WHO’S WATCHING BIOCROPS?

UNITED STATES IS TOP BIOCROP PLANTER BUT REGULATORS ARE BEHIND THE CURVE
ARE U.S. REGULATORS DROPPING THE BALL ON BIOCROPS?

SPECIAL REPORT

• Growing calls for independent scientific testing of crops
• EPA might reassess key ingredient of Monsanto’s Roundup
• U.S. Supreme Court to hear GMO regulation case April 27

BY CAREY GILLAM

COLUMBIA, Mo. - Robert Kremer, a U.S. government microbiologist who studies Midwestern farm soil, has spent two decades analyzing the rich dirt that yields billions of bushels of food each year and helps the United States retain its title as breadbasket of the world.

Kremer’s lab is housed at the University of Missouri and is literally in the shadow of Monsanto Auditorium, named after the $11.8 billion-a-year agricultural giant Monsanto Co. Based in Creve Coeur, Missouri, the company has accumulated vast wealth and power creating chemicals and genetically altered seeds for farmers worldwide.

But recent findings by Kremer and other agricultural scientists are raising fresh concerns about Monsanto’s products and the Washington agencies that oversee them. The same seeds and chemicals spread across millions of acres of U.S. farmland could be creating unforeseen problems in the plants and soil, this body of research shows.

Kremer, who works for the U.S. Department of Agriculture’s Agricultural Research Service (ARS), is among a group of scientists who are turning up potential problems with glyphosate, the key ingredient in Monsanto’s Roundup and the most widely used weed-killer in the world.

“This could be something quite big. We might be setting up a huge problem,” said Kremer, who expressed alarm that regulators were not paying enough attention to the potential risks from biotechnology on the farm, including his own research.

Concerns range from worries about how nontraditional genetic traits in crops could affect human and animal health to the spread of herbicide-resistant weeds.

“WE DON’T HAVE A ROBUST ENOUGH REGULATORY SYSTEM.”

Biotech crop supporters say there is a wealth of evidence that the crops on the market are safe, but critics argue that after only 14 years of commercialized GMOs, it is still unclear whether or not the technology has long-term adverse effects.

But whatever the point of view on the crops themselves, there are many people on both sides of the debate who say that the current U.S. regulatory apparatus is ill-equipped to adequately address the concerns. Indeed, many experts say the U.S. government does more to promote global acceptance of biotech crops than to protect the public from possible harmful consequences.

“We don’t have a robust enough regulatory system to be able to give us a definitive answer about whether these crops are safe or not. We simply aren’t doing the kinds of tests we need to do to have confidence in the safety of these crops,” said Doug Gurian-Sherman, a scientist who served on a FDA biotech advisory subcommittee from 2002 to 2005.

“The U.S. response (to questions about biotech crop safety) has been an extremely patronizing one. They say ‘We know best, trust us,’” added Gurian-Sherman, now a senior scientist at the Union of Concerned Scientists, a nonprofit environmental group.

CALL FOR CHANGE

The World Health Organization has not taken a stand on biotech crops generally, simply stating “individual GM foods and their safety should be assessed on a case-by-case basis.”

And while many scientists around the world cite research they say shows health and environmental risks tied to GMOs, many other scientists say research proves the crops are no different than conventional types.
With a growing world population and a need to increase food production in poor nations, confidence in the regulatory system in the leading biotech crop country is considered critical.

“One of the things that we think is important to do is to have regular reviews and updates of our strategies for regulating products of biotechnology,” said Roger Beachy, a biotech crop supporter who was appointed last year as director of the National Institute of Food and Agriculture.

“We want to look carefully to see that they are logical and science-based but still maintain the confidence of the consumer to ensure that the projects that are developed and released have the highest level of oversight,” added Beachy.

So far, that confidence has been lacking. Courts have cited regulators for failing to do their jobs properly and advisers and auditors have sought sweeping changes.

Even Wall Street has taken note. In January, shares in Monsanto fell more than 3 percent amid a rush of hedging activity during a morning trading session after a report by European scientists in the International Journal of Biological Sciences found signs of toxicity in the livers and kidneys of rats fed the company’s biotech corn.

Monsanto has said the European study had “unsubstantiated conclusions,” and says it is confident its products are well tested and safe.

Indeed, farmers around the world seem to be embracing biotech crops that have been altered to resist bugs and tolerate weed-killing treatments while yielding more. According to an industry report issued in February, 14 million farmers in 25 countries planted biotech crops on 330 million acres in 2009, with the United States alone accounting for 158 million acres.

REGULATORY ODDITIES

A common complaint is that the U.S. government conducts no independent testing of these biotech crops before they are approved, and does little to track their consequences after.

The developers of these crop technologies, including Monsanto and its chief rival DuPont, tightly curtail independent scientists from conducting their own studies. Because the companies patent their genetic alterations, outsiders are barred from testing the biotech seeds without company approvals.

Unlike several other countries, including France, Japan and Germany, the United States has never passed a law for regulating genetically modified crop technologies. Rather, the government has tried to incorporate regulation into laws already in existence before biotech crops were developed.

The result is a system that treats a genetically modified fish as a drug subject to Federal Drug Administration oversight, and a herbicide-tolerant corn seed as a potential “pest” that needs to be regulated by USDA’s Animal Plant Health Inspection Service (APHIS) before its sale to farmers.

The process is also costly and time-consuming for biotech crop developers, which might need to go through three different regulators before commercializing a new product.

“14 MLN FARMERS IN 25 COUNTRIES PLANTED BIOTECH CROPS ON 330 MLN ACRES IN 2009.”

Nina Fedoroff, a special adviser on science and technology to the U.S. State Department, which promotes GMO adoption overseas, said even though she is confident that biotech crops are ultimately safe and highly beneficial for agriculture and food production, an improved regulatory framework could help boost confidence in the products.
“We preach to the world about science-based regulations but really our regulations on crop biotechnology are not yet science-based,” said Fedoroff in an interview. “They are way, way out of date. In many countries scientists are much better represented at the government ranks than they are here.”

Agriculture Secretary Tom Vilsack, a former governor of top U.S. corn producing state Iowa, also said he recognizes change is needed. The USDA is in fact developing new rules for regulating genetically modified crops but the process has dragged out now for more than six years amid heavy lobbying from corporate interests and consumer and environmental groups.

“There is no question that our rules and regulations have to be modernized,” Vilsack told Reuters. “The more information you find out, the more you have to look at your regulations to make sure they are doing what they have to do. There are some issues we are still grappling with.”

UNDER ATTACK

Fourteen years after commercialization of the world’s first biotech crop, the trio of U.S. regulatory agencies charged with overseeing biotech crops -- USDA, the Environmental Protection Agency, and the U.S. Food and Drug Administration -- are under attack on several fronts.

The USDA is most directly in the line of fire after a string of federal court decisions found its officials acted illegally or carelessly in approving some biotech crops.

In one recent case, a federal court banned the sale of a herbicide-tolerant alfalfa engineered by Monsanto until the government more thoroughly evaluates its safety.

In a similar case, a federal court found that sugarbeets altered to be “Roundup Ready” were approved without adequate USDA evaluation.

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“We can only influence agencies to take action. We can’t compel them to,” she said.

OVERHAUL EYED AMID PROTESTS

Since 1987, the USDA has overseen genetically modified organisms through the Animal and Plant Health Inspection Service. APHIS’s Biotechnology Regulatory Services (BRS) regulates GE organisms based on “plant pest risk.”

Monsanto and other biocrop developers must petition APHIS to grant their genetically altered organisms “nonregulated status” -- that is, permission to grow these plants without official oversight. To win approval, the companies must demonstrate that their tests show the new varieties do not pose a risk to plant health.

“APHIS grants nonregulated status only when it determines that the new genetically engineered variety is unlikely to pose a plant pest risk,” said USDA spokesman Michael Pina, who labeled the current regulatory system “strong.”

USDA has said it wants to make changes that ensure safety while making the process more transparent to the public, and more efficient and easier for the companies developing the technologies to navigate.

Still, the USDA has been formally debating regulatory changes for more than six years and issued proposed new rules in fall 2008, allowing public comment through last summer, as it must under the law.

The proposed overhaul drew more than 15,000 comments, many of them expressing fears that the regulatory changes as laid out would not address key concerns.

In one public comment, physician Amy Dean, a board member for the research and education group American Academy of Environmental Medicine which is seeking a moratorium on GM food, said the proposed changes would “significantly weaken or eliminate oversight of GM crops.”

And Robert Peterson, a Montana State University scientist and leader of the university’s “biological risk assessment” program, told regulators that while he agreed with some of the proposed regulatory changes, he thought the agency’s risk assessment protocols were “fundamentally flawed.”

“Recent research reveals that the approach advocated by APHIS is not scientifically sound and can lead to bad decisions,” Peterson said.

At the FDA, genetically engineered organisms are treated much the same as foods from all other plant varieties.

GE developers are not required to consult with FDA on safety issues, and the agency sees no need now for risk-based monitoring efforts for GE crops because there are no current safety concerns, FDA spokeswoman Rita Chappelle said.

The agency stressed that the burden for ensuring safety lies with the companies. “Manufacturers have an obligation to ensure that their products continue to be safe each and every day,” Chappelle said.

At the EPA, officials also say the burden of proof is with the corporate developers of the technology. And they say they have at least 20 scientists conducting comprehensive analyses for the products that come before the agency, such as BT corn and BT cotton, which are altered to protect the plants against pests. The agency also routinely seeks outside advice from experts who sit on its scientific advisory panels.

Over the last several months, the EPA has also started allowing more public input into its review of new products.

“WE CAN ONLY INFLUENCE AGENCIES TO TAKE ACTION. WE CAN’T COMPEL THEM TO.”

“Transparency and open government is a major priority of the Obama administration. We are adding a significant amount of public participation,” said Keith Matthews, acting director of the U.S. Biopesticides and Pollution Prevention Division.

Further to its mission of environmental protection, EPA officials said the agency reviews products every 15 years for adverse effects. EPA senior policy advisor Bill Jordan said glyphosate, the popular weed-killing chemical, could come under review soon.

“We have an ongoing responsibility to make sure products that are in the marketplace continue to meet the safety standards of the pesticide law,” he said. “We have a program called registration review. Sometime soon we’ll be getting to glyphosate. I would expect that we would look at emerging research on its environmental effects and see whether that leads us to change the terms and conditions of registration or limit its use in some way.”
Concerns about genetically altered crops and the lack of broad testing hit a boiling point last year. In February 2009, 26 leading academic entomologists -- scientists specializing in insects -- issued a public statement to the Environmental Protection Agency complaining that they were restricted from doing independent research by technology agreements Monsanto and other companies attach to every bag of biotech seed they sell. The agreements disallow any research that is not first approved by the companies.

“No truly independent research can be legally conducted on many critical questions regarding the technology,” the scientists said in their statement.

University of Minnesota entomologist Ken Ostlie, who co-authored the statement, said some of the concerns involve corn engineered to resist corn rootworm pests. Biotech corn crops in Minnesota, Iowa, and parts of Wisconsin and South Dakota harvested last fall showed damage and disease, and some fear the biotech corn could sicken livestock.

“We don’t know if something is going on with the plant and the technology or with the insect. We just know things didn’t work the way they were supposed to,” said Ostlie. “It would be nice to have independently verifiable information going into EPA’s decision-making beyond just what the company provides.”

Christian Krupke, an entomologist at Purdue University, said the technology engineered into the plants has many benefits, but more research is needed on effects.

“We are all fans of this technology. The problem is we are not getting access to ask the questions that need to be asked that maybe the companies don’t want to ask,” Krupke said.

BACKLASH ABROAD

A backlash against biotech crops has swept many countries. India became one of the latest hot spots in February when biotech opponents created such an uprising that the Environment Minister, Jairam Ramesh, blocked the release of a genetically modified eggplant made by Monsanto.

India already allows planting of altered cotton, but Ramesh said there was not enough public trust to support the introduction of a GM food crop until more research was done.

Among the critics of the engineered eggplant was Tiruvadi Jagadisan, a former managing director of Monsanto’s India operations.

In an interview with Reuters, Jagadisan, who worked with Monsanto for 18 years, said he believed there were “very many legitimate concerns about the safety of GM food crops for humans, animals and the environment.” He said Monsanto did not give “accurate information to the public” about its eggplant.

“No extensive tests have been done to assess the effect of consuming GM crops on future generations,” Jagadisan said, an assertion common among critics, but one Monsanto has repeatedly denied.

Monsanto called Jagadisan’s assertions “baseless” and said India’s regulatory regime requires “extensive and rigid crop safety assessments, following strict scientific protocols.”

The state department’s Fedoroff, a supporter of Monsanto’s technology, called the incident “one little setback” to gaining worldwide acceptance of biotech crops.

She said with rising food prices and population growth, biotech crop technology will become increasingly important, and criticisms of Monsanto and its technology were unfair.

“They’ve certainly made mistakes but they’ve done a whole lot more good than harm. They are investing more in crop improvements than our government is,” she said.

seeking answers

Back in his USDA laboratory, Kremer’s assigned government work is focused on general soil quality. As a side project in support of that research, he has spent the last several years studying soil and plant growth tests that appear to show ravaged root systems in biotech “Roundup Ready” plants.

The crops have been subjected to glyphosate applications and on the surface appear to be impervious to the weed-killing treatments as the genetic alteration allows. But the roots seem to tell a different story.
“This is supposed to be a wonderful tool for the farmer ... but in many situations it may actually be a detriment,” Kremer said. “We have glyphosate released into the soil which appears to be affecting root growth and root-associated microbes. We need to understand what is the long-term trend here,” he said.

The development of crops engineered to tolerate glyphosate spurred a surge in use of the chemical -- an extra 383 million pounds were sold from 1996 to 2008, according to a report released by The Organic Center (TOC), the Union for Concerned Scientists (UCS) and the Center for Food Safety (CFS).

Monsanto says the chemical binds tightly to most types of soil, is not harmful and does not harm the crops.

But some scientists say there are indications of increased root fungal disease as well as nutrient deficiencies in Roundup Ready crops. They say manganese deficiency in soybeans in particular appears to be an issue in key farming areas that include Indiana, Michigan, Kansas and Wisconsin.

Outside researchers have also raised concerns over the years that glyphosate use may be linked to cancer, miscarriages and other health problems in people.

Monsanto says extensive research shows glyphosate is safe for humans and the environment, and has an entire section on its website devoted to refuting the reports. Monsanto says extensive investigation of questions about changes in soil micro-organisms has found no long-term ill effects.

Peering into his petri dishes, Kremer isn’t so sure.

“Science is not being considered in policy setting and deregulation,” said Kremer. “This research is important. We need to be vigilant.”

(Editing by Jim Impoco and Claudia Parsons)