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The Next Pig Thing

#### By Leora Broydo Vestel

Once upon a time there were three little pigs. They were very special pigs. Their genes were engineered by scientists to make them less damaging to the environment than any of their swine brethren. And everybody lived happily ever after.

Or maybe not. The three pigs in question, developed by researchers in Canada and already patented as 'Enviropigs,' represent a unique dilemma for environmentalists. Major green environmental organizations are virtually unanimous in the view that genetically-modified products should be banned. But the Enviropigs address a major environmental problem — one those same groups have been fighting for years.

At this point, while researchers and pig farmers have extolled the environmental benefit Enviropigs present, most of the leading environmental groups aren't following suit. While the hogs' virtues may be attractive to the green groups, their modified genes represent a vice too significant to overlook.

The crux of the debate centers around the manure pigs produce. Modern pig farming often involves raising thousands of swine in a single facility — which can in turn generate thousands of tons of manure every year. That manure is then spread in fields or stored in "lagoons." The contaminants in the manure can spread from either fields or lagoons into water sources. In 1995, for instance, an eight-acre hog-waste lagoon in North Carolina burst, spilling 22 million gallons of manure into a nearby river and killing enormous numbers of fish. Concentrations of manure rank "among the greatest threats to our nation's waters and drinking water supplies," according to a recent Environmental Protection Agency study.

The Enviropig, developed at the University of Guelph in Ontario and introduced to the world in August, have been modified so that their manure contains up to 75 percent less phosphorus than the average swine. Several substances in pig manure cause environmental damage, but phosphorus is one of the major culprits. The presence of phosphorus in waterways can cause fish kills, biodiversity loss and foster the growth of toxic organisms, according to the EPA.

Unlike their predecessors, such as a salmon that are designed to grow faster, the Enviropig is the first animal engineered for environmental benefit. Not surprisingly, scientists and pork industrialists are thrilled, since proposed government limits on phosphorus output threaten the industry's growth. Ontario Pork, a trade association representing pig farmers in the Canadian province, calls the Enviropig "the biggest breakthrough in pig farming since the invention of the trough."

"The environmental barriers are the largest in terms of growing as an industry," says Clare Schlegel, chairman of Ontario Pork, which represents 4,400 hog farmers in the province and has been a primary funder of the Enviropig research. "[Pork producers] are being looked at as polluters — this is one technology to show that we do care."

Environmentalists aren't buying it. The Sierra Club, which has made lobbying for controls on pig manure pollution a centerpiece of its clean water campaign, calls the Enviropig a load of hogwash. "This is just another quick fix," says Laurel Hopwood, chair of Sierra Club's genetic engineering committee. "The way to reconcile [the problem] is to stop factory farming." Greenpeace and other environmental groups have echoed the Sierra Club message, arguing that the only real solution is moving away from massive industrial-style hog-growing and instead raising fewer pigs in bigger outdoor spaces.

Other technical fixes also exist. Pigs don't digest most of the phosphorus in their grain-based diet, so it ends up in their manure. A new breed of corn, developed by a USDA researcher, reduces phosphorus in manure by up to 50 percent. A widely practiced strategy of adding the enzyme phytase to feed can also reduce phosphorus content by 56 percent.

"There are a lot of sustainable agriculture programs that offer real benefits to food security and to the environment that take far less resources than the biotech solutions being proposed," says Michael Khoo of the Union of Concerned Scientists.

The Guelph researchers addressed the problem by modifying the pigs' digestive abilities. They combined a bacterial gene which makes an enzyme that breaks down the form of phosphorus found in pig feed with a mouse gene that causes the enzyme to be secreted from an animal's mouth. The composite gene was then injected into one-celled pig embryos that were subsequently surgically implanted into a surrogate mother.

The results were the first three Enviropigs, which researchers named Wayne, Jacques and Gordie after famous Canadian hockey players. Today, Guelph houses more than 100 Enviropigs — the result of three generations of breeding, and all of them have inherited the genetic trait that allows for the digestion of phosphorus. All produce manure that contains 60–75 percent less phosphorus than non-engineered pigs.

Apart from that helpful trait, "there's nothing we've seen so far that would indicate that there's any abnormality" with the pigs, says molecular biologist Dr. John Phillips, the lead researcher in the Enviropig project. Nonetheless, he adds, these piggies still must undergo three to five years of testing before they can go to market.

"These animals are going to be tested like no other animals have been tested before they're certified to go into the human food chain," says Phillips.

Pig farmers are apparently eager for the day when they can begin raising Enviropigs, saying they represent a particularly promising solution to the phosphorus problem. Some independent experts also think Enviropig is a solid bet. Dr. Joann Whalen a soil expert at McGill University in Montreal, Canada, thinks Enviropig is even better than a non-biotech solution to the phosphorus problem that she helped develop. Whalen found that mixing limestone in with hog manure could net a 50 percent reduction in phosphorus content. But, she says, this method is expensive and impractical, as the limestone has to be trucked in to farms and requires extensive manpower to spread.

"It's dealing with the problem after the fact," Whalen concedes. "[Enviropig] is definitely a much better approach — it's more cost effective to have a pig that excretes less phosphorus."

Still, for virtually all major environmental groups, the matter boils down to the fact that they oppose the introduction of genetically-engineered organisms into the environment.

"The GMO issue is a deal breaker," says Melanie Shepherdson Flynn, an attorney with National Resource Defense Council's Clean Water Project. "It's an extreme solution without knowing what the result will be."

If Enviropig passes regulatory muster, the rights to the technology will be sold to pig breeders. But given the charged debate developing around it, Enviropig's path to the dinner table remains questionable.

"It's a technology that adds a great deal of value," says Schlegel. "But we're not interested in seeing the technology commercialized if the public is not interested in genetically modified foods."

## **The New York Times**

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#### Without U.S. Rules, Biotech Food Lacks Investors

#### **By ANDREW POLLACK**

This little piggy's manure causes less pollution. This little piggy produces extra milk for her babies. And this little piggy makes fatty acids normally found in fish, so that eating its bacon might actually be good for you.

The three pigs, all now living in experimental farmyards, are among the genetically engineered animals whose meat might one day turn up on American dinner plates. Bioengineers have also developed salmon that grow to market weight in about half the typical time, disease-resistant cows and catfish needing fewer antibiotics, and goats whose milk might help ward off infections in children who drink it.

Only now, though, do federal officials seem to be getting serious about drafting rules that would determine whether and how such meat, milk and filets can safely enter the nation's food supply.

Some scientists and biotechnology executives say that by having the Food and Drug Administration spell out the rules of the game, big investors would finally be willing to put up money to create a market in so-called transgenic livestock.

"Right now, it's very hard to get any corporate investment," said James D. Murray, a professor at the University of California, Davis, who developed the goats with the infection-fighting milk. "What studies do you need to do? What are they looking for?" he said, referring to government regulators. "That stuff's not there."

But some experts caution that even if the F.D.A. clears the regulatory path in coming months, investors and agribusiness companies might still shy away. Many fear that consumers would shun foods from transgenic animals, sometimes referred to as genetically modified organisms, or G.M.O.'s.

"The companies we have spoken to have gone organic, and they are very concerned, at least up to the present time, of having G.M.O. associated with their name," said Cecil W. Forsberg, a professor at the University of Guelph in Ontario, Canada, who helped developed the "Enviropig" with the cleaner manure. Smithfield Foods, for one, the world's largest hog producer and pork processor, says it is doing no research on genetically engineered animals.

Critics say changing the genes of animals could lead to potentially harmful changes in the composition of milk or meat, like the introduction of a protein that could cause allergic reactions. They say there could also be risks to the environment if, for example, extra-large salmon were to escape into oceans and out-compete wild salmon for food or mates. Some also say that some of the processes used to create transgenic livestock can harm the animals themselves.

The federal guidelines would come after more than 15 years of talks and false starts at the F.D.A., a delay irking not only developers of the transgenic animals but also critics of biotechnology.

"The fact that the agency has sat there for years staring this problem in the face and really hasn't come up with a clear way to regulate this is abdicating its responsibilities," said Joseph Mendelson, the legal director of the Center for Food Safety, a Washington advocacy group.

Even now, the F.D.A. will not say when the rules will be ready.

"We want to get it out, but we also want to get it right," said Julie Zawisza, a spokeswoman for the agency, which declined to make any other officials available for comment.

Some industry executives and former and current government officials say one reason for the delay was that some government officials, in part because of a preference for fewer regulations, wanted less stringent rules than the F.D.A. is considering.

Meanwhile, the biotechnology industry is actually pushing for the tougher standards.

"Our overarching goal is to have public confidence in our products," said Barbara Glenn, the managing director for animal issues at the Biotechnology Industry Organization, a trade group. "We won't have that unless we have a very strong review process."

The F.D.A. is turning to transgenic animals after having tentatively declared in December that milk and meat from livestock that is cloned — but not otherwise genetically manipulated — was safe for people to eat.

The F.D.A. considers clones to be less biologically radical than genetically engineered animals — which instead of being mere replicas of naturally occurring animals are given foreign DNA, usually from another species.

Larisa Rudenko, a senior biotechnology adviser in the F.D.A.'s veterinary drug division, said in a May presentation at the biotechnology industry's annual convention that each new type of genetically engineered animal would require approval for use in the food supply. That will be done, she said, under the umbrella of existing rules for drugs used in treating animal diseases.

While the implanted gene is somewhat like a drug, the existing rules would have to be stretched to fit.

But industry executives and some former agency officials said it was unlikely that Congress would enact totally new laws for transgenic animals. And using the drug laws, they say, would provide tighter control than an alternative approach of using the rules governing food additives. Agency officials have said that the veterinary drug rules would be used, and they have already been overseeing some experimental work on that basis. But they continued to debate the issue, and the policy has never been made official.

The regulatory guidelines would indicate how the drug rules would be interpreted for transgenic animals, and what types of data would be needed to prove safety and efficacy. But there are open questions about how the drug rules would actually translate. While a chemical drug must be shown to be consistent and stable, for instance, it is unclear how that standard would apply to a gene passed from generation to generation. Some critics say that while the drug rules do provide fairly strict regulation of food safety, there are drawbacks to adapting that approach. Because applications for approval of drugs are confidential, for instance, there would be no opportunity for public comment before the agency acted.

"In order to create confidence in a new technology, you really don't want behind-closed-door proceedings," said Margaret Mellon, director of the food and environment program at the Union of Concerned Scientists.

Another worry is that the F.D.A. might not have enough expertise or authority to conduct a vigorous review of the environmental impact of transgenic animals. The F.D.A. has dismissed this concern, however, saying it has sufficient expertise and can consult with other agencies.

The biotechnology regulatory branch of the Department of Agriculture created an animal division last December to figure out what its role should be.

Genetically engineered animals are often created by injecting the gene of interest into a singlecell embryo. A more recent technique that is more efficient is to put the gene into a skin cell and create an embryo from that cell by cloning.

In both cases, the embryo with the foreign gene is then implanted into the womb of a surrogate mother. After some transgenic animals are born, additional ones can be made by conventional breeding, because the foreign gene generally will be passed on to some of the offspring, as would any other gene.

The fast-growing salmon is the transgenic animal that has been swimming upstream the longest at the F.D.A. Its developer, Aqua Bounty Technologies of Waltham, Mass., has been working to win agency approval for about 10 years. Aqua Bounty's fish are Atlantic salmon that have been given a growth-hormone gene from the Chinook salmon. They have also been equipped with a genetic on-switch from a fish called the ocean pout, a distant cousin of the salmon.

Normally, salmon produce growth hormone only in warmer months, but the pout gene's onswitch keeps the hormone flowing year round. That enables the Aqua Bounty fish to grow faster, reaching their market weight in about 18 months instead of 30.

Elliot Entis, Aqua Bounty's chief executive, said the company had already given the F.D.A. studies showing that the fish were healthy and that the implanted gene remained stable over generations.

He said the company also had tests done to show that its fish contained the same level of fats, proteins and other nutrients as other farmed salmon and would not set off unexpected allergic reactions in people who eat them. The fish also taste the same as other farmed Atlantic salmon, Mr. Entis said.

"Nobody has ever analyzed salmon as closely as we have had done," he said. But the F.D.A. is asking for more data on safety and potential environmental effects on wild salmon.

Industry executives say the Enviropigs would be the next candidate for F.D.A. approval. The pigs contain a bacterial gene that allows them to produce an enzyme that helps them more fully digest a vital nutrient, phosphorus, in their feed. That means less phosphorus in the manure, which in turn could mean less phosphorus running off into lakes and oceans, where it can cause algal blooms and fish kills.

MaRS Landing, a technology promoting organization in Ontario, is trying to find a corporate partner for the pig, said John Kelly, the agency's executive director.

Less far along in the approval pipeline are pigs that contain a gene from the roundworm allowing them to produce omega-3 fatty acids, a nutrient normally found in fish that is good for the heart. That, in theory, could make eating pork or bacon healthier, although that has yet to be tested.

Jing X. Kang, an associate professor at Harvard Medical School who helped direct the project, said the researchers were looking for corporate backers while also trying to raise the level of omega-3 in the meat.

Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, a consumer advocacy group in Washington, said regulations might not assuage consumers, many of whom object to the genetic engineering of animals on humane or ethical grounds, more than on safety concerns.

"The fact that the F.D.A. has a powerful regulatory process for reviewing genetically engineered animals, far greater than they apply to genetically engineered crops, may not make any difference at all," Ms. Foreman said. "Because that's not what it's all about."