it had been tested for only two weeks with three cows. Actually, there were four cows at the start of the study, but one died and was removed.

The toxicologist is also on the European Food Standards Agency that endorsed Mon 863. EFSA has come under attack for including primarily pro-GM scientists. According to a November 2004 report by Friends of the Earth, "One member has direct financial links with the biotech industry and others have indirect links. . . . Two members have even appeared in promotional videos produced by the biotech industry." And several members, including the chairman, have been part of an EU-funded project with the stated goal to "facilitate market introduction of GMO's in Europe."

**US Pushes its Agenda, and its Pests, on Europe**

The United States government's support for biotech is no secret. In fact, it is the official policy in several US agencies to promote the industry, and some of them have attempted to push acceptance of GM crops in Europe. In the case of Mon 863, it seems that the corn is designed to solve a European problem that the US introduced. The corn is engineered with a pesticide to attack insects such as Diabrotica. According to Seralini, "Diabrotica is from a very dangerous family of insects for a wide range of crops and was absent from the European countries until the late 1990s, forbidden even in laboratories because it is very difficult to eliminate it with known chemical insecticides." He says it appears to have entered Europe from the US in large numbers during the Balkan war. Specifically, it was widespread around US military airports, whose planes were likely to have carried the pest. It has since spread primarily in Italy, France, and Germany.

According to Seralini, "Monsanto seems to have anticipated this problem." Before any infestation had been discovered, they were already field testing their corn in France in the late 1990s. Since it takes about five years of local field trials for a GM variety to be accepted in an EU nation, such early testing was necessary.

In addition to the crop pests, Europe may have also imported the US tradition of approving GM products based on faulty studies. Documents stolen from the US FDA reveal that when Monsanto's researchers intended

to illustrate that their GM bovine growth hormone did not interfere with cows'; fertility, they allegedly added cows to the study that were pregnant prior to injection. An FDA whistleblower also charged that sick cows were removed from industry studies altogether (see [Seeds of Deception](#), chapter 3).



Critics demand that regulators use independent studies, not industry studies, to prevent manipulation of data. But there are only a few independently funded researchers. Biology professor Bela Darvas of Hungary's Debrecen University is one of them. After discovering that one of Monsanto's Bt corn varieties, Mon 810, is lethal to two Hungarian protected species and one insect classified as a rare, he ran into an unexpected obstacle. Now Monsanto refuses to give him any more Mon 810 corn to use in his tests. They also refused his request for Mon 863.

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Perhaps with the court's release of Monsanto's rat study, the public will demand a more thorough investigation into GM foods and a change in the review and approval process. Until then, Europeans are relatively safe from the unintended effects, since most

manufacturers refuse to use even approved GM ingredients there (with the exception of animal feed). Meanwhile, consumers in the US will unwittingly serve as the guinea pigs.

### **Additional Information**

**1,** Dr. Arpad Pusztai's [review comments commissioned by the German authorities on both the full 90-day study and a Monsanto summary.](#)

**2,** For Dr. Pusztai's review, in easy-to-read table form, of some of the significant differences found in the rat-feeding study, [click here.](#)

**3,** For Dr. Pusztai's list of reasons why the Mon 863 study should have been rejected, [click here.](#)

**4,** See detailed information on the study provided by Professor Seralini to the Greenpeace press conference at: [Click Here.](#)

**5,** For the full 1139 page study, go to: [click here.](#)

**6,** For Monsanto's 11 page summary of safety information, go to: [click here.](#)

**7,** For the Friends of the Earth report on conflicts of interest in the European Food Standards Agency, go to: [click here.](#)

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*Jeffrey M. Smith has been involved with genetically modified (GM) foods for nearly a decade. He worked for*

*non-profit and political groups on the issue and in 1998, ran for U.S. Congress to raise public awareness of the health and environmental impacts. To protect children-who are most at risk from the potential health effects of GM foods-Smith proposed legislation to remove the foods from school meals. He also proposed legislation to help protect farmers from cross-pollination by GM crops. Later, he was vice president of marketing for a GMO detection laboratory.*

*Smith has lectured widely, spoken at conferences, and has been quoted in articles around the world. Prior to working in this field, he was a writer, educator, and public speaker for non-profit groups, advancing the causes of health, environment, and personal development. This book *Seeds of Deception*, researched and written after he left the industry, combines Smith's passion for these causes with his extensive knowledge of the risks and cover-ups behind genetically modified foods.*

*Smith is the founding director of the Institute for Responsible Technology, a member of the Sierra Club Genetic Engineering Committee, and a member of the advisory board of the Campaign to Label Genetically Engineered Foods. He has a master's degree in business administration and lives with his wife in Iowa, surrounded by genetically modified corn and soybeans.*

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