

Chemically Speaking

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April 2013

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EPA Sued by Beekeepers/ Nicotinoids Questioned

A lawsuit filed by a coalition of beekeepers and activists seeks to ban certain nicotinoid insecticides. The lawsuit accuses the Environmental Protection Agency (EPA) of failing to protect pollinators and the use of these materials should be suspended. Nicotinoids, the world’s most widely used insecticides, are also facing the prospect of suspension in the European Union, after the health commissioner pledged to press on with the proposed ban despite opposition from the UK and Germany.

“We have demonstrated time and time again over the last several years that the EPA needs to protect bees,” said Peter Jenkins, an attorney at the Center for Food Safety who is representing the coalition. “The agency has refused, so we’ve been compelled to sue.”

“America’s beekeepers cannot survive for long with the toxic environment EPA has supported,” said Steve Ellis, a Minnesota and California beekeeper and one of the plaintiffs who filed the suit at a federal district court. “Bee-toxic pesticides in

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dozens of widely used products, on top of many other stresses our industry faces, are killing our bees.” The EPA has not commented about the lawsuit, but said in a statement: “We are working aggressively to protect bees and other pollinators from pesticide risks through regulatory, voluntary and research programs. Specifically, the EPA is accelerating the schedule for registration review of the neonicotinoid pesticides because of uncertainties about them and their potential effects on bees.” However, even the accelerated review will not be completed before 2018. The insecticides named in the lawsuits are clothianidin, manufactured by Bayer, and thiamethoxam, made by Syngenta. Neither company chose to comment on the lawsuit, but industry group Crop Life America (CLA) is representing some of the companies.

A series of scientific studies in the last year have increasingly linked neonicotinoids to harmful effects in bees, including huge losses in the number of queens produced, and big increases in “disappeared” bees that fail to return from foraging trips. Disease and habitat loss are also thought to be factors in the recent declines in populations of bees and other pollinators. A proposal to suspend the use of three neonicotinoids across the EU ended in a hung vote in mid-March. But Tonio Borg, the European commissioner for health and consumer policy, said that he would take the proposal to appeal. If member states maintained their positions, the insecticides would be suspended. “The health of our bees is of paramount importance,” said Borg. “We have a duty to take proportionate yet decisive action to protect them wherever appropriate.”

The lawsuit against the EPA argues that, via conditional registrations, the Agency rushed the neonicotinoids into the market without sufficient examination and since that time has failed to take account of new information. The action by the

coalition, which also includes the Sierra Club and the Center for Environmental Health, follows an emergency petition in March 2012 which demanded the EPA suspend the use of clothianidin but was not acted upon.

In contrast, recent research commissioned in the UK has differed from studies suggesting neonicotinoid effects on honeybees. On March 26, agriculture minister David Heath confirmed that the results of research into the field effects of neonicotinoid seed treatments on bumble bee colonies showed no relationship between colony growth and residues in pollen or nectar in the colonies. The research, conducted by the Food and Environment Research Agency (FERA), reinforces previous advice by Government scientists and the independent Advisory Committee on Pesticides that the evidence available does not indicate harmful effects of neonicotinoid use on bees under field conditions.

A second study published by the UK Department of Environment, Food, and Rural Affairs (DEFRA), on March 27 assessing the key evidence available on neonicotinoids and bees, found that laboratory based studies demonstrating sub-lethal effects on bees from neonicotinoids did not replicate realistic conditions. Commenting on the new research, Crop Protection Association chief executive Nick von Westenholz said: “The crop protection sector welcomes the robust, evidence-based approach taken by DEFRA on this issue, which stands in stark contrast to the knee-jerk response we have seen in Brussels. I hope it will encourage those who have been calling for a ban on products such as these to take a step back and consider what measures are really needed to protect bee health, rather than simplistically blaming the nearest chemical. These products undergo an incredibly rigorous approvals process, which ensures their environmental impact is minimized.

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Removing crop protection products from use is not 'playing it safe', but has serious implications for the production of safe and affordable food in the UK and Europe." (*The Raw Story*, 3/22/13 & Crop Protection Association, April, 2013).

Stacked Traits Still Need Refuge

The strategy widely used to prevent pests from quickly adapting to plant-incorporated products may fail in some cases unless better preventive actions are taken, suggests new research by University of Arizona entomologists Bruce Tabashnik and Yves Carrière. Corn and cotton have been genetically modified to produce pest-killing proteins from the bacterium *Bacillus thuringiensis*, or Bt for short. Compared with typical insecticide sprays, the Bt toxins produced by genetically engineered crops are much safer for people and the environment. Although Bt crops have helped to reduce insecticide sprays, boost crop yields and increase farmer profits, their benefits will be short-lived if pests adapt rapidly. Bt crops were first grown widely in 1996, and several pests have already become resistant to plants that produce a single Bt toxin. To thwart further evolution of pest resistance to Bt crops, farmers have recently shifted to the "pyramid" strategy: each plant produces two or more toxins that kill the same pest. As reported in the study, the pyramid strategy has been adopted extensively, with two-toxin Bt cotton completely replacing one-toxin Bt cotton since 2011 in the U.S.

Most scientists agree that two-toxin plants will be more durable than one-toxin plants. The extent of the advantage of the pyramid strategy, however, rests on assumptions that are not always met, the study reports. Using laboratory experiments,

computer simulations and analysis of published experimental data, the new results help explain why one major pest has started to become resistant faster than anticipated. "The pyramid strategy has been touted mostly on the basis of simulation models," said Carrière. "We tested the underlying assumptions of the models in laboratory experiments with a major pest of corn and cotton. The results provide empirical data that can help to improve the models and make the crops more durable." One critical assumption of the pyramid strategy is that the crops provide redundant killing. "Redundant killing can be achieved by plants producing two toxins that act in different ways to kill the same pest," he said, "so, if an individual pest has resistance to one toxin, the other toxin will kill it."

In the real world, things are a bit more complicated, Carrière's team found out. Cotton bollworm, also known as corn earworm (*Helicoverpa zea*) is a major agricultural moth pest which the researchers selected for its resistance against one of the Bt toxins, Cry1Ac. As expected, the resistant caterpillars survived after munching on cotton plants producing only that toxin. The surprise came when Carrière's team put them on pyramided Bt cotton containing Cry2Ab in addition to Cry1Ac. If the assumption of redundant killing is correct, caterpillars resistant to the first toxin should survive on one-toxin plants, but not on two-toxin plants, because the second toxin should kill them, Carrière explained. "But on the two-toxin plants, the caterpillars selected for resistance to one toxin survived significantly better than caterpillars from a susceptible strain." These findings show that the crucial assumption of redundant killing does not apply in this case and may also explain the reports indicating some field populations of cotton bollworm rapidly evolved resistance to both toxins. Moreover, the team's analysis of published data from eight species of pests reveals that some degree

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of cross-resistance between Cry1 and Cry2 toxins occurred in 19 of 21 experiments. Contradicting the concept of redundant killing, cross-resistance means that selection with one toxin increases resistance to the other toxin. The authors' conclude that even low levels of cross-resistance can reduce redundant killing and undermine the pyramid strategy. Carrière explained that this is especially problematic with cotton bollworm and some other pests that are naturally not highly susceptible to Bt toxins.

The team also found another assumption violation required for optimal success of the pyramid strategy. In particular, inheritance of resistance to plants producing only Bt toxin Cry1Ac was dominant, which is expected to reduce the ability of refuges to delay resistance. Refuges consist of standard plants that do not make Bt toxins and thus allow survival of susceptible pests. Under ideal conditions, inheritance of resistance is not dominant and the susceptible pests emerging from refuges greatly outnumber the resistant pests. If so, the matings between two resistant pests needed to produce resistant offspring are unlikely. But if inheritance of resistance is dominant, as seen with cotton bollworm, matings between a resistant moth and a susceptible moth can produce resistant offspring, which hastens resistance. According to Tabashnik, overly optimistic assumptions have led the EPA to greatly reduce requirements for planting refuges to slow evolution of pest resistance to two-toxin Bt crops.

The new results should come as a wakeup call to consider larger refuges to push resistance further into the future, Carrière pointed out. "Our simulations tell us that with 10 percent of acreage set aside for refuges, resistance evolves quite fast, but if you put 30 or 40 percent aside, you can substantially delay it. Our main message is to be more cautious, especially with a pest like the cotton

bollworm. We need more empirical data to refine our simulation models, optimize our strategies and really know how much refuge area is required. Meanwhile, let's not assume that the pyramid strategy is a silver bullet." (University of Arizona, 4/2/13).

Section 735 Tumult

A number of stories have been generated by a section of the agricultural spending bill signed into law in March. Many authors phrase Section 735 as the "Monsanto Protection Act." This provision was drafted last year and has been in printed versions of the bill that have been circulating widely in Washington for more than nine months. To date, no court has ever held that a biotechnology crop presents a risk to health, safety or the environment. Getting approval for any transgenic crop or food is a long process, with companies providing years of internal and independent data, which are then carefully reviewed by various government agencies. Beyond that, the USDA cannot approve a new seed variety until it conducts an Environmental Assessment (EA). This is the point in the process where critics hope to generate a critical mass of negative public opinion. By law, the EA must consider any and all factors relating to the "human environment," which is very ambiguously defined, encompassing human health and leaving all kinds of legal openings for groups to target. If a group such as the Center for Food Safety or the Institute of Responsible Technology or the Union of Concerned Scientists challenges the EA for not considering one issue or another, the assessment can be deemed insufficient and a new one must be ordered. This has happened twice in recent years, with alfalfa and sugar beets. Alfalfa hay, a nutritious, easily digestible livestock feed, is an \$8 billion a year business and country's fourth-most-valuable crop.

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Monsanto makes GM alfalfa seeds, as part of the company's Roundup Ready® line. They are genetically modified to tolerate glyphosate, the herbicide commercially known as Roundup®. When farmers use Roundup®, a comparatively mild herbicide, instead of other harsher chemicals to kill weeds, they actually cut down on overall toxic chemical use.

After an exhaustive review, the USDA gave Roundup Ready® permitted alfalfa in 2005. But the Center for Food Safety contended that the government hadn't adequately evaluated the potential environmental consequences. In 2007, in *Monsanto Co. v. Geertson Seed Farms*, a federal court agreed with the Center for Food Safety, prohibiting Monsanto from selling Roundup Ready Alfalfa pending yet another assessment. This was incredibly disruptive to thousands of farmers, who had planted alfalfa, which is a perennial crop so does not have to be reseeded each year. The legal status of a field of GM alfalfa planted legally after the USDA had deregulated GM alfalfa was suddenly changed under the court ruling. Farmers were being told that they had to follow a new set rules in handling their crop. For more than four years, they didn't know if the technology was going to be available for their use. The confusion and patchwork of conflicting regulations, court decisions and labeling requirements dealt a sizable economic blow to one of the country's most important export crops.

The alfalfa case standoff eventually made it to the Supreme Court. The evidence in support of the safety and public benefits of GM alfalfa was so strong that in 2009, the Obama administration had Solicitor General Elena Kagan file a brief on the biotechnology company's behalf, even though the government was not a defendant in the appeal. To

no scientist's surprise, in June 2010 the Supreme Court overturned the lower court's injunction that had prohibited Monsanto from selling pesticide-resistant alfalfa seeds. "An injunction is a drastic and extraordinary remedy, which should not be granted as a matter of course," Justice Samuel Alito wrote for the 7-1 majority, concluding that the U.S. District Court in San Francisco had "abused its discretion." The temporary injunction, by then determined to be abusive, proved a financial disaster for the farm industry and many individual farmers who had suspended planting alfalfa pending a final resolution.

An almost identical situation occurred with sugar beets, 95% of which are grown from GM seeds. In 2010, the Center for Food Safety and some organic farmers who stood to gain by attacking conventional and GM crops convinced a court on procedural grounds - there was no finding of environmental or health dangers - to void the five-year-old approval of transgenic sugar beet seeds. Despite no evidence of any potential harm, that November, a federal judge ordered the GM sugar beet seedlings - all but 5% of the nation's beet crop - pulled from the ground, as required by law. If the decision had stood, it could have destroyed as much as half of America's granulated sugar production on purely technical grounds. The saga only ended in July of last year when the USDA allowed unrestricted planting of GM sugar beets.

Section 735 provides legal consistency for farmers and businesses so that they will not be affected by temporary findings by competing court systems as activist challenges make their way up the legal food chain. The provision will protect farmers who buy GM seeds and plant them under the belief that it is legal to do so because the seeds have been subjected to extensive USDA scrutiny and approval. (American Enterprise Institute, 4/1/13).

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Pesticide Registrations and Actions

Food Related Actions

- Based on a request by Consumo Em Verde S.A. Biotecnologia De Plantas, an exemption from the requirement of a tolerance was granted for a fungicide extracted from lupine. Residues of banda de *Lupinus albus* doce (BLAD), a naturally occurring polypeptide from the catabolism of a seed storage protein are exempt on all food commodities. (*Federal Register*, 3/22/13).
- Based on a request by Veto-Pharma SA, a tolerance has been granted for residues of the miticide amitraz in honey. (*Federal Register*, 3/22/13).
- Based on a request by Valent U.S.A. corp., tolerances have been granted for the fungicide fenpyrazamine. Tolerance of interest to the region include small climbing fruit, blueberry, and leaf/head lettuce. (*Federal Register*, 3/6/13).

Other Actions

- The EPA seeks to ensure that antimicrobial products that are intended to control public health microorganisms, and are applied by fogging or misting, are effective as claimed and are labeled in a manner that will prevent unreasonable adverse effects on human health or the environment. Registrants of

antimicrobial products that contain fogger/mister label instructions are being asked either to provide existing efficacy data, or to commit to provide new data that address the public health claims for their fogger/mister products. In a letter to registrants of these products, the EPA is asking that registrants submit for each product bearing fogging/misting application instructions, efficacy test data from their files regarding this use. If the efficacy data are not available, the EPA expects the company to provide new efficacy data using a protocol approved by the agency. When antimicrobial fogging/misting products were originally registered, data in support product efficacy for the use were not required to be submitted to the agency because the claims were not then considered to be public health related. The agency now considers the claims made for disinfection and sanitization products applied by fogging/misting to be public health related. The EPA recognizes that there is a need for these fogging/misting products under many conditions where sanitization and disinfection are the desired effect. However, the agency has an ongoing responsibility to ensure that products applied by fogging/misting are effective. (EPA OPP Update, 4/17/13).

Pesticide Potpourri

- DuPont de Nemours & Co. (DuPont), reached technology licensing deals with Monsanto on genetically modified seed traits in March. Both the companies also agreed to dismiss their antitrust and patent

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infringement lawsuits pending against each other in U.S. federal court. The agreements between DuPont and Monsanto include a multi-year, royalty-bearing license for Monsanto's next-generation soybean technologies in the U.S. and Canada.

Through these deals, DuPont's subsidiary, DuPont Pioneer will be able to offer Genuity Roundup Ready 2 Yield soybeans as early as 2014, and Genuity Roundup Ready 2 Xtend glyphosate and dicamba tolerant soybeans as early as 2015, pending regulatory approvals.

DuPont Pioneer also will receive regulatory data rights for the soybean and corn traits previously licensed from Monsanto, enabling it to create a wide array of stacked trait combinations using traits or genetics from DuPont Pioneer or others. Meanwhile, Monsanto will receive access to certain DuPont Pioneer disease resistance and corn defoliation patents. (*RTTNews*, 3/25/13).

- In early April, organic food watch dog groups called for organic food regulators to ban the practice of using tetracycline in organic orchards. Consumers Union, Food & Water Watch, and the Center for Food Safety are urging the National Organic Standards Board (NOSB) to ban the use of antibiotics in organic apple and pear production.

The groups cite the undermining of the integrity of the organic label and threats to public health and consumer expectations. Some organic apple and pear producers use oxytetracycline and streptomycin to manage the disease fire blight, which is caused by a bacterium. A Consumer Union poll found that when asked whether antibiotics are used to treat disease in apple and pear trees, 68% of people said they don't know, 17% said they don't think they are, and 15% said that antibiotics are used. When told that apple and pear trees can be sprayed with antibiotics to treat disease and then asked whether fruit from these trees should be allowed to have an organic label, 54% said they should not be labeled as organic. (*Examiner.com* 4/10/13).



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