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Silent Winter?

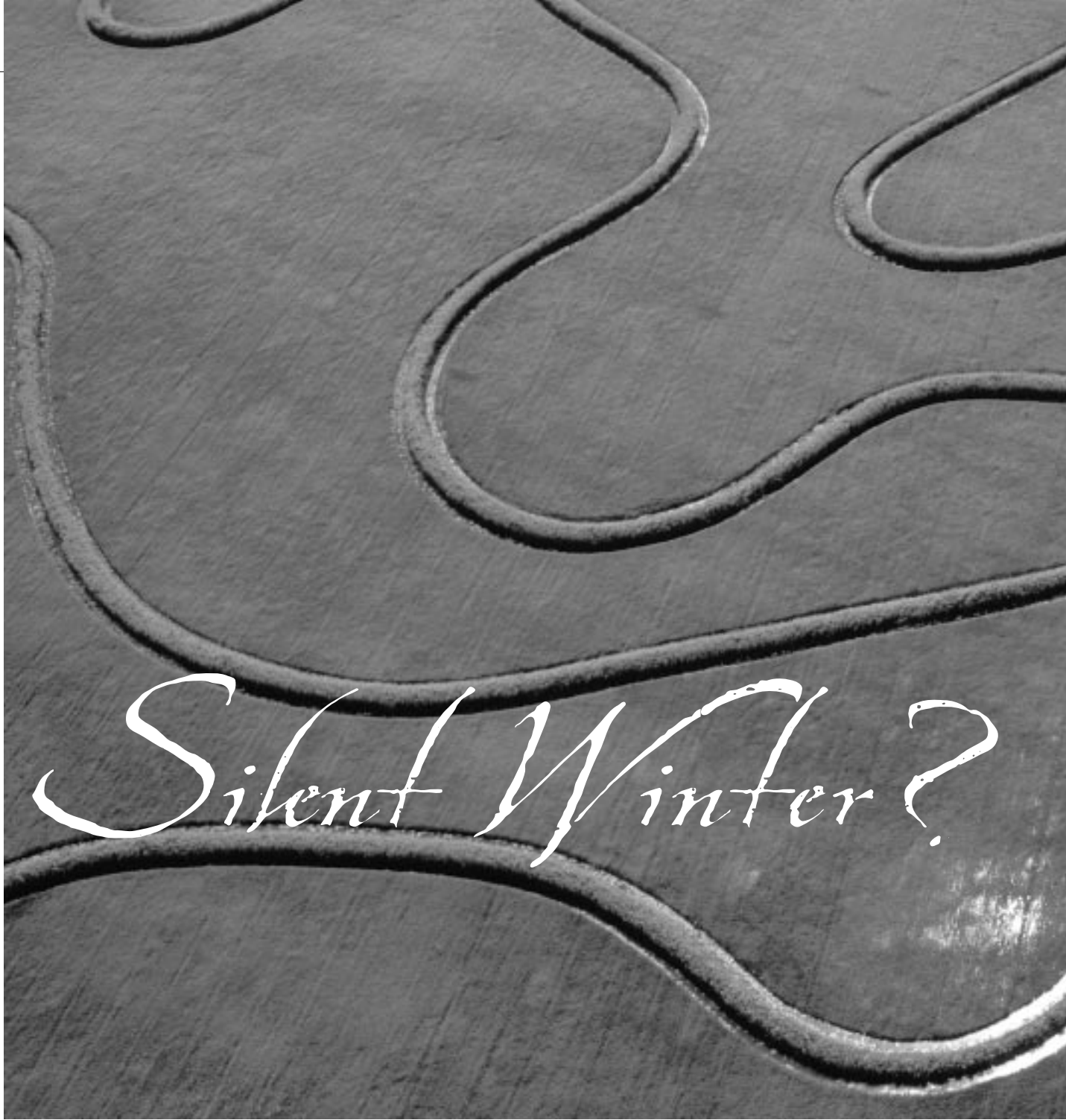
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Silent Winter?

Biopharmed crops are turning wildlife—and us—into lab animals.

by Claire Hope Cummings

WILLOWS, California—A winter storm is arriving here at the Sacramento National Wildlife Refuge. Ducks and geese are circling above the ponds, and as the first rain drops begin to fall, the birds start to drop from the sky by the thousands—feet outstretched, necks arched, and wings beating back as they land on the water. Overhead, hundreds of black ibis etch thin rippling lines against the dark gray clouds. The noise is phenomenal—

the squawking of mallards and pintails, the honking of Snow and Ross's geese, along with the sound of their wings flushing the air. In the background, resident red-wing blackbirds, already hidden in the reedy marshes, let out an occasional high-pitched trill.

The annual return of hundreds of thousands of migratory waterfowl to the Sacramento Valley is quite a spectacle. From the birds' perspective, the Valley is a



tempting buffet. In the winter, flooded rice fields and riparian habitat offer their favorite aquatic foods and grasses. There are tons of seeds and grains to glean, left over from harvesting almost a half million acres of rice and other crops, and no less than six carefully managed National Wildlife Refuges to choose from. But these days, both resident and returning birds are feeding on experimental rice fields that have been planted with genetically engineered strains, including at least 50 acres of rice that has been engineered with human genes.

The intrusion of transgenic rice into the Sacramento Valley presents significant risks to wildlife and to the delicate ecosystems on which it depends. And it

threatens the \$500 million California rice industry, which has worked hard to develop a high quality product (including a thriving organic rice business) and an environmentally friendly image through its efforts to protect waterfowl and shorebird habitat. Now the possibility that rice with human genes and other novel proteins could also contaminate the human food supply is stirring up a storm of controversy.

So far, California's food crops have been free of genetically modified organisms (GMOs.) But two agrochemical corporations, Monsanto and Aventis/Bayer CropScience, are pushing for the right to grow herbicide tolerant (HT) rice here. And Ventria Bioscience,

a small biotechnology company located in Sacramento, is seeking approval to enlarge the area they use to test their transgenic human protein rice. While they await approval for full commercial planting, both types of transgenic rice are being grown in the open air in the Sacramento Valley, where birds, insects, and other wildlife have unfettered access to them.

Ventria Bioscience's rice is generating the most debate. Currently, the company is testing rice that has been genetically engineered with human genes to make two proteins found in human breast milk, lysozyme and lactoferrin. Nursing mothers supply these proteins to their babies in their milk, offering them enhanced resistance to bacteria, viruses, fungi, and other microbes. Lactoferrin provides an iron supplement as well. While Ventria is experimenting with several human gene-enhanced rice strains, it plans to use its human-breast-milk-laced rice as an "alternative to the use of antibiotics in poultry diets" and as a supplement in infant formula. Why would anyone take proteins that are already available in their natural form and genetically engineer them to create new recombinant forms of these same proteins? Because this is the only way a company can patent and own these valuable substances. This new and largely untested scheme raises unprecedented agricultural, economic, legal, environmental, and ethical questions. So, the general public might assume that the regulatory agencies involved in approving such experimental uses of food crops are addressing these issues adequately. Unfortunately, that is not happening.

Risk Paralysis

When it comes to GMOs in general, and transgenic pharmaceutical rice in particular, the regulatory field is muddy. Responsibility for field testing GMOs falls to the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). APHIS's job is to ensure that plant and animal diseases don't proliferate. It does not look at the larger ecological impacts of newly created organisms. Basically, APHIS is concerned with protecting agricultural plants and animals from invasive pests and pathogens, including protecting crops from wildlife, not the other way around. To do its job, APHIS depends on applicants to volunteer information about the potential risks their products might pose. But once permitted field tests are completed, the products are "deregulated" and APHIS conducts no further monitoring or evaluation.

GMO crops that involve pesticides come under the purview of the Environmental Protection Agency, but the two forms of rice currently proposed for commercialization in California are not pesticidal GMOs. The Food and Drug Administration regulates drugs, of course, but they ruled long ago that GMO foods were equivalent to conventional foods, so unless something

like a food allergy might be involved, they are not concerned. Ventria Bioscience, a company founded by some long-time biotech veterans, is calling its rice a "medicinal food," a term that is undefined. If their products are not used as drugs, they just might fall between cracks in the regulatory framework.

That leaves the state regulatory process to deal with this problem. California rice is unique in that the state legislature created a quasi-public body (the California Rice Commission, or CRC) to handle certain regulatory, educational, and promotional matters. It's a combination grower-processor-commodity-trade group. Recently the state charged it with reviewing proposals for transgenic rice and offering rulemaking recommendations to the state department of agriculture.

Tim Johnson, CRC's president, said that California rice growers are the only commodity industry that has the ability to review new varieties and implement planting and handling protocols. "Otherwise," he said, "there would be no process beyond what APHIS does." He said that the CRC does not have the power to stop a particular rice variety from being planted and that he would give GMO rice the same respect as any variety that had commercial value. Johnson is confident that the California rice industry can develop protocols that will contain transgenic rice varieties and avoid the rampant contamination that has, for instance, plagued the corn industry.

This echoes what Ventria Bioscience is saying: their rice does not pose a risk to the environment or other rice growers because, unlike corn, rice is a self-pollinating plant. And they say the protocols they are proposing to the CRC, which will impose extensive human controls over planting, harvesting, and handling—including using "dedicated" equipment and harvesters—will ensure that contamination does not occur. Other commodity crops have achieved some success at such "identity preservation" efforts, but the process is expensive and it allows for a small amount of background GMO contamination.





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In conventional corn, soy, and canola crops in the United States, such contamination is now rampant. In February the Union of Concerned Scientists (UCS) reported that more than two-thirds of these crops were contaminated with genetically engineered DNA. And contamination of the food supply by biopharmaceuticals is also now a fact, not just a fear. In 2002, biopharmed corn was found to have contaminated conventional soy grown for food. Dr. Jane Rissler, a plant pathologist at UCS and the report's co-author, says that now, in addition to GMO contamination, "among the potential contaminants are genes from crops engineered to produce drugs, plastics, and vaccines." When it comes to these new recombinant pharmaceutical and industrial proteins, experts like Bill Freese, a research analyst for Friends of the Earth (FOE) and author of an FOE report on biopharming, says there can be nothing less than "zero tolerance" for

contamination of the human food supply.

In California, the possibility that any GMO rice, let alone biopharmed rice, might get into other rice fields or mills is causing real concern. Millers say they won't touch transgenic rice because they have no means of keeping it separate from ordinary rice. The insurance industry will not consider taking on any GMO risks. Organic rice farmers say they are feeling particularly vulnerable because GMO contamination of their crops would cost them both their certification and their premium markets. And the legal questions about who is liable for contamination have not been sorted out; so far, farmers and processors have been left holding the bag. Still, Aventis (now Bayer Crop Science), the same company that was responsible for extensive GMO contamination in Europe and the Starlink food recall fiasco in the United States (which cost taxpayers, farmers, and food processors millions), is proceeding as if their trans-

genic rice will not cause contamination problems.

There is nothing in the pending protocols or in the field practices currently being used by biopharming companies that would require them to take precautions against exposing wildlife to these novel proteins, such as netting to protect the health of birds or prevent them from transporting the grain to other rice fields. Other countries are not so sanguine. Brazil, for instance, requires protective netting over test plots of herbicide-tolerant rice. When authorities found test plots without it, they ordered the crops destroyed.

I asked the CRC if they were considering insisting on wildlife protections in their protocols. Johnson emphasized that all questions were still open, but that they were satisfied with an APHIS finding that biopharmed rice would have “no significant impact” on wildlife. Any restrictions CRC imposed, Johnson said, would require a scientific basis. However, there *is* no scientific basis for coming to a conclusion, one way or another. The CRC’s current position is based on an oral communication from APHIS, which bases their conclusion on a single environmental assessment they did on another variety of Ventria’s biopharmaceutical rice in 1997. That assessment relied only on general assumptions about transgenics plus information “supplied by the applicant.” Without any independent analysis or studies, APHIS concluded that there is “no reason to believe” there would be any impact on wildlife or other “non-target organisms.”

The dismal lack of research on how genetically engineered crops affect wildlife demonstrates just how inadequate the federal regulatory system is. In the 1980s the biotechnology industry successfully lobbied the government to forgo any new legislation governing GMOs. Today, federal agencies use the same laws that were passed to control chemicals to address the impacts of GMOs, even though GMOs are living organisms that behave very differently in the natural world. When Dan Quayle announced the regulatory framework for biotechnology in 1986, he set forth the system that is, with minor revisions, still used: industry voluntarily provides information on their products to the government and it is accepted at face value. No independent analysis or review is conducted. Thus, biotechnology companies do not need to reveal flaws in their products or even study environmental impacts. And they use the cloak of “confidential business information” to hide crucial facts, such as the locations of open-air test plots. The public, nearby farmers, or even school gardens, cannot find out if a biopharm is planted next door. There are thousands of such secret test plots all over the country, growing biopharmed plants that are visually indistinguishable from conventional crops.

Federal agencies simply ignore studies document-

ing the environmental and human health problems caused by transgenic crops. But opponents of transgenic rice hope that the scientific evidence they are presenting to the CRC will get a fair review. They are challenging the biopharming industry’s claim that rice is a self-contained crop, for instance, citing studies done in Canada and Europe that show a high degree of interbreeding between rice varieties. Commercial rice is also known to cross with nearby weedy relatives such as red rice. Farmer groups are pointing out that growing transgenic rice will have serious environmental side-effects. There are two basic types of GMO crops (“herbicide-tolerant” and “insect-resistant”), and in many cases both are using more herbicides and exposing the environment to more insecticides than conventional crops. A recent study in Britain found that herbicide-tolerant crops lower insect populations and harm biodiversity. Through cross-pollination and natural selection (driven by heavy doses of herbicides), the planting of herbicide-tolerant crops can lead to the creation of so-called superweeds that are resistant to one or more herbicides. And insect-resistant crops can create resistance to commonly used pesticides in the insects they target, as well as harm beneficial insects.

One group that is actively engaged in educating both the regulators and the general public is Californians for GE-Free Agriculture, a coalition of farmer, environmental, and consumer groups. Their campaign coordinator, Renata Brillinger, says that as important as the environmental issues are, she thinks the economic issues will determine whether GMO rice will be grown in California. Brillinger points out that the industry would be taking a big risk by approving transgenic rice, because California rice is sold to discerning domestic customers who do not want GMOs and is shipped to Asian markets that have already rejected GMOs. Brillinger points out that there are no real agronomic benefits to transgenic rice, and the farmers who are getting a premium for their rice are going organic, not transgenic. And, she asks, what would be the benefit for the few farmers who might grow bio-





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pharmed rice, given the enormous risks to the environment and food supply? The key consideration, she says, is that, as with any GMO crop, “contamination of the food supply is virtually inevitable”—and that is a risk the rice industry can’t afford.

A Solution in Search of a Problem?

What about consumers? When they have a choice, they reject GMOs. Why would they want biopharmaceutical GMOs? The proteins Ventria Bioscience grows in their transgenic rice are recombinant plant-produced proteins, which, as explained earlier, are already available in their natural form. Even if Ventria could prove that their plant-based recombinant genes were as useful as the natural proteins are—and that is still an open question—there is no good reason why a mother would pay the higher price, and take the extra risk, of feeding

her baby transgenic infant formula.

Experts like Bill Freese of FOE and Michael Hanson of the Consumers Union question whether biopharming can produce as promised. They are concerned with the different ways that plants, as opposed to animals, produce proteins. And if that issue does not cause regulators to pause, then they point out that biopharmaceuticals in foods have enormous potential for causing catastrophic human health problems. These recombinant proteins are likely to contain allergens, particularly dangerous for infants. Does Ventria Bioscience really intend to use their products in infant formula? Or are they actually aiming at the far more lucrative, and far less regulated, poultry feed market? You would think that biopharmaceutical companies would question the wisdom of producing a crop that poses so many dangers and that customers wouldn’t want. Instead, like the ducks rushing to find a place to ride out the rain, Ven-



tria seems to be hunkering down, weathering the storms of protest around it.

Are biopharmaceuticals in food another extremely expensive biotechnological fix for third-world problems that we already know how to solve, like treating infant diarrhea? Is agriculture now going to be used as a public health tool without public debate or any process that compares its risks and benefits with existing, and perhaps less expensive and more socially acceptable, means? And, in the final analysis, isn't there something just fundamentally creepy, if not unethical, about putting patented human genes into a food crop?

It's unlikely that the CRC will complete its review in time for Ventria to commercialize their rice this year. Time will tell if the CRC process, and the state rulemaking that will follow, will result in effective containment or elimination of the risks posed by biopharmed and transgenic rice. As of early 2004, the APHIS field test database lists 190 permits for release of transgenic rice into the environment in California.

Ventria has been issued 12 APHIS field test permits for GMO rice, seven of them for California. The other five are for Hawaii, the state with the most biopharming and transgenic seed production. But compared to California, Hawaii has much weaker regulatory oversight and a much more vulnerable environment. It is also home to some of the most endangered biodiversity in the world.

Last winter was the centennial of the National Wildlife Refuge system, created by President Theodore Roosevelt in March 1903. Not long after that, the United States signed the Migratory Bird Treaty Act. And throughout the 20th century, while development and agriculture took their toll, efforts to protect wildlife continued. Even the rice industry began to balance production with conservation. As a result of all these efforts, our covenant with migratory birds—that they would return each year as long as we left them something to eat and a decent place to rest—seems to be holding.

While I was visiting the Sacramento National



Snow geese in Merced National Wildlife Refuge, California

Courtesy U.S. Fish and Wildlife Service, photo by Gary Zahm

Wildlife Refuge, and listening to the gabble of the returning geese, I was thinking about Rachel Carson's classic *Silent Spring*. She documented the damage being done to birds by chemicals, and in the following decades the public responded to her work with robust environmental laws. Today, we are still dealing with pesticides, which Carson called "weapons against nature." And we are contending with new weapons against nature: transgenic crops, and the even more frightening biopharmaceutical crops. As a result, birds and people alike are unwittingly consuming both toxic chemicals and GMOs. Given how little we know about the impacts of GMOs, that means we are all participating in a vast, uncontrolled genetic experiment.

Carson's fears that chemical contamination would hush the voices of the natural world were well founded. Now we need to know how genetic contamination will affect birds, the environment, and even ourselves. But because of a compromised governmental role and an industry backlash against environmental regulation, the

studies that would address these questions are not being done. Today, compared to the rise of the environmental movement 40 years ago, there is almost no public clamor calling for new laws and insisting that scientists working in the public interest address the impacts of genetic contamination. This subdued nature of public protest, this political quiescence, particularly in the face of so much that is threatening an increasingly vulnerable natural world, is, perhaps, a far more perilous silence.

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