Executive Summary

In the spring of 2003, the Union of Concerned Scientists (UCS) convened an expert workshop on protecting the U.S. food and feed supply from contamination by crops genetically engineered to produce pharmaceuticals and industrial chemicals. The experts who participated in that workshop wrote the technical report A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops *independently of UCS, which developed policy recommendations based on its own analysis of this report.*

Below is the executive summary of the experts' report, followed by the executive summary of UCS's conclusions and policy recommendations.

TECHNICAL REPORT

AUTHORS: *David Andow, Henry Daniell, Paul Gepts, Kendall Lamkey, Emerson Nafziger, and Dennis Strayer*

Food crops, primarily corn, are currently being genetically engineered to produce pharmaceuticals and industrial chemicals. These crops are referred to as "pharma" crops when they produce drugs, hormones, and other therapeutic agents, and industrial crops when they produce compounds such as plastics for use in industry. Throughout our report, the term pharma crop is used to encompass both types.

While the commercial and health benefits of these crops could be substantial, there are risks to the food supply and the environment associated with their commercial production. Many pharma and industrial products could harm humans, livestock, or wildlife if ingested in active forms. Of the many possible risks associated with these products, this report focuses only on those related to contamination of the human food and animal feed supplies.

There are two major routes by which pharmaceutical and industrial transgenes can inadvertently contaminate commodity crops and, therefore, the food and feed supply. One of these is the physical mixing of seed—pharma seed can be inadvertently spilled or mixed during seed production, harvest, storage, transport, and handling. Contamination can occur by direct mixing of the crops in the growing year or potential future contamination from volunteer plants the following year. The other route is pollen, which contains the male reproductive cells necessary for the fertilization of plants and the production of seed. Pollen containing genes for the pharma product can pollinate commodity crops, leading to contamination during the growing year.

The Central Dilemma

The U.S. commodity corn and soybean production systems are structured to mix grain from many sources before it is ultimately used. Without substantial modification, such a system cannot protect the human food and animal feed supply systems from contamination by pharma crops.

This problem raises the fundamental dilemma associated with pharma crops. The compounds produced by genetically engineered pharma plants are expected to lead to useful products that would have beneficial effects on human or animal health. At the same time, these compounds can

contaminate the food supply and the environment, possibly resulting in detrimental health effects on humans or animals and putting food companies at risk for lost markets, legal liability, and brand damage.

We addressed this problem by answering the following question: Is it possible to design a system for producing pharma products in genetically engineered corn or soybean—two plants often used or proposed for pharma production in the United States—without contaminating human food or animal feed?

Virtually Zero Contamination

In determining how to maintain a food/feed supply without contamination by pharma and industrial crops, our report first addresses the meaning of the term "without contamination," then adopts the standard of *virtually* zero contamination (rejecting a zero contamination standard as impossible to attain). A virtually zero standard recognizes the impossibility of preventing contamination entirely.

By promoting a virtually zero contamination standard, we advocate for pharma crop production to be conducted in such a way that the likelihood of contamination would be so low as to be nearly zero. The adequacy of existing pharma crop confinement systems is assessed against this standard throughout the report.

Report Outline

A Growing Concern identifies the points at which commodity corn and soybean production—and therefore the U.S. food and feed system—could be contaminated by pharma crops.

Chapter 1 provides background material and defines the scope of the report. Chapter 2 describes the potential routes of contamination of non-pharma corn and soybean, concentrating on those related to pollen movement and seed mixing. Chapter 3 discusses various methods by which contamination could be blocked; these confinement measures are broadly classified as zoning, spatial separation, temporal separation, dedication of machinery and infrastructure, physical and biological confinement, and disallowing food and feed crops as pharma crops.

The report then addresses the three phases of corn and soybean production in depth, identifies points at which food/feed crops are vulnerable to contamination by pharma crops, and evaluates the confinement measures suggested in Chapter 3. Chapter 4 describes the seed production processes for both crops; Chapter 5 addresses on-farm production; and Chapter 6 examines post-harvest shipping, handling, and storage.

Chapter 7 briefly addresses the potential for using non-food/feed plants for pharma production, recognizing that a full examination of this topic is beyond the scope of this report. Chapter 8 synthesizes the report's major conclusions and makes recommendations.

Conclusions and Recommendations

The Current Corn and Soybean Production Process. Our report concludes that the current production process and production areas for corn and soybean cannot be used without substantial modification to ensure virtually zero contamination of the human food and animal feed supplies.

Recommendations:

- Eliminate as many steps as possible in each of the seed development, seed production, crop production, and handling, storage, and delivery operations.
- Develop corn and soybean production and management systems that will ensure virtually zero contamination of the food and feed supplies through collaboration between

industry, academia, and regulatory bodies. If broad-based consensus cannot be reached, it would be inadvisable to initiate further use of corn and soybean as pharma crops.

Future Prospects for Pharma Corn and Soybean. Theoretically, the goal of virtually zero contamination could be achieved using corn and soybean as pharma crops, but this would require such substantial changes in production practices, management systems, and oversight that a major effort will be required. Our conclusion is that the pharma crops system must be completely separate from the food/feed system. Specifically, although pharma corn and soybean could be grown either in geographically isolated regions of the country or embedded in areas of commodity crop production, both would require new production systems be put in place.

It would be possible to produce pharma crops in areas isolated from commodity crop production if geographic isolation zones and the necessary management and oversight can be established and maintained in a way that ensures virtually zero contamination of the food and feed supplies. Similarly, it would be possible to grow corn and soybean pharma crops embedded in the same areas as corn and soybean commodity production if appropriate management, spatial separation, and biological confinement can be developed, implemented, and enforced in a way that ensures virtually zero contamination of the food and feed supply.

An appropriate management and oversight system would involve considerable discipline and reproducibility in the production process, predetermined performance standards, documentation and auditing, and third-party monitoring and approval. Such a system and any associated biological confinement must also include redundancy and fail-safe mechanisms.

Recommendations:

- Develop the infrastructure and information needed to implement and maintain pharma crop production in areas geographically isolated from commodity crops. Specifically, synthesize studies of pollen flow, isolation, and crop production areas to determine whether further research is needed to establish the scientific basis for geographic isolation zones.
- Develop strategies that would allow individual growers or groups of growers to develop case-by-case plans for well-defined spatially separated production areas embedded within commodity production areas. These strategies would need to meet the specific management, separation, confinement, and oversight objectives outlined above.

Use of Non-Food/Feed Crops. Our report suggests that non-food/feed crops should be seriously considered as pharma crops in order to ensure virtually zero contamination of food and feed. However, additional safeguards will be necessary, including: confinement management systems and third-party oversight similar to that proposed for corn and soybean; barriers to pollen and seed gene flow (e.g., no wild relatives, low propagule viability, sterility); minimum production areas for the pharma crop; and limited acreage for the non-pharma crop.

Recommendations:

- Encourage research on non-food/feed crops as potential pharma crops.
- Develop the information and technology necessary for pharma crop production in non-food/feed crops as soon as possible to ensure virtually zero contamination of the

food/feed supply and enable pharma crop production to succeed. This may require some research incentives, as our genetic engineering expertise with other crops is not on the same level as corn and soybean.

CONCLUSIONS AND POLICY RECOMMENDATIONS OF THE UNION OF CONCERNED SCIENTISTS

AUTHORS: *Margaret Mellon and Jane Rissler*

UCS carefully reviewed the technical report *A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops* and developed its own conclusions and policy recommendations. We strongly agree with the experts' major conclusion that corn and soybean cannot be used for pharma crop production without major changes designed to protect our food system from contamination.

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Since contamination of the food supply is likely to be ongoing, we believe that pharma crops should not continue to be developed. Considering the serious potential health and economic consequences of a contamination event, *UCS recommends that the United States Department of Agriculture (USDA) halt the outdoor production of genetically engineered pharma and industrial crops immediately, until a system is put in place that can produce drugs and industrial substances without putting our food system and food industry at risk.*

UCS also recommends that the USDA explore the indoor cultivation of engineered food and feed crops to produce drugs and industrial chemicals. This system would employ artificially illuminated facilities such as caves or secure greenhouses, operated in conjunction with a new management system along the lines discussed in Chapter 6 of the technical report.

We agree with the report's authors that it might be possible in the future to put together an effective new system that would allow corn or soybean to be used as pharma crops. But as the experts make clear, such a system would require extensive changes. Establishing that system, especially if it permits pharma crop production embedded in commodity crop regions, would require new management systems, new regulations, new restrictions on farmers who do not grow pharma crops, and new equipment and technologies—all built from the ground up. Although theoretically possible, the magnitude of this undertaking leads us to doubt that the USDA could establish, monitor, and ensure the successful operation of the new system.

The best way to reap the benefits of pharma crops and simultaneously protect the food system is to stop now and begin investing in other methods of biopharmaceutical production such as alternative crops and fermentation and cell culture systems. Therefore, *UCS recommends that the USDA spearhead a major campaign to encourage and fund alternatives to the use of food and feed crops in pharma and industrial crop production, particularly the search for suitable non-food/feed crops.* We agree with the experts that this effort should begin as soon as possible and should include incentives that enable scientists to explore new crops and agronomic systems.

A Final Note on the Relationship between the Experts' and UCS's Recommendations

The conclusions and policy recommendations of the Union of Concerned Scientists are based on the expert analyses in the technical report, but are solely the views of UCS. One of our policy recommendations—that the outdoor production of genetically engineered pharma food and feed crops be halted immediately—is not addressed in the technical report and is not necessarily shared by its authors.