US Government and Biotech Firm Deceive Public on GM Corn Mix-up

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By Jeffrey M. Smith, author of the international bestseller, Seeds of Deception.

"This seems to be yet another display of deceit, secrecy, incompetence and arrogance from the GM [genetic modification] industry." This condemnation from Francis Blake of the organic farmers association in Europe was one of several choice comments hurled at the biotech firm Syngenta after it was revealed that their unapproved genetically engineered corn variety had contaminated the food supply for four years. Furthermore, after it was made public, both Syngenta and the US government misled the public about its composition and safety.

The German consumer protection minister described the whole affair as "Unbelievable sloppiness!" The European commissioner for health and consumer affairs said, "We deplore the unauthorized imports of this corn."

The controversy, which may eventually cost hundreds of millions of dollars, is centered on Syngenta's Bt10, an experimental, unapproved corn variety genetically, engineered to produce its own pesticide. In mid December 2004, the company informed the US government that it had just learned that the corn had been mislabeled in the 1990s as Bt11, an approved variety. From 2001 - 2004, about 14,000 bags of Bt10 seed were grown on 37,000 acres in the US and the resultant 165,000 tons of corn was sold as food and feed in the US and abroad.

This was not good news for the US government, which vigorously promotes GM crops and downplays health and environmental concerns. Bt10 is technically illegal, since it is a pesticide producing crop not registered by the EPA. News of its contamination ironically coincided with the public comment period for an FDA proposal, designed to calm public fears if unapproved GM varieties were discovered in the food supply. It also came at a time when the US was challenging the EU's regulations on genetically engineered crops in the

World Trade Organization.

The FDA, EPA, and USDA, along with the White House, decided to keep everything secret-for the time being-while they investigated. They reviewed seven information packets received from Syngenta from Jan. 7 to March 10, 2005. In late March, the story was leaked to the journal Nature. When their reporter called to check the facts, the government was forced to go public.

4When the story broke, federal agencies assured the public that there was nothing to worry about. They reasoned that the pesticide that Bt10 produces is the exact same protein produced by Bt11. Since Bt11 is approved and considered safe, Bt10 must likewise be harmless to health and the environment. Jeff Stein, head of regulatory affairs at Syngenta said, "What makes this somewhat unique is that Bt10 and Bt11 are physically identical and the proteins are identical."

While these assurances were accepted by the public and repeated in media reports, experts in genetic engineering knew the statements to be misleading. As their concerns were made public, Syngenta backed down from its original position and said Bt10 "differs from approved seeds only where the foreign genetic material is placed in the plant's genome." They further qualified "that the Bt 10 corn was almost biologically identical to Bt 11."

The "almost" is significant.

When the corn was genetically modified, scientists altered a gene from a soil bacterium, attached an antibiotic resistant marker gene and a promoter to turn them on, and multiplied this "genetic cassette" thousands of times. These were then shot through a gene gun into thousands of corn cells, in the hopes that some of the genes made it into the DNA of some of the cells. Scientists do not know which cells get the genes, so they douse them with an antibiotic, killing almost all of them. The few that survive, do so because the genetic cassette made it into their DNA, allowing the antibiotic resistant marker gene to protect the cell from the antibiotic.

The inserted genes function differently depending on where they end up in the DNA. Natural genes along the DNA can also get deleted, destroyed, relocated or mutated by the insertion process, and several genes or gene fragments can be inserted simultaneously. Recent studies suggest that the DNA of GM crops may typically contain hundreds or thousands of separate mutations, not found in natural

varieties. Thus, identical genes inserted into the same type of corn will each bring unique and unpredictable risks. According to an FDA document, these "unintended changes" are one reason why biotech companies submit safety information about each GM variety, even if they are engineered to create the "same intended new trait" as a GM crop that is already approved. The risks associated with Bt10 are therefore not the same as Bt11, but this critical difference was not acknowledged by Syngenta or the US government.

They also ignored recent evidence showing that genes inserted into the DNA are unstable. Their sequence can rearrange over time. Government scientists in France and Belgium reported that Syngenta's Bt11 had "rearrangements, truncations and unexpected insertions." In fact, its DNA was contaminated by Bt176, another Syngenta corn variety that was also found to be unstable. (Bt176 was quietly removed from the US market soon after it was discovered that the plant's pollen was particularly lethal to monarch butterflies. When Bt176 was the exclusive diet fed to a herd of cows in Germany, several became seriously ill and twelve died. Syngenta partially compensated the farmer's losses, but critics' demands for an in-depth investigation were not met.)

According to tests conducted 11 years ago, Bt10 produces only about 1/7th the amount of the pesticidal protein as Bt11. It is unclear whether this is due to the placement of the gene, genetic rearrangements or other reasons. Furthermore, the Canadian Food Inspection Agencymreported that the Bt11 produced four separate Bt proteins, each of different sizes. Some scientists suggest that the toxic protein may be "processed or degraded in Bt11." It is not clear whether Bt10 exhibits similar mysterious characteristics.

The US government did not discuss these issues with Bt10, in part because they don't even deal with them for approved varieties. Their safety protocols ignore these and many other sources of potential side-effects. An Austrian government report concluded that claims of safety for Bt11 were based on assumptions, not scientific evidence. According to the Institute of Science in Society, "To date there are no scientific studies on the long-term effects of eating Bt 11 and no toxicological testing on the whole GM corn plant. Tests for allergic reactions to Bt 11 were insufficient and relied on theoretical argument rather than scientific evidence." Even those theoretical arguments have been called invalid, since the Bt11 protein has several characteristics that increase the likelihood that it is allergenic. The Bt10 protein may similarly be allergenic.

One characteristic of Bt10 that is not shared with Bt11 is its antibiotic resistant marker (ARM) gene that codes for resistance to ampicillin. When this fact surfaced a week after the US government and Syngenta assured the world that the two varieties were identical, it drew anger and outrage. According to Nature, this is "a difference that most experts agree is of some significance." Failure to mention it was most certainly pre-meditated.

Antibiotic Resistant Markers May Create Super Diseases

The use of ARM genes is highly controversial. Practically every medical organization that has looked at GM crop safety has expressed concern, including the American Medical Association, World Health Organization, UK Royal Society, United Nations Food and Agriculture Organization, Pasteur Institute, European Food Safety Authority, and Codex Alimentarius. The British Medical Association even cited ARM genes as one of their reasons for proposing a ban of GM crops.

The fear is that ARM genes will transfer to pathogenic bacteria in the gut or environment and unintentionally create a super disease that is untreatable by antibiotics. Such hard-to-kill infectious bacteria are already a serious problem, exacerbated by the overuse of antibiotics in humans and animals According to the FDA website, such infections "increase risk of death, and are often associated with prolonged hospital stays, and sometimes complications. These might necessitate removing part of a ravaged lung, or replacing a damaged heart valve."

The first time the FDA looked at ARM genes, it was in response to plans by Calgene in the early 1990s to use one that was resistant to the medicine kanamycin, in their GM FlavrSavr tomato. The Division of Anti-Infective Drug Products was appalled. In a December 1992 memo that was later made public by am lawsuit, the division emphasized in all capital letters, "IT WOULD BE A SERIOUS HEALTH HAZARD TO INTRODUCE A GENE THAT CODES FOR ANTI-BIOTIC RESISTANCE INTO THE NORMAL FLORA OF THE GENERAL POPULATION." After presenting this to their superiors at the agency, the division director sent it to a colleague with a cover letter that said, "The Division comes down fairly squarely against the [kanamycin] gene marker in the genetically engineered tomatoes. I know this could have serious ramifications." For emphasis, his letter was entitled, "The tomatoes that will eat Akron."

This was a period of time, however, where concerns by FDA scientists about genetically engineered products were routinely ignored by the agency's political appointees, who had been mandated by the White House to promote the biotech industry (see Seeds of Deception, chapters 3, 4, and 5). The FDA had even created a special position for Michael Taylor, a former outside attorney for Monsanto and later their vice president, to oversee US policy development. Thus, in spite of their scientists' concerns, and in spite of the fact that other less risky but more expensive methods were available, the FDA allowed the use of ARM genes. Their website claims, "It is highly unlikely that antibiotic resistance genes could be transferred from plant genomes to gut microorganisms." They had accepted industry assurances that DNA was destroyed during digestion and gene transfer was therefore not a problem. The only human feeding study on GM crops ever conducted, published in February 2004, overturned this baseless assumption. Not only did altered genes in GM soy survive digestion, they spontaneously transferred into the DNA of gut bacteria in human subjects. No one has yet commissioned a study to see if ARM genes also transfer.

The FDA does not entirely deny the possibility that ARM genes might create super diseases by rendering antibiotics powerless. They acknowledge, therefore, that ARM genes would be more risky if they threatened the use of popular and important antibiotics. Since kanamycin is not used much by doctors anymore, they reasoned that it wouldn't be too dangerous if kanamycin ARM genes were used. Most of the GM crops on the market today use Kanamycin resistant genes. But ampicillin is widely used; it is the drug of choice for several types of infections. If an ARM gene promoted ampicillin-resistant infections, it would be serious.

While the FDA simply discusses risks associated with gene altered crops, it does not establish any requirements for the biotech industry, just voluntary guidelines. In Europe, they are not so feeble. In April 2004, the European Food Safety Authority declared that ampicillin resistant marker genes "should be restricted to field trials and not be present in genetically modified plants placed on the market." At that time, about 79,000 acres of GM corn were planted in Spain-the only EU country growing GM crops commercially. About two thirds of the corn was a variety that used an ampicillin marker. The government promptly banned it, setting back the biotech industry's small foothold in Europe. The significance of this was certainly not lost on Syngenta.

It was their corn variety Bt176 that was banned.

Despite Syngenta's intimate knowledge of Europe's disdain for ampicillin-resistant markers, and despite the fact that an estimated 1000 tons of Bt10 was shipped to the EU from 2001-2004, and that batches of the Bt10 were also mistakenly sent to France and Spain "for research purposes," the company and the US government left out the fact that Bt10 contains an ampicillin-resistant gene. When challenged on this omission by the journal Nature, a Syngenta spokesperson offered, "it wasn't relevant to the health and safety discussion." According to a USDA official, Syngenta similarly did not inform the US government about the contentious ampicillin issue when they first reported the contamination in December 2004. The information came out sometime over the following months.

It is telling that Syngenta, a Swiss company that was responsible for illegal GM varieties entering the EU, reported the contamination to US authorities but not to the Europeans. Likewise, the US government also withheld the information from their EU counterparts. According to the German publication Spiegal, "The nonchalant behavior of the Americans infuriated the environmental protection authorities in Brussels and Berlin more than anything else."

On April 15, the EU Commission voted overwhelmingly to enact "emergency measures. . . in order to achieve the high level of health protection chosen in the Community." Since imports of food-grade GM corn has been virtually nil for years, the commission placed restrictions on the corn products from the US that are used for animal feed-corn gluten meal and brewers grain. The US had shipped 3.5 million tons of this to the EU in 2004 for about $450 million. But all shipments were halted by April 17, when they were required to be certified free of Bt10.

Japanese authorities have not yet ruled on whether they will also require certification of US corn imports, but many Japanese buyers have already delayed their purchases from the US or switched to non-U.S. sources, especially for food grade. Japan is the biggest foreign market for US corn, importing approximately 4.4 million tons for food and 12 million tons for feed. South Korea, the sixth largest importer of US grain, has also discussed the possibility of requiring tests.

According to Spiegel, "In addition to the ban on feed, the US faces recalls, actions for liability and above all enormous damage to the image of US corn." The German publication said that the cost of the Bt10 contamination could be much higher than the $1 billion price tag for StarLink, "especially if until-now lethargic US consumers begin to question the safety of genetically modified varieties of grain." StarLink was another unapproved GM corn discovered in the food supply in 2000.

The editors of Nature have urged European regulators to "pursue their own investigation," since "their US equivalents show little sign of rising to the challenge." Friends of the Earth, the Third World Network and others, demand that Syngenta pay for the costs of testing their products. , And everyone appears to be calling for Syngenta to provide their safety studies, molecular characterization, genetic profile, and complete history of the planting and shipments of Bt10. They have not been forthcoming. This is not the first time Syngenta was unresponsive to government and consumer demands.

In 2000, they imported an illegal corn variety into New Zealand and, according to member of parliament Jeanette Fitzsimons, "refused to allow our Parliament to see lab records or talk to the company who did the testing that showed Bt contamination." She said. "Syngenta has developed a reputation for thinking it is above the law, and for refusing to provide regulatory bodies with information that is needed to assess whether its activities are in the public interest."

Syngenta is one of the five agricultural biotech companies and the world's largest agro-chemical company. Their sales were $6.6 billion last year. They settled with the US for the Bt10 contamination by agreeing to pay a fine of $375,000 and to "teach its employees the importance of complying with all rules."

Both a Syngenta representative and a USDAm spokesperson claimed that since Syngenta promptly reported the contamination to the government as soon it was discovered, it shows "that the system is working." ,

With that criterion, the system also appears to be working in China,

where it was revealed on April 13, 2005 that about 1,000 tons of unapproved GM rice were sold locally and possibly shipped worldwide. Let's hope the system doesn't work quite so well for Ventria. The company has requested a permit from the USDA to plant rice in Missouri that is genetically engineered with human genes in order to createpharmaceutical drugs.

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