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COMPANY RESEARCH ON GENETICALLY MODIFIED FOODS IS RIGGED

In 2004, four advocates of genetically modified (GM) foods published a study in the *British Food Journal* that was sure to boost their cause [1] According to the peer-reviewed paper, when shoppers in a Canadian farm store were confronted with an informed and unbiased choice between GM corn and non-GM corn most purchased the GM variety. This finding flew in the face of worldwide consumer resistance to GM foods, which had shut markets in Europe, Japan, and elsewhere. It also challenged studies that showed that the more information on genetically modified organisms (GMOs) consumers have, the less they trust them.[2] The study, which was funded by the biotech-industry front group, Council for Biotechnology Information and the industry's trade association, the Crop Protection Institute of Canada (now Croplife Canada), was given the Journal's prestigious Award for Excellence for the Most Outstanding Paper of 2004 and has been cited often by biotech advocates.

Stuart Laidlaw, a reporter from Canada's *Toronto Star*, visited the farm store several times during the study and described the scenario in his book *Secret Ingredients*. Far from offering unbiased choices, key elements appeared rigged to favor GM corn purchases. The consumer education fact sheets were entirely pro-GMO, and Doug Powell, the lead researcher, enthusiastically demonstrated to Laidlaw how he could convince shoppers to buy the GM varieties. He confronted a farmer who had already purchased non-GM corn. After pitching his case for GMOs, Powell proudly had the farmer tell Laidlaw that he had changed his opinion and would buy GM corn in his next shopping trip.

Powell's interference with shoppers' "unbiased" choices was nothing compared to the effect of the signs placed over the corn bins. The sign above the non-GM corn read, "Would you eat wormy sweet corn?" It further listed the chemicals that were sprayed during the season. By contrast, the sign above the GM corn stated, "Here's What Went into Producing Quality Sweet Corn." It is no wonder that 60% of shoppers avoided the "wormy corn." In fact, it may be a testament to people's distrust of GMOs that 40% still went for the "wormy" option.

Powell and his colleagues did not mention the controversial signage in their study. They claimed that the corn bins in the farm store were "fully labelled"—either "genetically engineered Bt sweet corn" or "Regular sweet-corn." When Laidlaw's book came out, however, Powell's "wormy" sign was featured in a photograph, [3] exposing what was later described by Cambridge University's Dr. Richard Jennings as "flagrant fraud." Jennings, who is a leading researcher on scientific ethics, says, "It was a sin of omission by failing to divulge information which quite clearly should have been disclosed." [4]

Jennings is among several scientists and outraged citizens that say the paper should have been withdrawn, but the Journal refused. Instead, it published a criticism of the methods by Canadian geneticist Joe Cummins, and allowed Powell to respond with a lengthy reply.[5]

In his defence, Powell claimed that his signs merely used the language of consumers and was "not intended to manipulate consumer purchasing patterns." He also claimed that the "wormy" corn sign was only there for the first week of the trial and was then replaced by other educational messages. But eye witnesses and photographs demonstrate the presence of the sign long after Powell's suggested date of replacement.[6]

This incident illustrates how so-called scientific papers can be manipulated to force conclusions favourable to authors or funders and how peer-reviewed journals may be complicit. While the subject of this particular study provided ammunition in the battle to deny choice to consumers in North America, there is similar "cooked" research in the more critical area of GMO safety assessments.

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SECRET, INADEQUATE, AND FLAWED

THE UNPUBLISHED INDUSTRY STUDIES SUBMITTED TO REGULATORS ARE TYPICALLY KEPT SECRET BASED ON THE CLAIM THAT IT IS "CONFIDENTIAL BUSINESS INFORMATION." THE ROYAL SOCIETY OF CANADA IS ONE OF MANY ORGANIZATIONS THAT CONDEMN THIS PRACTICE. THEY WROTE:

IN THE JUDGMENT OF THE EXPERT PANEL, THE MORE REGULATORY AGENCIES LIMIT FREE ACCESS TO THE DATA UPON WHICH THEIR DECISIONS ARE BASED, THE MORE COMPROMISED BECOMES THE CLAIM THAT THE REGULATORY PROCESS IS 'SCIENCE BASED.' THIS IS DUE TO A SIMPLE BUT WELL-UNDERSTOOD REQUIREMENT OF THE SCIENTIFIC METHOD ITSELF—THAT IT BE AN OPEN, COMPLETELY TRANSPARENT ENTERPRISE IN WHICH ANY AND ALL ASPECTS OF SCIENTIFIC RESEARCH ARE OPEN TO FULL REVIEW BY SCIENTIFIC PEERS. PEER REVIEW AND INDEPENDENT CORROBORATION OF RESEARCH FINDINGS ARE AXIOMS OF THE SCIENTIFIC METHOD, AND PART OF THE VERY MEANING OF THE OBJECTIVITY AND NEUTRALITY OF SCIENCE." [7]

Whenever private submissions *are* made public through lawsuits or Freedom of Information Act Requests, it becomes clear why companies benefit from secrecy. The quality of their research is often miserable, incompetent, and unacceptable for peer-review. In 2000, for example, after the potentially allergenic StarLink corn was discovered in the food supply, Aventis Crop Science presented wholly inadequate safety data to the EPA's scientific advisory panel. One frustrated panel member, Dean Metcalfe, MD,—the government's top allergist—said during a hearing, "Most of us review for a lot of journals. And if this were presented for publication in the journals that I review for, it would be sent back to the authors with all of these questions. It would be rejected."[8]

Submissions to the US Food and Drug Administration (FDA) may be worse than in other countries, since the agency doesn't actually require *any* data. Their policy—overseen by Monsanto's former attorney who later became the company's vice president—says that biotech companies can determine if their own foods are safe. Anything submitted is voluntary and, according to former Environmental Protection Agency scientist Doug Gurian-Sherman, "often lack[s] sufficient detail, such as necessary statistical analyses needed for an adequate safety evaluation." Using Freedom of Information Requests, Gurian-Sherman analyzed more than a fourth of the data summaries (14 of 53) of GM crops reviewed by the FDA. He says, "Our evaluation found that the biotechnology companies provide inadequate data to ensure their products are safe." [9]

UNSCIENTIFIC ASSUMPTIONS ARE THE BASIS OF APPROVALS

"Most or all of the conclusions of food safety for individual GM crops are based on inferences and assumptions, rather than on actual testing," says Professor E. Ann Clark, who analyzed submissions to Canadian regulators. For example, rather than actually testing to see if the amino acid sequence produced by their inserted gene is correct, "the standard practice," according to research analyst William Freese, "is to sequence just 5 to 25 amino acids, even if the protein has more than 600 in total. If the short sample matches what is expected, they assume that the rest are also fine. If they are wrong, however, a rearranged protein could be quite dangerous."

Monsanto's submission to Australian regulators on their high lysine GM corn provides several examples of optimistic assumptions used in place of science. The GM protein produced in the corn is also found in soil. The company claimed that since people consume small residues of soil on fruits and vegetables, the protein has a history of safe consumption. An independent calculation by the Centre for Integrated Research on Biosafety (INBI), however, reveals the weakness of this argument. Based on the amount of GM corn protein an average US citizen would consume (if all their corn were Monsanto's variety), "for equivalent exposure" of the protein from soil "people would have to eat between 80-800 million (males) or 60-700 million (females) kilograms of soil each day, or nearly as much as 10,000kg/second 24 hours a day seven days a week." INBI estimated that the normal exposure to the protein from soil residues was actually "about 30 billion-4 trillion times less than exposure through [high lysine] corn." [10]

In addition, certain nutritional components of this GM variety (i.e. protein content, total dietary fiber, acid detergent fiber, and neutral detergent fiber) lie far outside the normal range for corn. Instead of comparing their corn to normal controls, which would reveal this disparity, Monsanto compared it to obscure corn varieties that were also substantially outside the normal range *on precisely these values*.

Epidemiologist Judy Carman points out that GM "experiments used some very unusual animal models for human health,

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such as chickens, cows and trout. Some of the measurements taken from these animals are also unusual measures of human health, such as abdominal fat pad weight, total de-boned breast meat yield, and milk production." In her examination of the full range of submittals to authorities in Australia and New Zealand, she says that there was no proper evaluation of "biochemistry, immunology, tissue pathology, and gut, liver and kidney function." [11] Writing on behalf of the Public Health Association of Australia, Carman says, "The effects of feeding people high concentrations of the new protein over tens of years cannot be determined by feeding 20 mice a single oral gavage of a given high concentration of the protein and taking very basic data for 13-14 days...The acute toxicity testing proposed as adequate would simply not pick up cancer, teratology [birth defects] or the long-tem effects of nutrient deficiencies or increases in anti-nutrients." [12]

THE SCIENCE OF RIGGING STUDIES

When independent researchers published a study in July 1999 showing that GM soy contains 12%-14% less cancer-fighting phytoestrogens, Monsanto responded with its own study, concluding that soy's phytoestrogen levels vary too much to even carry out a statistical analysis. Researchers failed to disclose, however, that they had instructed the laboratory to use an obsolete method of detection—one that had been prone to highly variable results. [13]

WHEN AVENTIS PREPARED SAMPLES TO SEE IF THE POTENTIAL ALLERGEN IN STARLINK CORN REMAINED INTACT AFTER COOKING, INSTEAD OF USING THE STANDARD 30-MINUTE TREATMENT, THEY HEATED CORN FOR TWO HOURS.

TO SHOW THAT PASTEURIZATION DESTROYED BOVINE GROWTH HORMONE IN MILK FROM COWS TREATED WITH RBGH, THEY PASTEURIZED THE MILK 120 TIMES LONGER THAN NORMAL. UNABLE TO DESTROY MORE THAN 19%, THEY THEN SPIKED THE MILK WITH A HUGE AMOUNT OF THE HORMONE AND REPEATED THE LONG PASTEURIZATION, DESTROYING 90%. (THE FDA REPORTED THAT PASTEURIZATION DESTROYS 90% OF THE HORMONE.)

TO DEMONSTRATE THAT INJECTIONS OF RBGH DID NOT INTERFERE WITH COW'S FERTILITY, MONSANTO APPARENTLY ADDED COWS TO THE STUDY THAT WERE PREGNANT PRIOR TO INJECTION. AND IN ORDER TO PROVE THAT THE PROTEIN FROM THEIR GM CROPS BREAKS DOWN QUICKLY DURING SIMULATED DIGESTION, BIOTECH COMPANIES USED THOUSANDS OF TIMES THE AMOUNT OF DIGESTIVE ENZYMES AND A MUCH STRONGER ACID COMPARED TO THAT RECOMMENDED BY THE WORLD HEALTH ORGANIZATION. METHODS USED TO HIDE PROBLEMS ARE VARIED AND PLENTIFUL. FOR EXAMPLE, RESEARCHERS:

USE HIGHLY VARIABLE ANIMAL STARTING WEIGHTS TO HINDER DETECTION OF FOOD-RELATED CHANGES

KEEP FEEDING STUDIES SHORT TO MISS LONG-TERM IMPACTS

TEST EFFECTS OF ROUNDUP READY SOYBEANS THAT HAVE NOT BEEN SPRAYED WITH ROUNDUP

AVOID FEEDING ANIMALS THE ACTUAL GM CROP, BUT GIVE THEM INSTEAD A SINGLE DOSE OF THE GM PROTEIN THAT WAS PRODUCED INSIDE GM BACTERIA

USE TOO FEW SUBJECTS TO DERIVE STATISTICALLY SIGNIFICANT RESULTS.

USE POOR STATISTICAL METHODS OR SIMPLY LEAVE OUT ESSENTIAL METHODS, DATA, OR STATISTICS

USE RIGGED OR IRRELEVANT CONTROL GROUPS, AND EMPLOY INSENSITIVE OR OBSOLETE EVALUATION TECHNIQUES

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Monsanto's 1996 Journal of Nutrition study [14] [15] provides plenty of examples of scientific transgressions. Roundup Ready soybeans are engineered to withstand the normally fatal effects of Monsanto's herbicide called Roundup. Monsanto scientists published a feeding study that purported to test their soybeans' effect on rats, catfish, chickens, and cows. The study has been used often by the industry as validation for safety claims. According to Dr. Arpad Pusztai, however, "It was obvious that the study had been designed to avoid finding any problems. Everybody in our consortium knew this." Pusztai was commissioned at the time by the UK government to develop rigorous testing protocols on GM foods—protocols that were never implemented. Pusztai, who had published several studies in that same nutrition journal, said the Monsanto paper was "not really up to the normal journal standards." Pusztai says that if he had been asked to referee the paper for publication, "it would never have passed." He's confident that even his graduate assistants would have taken the study apart in short order. Some of the flaws include:

- Researchers tested GM soy on mature animals, not young ones. Young animals use protein to build their muscles, tissues, and organs. Problems with GM food could therefore show up in organ and body weight. But adult animals use the protein for tissue renewal and energy. "With a nutritional study on mature animals," says Pusztai, "you would never see any difference in organ weights even if the food turned out to be anti-nutritional. The animals would have to be emaciated or poisoned to show anything."
- Even if there were an organ development problem, the study wouldn't have picked it up since the researchers didn't weigh the organs.
- In one of the trials, researchers substituted only one tenth of the natural protein with GM soy protein. In two others, they diluted their GM soy six- and twelve-fold. [16] Scientists Ian Pryme of Norway and Rolf Lembcke of Denmark wrote, the "level of the GM soy was too low, and would probably ensure that any possible undesirable GM effects did not occur."
- Pryme and Lembcke, who published a paper in *Nutrition and Health* that analyzed all peer-reviewed feeding studies on GM foods as of 2003, also pointed out that the percentage of protein in the feed used in the Roundup Ready study was "artificially too high." This "would almost certainly mask, or at least effectively reduce, any possible effect of the [GM soy]." They said it was "highly likely that all GM effects would have been diluted out." [17]
- Proper compositional studies filter out effects of weather or geography by comparing plants grown at the same time in the same location. Monsanto, however, pooled data from several locations, which makes it difficult for differences to be statistically significant. Nonetheless, the data revealed significant differences in the ash, fat, and carbohydrate content. Roundup Ready soy meal also contained 27% more trypsin inhibitor, a potential allergen, which might explain the sudden jump in soy allergies in the UK beginning right after Roundup Ready soy was introduced. Also, cows fed GM soy produced milk with a higher fat content, demonstrating another disparity between the two types of soy.
- One field trial, however, did grow GM and non-GM plants next to each other, but this data was not included in the paper. Years after the study appeared, medical writer Barbara Keeler discovered the data that had been omitted. It showed that Monsanto's GM soy had significantly lower levels of protein, a fatty acid, and phenylalanine, an essential amino acid. Also, toasted GM soy meal contained nearly twice the amount of a lectin—one that may interfere with the body's ability to assimilate other nutrients. And the amount of trypsin inhibitor in cooked GM soy was as much as seven times higher than a cooked non-GM control.
- The study also omitted many details normally required for a published paper. According to Pryme and Lembcke, "No data were given for most of the parameters."
- And when researchers tested the effects of Roundup Ready protein on animals, they didn't extract the protein
 from the soybeans. Instead, they derived it from GM bacteria, claiming the two forms of protein were equivalent.
 There are numerous ways, however, in which the protein in the soy may be different. In fact, nine years after this
 study was published, another study showed that the gene inserted into the soybeans produced unintended
 aberrant RNA strands, meaning that the protein may be quite different than what was intended.

In Pryme and Lembcke's analysis, it came as no surprise that this Monsanto study, along with the other four peer-reviewed animal feeding studies that were "performed more or less in collaboration with private companies," reported no negative effects of the GM diet. "On the other hand," they wrote, "adverse effects were reported (but not explained) in [the five] independent studies." They added, "It is remarkable that these effects have all been observed after feeding for only 10–14 days." [19]

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TOXIC GM FOODS COULD HAVE BEEN APPROVED

Two GM foods whose commercialization was stopped because of negative test results give a chilling example of what may be getting through. Rats fed GM potatoes had potentially precancerous cell growth in the stomach and intestines, less developed brains, livers, and testicles, partial atrophy of the liver, and damaged immune systems. [20] GM peas provoked an inflammatory response in mice, suggesting that the peas might trigger a deadly anaphylactic shock in allergic humans. [21] Both of these dangerous crops, however, could easily have been approved. The problems were only discovered because the researchers used advanced tests that were never applied to GM crops already on the market. Both would have passed the normal tests that companies typically use to get their products approved.

Ironically, when Monsanto was asked to comment on the pea study, their spokesperson said it demonstrated that the regulatory system works. He failed to disclose that none of the company's GM crops had been put through such rigorous tests.

RAMPANT UNRELENTING INDUSTRY BIAS

Industry-funded research that favors the funders is not new. Bias has been identified across several industries. In pharmaceuticals, for example, positive results are four times more likely if the drug's manufacturer funds the study. [22] When companies pay for the economic analyses of their own cancer drugs, the results are eight times more likely to be favorable. [23] Compared to drug research, the potential for industry manipulation in GM crop studies is considerably higher. Unlike pharmaceutical testing, GM research has no standardized procedures dictated by regulators. GM studies are not usually published in peer-reviewed journals and are typically kept secret by companies and governments. There is little money available for rigorous independent research, so company evidence usually goes unchallenged and unverified. Most importantly, whereas drugs *can* show serious side-effects and still be approved, GM food cannot. There is no tolerance for adverse reactions; feeding trials *must* show no problems.

Thus, when industry studies show problems (in spite of their efforts to avoid them), serious adverse reactions and even deaths among GM-fed animals are ignored or dismissed as "not biologically significant" or due to "natural variations." Numerous reports including peer-reviewed articles and part 3 of the book *Genetic Roulette* are replete with examples of rigged research. But making these public does not seem to curtail its practice. Consider the wormy corn of the *British Food Journal*. Not only has the editor refused to retract the paper, he has not even agreed to reconsider its Award for Excellence. A blatant propaganda exercise still stands validated as exemplary science.

In the critical arena of food safety research, where the health of society is caught in the balance, it is entirely unacceptable that the biotech industry is without accountability, standards, or peer-review. At our expense, they've got bad science down to a science.

THIS ARTICLE IS BASED ON PART 3 OF THE BOOK, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS, BY JEFFREY M. SMITH. www.GeneticRoulette.com

Jeffrey M. Smith is the author of the new publication Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods, which presents 65 risks in easy-to-read two-page spreads. His first book, Seeds of Deception, is the top rated and #1 selling book on GM foods in the world. He is the Executive Director of the Institute for Responsible Technology, which is spearheading the Campaign for Healthier Eating in America. Go to www.seedsofdeception.com to learn more about how to avoid GM foods.

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