

INTRODUCTION

Deceptions, Assumptions, and Denial— Exposing the roots of genetically modified crops

When Kirk Azevedo accepted a Monsanto Company recruiter's offer in 1996 to sell genetically modified (GM) crops, it wasn't the pay increase that inspired him. It was the writings of Monsanto CEO Robert Shapiro that were his motivation. Shapiro had painted a picture of feeding the world and cleaning up the environment with his company's new technology. Kirk was fascinated by the idea of swapping genes between species, creating designer organisms that could reduce manufacturing waste, turning "fields into factories and producing anything from lifesaving drugs to insect-resistant plants."¹ When he visited Monsanto's St. Louis headquarters for new employee training, Azevedo shared his enthusiasm for Shapiro's vision during a meeting. When the session ended, a company vice president pulled him aside and set him straight.

"Wait a second," he told Azevedo. "What Robert Shapiro says is one thing. But what we do is something else. We are here to make money. He is the front man who tells a story. We don't even understand what he is saying."

Azevedo was jolted. His image "of helping and healing" the world through GM crops turned out to be a manufactured reality—a lie—crafted to gain public acceptance and to push products. Azevedo realized he was working for "just another profit-oriented company."

Helping the world is only one of several manufactured realities about GM crops, the most fundamental of which is that the foods are safe. The key source for this claim is the United States Food and Drug Administration (FDA). According to their 1992 policy on GM foods, "**The agency is not aware of any information showing that foods derived by these new methods differ from other foods in any meaningful or uniform way.**" On the basis of that sentence, the FDA claimed that no safety studies are necessary and that "Ultimately, it is the food producer who is responsible for assuring safety."² Biotech companies thus determine on their own if their products are harmless. This policy set the stage for the rapid deployment of the new technology. The seed industry was consolidated, millions of acres were planted, hundreds of millions were fed, consumers and nations objected, laws were passed, crops were contaminated, billions of dollars were lost—and it turns out that sentence was a lie.

The FDA was *fully* aware that GM crops were meaningfully different. That, in fact, was the overwhelming consensus among "the technical experts in the agency." The scientists agreed that genetic engineering leads to "different risks"³ than traditional breeding and had repeatedly warned their superiors that GM foods might create unpredictable, hard-to-detect side effects. They urged the political appointees who were in charge at the FDA to require long-term safety studies, including human studies, to guard against possible allergies, toxins, new diseases, and nutritional problems.

The scientists' concerns were kept secret in 1992, when FDA policy was put into place. But seven years later, internal records were made public due to a lawsuit and the deception came to

light. The agency's newly released 44,000 pages revealed that government scientists' "references to the unintended negative effects ... were progressively deleted from drafts of the policy statement (over the protests of agency scientists)."⁴ They further revealed that the FDA was under orders from the White House to promote GM crops and that Michael Taylor, Monsanto's former attorney and later its vice president, was brought into the FDA to oversee policy development. With Taylor in charge, the scientists' warnings were ignored and denied.

As a result, consultation with the FDA on GM food safety is a voluntary exercise, in which the agency receives summaries without data and conclusions without foundation. If the company claims that its foods are safe, the FDA has no further questions. Thus, GM varieties that have never been fed to animals in rigorous safety studies and probably *never* fed to humans at all are approved for sale in grocery stores.

In the mid-1990s, the UK government decided to institute what US leaders refused to—rigorous, long-term safety testing. They commissioned scientists to develop an assessment protocol for GM crop approvals that would be used in the UK and eventually by the EU. In 1998, three years into the project, the scientists discovered that potatoes engineered to produce a harmless insecticide caused extensive health damage to rats. The pro-GM government immediately canceled the project, the lead scientist was fired and the research team dismantled. The assessment requirements that were eventually adopted by the EU were a far cry from those that were being developed in the UK. The superficial testing schemes still have yet to meet the demands of the FDA's stifled scientists.

Industry is in charge of safety

Ironically, policy makers around the world gain confidence in the safety of GM crops because they wrongly assume that the US FDA has approved them based on extensive tests, and approvals everywhere rely on the developers to do safety studies on their own crops. Research does not need to be published and most is kept secret under the guise of "confidential business information." Very little data is available for public scrutiny. In 2003, for example, researchers reviewed published, peer-reviewed animal feeding studies that qualified as safety assessments. There were ten. The correlation between the findings and the funding was telling. Five studies "performed more or less in collaboration with private companies" reported no adverse effects. In the three independent studies, "adverse effects were reported." The authors said, "It is remarkable that these effects have all been observed after feeding for only 10–14 days."⁵

Biotech advocates claim that there is plenty of evidence for safety. In December 2004, for example, Christopher Preston did a database search of peer-reviewed animal feeding studies worldwide and came up with 41.⁶ Although this is still an incredibly low number of papers by which to judge safety, according to Arpad Pusztai, an expert in feeding studies, Preston's list failed "to distinguish between a scientific study and an animal production exercise." The latter "may be of some value to commercial animal production but have limited scientific value."⁷ When the commercial studies were removed from the list, it left only 18 (4 of which are in Russian or Chinese).

In October 2005, Wayne Parrot compiled 60 abstracts entitled, "General Safety and Safety As-

essment of Specific Genetically Modified Crops from Scientific Journal Articles.”⁸ The list was presented to the minister for agriculture and food in the government of western Australia as evidence that sufficient research had been conducted to conclude that GM food was safe. According to an analysis by epidemiologist Judy Carman, “A review of these abstracts found that most were animal production studies. . . . In fact, only nine abstracts could be considered to contain measures applicable to human health. The majority of these (six abstracts; 67%) found adverse effects from eating GM crops.” Carman pointed out that several other studies with adverse findings had been omitted from the compilation. She concluded, “The list of abstracts therefore does not support claims that GM crops are safe to eat. On the contrary, it provides evidence that GM crops may be harmful to health.”⁹

By the beginning of 2007, there were just over 20 peer-reviewed animal feeding safety studies on GM crops. Only a single human feeding trial has been published and there is no post-marketing surveillance on those eating GM foods. Trials funded or conducted by the GM crop producers, however, are consistently substandard. They typically fail to investigate the impacts of GM food on gut function, liver function, kidney function, the immune system, the endocrine system, blood composition, allergic response, effects on the unborn, the potential to cause cancer, or impacts on gut bacteria. In addition, the industry-funded studies have become notorious for using creative ways to avoid finding problems. They feed older animals instead of more sensitive young ones, keep sample sizes too low to achieve the statistical significance needed for proof in scientific studies, dilute the GM component of the feed, overcook samples, compare results with irrelevant controls, choose obsolete insensitive detection methods, limit the duration of feeding trials, and even ignore animal deaths and sickness. They’ve got “bad science” down to a science.

Genetic engineering creates wide-spread, unpredictable changes

The prevailing worldview behind the development of GM foods was that genes were like Lego blocks, independent pieces that snap into place. This is false. The process of creating a GM crop can produce massive changes in the natural functioning of the plant’s DNA. Native genes can be mutated, deleted, permanently turned off or on, and hundreds may change their levels of expression. The inserted gene can become truncated, fragmented, mixed with other genes, inverted or multiplied, and the GM protein it produces may have unintended characteristics with harmful side effects.

To make this clear, we’ll use the popular analogy comparing DNA to a book. The four bases that make up the genetic sequence are the letters in the book; the genes are special pages that describe characters called proteins. The common way people explain and promote genetic engineering is to say, “It is just like taking a page out of one book and putting it into another.”

In reality, a book would look quite different after it had undergone genetic engineering. The inserted page (gene) may turn out to be multiple identical pages, partial pages, or small bits of text. Sections of the insert are misspelled, deleted, inverted, or scrambled. Next to the inserts, the story is often indecipherable, with random letters, new text, and pages missing. The rest of the book has also changed. There are now typos throughout, sometimes hundreds or thousands of them. Letters are switched, words are scrambled, and sentences are deleted, repeated, or reversed.

Passages from one part of the book, even whole chapters (chromosomes), may be relocated or repeated elsewhere, and bits of text from entirely different books can show up from time to time. Many of the characters in the story (proteins) now act differently. Some minor roles have become prominent, leads have been demoted and some may have switched roles from hero to villain or vice versa. And, if you get bored with this story, take the original book, insert another page—even the same one—and the changes will be completely different. Or stick with the original book and over time, it might actually rearrange the inserted page.

In addition to unintended changes in the DNA, there are health risks from other aspects of GM crops. When a transgene starts to function in the new cell, for example, it may produce proteins that are different than the one intended. The amino acid sequence may be wrong, the protein's shape may be different, and molecular attachments may make the protein harmful. The fact that proteins act differently in new plant environments was made painfully clear to developers of GM peas in Australia. They canceled their 10-year, \$2 million project after their GM protein, supposedly identical to the harmless natural version, caused inflammatory responses in mice. Subtle, unpredicted changes in molecular attachments might have similarly triggered deadly allergic reactions in people if the peas were put on the market.

Even if the GM protein is exactly what is intended, there are still problems. For example, corn and cotton varieties are engineered to produce a pesticidal protein called *Bt*-toxin (from *Bacillus thuringiensis*). Because it is used in spray form by farmers, it was claimed to be harmless to humans. That's clearly wrong. People exposed to *Bt*-toxin spray had all sorts of allergic-type symptoms; mice that ingested *Bt* had powerful immune responses and abnormal and excessive cell growth; and *Bt* crops are being blamed for a growing number of human and livestock illnesses.

Another problem is that inserted genes may transfer from food into gut bacteria or internal organs. This possibility had been dismissed earlier based on the assumption that ingested genes are quickly destroyed by the digestive system. Not so. Animal studies demonstrate that ingested DNA can travel throughout the body, even into the fetus via the placenta. Transgenes from GM crops fed to animals have been found in the blood, liver, spleen, and kidneys. The only published human feeding trial on GM food verified that genetic material inserted into GM soy transfers into the DNA of our intestinal bacteria.

Now combine the two risks above and get a third. If the corn gene that creates *Bt*-toxin were to transfer into gut bacteria (like parts of the soy gene have been doing), it might turn our intestinal flora into living pesticide factories. A biotech proponent may argue that this is just speculation since there are no studies to show that *Bt* genes also transfer. But that is the point. There *are* no studies on *Bt* gene transfer to human gut bacteria—*period*. We don't know if this happens because no one is looking. Thus, biotech companies are gambling that this and many other untested dangers won't materialize. And so are regulators. And so are consumers. It's genetic roulette.

If results from the few animal feeding safety studies are any indication, then the odds are stacked against us. Lab animals tested with GM foods had stunted growth, impaired immune systems, bleeding stomachs, abnormal and potentially precancerous cell growth in the intestines, impaired blood cell development, misshapen cell structures in the liver, pancreas, and testicles, altered gene expression and cell metabolism, liver and kidney lesions, partially atrophied livers, inflamed kidneys, less developed brains and testicles, enlarged livers, pancreases, and intestines,

reduced digestive enzymes, higher blood sugar, inflamed lung tissue, increased death rates, and higher offspring mortality. About two dozen farmers report that GM corn varieties caused their pigs or cows to become sterile, 71 shepherds say that 25% of their sheep died from grazing on *Bt* cotton plants, and others say that cows, water buffaloes, chickens, and horses also died from eating GM crops. Filipinos in at least five villages fell sick when nearby *Bt* corn was pollinating and hundreds of laborers in India report allergic reactions from handling *Bt* cotton. Soy allergies skyrocketed by 50% in the United Kingdom, soon after genetically engineered soy was introduced; and one human subject out of the few tested showed a skin prick allergic-type reaction to GM soy, but not to natural soy. In the 1980s, a GM food supplement killed about one hundred Americans and caused sickness and disability in another five to ten thousand people.

How do biotech companies deal with adverse reactions to their products? A cursory look at how Monsanto responded to adverse reactions from its toxic chemical PCBs (polychlorinated biphenyls) gives us some insight. In communication with the US Public Health Service, Monsanto claimed their experience “has been singularly free of difficulties.” Their internal files¹⁰ obtained from a lawsuit, however, reveal that this was part of a cover-up and denial that lasted decades. Company memos referred to liver disease, skin problems, and even deaths in workers associated with exposure. Monsanto’s medical department wanted to prohibit employees from eating at the factory because research showed that PCBs “were quite toxic materials by ingestion or inhalation.”¹¹ The US Navy refused the product because in their safety study, all exposed animals died.

Monsanto was aware that their industrial customers were mixing PCBs into coatings applied inside “potable water supply storage tanks,” swimming pools,¹² and grain silos. In the latter case, Monsanto knew that high levels of PCBs ended up in the milk of cows fed the grain.¹³ A Monsanto memo also acknowledged that “one million lbs/year” of PCBs were used in highway paints, and “through abrasion and leaching we can assume that nearly all of this ... winds up in the environment.”¹⁴ But Monsanto refused to warn consumers or protect the environment because, as an executive made clear in a 1970 memo, “We can’t afford to lose one dollar of business.”¹⁵ The court fined the company \$700 million.

Monsanto has brought this type of reckless denial into the field of GM foods. They have also added to their repertoire extensive bribery,¹⁶ hijacking of regulatory agencies, and threats to reporters and scientists.

Kirk Azevedo experienced firsthand how the company responded to a potentially serious safety hazard in its GM cotton. In 1997, a few months after he was set straight by the Monsanto Vice President at headquarters, a company scientist told him that Roundup Ready cotton plants contained new, unintended proteins that had likely resulted from the gene insertion process. No safety studies had been conducted on the proteins, none were planned, and the cotton plants, which were part of field trials near his home, were being fed to cattle. Azevedo “was afraid at that time that some of these proteins may be toxic.” Azevedo asked the PhD in charge of the test plot to destroy the cotton rather than feed it to cattle. He argued that until the protein had been evaluated, the cows’ milk or meat could be harmful. The scientist refused.

He approached everyone on his team at Monsanto to raise concerns about the unknown protein, but no one was interested. “Once they understood my perspective, I was somewhat ostracized,” he said. “Once I started questioning things, people wanted to keep their distance from

me. I lost cooperation with other team members. Anything that interfered with advancing the commercialization of this technology was going to be pushed aside.”

Azevedo believed that Monsanto’s irresponsible practices might devastate the health of consumers. “These Monsanto scientists are very knowledgeable about traditional products, like chemicals, herbicides, and pesticides,” he said, “but they don’t understand the possible harmful outcomes of genetic engineering.”

He tried to blow the whistle. “I spoke to many Ag commissioners. I spoke to people at the University of California. I found no one who would ... even get the connection that proteins might be pathogenic, or that there might be untoward effects associated with these foreign proteins that we knew we were producing. They didn’t even want to talk about it really. You’d kind of see a blank stare.” Azevedo decided to leave Monsanto. He said, “I’m not going to be part of this disaster.”¹⁷

Azevedo had witnessed an example of an assumption-based safety assessment. His colleagues *assumed* that the protein was safe, so they put it into the food supply without testing their assumptions. Similarly, scientists and regulators assumed that genes act as isolated units, produce only one protein, and are destroyed during digestion. They assumed that GM protein will act the same as before in new organisms, that *Bt*-toxin is harmless, and that disruption of the host DNA poses no concern. These and many other assumptions used as the basis of safety claims have been proven wrong. In spite of that, biotech proponents either adamantly repeat their now-obsolete arguments, or declare that it doesn’t matter anyway—the crops are still safe.

But the converging lines of evidence in this book suggest, in fact, that GM crops are inherently dangerous and may be responsible for an unfolding health disaster. What is astounding, moreover, is the absence of research following up this mounting evidence and the continued dismissal of serious adverse reactions. It demonstrates a reckless disregard for safety by the biotech industry and by governmental bodies charged with regulating and ensuring the safety of their products.