THREE YEARS LATER:

Genetically Engineered Corn and the Monarch Butterfly Controversy

Pew Initiative on Food and Biotechnology

Introduction

In the summer of 1999, Cornell entomologist John Losey sparked a worldwide controversy with the publication of a short paper in the scientific journal *Nature* reporting laboratory findings that monarch butterfly larvae died after eating milkweed plants dusted with pollen from genetically modified (GM) corn. That paper generated intense national and international news coverage transforming the monarch butterfly overnight into a dramatic symbol of what environmentalists and some scientists saw as the dangers of agricultural biotechnology.

Now, three years later, scientific studies show that the risks to monarchs from genetically modified corn are fairly small, primarily because the larvae are exposed only to low levels of the corn's pollen in the real-world conditions of the field. While some long-term exposure questions remain, the feared, acute threat to monarchs from genetically modified corn appears small, particularly in comparison to other threats such as conventional pesticides and drought.

While this specific controversy may be largely over, the greater controversy over genetically modified crops is not. Can we learn anything about ways to resolve these controversies through the scientific process from a closer examination of the monarch butterfly story?

In this retrospective of events, at least three critical issues emerge as key elements, both for the creation of the public controversy as well as its resolution.

- First, the events raise questions about how scientific questions get raised and resolved in the midst of a highly politicized environment. Initial scientific efforts to respond to Losey's paper were not viewed as credible by some scientists and by environmental groups because they were largely seen as industry-funded or industry-driven. Eventually, with the leadership of the U.S. Department of Agriculture (USDA), scientists from government, industry, academia and environmental groups worked together to develop a consensus set of experiments needed to answer the question of whether genetically engineered corn posed a risk. The effort was successful in funding research that virtually all of the participants found to be credible and useful in answering many of the key scientific questions.

- Second, the monarch controversy raises broad and important questions about the role of scientific journals as well as the mainstream press in covering scientific news, particularly in those areas that have politically controversial implications. How do the imperatives of the

media to report news mesh with the incremental self-correcting process of science? These are clearly broad issues that go beyond monarchs and biotechnology debates, and scientists and journalists need to continue to discuss these issues.

- Finally, the events raise important issues about the adequacy of the U.S. Environmental Protection Agency's (EPA) process of reviewing genetically modified crops for potential adverse environmental effects. While there are specific questions relating to this particular case, there is also a broader question: how do agencies decide what risks to look at, given a potentially large range of issues to investigate? How much information is enough, given the reality that there will always be some inability to predict all impacts in advance?

In this paper, we review the chronology of the monarch butterfly controversy from the perspective of a number of key players. We also provide a brief review of the current state of scientific knowledge on the issue—what is now known, and what questions remain.

The Pew Initiative on Food and Biotechnology believes that this retrospective of the monarch butterfly controversy will both help promote understanding of the issue and stimulate broader discussion about how this issue unfolded and how innovative methods were used to ultimately resolve some key issues in this debate.

The Chronology

IN THE BEGINNING: EPA APPROVAL OF GENETICALLY MODIFIED CORN

In 1995, the EPA for the first time approved the marketing of a genetically engineered crop—a variety of corn bred to be insect resistant.

The EPA approval came into play because the corn in question was engineered to produce a toxin derived from the *Bacillus thuringiensis* (Bt) bacteria. In the corn, the Bt toxin serves as a biopesticide targeted against the European corn borer. In its natural form, Bt has been widely used as a biopesticide against other plant pests by both organic and conventional farmers, and EPA has regulated its use for years.

EPA is charged with regulating pesticides under two separate statutes: the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food Drug and Cosmetic Act (FFDCA). Under FIFRA, EPA needs to ensure that Bt corn does not pose an "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide."

Under FFDCA, the EPA also needs to determine a safe level of pesticide residues in foods—referred to as a tolerance. EPA must grant an exemption for products in need of a tolerance if there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."

The regimen established under FIFRA and FFDCA was enacted long before the development of applications of modern biotechnology, but both laws have broad enough definitions to enable EPA to regulate pesticides made by genetically modified crops. In 1994, EPA proposed a set of rules under FIFRA to clarify requirements for pesticides produced by genetically modified plants. (The plants themselves are not subject to FIFRA.) Since 1995, when EPA granted its first approval of a corn genetically engineered to produce the Bt toxin, ten different varieties of Bt corn have been registered by EPA, though not all remain on the market today.

U.S. farmers started planting Bt corn varieties far more rapidly than EPA originally expected. Janet Andersen, director of the Biopesticides and Pollution Prevention Division at EPA, notes that

when the agency conducted its original assessment, it estimated—based on information provided by the companies seeking to sell the corn—that by 2000, about five percent of field corn would be Bt corn. In fact, adoption of field corn has been significantly more robust. Current EPA estimates are that one percent of field corn was Bt corn in 1996, six percent in 1997, 18 percent in 1998, 26 percent in 1999, and 25 percent in 2000, the last year for which EPA has firm data.

Some of the benefits to farmers identified by EPA during its assessment of Bt corn help to explain its growing popularity. According to EPA, growers who use Bt corn may see benefits including improved corn yield and profitability, improved crop management effectiveness, reduction in farming risk, and improved opportunity to grow field corn in the event of severe pest infestations. The agency estimates that even with the higher seed prices the total annual benefits to growers from the use of Bt field corn are valued somewhere between $38 million to $219 million annually. The magnitude of benefits is obviously higher when the pest insect population is higher.

"The primary reaction of growers to corn borers before Bt corn came along was to do nothing," says Kevin Steffey, an entomologist with the University of Illinois Extension. The pests burrow inside corn stalks where they are difficult to see and inaccessible to most pesticides. "Although European corn borers were costing them yield, as a general rule farmers were unwilling to scout out and treat infestations because it is difficult, the timing is complex, and the efficacy of the insecticide was not that good," he says. "Now they have a way to treat it, so Bt corn is widely used."

In addition to economic benefits, EPA also considered possible environmental and health benefits of Bt corn in the registration process. Since the overall use of insecticides in field corn is relatively low, EPA did not believe that the use of Bt corn would result in a significant reduction in their use. It recognized, however, that even a small reduction could offer some environmental benefit because of the large acreage planted in corn. EPA also noted that Bt corn can reduce mycotoxins, fungal toxins that can infect corn that has been damaged by insect pests and are human carcinogens.

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In its assessment, EPA also considered potential risks of Bt corn to humans and to the environment. EPA requested evidence of the product's safety in people, including testing for allergenicity. Like any other pesticide, the GM corn was also tested on a variety of animals: birds, aquatic invertebrates, honeybee larvae, earthworms, and ladybugs, among others. EPA was able to rely on extensive prior experience with Bt spray for assessing health and environmental risks.

In a decision that was later criticized, EPA did not specifically require tests for possible effects of Bt on monarch butterfly larvae. Since it was well known that Bt was toxic to many butterfly and moth species, Andersen notes the agency

assumed that Bt corn could harm monarchs if they were exposed to it, but believed that monarchs were unlikely to be present in cornfields. They also calculated that the butterflies were most likely to be exposed to Bt from periodic sprayings of the Bt toxins in woodland areas to control gypsy moth infestations, rather than from Bt corn.

EPA approvals were granted beginning in 1995, although EPA took the additional step of limiting the registrations to five years in order to give the Agency an opportunity to review any possible adverse experiences with growing the corn. (Ordinarily, pesticide registrations are not time limited.) As a result, the manufacturers would be required to come back and re-register Bt corn in 2001 in order to continue to sell it.

LOSEY'S STUDY AND THE ENSUING CONTROVERSY

In 1998-1999, Dr. John Losey of Cornell University had a grant from the U.S. Department of Agriculture's Agricultural Research Service (USDA/ARS) to study whether the weeds in Bt cornfields could serve as an alternate host for the European corn borer—the very insect Bt toxin killed. In the process of conducting that research, Losey noticed the large amount of milkweed in and around the cornfields.

"You really can't miss it, it's a large abundant plant," Losey says. Milkweed is a wholly unsatisfactory food for the European corn borer. It is, however, the only source of nutrition for the monarch butterfly larvae. Because of the milkweed's close proximity to Bt corn, and hence its pollen, monarch larvae could eat pollen that had fallen on milkweed.

"I wanted to know if the butterfly larvae would eat the pollen, and if they did, would Bt pollen harm them," Losey says. "It was a first step in the research. Because the Bt toxin affects lepidopterans [butterflies and moths] to widely varying degrees, it wasn't altogether clear whether the monarch larvae would suffer any ill effects at all."

Around the same time, Iowa State University entomologist John Obrycki and a graduate student Laura Jesse were studying predatory insects in Bt cornfields to see if the Bt toxin harmed these "non-target" insects. Obrycki says since they were looking at non-target insects and milkweed is all over cornfields, they also thought studying the monarch was a pretty obvious step to take.

Losey conducted a laboratory experiment where he misted milkweed leaves with water and sprinkled corn pollen onto the leaves to a density that visually mimicked the pollen density he observed in the field. He used pollen from two different types of corn to conduct his study, one

from the Bt corn produced by Novartis, known as N4640, and the other from an unmodified corn hybrid. He then placed five three-day-old Monarch larvae on each milkweed leaf, and he tested and observed their feeding habits and survival rates over four days.

Jesse and Obrycki took a different tack than Losey and placed potted milkweed plants in the cornfields during the corn's pollen shed—the time in the growing season when corn pollen is released. Using this naturally deposited pollen, the scientists took the milkweed plants back to the lab and placed first instar monarch larvae—or larvae that have yet to experience a molt—on the milkweed plants. What they found was that the Bt pollen can cause mortality for these first instar larvae.

Jesse reported their results at a meeting in March 1999. Obrycki notes, "At that time, we weren't ready for publication."

Losey, however, reported his findings in the Scientific Correspondence section in the May 20, 1999 issue of the journal *Nature*. That section of the journal, similar to the current Brief Communications, was a place for very short articles or commentary. Each article is peer-reviewed by one or two outside reviewers and Losey's paper had two outside reviewers.

Losey's short paper reported that monarch larvae exposed to the Bt corn pollen ate less milkweed than those exposed to the conventional hybrid pollen. More significantly, 44 percent of the larvae feeding on the milkweed dusted with Bt corn pollen died after four days whereas none of the larvae exposed to conventional corn pollen died.

"I knew there would be a lot of interest in the results of this paper because it involved Bt corn and monarch butterflies, two things of interest to the general population," Losey says. What followed, however, was a media firestorm that lasted through the summer. "I don't think I'd ever seen that level of interest in any paper, let alone one I had published," he says.

Public advocacy and environmental groups leapt on Losey's results as confirmation that EPA's registration system for bioengineered crops was not stringent enough to adequately protect people and the environment. Greenpeace demonstrated in front of the U.S. Capitol dressed as monarch butterflies that collapsed as they were felled by "killer GM corn."

"Once we heard about the *Nature* paper, we called reporters and sent out press releases for days," says Margaret Mellon of the Union of Concerned Scientists in Washington, D.C. "We worked very had to make this a high-profile issue because without media attention we knew nothing would be done," she says. "We saw the findings as an illustration of how superficial risk assessment [for genetically modified foods] was ... The question still remains, would this science have been done if the monarch wasn't such a beautiful butterfly?"

The environmental advocates' efforts bore fruit as headlines from around the country emphasized the risk to the beloved butterflies. The *San Francisco Chronicle* warned "Gene Spliced Corn Imperils Butterflies." In Boston, the *Globe* headline read, "Butterfly Deaths Linked to Altered Corn." And, the *Los Angeles Times* maintained "Genetically Engineered Corn May Have Adverse Effects on Monarch Butterflies."

"Nobody ever claimed [the *Nature* paper] was more than it was. It simply raised the possibility of risk," Mellon says. "This would not have been a front-page story in the *New York Times* if EPA had examined this carefully at any level ... or if industry had said, look, this is a complex area, there are legitimate concerns that need to be addressed. But Losey's findings undercut a vision of biotech as wholly safe and without problems."

Not everyone sees it that way. "All the environmental groups came out immediately with cries of high risks to monarchs and possibly other insects from the Bt corn, a conclusion that turns out to be totally unjustified," says Mark Sears, an environmental biologist at the University of Guelph in Ontario, Canada. "They already had their minds made up."

The news that Bt corn could harm monarch butterflies might have come as a surprise to the public in general, but scientists and the agricultural biotechnology industry were aware of Jesse and Obrycki's March presentation. Shortly before the *Nature* paper hit the newswires, EPA received notification of Obrycki's abstract from industry sources as a legally required notification of any potential adverse effects of the Bt corn. Soon thereafter, EPA's Andersen says the Agency talked to the companies about the need for additional research to address these concerns.

In addition, once his paper had been accepted for publication by *Nature*, Losey informed both Monsanto and Novartis (now Syngenta), makers of the Bt corn varieties, about its pending publication and sought their advice. "Our goal wasn't to blindside anyone," Losey says. "And, in our conversations with industry, we got some helpful suggestions about wording parts of the paper and the direction of future studies."

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QUESTIONS ABOUT THE STUDY, AND INDUSTRY RESPONSE

Monsanto's Vice President of Scientific Affairs, Eric Sachs, sent a Monsanto entomologist, Steven Spangler, to discuss the data with Losey. Sachs says the concern at the time was that the data weren't robust enough and the study wasn't thorough enough for publication.

"Even if we didn't think the results were robust, we did recognize that [Losey] was raising important questions," Sachs says. "We felt that we could reasonably predict that the

harm to monarchs would be quite limited, but we knew we could only get a complete answer through a risk analysis. And it was obvious we needed much more research."

Sachs says he knew media coverage of the paper would be high even though the paper was a short scientific correspondence. "We saw an embargoed copy of a Cornell press release where we thought the risk seemed exaggerated," Sachs says. "We knew what we needed was more research and that we needed to make it an inclusionary process and have third parties develop the data."

Sachs noted Losey's paper had clearly identified a hazard—that monarch butterfly larvae were harmed or killed at certain exposures to Bt pollen. What remained to be determined was whether the butterflies were being harmed in the real world setting of the cornfield. Losey's study, as a laboratory experiment, couldn't address that question because what happened in the field depended on whether the butterfly larvae were being exposed to high enough levels of the pollen while they fed on milkweed. In order for that to happen, monarch larvae would have to be feeding on milkweed at the same time that the corn pollen was being shed.

As a result, Sachs and other industry leaders worked through the Agricultural Biotechnology Stewardship Technical Committee (ABSTC), an industry group that works on insect resistance as well as other agricultural biotechnology issues, to fund field research by leading academics in the fields of agricultural biotechnology and entomology to answer the questions raised by the Losey paper. Sachs says the industry asked Losey to participate in the research. Losey, however, declined because he wanted to take the research in his lab in a different direction than what the ABSTC was offering to support.

INITIAL RESEARCH EFFORTS GENERATE MORE CONTROVERSY

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The clock was ticking for the scientists who undertook the research. Field studies would need to be in place in late July and early August when corn shed its pollen. The research was conducted and completed over the summer of 1999. The ABSTC arranged for the data to be presented at a meeting in November 1999 in Rosemount, Ill. Sachs says, "At that meeting we invited both people we had funded and those we hadn't to present data on Bt corn and monarch butterflies."

Sachs says industry had funded approximately 60 percent of the research presented while 40 percent of the research was funded by government grants and other sources. Scientists participating in the meeting included Chip Taylor of the University of Kansas and Monarch Watch, an educational research program; Rick Hellmich of the USDA/ARS; Blair Siegfried of the University of Nebraska and

Galen Dively of the University of Maryland. In addition, members of the media and consumer advocacy groups were invited to attend as well. Sachs notes, "We wanted this information out there and we wanted our critics to have the opportunity to see the data as well."

The meeting was sponsored and organized by the ABSTC. The Biotechnology Industry Organization (BIO) played a role, however, by helping with the media coordination of the event.

"The ABSTC had enormous scientific talent so there wasn't much BIO could help with on that front," says Val Giddings, vice president for food & agriculture at BIO. "We figured there would be a feeding frenzy at the meeting so we decided to help with the media management."

The first thing that BIO did was have a pre-meeting teleconference with some of the scientists who were presenting data from their studies the following day. Then, Giddings and his staff wrote a press release based on the conference call stating the scientific participants were likely to conclude Bt corn wasn't a hazard to the monarch butterfly.

Rather than serving as a routine media advisory, that press release was more like a spark in a powder keg. When Carol Yoon from the New York Times asked the scientists during a question and answer session at the meeting whether they agreed with the press release that said they had decided that Bt corn wasn't a threat to the monarch, the meeting disintegrated into controversy.

"That meeting was a travesty," says Lincoln Brower, a monarch biologist at Sweet Briar College in Sweet Briar, Va. "While the seminar was still in progress, Carol Yoon got a press release saying scientists agreed that Bt corn had a minimal impact on monarchs, which not all researchers agreed with. The following press conference was highly orchestrated by the companies and the TV cameras ignored those scientists expressing concerns."

University of Guelph researcher Sears, however, doesn't agree with Brower's assessment at all. "The press beating we got over this meeting was not deserved," he says. While these were preliminary reports, he says, no one demonstrated the kind of mortality in monarch caterpillars exposed to Bt pollen that Losey's paper suggested. In fact, several field studies suggested that monarchs were unlikely to be exposed to Bt corn pollen because the caterpillars were not present during pollen shed, he added.

Sachs concurs with Sears' view that the press release itself wasn't a sign that industry had already made up its collective mind that Bt corn posed little threat to monarchs. "The release was obviously a media advisory. BIO wanted the public to be aware of the meeting and wrote the release announcing the meeting. The PR did upset some at the time, but this kind of release is done all the time by advocacy groups," Sachs says. "When PR and media engage before the science you can expect fireworks—and that is what happened here."

Because the biotechnology industry had underwritten a large number of the studies, some advocacy groups were claiming the results couldn't be trusted.

SEARCHING FOR A SOLUTION

Finding answers to these questions became more urgent as the initial five-year registrations for Bt corn granted by EPA began to run out. A month after the Rosemount conference, in December 1999, an EPA Scientific Advisory Panel looked at the ecological questions raised by all the monarch-related research that had come out since Losey's *Nature* paper. Subsequently, EPA issued a data call-in for studies relating to monarchs and Bt. In other words, EPA said that in order to continue to sell Bt corn, manufacturers would need to submit data about the toxicity of Bt corn pollen, the level to which monarch caterpillars would be exposed to Bt corn pollen, and the potential impact of such exposures on monarch populations. The companies were required to submit study protocols by March 2000 and the results of the studies by March 2001. Because this data on the monarch butterfly issue was going to be important for deciding whether to extend the Bt corn registration and what limits, if any, to put on its planting, the data needed to be sound and accepted.

USDA representatives attending the November 1999 scientific meeting in Rosemount realized the controversy was only going to continue if there wasn't a plan to address the issue in a transparent and scientifically appropriate manner. What the USDA and the industry came up with was an approach where USDA contributed $100,000 and the industry group ABSTC matched that amount to conduct the studies. In addition, a panel consisting of scientists representing academia, industry and advocacy groups formed a consortium that would set priorities and review research proposals to determine how to divvy up the $200,000 in research funds. The results from the research would also be submitted for peer review to ensure it was of the highest quality.

The EPA data call-in "put the official pressure on," Sears says. While industry needed to respond to the data call-in, the availability of grant money and the desire to provide a scientific basis for decision drove the organization of a second Bt corn and monarch butterfly workshop in Kansas City in February 2000. The goal of the workshop was to identify research priorities regarding Bt corn and monarch butterflies and enhance cooperation among researchers. Approximately 40 scientists from government, universities, industry and environmental groups participated in the workshop. Attendees identified short- and long-term research priorities, which were summarized by the steering committee. The consortium's steering committee included Adrianna Hewings (USDA/ARS); Eldon Ortman (Purdue University); Mark Scriber (Michigan State University); Eric Sachs (Monsanto) and Margaret Mellon (Union of Concerned Scientists).

At that meeting, researchers identified five short-term research objectives: 1) determine the importance of cornfields for sustaining the monarch population; 2) continue laboratory studies to determine how monarch caterpillars are affected by different amounts of Bt; 3) determine the abundance and location of milkweed; 4) determine monarch distribution, abundance and survival in Bt and non-Bt corn fields; and 5) collect data to see if what happens in the laboratory actually happens in the field.

"[The steering committee] adopted these priorities and put out a request for proposals for scientists to design studies that addressed the questions and the grants were made in April 2000," USDA's Hellmich says. "The plan was to develop the data and present them in a peer-reviewed scientific journal so the data and conclusions would be above reproach."

A RACE AGAINST THE REGULATORY CLOCK

During the summer of 2000, a team of 26 academic and government scientists, including John Losey and John Obrycki, conducted various parts of the research needed to come up with answers for the five research priorities. With the research completed in the fall of 2000, the consortium met again to analyze and interpret the data. They also set about writing the six papers that would be submitted to *The Proceedings of the National Academy of Sciences (PNAS),* which requires that two outside reviewers examine the papers.

The industry wanted the data sent to EPA in order to meet its data call-in deadline of March 2001. The scientific team, however, was concerned that the public release of the data to EPA would jeopardize their ability to publish in a respected peer-reviewed scientific journal. For that reason, the scientific team requested that industry submit the information as confidential business information (CBI) until the papers had entered publication. As CBI, the information is protected by statute and EPA can't disclose it to the public record.

As it turns out, that move created a serious conflict. EPA needed to make a decision on Bt corn by September 30, 2001, in order to allow the corn to be bought in time for planting for the 2002 growing season. But given the long process involved in readying studies for publication and peer review, the studies were unlikely to be published in *PNAS* until after September 30th. Public interest advocates were upset, arguing that the data should be made public so that the public would have an opportunity to review and comment on the data in advance of EPA's decision to re-register Bt corn.

EPA responded by working out a deal with the companies allowing public access to the original data in ten reading rooms across the country starting on August 24, 2001. People were welcome to come into the reading rooms, view the data and comment on the data

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as long as they didn't remove the information from the reading room or discuss the data publicly afterwards. Few people availed themselves of the opportunity: only Greenpeace and the Hudson Institute visited the reading rooms.

Without knowing about EPA's plans to make some of the data available, one of the members of the scientific research team, Karen Oberhauser, an entomologist with the University of Minnesota, decided to press the timing issue at EPA. On September 1, 2001, Oberhauser wrote a letter to EPA discussing parts of the undisclosed data and urging caution because she felt the toxicity data was misleading and because she felt long-term data studies were important. The letter was later included in part of a docket that was eventually made public and obtained by members of the media.

At the same time, EPA requested that *PNAS* expedite the publication of the papers because of the intense public scrutiny of the Bt corn reauthorization decision. *PNAS* complied with EPA's request and made the papers available to the media on September 7, 2001 and published them on their website on September 14, 2001, in order to ensure the public had access to the information that EPA was using for its decision. Unlike some journals, *PNAS* has no prohibition against publication of data in the popular media before publication in its journal. Even so, the early publication—especially the early release to journalists—caught the scientific team off guard.

"The publication process was expedited, and, as a result, we had scientists with unchecked galley proofs being shared with the media that had to be changed later," Hellmich says. "It was pretty extraordinary."

WHAT THE STUDIES SHOWED

The six studies published in *PNAS* showed there was little risk to monarch larvae from the two most commonly grown types of Bt corn because the pollen isn't toxic in the concentrations that monarch larvae would encounter in the fields.

The studies were intended to help answer the question whether monarch butterfly larvae were likely to be exposed to potentially lethal levels of Bt pollen in the field. The six studies published in *PNAS* showed there was little risk to monarch larvae from the two most commonly grown types of Bt corn because the pollen isn't toxic in the concentrations that monarch larvae would encounter in the fields. A type of Bt corn with a particular genetic combination known as Event 176 made by Novartis, (now known as Sygenta), proved capable of harming some larvae because of high levels of toxin in its pollen. This particular type of corn never gained a significant market share because the Bt toxin isn't expressed well in the corn stalk and as a result isn't particularly effective, Hellmich notes. In 2000 Syngenta announced its decision to phase its Event 176 Bt corn out of the market. The registration for the Event 176 Bt corn expired on April 1, 2001, and all remaining stocks must be used by the end of the 2003 growing season.

"The only pollen showing severe toxicity to monarch larvae was Event 176," says Sears. "Bt11 corn was the next most concentrated in pollen, at one-hundredth the amount of toxin in Event 176 pollen. At 1,000 grains or more of Bt11 pollen per square centimeter [of milkweed leaf], we did not show mortality. At 4,000 grains or more per square centimeter, the leaf surface was so dusty the larvae wouldn't eat it and they starved regardless of whether it was Bt pollen or not."

Further, the average amount of pollen found on milkweed leaves within cornfields was 150 grains per square centimeter, while the highest found was about 1500 grains per square centimeter, Sears points out. The researchers calculated that the percentage of larvae encountering pollen grains denser than 1000 grains/cm^2 would be less than 0.007 percent. "Overall," Sears concludes, "we estimated that fewer than one percent of all North American monarchs would be affected by doses of pollen high enough and at the right time to even see a subtle growth affect."

One new question that arose was whether the monarch larvae could also be eating anthers—small plant particles that produce the plant's pollen—that some of the studies suggested are more toxic than the pollen itself. Sears and other researchers purified their pollen, arguing that it is much more likely to be pollen than other plant bits falling on milkweed. In field studies, Sears says, they did not retrieve milkweed leaves with plant debris other than pollen and entire anthers. "To a caterpillar, an anther is about as big as a city bus," he says. "Maybe some of the larger [caterpillars] eat them but we haven't seen any evidence of that." Anthers only get broken up into caterpillar-sized bites during the processing and collection of corn pollen from the plants, he says.

However, Oberhauser, Obrycki, Losey and Laura Jesse of Iowa State University's Department of Entomology, submitted a letter to EPA on September 11, 2001 emphasizing the concerns about corn anthers falling on milkweed because they contain higher concentrations of Bt toxin than the pollen. Because some monarch larvae may be capable of eating these anthers, these scientists were concerned that the high Bt toxin concentration in the anthers may prove hazardous to the monarch and urged EPA to grant only a one-year reauthorization to Bt corn while additional research was conducted.

"I felt that the conclusions made from a one year study that excluded anthers were premature," Obrycki says. "That's why we requested that EPA shorten the reauthorization period until we had data from subsequent studies."

A second issue, according to Monarch Watch's Chip Taylor, is that the studies do not rule out very small effects, long-term or sublethal effects—damaging the fitness of a butterfly rather than killing it as a caterpillar. As an example, "What if monarchs feeding on milkweed dusted with Bt corn pollen weigh 10 to 20 percent less than their normal compatriots, can they migrate as effectively? Survive through the winter? Reproduce in the spring?," Taylor asks. "The answers to such questions are still unknown."

Overall, however, the studies suggest that "what's really an issue with monarch populations is probably not Bt corn," says Taylor. "These studies certainly show that the impact, if there is one, is very subtle." The weather seems to be by far the largest influence on monarch butterfly populations. Monarch populations tend to drop during droughts, for example. In general, the monarch population has fluctuated from 28 million butterflies over wintering in Mexico in 2000 to probably close to 100 million over wintering this year. Generally monarch mortality is high. Taylor estimates that a female monarch butterfly will lay about 400 eggs over her lifetime, of which just 2–8 larvae mature to butterflies. With those kinds of numbers, he says, "you need thousands of larvae to really rule out the possibility of an effect."

EPA REAUTHORIZES BT CORN

On October 16, 2001, EPA reauthorized the registrations of the five Bt corn products on the market for an additional five years. While overall the *PNAS* studies suggested that Bt corn was unlikely to pose an unacceptable hazard to monarchs, the agency determined that some questions remained unanswered. For example, the studies showed that there was a greater overlap between pollen deposition and larvae feeding than previously thought, especially in the Northern Midwest, raising a question about long-term exposure.

To deal with that question, EPA's Andersen says the agency has requested studies on monarchs that eat Bt corn pollen for a ten-day period, specifically looking at whether the monarchs are less likely to survive or reproduce than are monarchs who were not exposed to the genetically engineered pollen. Results from these studies are due Jan. 31, 2003 or earlier.

"The papers did not fully explain what might happen with long-term exposures to the pollen," says Andersen. "While pollen can be deposited for about a ten-day period, most of the papers just looked at the effects of the pollen during the early stages of life for the larvae."

The Agency continues to require companies to routinely monitor and collect data to ensure that the products' continued use does not lead to insect resistance or unexpected human health or environmental effects. Specifically, EPA is requesting additional data on the persistence of the active protein in soil, field studies on non-target insects, and studies examining long-term effects on monarch butterfly populations, along with other studies. EPA has also mandated several provisions to strengthen insect resistance management, to increase research data on potential environmental effects, and to improve grower education and stewardship.

Issues

SCIENCE, THE MEDIA, AND THE REGULATORY PROCESS

Environmental groups believe that the Losey paper illustrated that EPA's original decision in 1995 to approve Bt corn failed to include adequate tests on non-target species like monarch butterflies. Union of Concerned Scientists' Mellon argues, "If EPA had done the job it should have done, the studies in *PNAS* would have been published before Bt was approved in the first place." EPA's Anderson disagrees, pointing to the fact that tests had been conducted on a wide range of animals for toxic effects and that EPA had considered potential impacts on monarchs. When Losey's study raised some legitimate new issues, she says, EPA appropriately responded and asked companies for new data on those issues.

"The reality is, with any pesticide you can always learn more, but you can't test everything," Andersen says. "There were legitimate questions about what happened to monarchs," but the additional studies suggest that the Bt corn does not pose a significant threat to monarchs. "We think chemical pesticides are killing monarchs at a far higher rate than Bt corn pollen is," she concluded.

For Oberhauser's part, she believes that the *PNAS* studies showed an additional problem with EPA's original decision to approve Bt corn. The studies showed that one type of Bt corn, modified with a genetic combination called Event 176, produced significantly more toxic pollen than other types of Bt corn. She notes, "Event 176 expressed Bt in the wrong tissues—it expressed more strongly in pollen than in the stalk. Yet, the company had permission to plant a lot of this in the cornfield." To her, that result shows the EPA approval process broke down and allowed a dangerous product out on the market; it was only a fortunate accident that the product never gained wide market share.

Environmental groups and some scientists were also critical of EPA's decision to re-register Bt corn for an additional five years, particularly without an adequate opportunity to review and comment on the new scientific studies. "We are certainly reassured by the papers in some regards," says Mellon. But, she adds, "It is not reassuring that at the very end of getting these papers published, scientists raised a new concern [about possible toxicity caused by anthers] and yet the agency went ahead and made a decision without waiting for the answers to be resolved."

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The initial Losey study indicating potential harm to the monarch butterfly received widespread worldwide press attention. In contrast, the six studies published in *PNAS* in mid September 2001, received relatively little attention in the mass media. In part, coverage of the studies was eclipsed by the terror attacks on the World Trade Center and Pentagon on September 11, 2001. As a result, some of the scientists and members of industry are concerned the public may not understand how this data resolved the major concerns raised by the Losey paper. Hellmich notes, "The news of the attacks on 9-11 overshadowed the news of these papers, which is without a doubt understandable. Of course, it's possible we wouldn't have had much press in any event because the studies showed 'no effect'—which is less of a news story for the mass media than one about harm being done."

A MODEL PROCESS FOR RESOLVING SCIENTIFIC CONTROVERSIES

Hellmich and others believe the process used to evaluate risk in this case is as important as the actual data. By including industry and environmental groups in the process and developing a solid experimental design, the group was able to provide a credible risk assessment for a highly contentious issue. "This process really offers a blueprint for how to do research in the public interest," Hellmich says.

Overwhelmingly, the participants in the process agree with Hellmich's assessment. "This process was highly valuable," University of Guelph researcher Sears says. "It was done as a collaborative effort which is highly unusual, and the studies were designed to answer the most important questions. The methodology led to an objective approach to this issue ... which is more and more important to inform complex regulatory decisions." It's also important as a way to keep the general public aware of the science, he says.

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Monsanto's Sachs is also pleased with the way the studies were conducted. "I feel very good about the process," Sachs says. "We don't come to scientific conclusion quickly. We make sure we have dotted all the I's and crossed all the T's. What we ended up with was a series of solid peer-reviewed papers that answered the relevant questions for a risk assessment."

"I think the process was fair," says Chip Taylor of the University of Kansas and of Monarch Watch. "Almost all our questions were addressed, and many more." Overall, the process of multiple meetings and the research steering committee meant that people's concerns were heard and raised the right questions about Bt corn's potential effects on monarchs, and then addressed these questions with solid scientific studies, Taylor concurs.

Mellon agrees. “This was a model way to go about getting information on whether or not a risk exists. It brought scientists, environmental and government folks together with industry, found a pot of money, set a research agenda, got proposals, funded the research and got it done before [EPA] made a decision about renewal. This was a really important process that should be followed routinely by the government as it makes decisions about GM products—and it’s not.”

University of Illinois entomologist Kevin Steffey agrees, noting the whole process provided an objective voice in a debate characterized by animosity and distrust.

“Environmental groups have agendas and they don’t need to have proof … the same can be said for industry,” says Steffey. “Neither represents positions truly. You need objectivity, which I think was offered in these articles in *PNAS*.”

The process offered an alternative model to research funded by one side or the other on a particular issue. The question of whether agencies should rely on industry-funded research at all continues to generate disagreement. Sweet Briar College monarch researcher Brower charges that “You can’t have the fox guarding the chicken coop. The companies making these studies are biased and they have been in control of the information to a dangerous degree.” He calls for an independent system to perform experimental studies before genetically modified products are registered.

Steffey disagrees with Brower’s assertion. “Of course industry is going to conduct some of the research,” counters Steffey. “They are required to do the research before submitting any new project to EPA. If industry didn’t do it, it wouldn’t get done, because no one else has the motivation.” He points out that the U.S. Food and Drug Administration’s process for approving new drugs, which enjoys strong public confidence, relies upon industry-funded research.

With research into the effects of Bt corn on monarch butterflies and other non-target species continuing, most of the major questions about the acute risks to monarchs have been answered. And, Obrycki notes, the whole controversy over Bt corn and monarch butterflies has aided in the development of other GM crops.

Obrycki points to the development of Bt corn that expresses the toxin in its roots and releases it into the soil to combat corn rootworm. The companies involved in developing this Bt variety are testing the long-term impact of Bt toxin on other creatures living in the soil, including beneficial insects. He notes, “Now there is a better focus on the ecological effects of GM crops and you can see that with the way people are developing GM crops like one resistant to corn root worm.” ■