Union of Concerned Scientists
Skip to main content

a campaign to
Take the Harm Out of Pharma and Industrial Crops

PROTECT OUR FOOD CAMPAIGN
> Sign the USDA Petition
> Background Information
> UCS Position Paper
> Position Paper Q&A
> Protect Our Food Home
> F & E Home

UCS FEEDBACK TO GOVERNMENT AGENCIES
> Proposed Regulation of GE Organisms, June 2009
> Proposed Regulation of GE Organisms, November 2008
> Syngenta Ethanol Corn
> USDA Environmental Impact Statement
> Kansas Pharma Rice
> Washington Pharma Safflower

RELATED FEATURES
> Sensible Pharma Crops Slideshow
> Pharma/Industrial Crops in Your State
> Pharma/Industrial Crop Substances
> How Can Contamination Occur?
> Commercial Pharma Crop Products
> "Safe" Levels of Drugs in Food?

RELATED UCS REPORTS
> The Economics of Pharmaceutical Crops
> A Growing Concern

NEWS
> USDA Proposed Changes to GE Oversight
> Rice Report Shows Contamination Risk
> Food Industry on Pharma/Industrial Crops
> Companies Ramp up Pharma Production
> Lax Oversight of Pharma/Industrial Crops

Questions and Answers about the Union of Concerned Scientists' Proposed R on Outdoor Use of Pharma/Industrial Food and Feed Crops

1. How would a ban on the outdoor cultivation of food crops engineered for pharma/industrial purposes affect American consumers?

A ban on outdoor production of genetically engineered (GE) pharma/industrial food feed crops would greatly increase consumer confidence in the safety of the food su because it would drastically reduce the likelihood of pharmaceutical and industrial compounds showing up in food. To date, the U.S. Department of Agriculture's (USDA's) regulations are simply not strong enough to assure consumers that the numerous routes by which pharmaceutical and industrial crop products could make their way into food crops have been blocked.

2. Wouldn't a ban take valuable drugs and other chemicals off the market?

No. The ban would not require that already approved products be taken off the mar In any case, there are only a few products on the market that would be covered by ban. All are research chemicals or industrial oils; none is a drug. Several plant-mad

pharmaceuticals are reportedly undergoing clinical trials, which are necessary befo new drug is approved by the Food and Drug Administration (FDA). There are a few other plant-made industrial chemicals and special dietary ingredients, including a biofuels enzyme and a medical food, which are moving toward commercialization. Under the ban, all such plant-made compounds not yet commercialized would have their commercialization halted.

3. Will a ban deny patients a flow of inexpensive drugs in the future?

This seems unlikely. In many ways, the prospects for plant-made pharmaceuticals a not as commercially attractive as their proponents claim. Although crop-based syste have some advantages (for example, the ease of scaling production up or down) th theoretically could lower drug production costs, other features of the system, includ technical challenges and regulatory costs, offset those advantages. This may accou for the fact that after 15 years of research and development, not a single plant-produced drug has received the FDA's approval, and none is even nearing that stag In addition, production costs are typically a minor component of drug prices, and savings tend not to be passed on to consumers.

To the extent that the benefits from using engineered plants or plant cells to produc needed drugs prove to be commercially attractive, we believe they can be achieved alternative systems, such as outdoor production of GE non-food crops, enclosed production of GE plant cells, fungi, bacteria, and algae. That's why we're asking the USDA to provide support for the development of such safer alternatives.

4. Will a federal ban be costly to implement?

No, not compared with the resources that the USDA is currently expending to monit and inspect pharma/industrial crop production and enforce its regulations. With a simple ban on outdoor production of pharma/industrial food crops in place, these resources could be diverted to other uses. However, the USDA would have to strengthen its risk assessment process and develop confinement systems for the us of non-food crops.

5. Would the biotech industry be affected?

No. Most large biotechnology and pharmaceutical companies have shown little inte in pharma/industrial crop production. The set of small companies currently focused exclusively on the use of food crops as pharma/industrial crops would be set back, biotech companies developing plant cells as alternatives to whole plant crops would not be covered by the ban and might even benefit by being able to attract a greater share of venture capital.

6. How will other industries be affected by the ban?

Chemical industries. Chemical-based industries (for example, paper, plastics, lubricants, leather tanning) and the mining/mineral recovery industry will most likely unaffected, as we have seen no indication that any group of manufacturers/process was looking to pharma/industrial food crops as a significant source of important chemicals. Some industries may have used trypsin and maybe one or two other products from pharma/industrial food crops, but the impacts on these companies ar not likely to be significant. The same is true for suppliers and users of chemicals for research purposes.

Phytoremediation industry. Under our approach, phytoremediation (a process that u living plants to remove toxic metals from polluted soils) is considered a kind of mine recovery (as it is in the USDA's March 2006 Draft Guidance for APHIS Permits for Field Testing or Movement of Organisms with Pharmaceutical or Industrial Intent), a the use of food crops for this purpose would be covered by the ban. So far, howeve the infant phytoremediation industry appears to be primarily using non-food crops s as poplar and tobacco. According to the USDA's website, the only food crop that ha been engineered and field tested for phytoremediation is a Brassica known as brow mustard or Indian mustard.

Specialty food industries. Industries producing food additives, infant formulas, medi foods, and dietary supplements are unlikely to be affected, as it does not appear th any of these industries is looking to pharma/industrial food crops as a significant source of important ingredients. So far, lactoferrin, lysozyme, and brazzein appear t be the only compounds produced in pharma/industrial food crops that might be

destined for these markets. For lactoferrin, at least, a closed-system alternative is already available.

7. Isn't GE corn critical to the development of biofuels to replace fossil fuels?

Not so far. Biofuels based on corn, soybeans, or other biological materials are increasingly discussed as solutions to the problems of high gasoline prices, global warming, and geopolitical tensions. But like the production of pharmaceuticals and other industrial chemicals in plants, the large-scale development of agricultural biofi poses a raft of technical and policy challenges.

The role of genetic engineering in biofuel production is not clear. Its most promising use right now appears to be manufacturing new enzymes for use in the production so-called cellulosic ethanol. Cellulosic ethanol is made from biomass feed stocks—such as corn stover or rice straw—that are converted to ethanol through a complex multi-step biochemical process. The process is facilitated by enzymes capable of working under extreme conditions of acidity and heat, and GE microorganisms are attractive way to produce such enzymes.

The engineering of biofuel crops themselves is at very early stages, and whether th will be important in enhancing the usefulness of crops for fuel or energy purposes is unknown. Much more work is needed to determine what modifications are valuable whether they can achieved through conventional breeding, perhaps augmented by information coming out of genomics programs. Although we are not aware of any su products, we would be very wary of GE crops to modify basic carbohydrate or lignir metabolism.

If genetic engineering of food crops for energy purposes does go forward, the acrea needed will be so large that contamination of the food and feed supply will be inevitable. We think our proposed ban is a good way to encourage the developmen non-food-crop alternatives such as switchgrass (either conventionally bred or perha genetically engineered) for energy use. In so doing, this ban will potentially preserv piece of the U.S. Corn Belt for safe production of food and feed corn, which might b lost if corn engineered for energy purposes were commercialized on a large scale.

8. How will the food industry benefit from this ban?

The Grocery Manufacturers Association and the Food Products Association, which represent the nation's largest food companies, have already indicated their grave concerns about the potential for pharma/industrial crop contamination of food produ A ban on food crops as pharma/industrial crops would offer food companies a high degree of protection against contamination events, damage to their brands, and liability.

9. Won't a ban on pharma/industrial crops take value-added crop opportunitie away from farmers, grain distributors, and the seed industry?

No. There is little assurance that farmers would share appreciably in any profits this industry may reap. A recent analysis commissioned by UCS, The Economics of Pharmaceutical Crops, concluded that the relatively small acreages that would be required for most products would lead to intense competition to grow pharma/indust crops, driving down the prices farmers could expect. Thus, farmers are not likely to suffer from a ban, but instead, the ban will benefit conventional and organic growers grain handlers, exporters, and seed companies by significantly reducing the likeliho of contamination events that could have huge adverse impacts on them.

10. A ban is an extreme solution, isn't it? Aren't there other regulatory approaches that would work better?

There are approaches that would establish new regulatory regimes for GE crops intended as pharmaceutical or industrial crops. One idea is for the FDA to establish new policy to subject all plant-made substances to existing federal food laws and ensure that they meet standards for food safety. Implementing such an approach would require the evaluation of the risks of various substances to human (or animal health and the establishment of acceptable levels, or "tolerances," for these substances in the food supply. Although we believe that some novel pharmaceutica and industrial compounds probably could be safely consumed if their levels in the fo supply were kept low, we don't favor this approach because it would unnecessarily consume regulatory resources evaluating substances never intended for the food

supply, and because of the difficulty of enforcing the tolerances.

In addition, because an FDA safety assessment would not be required until crops w ready to be commercialized, this approach would allow unfettered, multi-year, open field-testing of pharma and industrial crops, with many opportunities for food-supply contamination.

11. Ok then, why not ban outdoor production of all pharma/industrial crops—just food crops?

UCS, consumer groups, the public, and food companies can all agree that food cro with pharma/industrial transgenes pose the most direct and obvious threat to commercial food crops. Therefore, a ban restricted to outdoor cultivation of food crc would focus a highly effective solution on the crops that pose the risks of greatest concern to the most stakeholders. Including non-food crops under the ban would of additional protection since non-food crops could contaminate the food supply, but th likelihood of contamination is much smaller.

12. What about indoor production of food crops—doesn't that pose food safe risks as well?

Indoor (for example, greenhouse) production of engineered corn or soybeans is possible, but is unlikely to be done extensively because of the technical challenges expense involved. In general, in our view, the likely small scale of such operation ar the low risks of food system contamination (primarily via transportation) do not justi ban.

13. What about environmental risks? Why not also ban outdoor production of non-food pharma/industrial crops because they pose risks to the environmen

The potential harm to the environment from non-food pharma/industrial crops is certainly a concern. If these crops are grown out of doors, grazing wildlife, pollinato herbivorous insects, and soil microbes will be exposed to pharma/industrial compou that may have adverse effects. The crops could also outcross with wild and weedy relatives, perpetuating the pharma/industrial transgenes in nearby ecosystems. However, the risks of such outcomes are less certain than the risks of contaminatio the food supply by food or feed crops grown as pharma/industrial crops. We believe that our approach, which combines a ban on outdoor production in food crops with tightening of regulations on production in non-food crops, effectively eliminates the greatest risk—that is, contamination of the food supply—and will be supported by a broad array of stakeholders, from consumer advocates to the food industry.

14. How are conventionally bred and GE pharma/industrial food crops differer Couldn't the USDA regulate them all the same way?

The ban we are proposing is consistent with the current federal biotechnology regulatory framework, which recognizes that GE crops are inherently riskier than th conventionally bred counterparts and, accordingly, subjects them to more stringent oversight. Among the key distinctions between GE and conventionally bred crops a

Experience—Conventional breeding is a powerful tool that can be use by adjusting the levels and sequences of genes already in the gene poo While not completely without risks, conventional breeding has a long history of safe use, whereas GE technology poses far more uncertainty and is still relatively untested, with few peer-reviewed studies on food safety.

Volume—GE technology can be used to produce many crops with nov traits because of the ease of introducing genes for new compounds fro greater range of sources, whereas conventional breeding is restricted t the genes in the gene pool of the crop and its near relatives.

New risks—Because of the greater range of sources of new compound genetic engineering presents a greater likelihood that some of the new substances will be significantly different or present at significantly hig levels than compounds introduced by conventional breeding.

—By increasing the range of potential proteins that can be introduced into crops, genetic engineering also increases the potential for introducing new allergens.

—Genetic engineering has the potential to cause unintended, and perh harmful, effects because scientists cannot control the site in the plant genome where the new gene will be inserted.[1]

---

[1] For more on the differences, see: Food and Drug Administration. 2001. Proposed rule: Premark notice concerning bioengineered foods. Federal Register 66:4706-38, January 18.

Union of Concerned Scientists
National Headquarters
2 Brattle Square, Cambridge, MA 02238-9105