Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

Briefing Paper:

Food Safety Assessments Won't Quell Consumer Fears About "Safe" Levels of Drugs in Food

August 2008

The U.S. Department of Agriculture (USDA) is in the process of revamping its regulation of genetically engineered (GE) plants and other organisms. As part of this process, the department is considering significant changes to the rules governing food crops engineered to produce pharmaceutical and industrial substances. When grown outdoors, these "pharma" crops threaten to contaminate the U.S. food supply through cross-pollination or seed mixing, with potential negative impacts on public health and consumer confidence. Nearly 100 environmental, agricultural, health, and consumer organizations and thousands of individual consumers have urged the USDA to ban the outdoor production of pharma food crops. Several major food companies and the Grocery Manufacturers Association—concerned about possible damage to food brands from a contamination incident—also have called for a ban.

At the same time, however, the USDA and some in the food industry have suggested that the damage from future contamination incidents could be ameliorated, short of a ban, if food safety considerations were added to the department's existing pharma crop permitting process. Under this approach, the USDA would allow pharmaceutical or industrial compounds from GE pharma crops in the nation's food supply at so-called "safe" or "acceptable" levels, as determined by food safety assessments.

With this paper, the Union of Concerned Scientists (UCS) evaluates the approach proposed by the USDA—that an outright ban is not necessary if food risk is assessed and confinement measures are adopted commensurate with risk.

Current Pharma Crop Oversight Is Lax

Since the early 1990s, the USDA has allowed biotechnology companies to grow food crops including corn, rice, and safflower genetically engineered to produce a variety of drugs and industrial chemicals. These crops are grown outdoors (often in food-producing areas) under USDA permits. The department's current regulations spell out a permitting and oversight program involving the issuance of annual permits setting growing conditions and confinement measures, regular inspection of pharma fields by USDA personnel, and self reporting by permit holders.[1] However, the USDA's Inspector General concluded in 2005 that elements of this program, as well as the department's oversight and follow through, were lax.[2] USDA documents subsequently obtained by UCS revealed continued shortcomings.[3] UCS has concluded that current USDA regulations and procedures for pharma crops are inadequate to ensure the safety of the food supply in the United States.

Contamination Incidents Illustrate Risk to Food Supply

This conclusion has been further borne out by a string of incidents of food contamination involving pharma crops and other experimental GE crops that were not approved for food use. In 2000, the news that taco shells and other food products were contaminated with StarLink corn, an unapproved and potentially allergenic GE variety, panicked consumers and ultimately led to efforts to remove the contaminant from the food supply, at a cost of hundreds of millions of dollars.[4] Two years later, a company called Prodigene allowed its pharma corn, containing a pig vaccine, to contaminate 500,000 bushels of soybeans destined for food and feed products.[5] And over a six-month period in 2006–2007, the USDA announced that two different unapproved GE rice varieties had mysteriously contaminated U.S. long grain rice stocks, resulting in the closure of export markets to U.S. rice growers.[6] These incidents illustrate the very real likelihood for drug-producing crops to end up in the food supply, with potentially costly consequences.

USDA Is Preparing New Pharma Crop Rules

In July 2007, the USDA published a draft environmental impact statement (DEIS) presenting options for revising various aspects of its existing biotechnology regulations, which cover pharma crops as well as crops genetically engineered for insect and herbicide resistance.[7] In the DEIS, the USDA proposed five alternatives for addressing oversight of pharma crops specifically. Alternative 1 would continue the current regulatory program for pharma crops. Two alternatives proposed bans: Alternative 3 would ban all outdoor production of pharma crops while Alternative 4 would ban the outdoor use of food and feed crops for pharma production. UCS supports Alternative 4.

The remaining two regulatory options (which we refer to as "food safety regulatory options") would each allow food crops to continue to be used outdoors as pharma crops, but with additional provisions aimed at allaying food safety concerns.

The USDA DEIS describes these options as follows:

> ***Alternative 2***—Continue to allow food and feed crops to be used for the production of pharmaceutical and industrial compounds. The agency would impose confinement requirements, as appropriate, based on the risk posed by the organism and *would consider food safety in setting conditions* (emphasis added).
>
> ***Alternative 5***—Allow field testing of food/feed crops producing substances not intended for food uses *only if food safety has been addressed* (emphasis added).

Department's Preferred Option "Tweaks" the Status Quo

The USDA indicated in the DEIS that it prefers Alternative 2 among the five regulatory options. With this preferred alternative, the department would essentially continue its existing oversight of GE pharma/industrial crops with some ill-defined consideration of food safety in setting standards. The status quo, as noted above, is insufficient to protect the public health, the environment, and the economic interests of farmers, food companies, and commodity exporters. Moreover, the DEIS offered no details on how food safety would be addressed under either alternative, and the department has been unwilling to share any such details in subsequent meetings with UCS scientists.

USDA Plans to Propose New Rules Summer 2008

In response to its DEIS, the USDA received a large number of comments from consumer and environmental organizations, scientists, the food industry, and members of the public. Most of the comments called for a ban alternative to minimize the potential for contamination of the food supply by pharma crops. Based on the DEIS and the subsequent public comment, the department is preparing to propose new rules on pharma crops. The USDA has said it intends to publish the proposed rules for public comment during the summer of 2008 and finalize the rules by the end of 2008.

The Fallacy of a "Food Safety" Approach for Pharma Crops

Whatever the details of the food safety assessment, the USDA's adoption of a food safety regulatory option would ultimately result in the presence of some pharmaceutical or industrial compounds from GE pharma crops in the nation's food supply. The department would allow these compounds at so-called safe or acceptable levels, as determined under the food safety evaluations.

So what's wrong with this approach?

Consumers Will Not Accept "Safe Drugs" in Their Food

Public response to the discovery of a drug in food could have enormously disruptive effects regardless of the substance's effects or the levels at which it is found, as demonstrated by the StarLink incident, noted above.

Contamination of food by drugs poses especially large risks to retail food companies. Consumers who unwittingly ingest pharma products in foods are likely to direct their ire—and their lawsuits—against the companies that manufactured and sold the food. Apart from any legal liability, the publicity associated with such incidents could severely damage valuable brands. Purveyors of organic food products are at special risk because many consumers expect organic food to be free of all engineered genetic sequences and products, not just pharmaceuticals.

Importantly, contamination can have negative economic consequences even if the substances involved do not cause demonstrable harm to consumers or are present below legal tolerances. For many consumers, the publicity surrounding the discovery of any amount of drugs in a well-known brand of breakfast cereal would be reason enough to turn toward competitors' products. Such changes in consumer preferences can cost food companies millions of dollars.

Consumers simply will not accept a government program that sanctions drugs in the food system. The idea that adding some sort of food safety review to the current system would make the inevitable contamination event more palatable to the public is illusory. The notion that "safe drugs" will be acceptable in breakfast flakes or exports is naïve. Consumers whether here or elsewhere in the world will react negatively to the presence of drugs or plastics in retail or commodity foods. The availability of a food safety review for the drug will not dampen the outrage.

A Regulatory System Establishing Safe or Acceptable Levels for Pharma Crop Contaminants Would Be a Waste of Resources

A policy of reducing pharma contamination to acceptable levels would require a new regulatory system to evaluate substances and establish tolerance levels designed to protect public health. Such a system, processing hundreds or even thousands of applications for pharma and industrial chemicals, would be expensive to set up and operate. It would require scientifically trained professionals to conduct food safety evaluations and other personnel to enforce requirements once they are set. This expenditure of professional and other resources is not justified considering that none of the substances are intended for food use in the first place. It would be much more efficient to set up a system that prevents contamination completely.

Public Fears Would Not Be Assuaged by Imperfect Risk Assessments

Even if the government did set up an expensive new regulatory system, the public might still lack confidence that the approved levels of pharma compounds did not threaten its health. The regulatory evaluations of compounds would be based on risk assessment, an imperfect science dependent on what is known about the chemical activity and toxicity of substances, the degree to which they are in active or inactive form, and whether there are thresholds below which they are not harmful. Accurate assessment, therefore, requires an understanding of the connections between chemicals and a variety of disease or health-related end points. This understanding is incomplete at best.

In short, risk assessment science is not sufficiently robust to guarantee that all harmful chemicals will be screened from the food supply. In many cases, society must accept risk assessment as the best that can be done to inform regulatory decisions about chemical substances. That argument does not apply in this case.

Even the best food safety assessments will not protect the food industry from domestic economic and trade impacts of a future pharma crop contamination incident.

Furthermore, the USDA did not spell out in its DEIS who would perform food safety assessments under its preferred alternative. Presumably, either the USDA or the Food and Drug Administration (FDA) would conduct food safety reviews, but both agencies have drawbacks.

The USDA has neither the experience nor the expertise to conduct food safety reviews. Furthermore, even where the department does have expertise—in the area of environmental assessments of GE crops—it recently has produced assessments that federal courts have found to be lacking in rigor.

The USDA's failure to even mention a critical Australian study[8] in its DEIS discussion of GE food risks also suggests that the department may not be up to the challenge. This study, which resulted in Australia's national science

agency's abandoning a product that had been under development for 10 years, is a seminal paper in this field. Its major finding, that non-immunogenic crops can be converted into immunogens as a result of genetic engineering, has implications for every GE food crop and should have been discussed by the USDA. The paper also offers an animal test that might be useful to regulators assessing the potential of engineered crops to act as food allergens. This is a major omission in view of the admitted lack of predictive tests for food allergens.

One cannot reasonably expect the USDA to produce scientifically rigorous food safety assessments of pharma crops.

If the FDA were to undertake pharma crop food safety reviews, the picture would not be much more reassuring. While the agency has some experience with GE food crops, it has yet to establish a strong, mandatory approval system; its current reviews are voluntary and opaque (because confidential business information is withheld from the public).

Some in the food industry have suggested that a food safety regulatory option would protect the food supply if the FDA were to conduct pharma crop assessments consistent with the principles put forward by the intergovernmental Codex Alimentarius. These principles include the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants"[9] and "Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-Level Presence of Recombinant-DNA Plant Material."[10]

The Codex guidelines, however, are much more rigorous and call for the submission of far more data than FDA currently receives under its GE food oversight program. As a result, we doubt that the agency would even consider establishing a pharma crop regulatory program patterned after Codex. Moreover, we expect that the biotechnology industry would vigorously oppose any attempt to apply a Codex-like system to any segment of its industry, including pharma crops.

Conclusion—the USDA Should Adopt a Pharma Food Crop Ban

In summary, UCS believes that a food safety regulatory option is an inappropriate response to the real threat of food contamination with drug and chemical-producing crops. Using food safety assessments to determine the stringency of pharma crop confinement measures will neither reassure the public of the safety of the food supply nor eliminate the substantial risks to the food industry. Instead, UCS advocates complete contamination prevention—a ban rather than a system of tolerances that would allow contamination to occur. A ban on the outdoor production of pharma food crops (USDA's DEIS Alternative 4) is the only sure way to protect the public's health, the food industry, and export markets from pharma crop contamination of the food supply.

The USDA should therefore reject the false security of a food safety regulatory option and institute an outright ban on the outdoor use of pharma food crops.

[1] USDA Animal and Plant Health Inspection Service (APHIS). 2006. Draft Guidance for APHIS Permits for Field Testing or Movement of Organisms with Pharmaceutical or Industrial Intent. March 31. Online at *www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf.*
[2] USDA Office of Inspector General. 2005. Audit report: Animal and Plant Health Inspection Service Controls over Issuance of Genetically Engineered Organism Release Permits. Audit 50601-8-Te, December. Online at *www.usda.gov/oig/webdocs/50601-08-TE.pdf.*
[3] Union of Concerned Scientists (UCS). No date. UCS Uncovers Lax USDA Oversight of Pharma Crops. *Online at www.ucsusa.org/food_and_environment/genetic_engineering/usda-ventria-oversight.html.*
[4] Lambrecht, B. 2001. *Dinner at the New Gene Café.* New York: St. Martin's Press, pp. 52-55.
[5] Gillis, J. 2002. "Soybeans Mixed with Altered Corn." *The Washington Post*, November 13.
[6] Weiss, R. 2007. "Rice Industry Troubled by Genetic Contamination." *The Washington Post*, March 11.
[7] USDA APHIS. 2007. *Introduction of Genetically Engineered Organisms*. Draft Programmatic Environmental Impact Statement, July. Online at *www.aphis.usda.gov/brs/pdf/complete_eis.pdf*.
[8] Prescott, V.E., et al. 2005. Transgenic expression of bean α-amylase inhibitor in peas results in altered structure and immunogenicity. *Journal of Agriculture and Food Chemistry* 53:9023-9030.
[9] Codex Alimentarius. 2003. "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants." Online at *www.codexalimentarius.net/download/standards/10021/CXG_045e.pdf.*
[10] Codex Alimentarius. 2008. "Proposed Draft Annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants on Low-Level Presence of Recombinant-DNA Plant Material." Online at *www.codexalimentarius.net/download/report/693/al31_34e.pdf*. The proposed draft was adopted at the summer 2008 Codex Alimentarius Commission meeting. See *ftp://ftp.fao.org/codex/Alinorm08/al31REP_adv.pdf*, paragraphs 59-61.

For more information about pharma and industrial crops, and to sign on to a petition to the USDA, visit www.ProtectOurFood.org

Take the **harm** out of p**harm**a and industrial crops.