

## **Trouble Down on the Biopharm** *by Thomas O. McGarity*

How would you react to learning that the juicy ear of corn you just had for dinner also delivered a hefty dose of a highly active growth hormone or a potent blood-thinning agent? The prospect is not so remote as it might seem. The U.S. Department of Agriculture (USDA) has just announced that it will tighten its requirements for certain genetically modified plants and increase its field inspections to avoid just that scenario.

Unfortunately, the regulatory program USDA administers is so shrouded in secrecy that it is impossible to know whether the modest changes it is proposing will adequately protect the public from the risk of encountering hidden pharmaceutical and industrial chemicals in commonly consumed vegetables like corn. And what we do know about the rapidly emerging industry of "biopharming" is not especially reassuring.

Several years ago, USDA began quietly issuing permits for "field tests" of plants, mostly corn, that had been genetically modified to produce valuable biological products and industrial chemicals. Agricultural biotechnology companies, like Monsanto Protein Technologies and Dow Agrosciences, plan to harvest the plants not for food, but for the novel chemicals they can extract from them. It turns out that it should be a lot cheaper to make some rare biologically active chemicals by genetically engineering plants than by culturing mammalian cells in traditional bioreactors.

What do we know about these new drug manufacturing facilities that look just like a corn plant? Sadly, the answer is that the public cannot find out how much the companies and USDA know about the potential risks of biopharming, because virtually all of the relevant information is deemed confidential business information and therefore not disclosed to the public. Alluding to the secrecy currently surrounding field tests of new biopharming technologies, Dr. Jane Rissler of the Union of Concerned Scientists says: "we don't know what's being done, we don't know where it's being done, we don't know how much of it is being done."

This veil of secrecy is especially troubling in light of recent experience with genetically modified crops. In the autumn of 2000, the Food and Drug Administration discovered that the nation's food supply had become contaminated with Cry9C, a pesticidal protein inserted into Starlink® corn by Aventis CropScience Company. Aventis spent hundreds of millions of dollars buying back corn that was potentially laced with Starlink because EPA had never granted permission for it to enter the food supply. It got into food because farmers planted it too close to conventional corn and because farmers and grain distributors failed to take adequate precautions to segregate Starlink corn from food corn.

Undaunted, the biotechnology companies now assure us that there is no reason for concern. The Biotechnology Industry Organization, an industry trade association, has developed "detailed guidelines" to prevent grain from biopharmed corn from entering the

food supply, they point out. But given the Starlink experience, it's hard to take much comfort in their assurances that the guidelines will protect us from inadvertent exposure to chemicals and pharmaceuticals in our food.

If the industry, itself, cannot be trusted to come up with an airtight stewardship program, we should be able to look to the government. But Starlink was a heavily regulated commodity, and it wound up in the food supply. This suggests that the government cannot be trusted to regulate the powerful biotechnology industry when it is aligned with politically potent agricultural interests. As both the promoter and regulator of agricultural biotechnology, USDA has a classic institutional conflict of interest when it comes to regulating biopharming.

The proof that the current heavily shrouded regulatory approach will not work is the discovery last November of the presence in harvested soybeans of corn that had been genetically modified to produce a pig vaccine. Although the soybeans were quarantined before being processed into food, the incident clearly demonstrated that we cannot rely upon the goodwill biotechnology companies and the oversight of a conflicted governmental agency to protect our food from what may next time become a chemical nightmare.

The simpler answer is to limit biopharming to plants that are not used for food. The industry is reluctant to do that because it has years of experience with corn already under its belt. But so long as industry uses food crops as biotech labs, the danger of unwelcome mixing will be with us. In the meantime, the federal government must do a much better job of regulating the industry. That begins with stripping away the unnecessary shroud of secrecy.

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The author is professor of law at the University of Texas School of Law and president of the Center for Progressive Regulation.