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Genetic Engineering Campaign

Briefing Paper on Pharmaceutical Rice

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Pharm Crops – A Food Accident Waiting to Happen

Quietly, the biotechnology industry has been planting fields of genetically engineered corn, rice, barley, and other crops throughout the US, but not for human consumption. Instead, these crop plants have been engineered to make novel compounds for medical and industrial purposes – pharmaceuticals, industrial enzymes, reagents for biochemical laboratories. About 20 companies worldwide are developing plants for the production of pharmaceutical or industrial proteins. Many of these crops are grown in open fields, and since companies in the U.S. are not required to disclose the information about these field tests, the location of the trials are generally closely held secrets.

But Greenpeace has exposed a field of pharmaceutical rice growing in Sutter County, California. The biotech company Applied Phytologics, Incorporated (API) is testing up to a dozen pharmaceutical compounds in rice that is planted in the heart of the state's rice growing region. Though the nature of most of the compounds in the rice is also kept confidential, Greenpeace uncovered the identity of two of the proteins, human lactoferrin and human lysozyme. Lactoferrin and lysozyme are commonly found in breast milk, as well as in human bile and tears. They both possess antimicrobial properties. Lactoferrin binds to iron and kills bacterial cells by depriving them of this essential mineral. It has also been shown to promote cell growth and has immune-modulating effects. Lysozyme breaks apart bacterial cells and is a common chemical used in molecular biology laboratories.

Environmental and Health Risks

There are already documented environmental risks from GE crops, including the transfer of engineered traits to neighboring crops, effects on non-target insects, impacts on soil ecology, and potential threats to endangered species, among others. The genetic engineering industry objects to restrictions on environmental release of GE crops, claiming that it is impossible to meet farmer and consumer demands to keep these crops out of the natural food stream. Pharm crops raise all these environmental concerns, with even higher stakes for the food supply and the environment.

While other GE crops are intended for general consumption, most pharm crops are developed to produce proteins meant only for people with certain health conditions, and crops that produce industrial or other non-food proteins are not intended for any human consumption. Contamination of the food supply from these varieties would be invisible but could cause numerous health impacts, dosing people with unexpected and unknown drugs or other compounds in common foods.

Such food contamination is virtually a given with GE crops. In 1999, corn grown for an organic food maker tested positive for contamination from GE corn, forcing the manufacturer to recall over \$100,000 worth of its products. Last year, lab tests showed that an unapproved variety of GE corn called StarLink had contaminated taco shells sold in supermarkets across the country. Government regulators allowed farmers to grow StarLink corn for animal feed or other non-food based on biotech industry promises that the corn, which scientists say may trigger allergies, would be kept out of the food supply. But environmental watchdogs, not government agencies, commissioned the tests showing that the genetic engineering industry had illegally contaminated the U.S. food supply. Though StarLink was grown on less than .4% of U.S. corn acres, testing eventually showed that over 300 food products were contaminated, and disruptions from continuing contamination of the corn supply are expected for at least another four years.

StarLink showed that such genetic contamination of food happens through all phases of production. Non-GE seeds have tested positive for StarLink contamination, despite the isolation distances used in seed propagation. Non-food crops were accidentally harvested with food and accidentally mixed in grain storage facilities. Even processing facilities with dedicated lines are subject to human error and accidental mixing. USDA considers grain contaminated if one kernel out of 2,400 is StarLink, and seed is considered contaminated if just one in a bag of 80,000 kernels tests positive.

Many farmers whose non-GE crop tested positive for StarLink suspect that pollen from nearby GE fields contaminated their corn. Aventis, the developer of StarLink, was eventually forced to agree with seventeen state attorneys general who argued that the company was responsible for contaminating natural corn even if it was grown further from StarLink than the recommended 660 foot isolation distance. Genetic engineers have repeatedly admitted that GE crops cannot be kept separate from food. When wheat growers demanded that systems to keep GE wheat out of the natural wheat supply be put in place before the altered crop is approved, a Monsanto spokesperson replied, "Nobody can guarantee zero tolerance. If that's what people want, then nobody can deliver it."

In addition to the threat of contaminating human food, developers of pharm crops recklessly endanger wildlife with open fields of these experimental plants. Animals and insects that feed on the crops will be exposed to proteins that have never before been part of their environment, and soil microorganisms and water supplies could also be affected. California rice growers have recently courted environmentalists' favor by promoting their fields as havens for ducks and other waterfowl; each year millions of ducks, geese and sandhill cranes migrate to the Central Valley of California to feed in these fields. The trial location is within thirty miles of no less than four National Wildlife Refuges; an important state waterfowl management area is fifteen miles away. Other animals that feed on rice plants include the rice seed midge, rice water weevil, tadpole shrimp, and crawfish. There is no evidence that pharm crop developers have any studies to show that their crops will be safe to animals, beneficial insects, soil microorganisms or any number of threatened or endangered species.

High Stakes. Few Regulations

There is precious little regulation of pharmaceutical and industrial crops in the United States. Remarkably, despite the environmental risks from releasing plants that produce proteins that have never before been part of any natural environment, it appears that the Environmental Protection Agency has no regulations and is playing no role in the oversight of field releases of pharm crops. Instead, regulation has been left largely to USDA, with the Food and Drug Administration (FDA) also taking a minimal role. Though pharm crops have been released in the U.S. yearly for the last decade, USDA and FDA are just now meeting to coordinate non-binding "guidelines" outlining recommendations for growing, transporting and processing the experimental plants.

USDA currently requires a permit for developers who conduct field trials of crops that produce pharmaceuticals or vaccines, but for crops producing industrial enzymes only notification is required. USDA issues "containment protocols" for permitted pharm crops, which may be as limited as setting an isolation distance, though in some cases can also include measures such as removing plant flowers prior to pollination. One pharm crop developer boasted that two rows of border corn around its pharm corn would protect any neighboring fields. But according to Farm Journal, most seed production fields have between 8 and 16 border rows to minimize pollen contamination.¹

Even with buffer rows, containment is never a sure thing. Corn, wheat and barley are among the plants currently used as pharm crops, yet a recent paper from the European Science Foundation found that "At present none of these crops has pollen which can be completely contained....The use of isolation zones, crop barrier rows and other vegetation barriers between pollen source and recipient crops can reduce pollen dispersal, although changing weather and environmental conditions mean that some long distance pollen dispersal will occur."² The U.S. Department of Agriculture requires biotech companies to isolate pharmaceutical corn from other fields by 1320 feet, double the usual distance for seed propagation. But a 1999 study by Britain's National Pollen Research Unit found that as much as a 1% concentration of corn pollen remains at distances of 1400 feet, and noted that bees or other pollinators could carry the pollen even further.³ Plant geneticist and pollen flow expert Norman Ellstrand told the New York Times that long-distance pollen flow is difficult to predict. "It's just not clear that setting a double distance is going to solve everything," he said.

The FDA claims authority to protect against the potential for pharmaceutical and industrial engineered crops to contaminate the food supply, but has yet to establish any requirements to keep the crops separate throughout the food stream. An FDA official told the L.A. Times that pharm crops would not be processed "anywhere near your food." But a recent presentation by an FDA official indicated that the guidelines would not forbid the use of food or feed mills for the processing of pharmaceutical crops, but merely recommend that equipment be dedicated to the pharm crop at the time of processing.

Both the California Rice Commission and the Farmers' Rice Cooperative have recently adopted policies to segregate GE and non-GE rice. But policies are not practice and industry insiders doubt that purity can be assured given the many potential points for contamination along the path from airplane seeding of fields to the final milling or malting process. Segregation is meaningless if the rice is accidentally pollinated, or if seeds are accidentally mixed.

Greenpeace Demands

Crops that are genetically engineered to produce pharmaceutical or industrial proteins should not be grown in open fields. All such plants should be raised in contained facilities. Greenpeace calls for a ban on the release of genetically engineered crops, since these plants will irreversibly alter the natural environment, with potentially devastating consequences for food production and biodiversity.

¹ Horstmeier, G.D. 2001. Pollen In The Air. *Farm Journal* (May/June).

² Sweet, J.B. 2001. Genetically Modified Organisms (GMO's): the significance of gene flow through pollen transfer. NIAB (UK).

³ Cited in Sands, L. 2001. Stalling StarLink. *Top Producer* (February).