

By Carolyn Raffensperger

Reg Chaos Seen In Biotech Corn Error

In September, the Food and Drug Administration recalled taco shells that contained genetically engineered corn approved only for animal use. The mistake was discovered by Friends of the Earth, which had hired a laboratory to test the shells.

How did the wrong corn get into tacos, and why didn't the FDA discover it? But more important, how are we regulating genetically engineered crops, and why isn't it working?

The answers to these questions provide a disturbing glimpse into a food and agriculture system on the verge of chaos as it confronts the fruits of genetic engineering. It is a sobering demonstration of how far biotechnology has outstripped the regulatory system.

StarLink, the brand name of the corn, was not approved for human consumption because it contains a protein, Cry9C, that was engineered into the corn to repel pests. This protein may be allergenic in people. Because allergies are person-specific some people are allergic to certain substances, some people are not; it is difficult to predict what proteins will induce allergies or to develop tests for allergenicity. There is, however, an allergen screen. Food allergens generally have two characteristics: they are insoluble in gastric juices and they are heat stable. This screen doesn't prove that something is allergenic; it only indicates whether it is more likely than not to be an allergen.

Cry9C comes from *Bacillus thuringiensis*, the famous Bt, a naturally occurring pesticide found in soil and frequently used in agriculture, particularly by organic farmers. StarLink corn

was the first of eight crops genetically engineered to produce Bt that failed this screen. Thus, the FDA banned it for human consumption.

Food crops that have been genetically engineered to produce their own Bt, most commonly soy beans, corn, and potatoes, have been at the center of numerous scientific and ethical debates about biotechnology. Biopesticides have been used for years as a spray applied to foliage, especially by organic farmers. But when produced through genetic engineering, Bt, instead of being applied to the exterior of plants, is expressed in every cell, and becomes part of the food. Thus the fear of allergies and other health problems from eating something that is not normally integral to food.

Then there is the problem that Bt crops could create for organic agriculture. Early in the regulatory discussion about whether Bt crops should be approved, entomologists pointed out that the nature of biological systems is that pests become resistant to pesticides when they are used frequently and indiscriminately. This means that Bt, if introduced wholesale into crops, would quickly become useless. Organic farmers in particular would be hurt, as would their customers.

Even more contentiously, because Bt is also expressed in pollen, which drifts with the wind, some inconclusive studies have suggested a risk to Monarch butterflies that feed on milkweed plants that can get dusted with Bt pollen. These studies have raised concerns and are at the heart of a raging debate.

Bt pollen can drift to neighboring crops as well. Because pollen is part of the mating system of plants, the drift contaminates the genetic material of other, different strains of corn planted nearby. While it is not clear how the nonapproved corn got into the mill that processed the taco shells, it may be that genetic drift was at fault. It may also have been a result of failing to segregate the corn throughout the process chain of harvesting, storing, shipping, and milling. Either way, the case demonstrates the difficulty of separating animal feed from commodities destined for human consumption.

Another level of confusion is added by the fact that genetically modified

crops are regulated by three federal agencies. The Department of Agriculture regulates the ecological safety of biotech plants and potential plant pesticides. In the case of plant pesticides — Bt in corn is one — EPA sets tolerances for the amount of the pesticide present in food for humans. FDA enforces EPA's pesticide limits and otherwise regulates the safety of genetically engineered plants intended for human or animal food. StarLink corn is the only variety that EPA has prohibited for humans and so is the only variety of edible genetically engineered Bt over which FDA has primary authority.

FDA's regulatory authority is derived from the Federal Food, Drug, and Cosmetic Act. In 1992, FDA issued its policy on genetically engineered foods, which says they are subject to regulation if they contain substances that are significantly different in structure, function, or quantity from non-engineered foods. Because Bt corn is composed of Bt, which is approved as a foliar spray, and corn, which is approved as a standard food, it is not considered significantly different and does not generally require pre-market approval by FDA.

Nevertheless, because StarLink failed the allergenicity screen, EPA prohibited it as food. However, EPA chose to approve StarLink for animal feed. Given the global industrial agricultural system, it was predictable that a nonapproved crop would get mixed in with approved crops.

The question is what should be done. Monsanto, Kraft, and other biotech companies are arguing that if a crop is not approved for humans, it should not be grown. This makes perfect sense. But until our understanding of the ecological impacts and the science of allergenicity and other potential human health impacts improves, and until we have a regulatory system that can handle the onslaught of innovation, the question is really whether we shouldn't have a moratorium on all genetically engineered crops. StarLink corn is likely just the first rotten apple to be discovered in the barrel.

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