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Pesticide & Chemical POLICY

Quote of the Week:

"Separating that gene from its surrounding genetic material is not an act of invention." – Justice Clarence Thomas (see story below)

Weekly report on pesticides, toxic substances and general issues of regulation and legislation

Court protects genes from patenting

By J.R. Pegg

Isolated human genes may not be patented, the Supreme Court ruled Thursday in a unanimous opinion that could have ripple effects on the future development of crop protection products, genetic tests, biotech drugs and perhaps thousands of existing products.

"We hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," Justice Clarence Thomas writes for the court in the 22-page opinion.

The case (*Association for Molecular Pathology et al. v. Myriad Genetics*) centers on a lawsuit brought in 2009 by physicians, scientists and cancer patients challenging patents on two genes held by Utah-based Myriad Genetics.

The company received the patents in the late 1990s from the U.S. Patent Office for "isolated" forms of the two genes, known as BRCA1 and BRCA2. Women who have mutations in the two genes have significantly higher chances of developing breast or ovarian cancer. The patents effectively gave Myriad a monopoly on testing for these mutations and impeded research efforts on the genes in question.

The issue sparked interest far beyond the medical community, including industry groups like CropLife International and the Biotechnology Industry Organization (BIO), which the patents could undermine research and development into an array of new technologies.

Myriad and its advocates argued that the company had created something new by locating the genes and extracting them and therefore should not be held the exclusion of natural substances from patent eligibility.

But the court sided with the plaintiffs' view that the patents should not have been given, agreeing that the isolated genes are products of nature and that Myriad did little more than carve out a specific piece of DNA.

"It is undisputed that Myriad did not create or alter any of the genetic information encoded in BRCA1 and BRCA2 genes," writes Justice Thomas for the court. "The location and order of the nucleotides existed in nature before Myriad found them."

What Mryiad did was uncover the precise location and genetic sequence of the two genes, he says, but this alone does not make the genes patentable.

"Myriad did not create anything," he adds. "To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the [patent requirements]."

The ruling, however, is not a total loss for Myriad. The court also ruled that the creation of a synthetic form of DNA -- known as cDNA -- could possibly be eligible for patent protection because it is not naturally occurring.

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In This Issue

Maine joins GM political theater

By Martin Zook

The Maine legislature this week became the second state in the country to pass a law that ostensibly requires labeling of GM food, except that the legislation is so burdened with contingencies that even proponents of disclosure admit it stands little chance of enactment.

The legislation, approved unanimously in the state's Senate and by a 141-4 margin in the House, in reality is a political exercise in which all parties get something, except for consumers who want GM food labeled. A leading lobbyist for labeling supporters says that the goal of mandated labeling of the modified food will not come before 2014.

Members of Maine's legislature -- including those who do not support labeling -- now can tell constituents, who overwhelmingly back labeling, that they voted for the Act to Protect Maine Food Consumers' Right to Know About Genetically Engineered Food and Seed Stock bill.

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Pesticide & Chemical POLICY

Watching laws being made is not for those who believe that legislatures work as portrayed in movies or on the idiot box.

As GM labeling plods toward a national standard, likely to be determined by the FDA at the direction of Congress, we are seeing some posturing that rivals a Las Vegas magic show.

Within recent weeks, the Maine and Connecticut legislatures have passed GM labeling bills (see story page 1), except they don't really require that anything be labeled, and aren't likely to require anything to be labeled. Maine's law doesn't even contain a viable definition of GM food.

But it's a "breakthrough" victory for the NGOs who started out the year with such promise but until the last two weeks had not a single piece of legislation to show for efforts in 25 states.

Now, they technically have two bills, and stand a good chance of getting a third when Washington State voters go to the polls to vote on a referendum that presumably would require labeling of GM foods.

All of that said, the three laws, or any combination of laws at the state level, are unlikely to result in the labeling of anything.

You see, after the Connecticut law passed, and Maine appeared on the verge of passing a similar law, it appeared something meaningful might be achievable. That's when the pesticide and agricultural interests succeeded in adding contingencies that make it nearly impossible for Maine's law to take effect, clearing the way for labeling opponents to vote for the popular legislation.

That defeat was actually ok with the NGOs, who realized better a labeling bill that didn't require labeling than none at all.

The show at the state level is just the warmup act for the national stage, anyway, where labeling legislation lies fallow.

In the meantime, by buying time, the pesticide and agriculture industries are given opportunity to figure out how to pull a rabbit out of the hat.

Martin Zook, Managing Editor
Pesticide & Chemical Policy

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THE DRIFT

Reporter's Notebook

Washington State upholds neonics

The State of Washington's top ag official says there is a lack of "sound evidence" tying honeybee die-offs to the application of neonicotinoid pesticides in denying a request by Thurston County commissioners to restrict the controversial chemicals.

The commissioners petitioned Ag Director Bud Hover to bar purchase of neonicotinoid pesticides by private individuals and require that only licensed applicators be allowed to apply the pesticides believed by many to be a significant contributor to the die-offs (see story page 1).

Hover's denial drew a derisive response from Beyond Pesticides on its Web site. "Sound science does not include, apparently, consideration of dozens of studies in the independent peer reviewed scientific literature that link neonicotinoid pesticides to bee health decline and colony collapse disorder," the environmental group responded.

Neonics tied to honey bee deaths in Canada

The preliminary results of an investigation conducted last year indicate insecticidal seed treatments may have contributed to unusual bee mortality rates in Ontario.

The PMRA investigation found that clothianidin was detected in some 70% of 104 dead bee samples tested in Ontario, while clothianidin and thiamethoxam were detected in the one reported incident in Quebec that involved eight bee yards. The PMRA investigated bee mortality reports from 40 beekeepers in Ontario involving 240 different bee yards. Residues of the insecticides were detected in about 80% of the yards where dead bee samples were collected and analyzed, the PMRA notes. Samples of unaffected bees were also analysed and clothianidin was detected in one sample at very low levels.

Corn seed in Ontario and Quebec is treated with either clothianidin or thiamethoxam in roughly equal quantities. Since thiamethoxam is converted to clothianidin, the detection of clothianidin in dead bees could indicate exposure to clothianidin or thiamethoxam.

Other pesticides were detected in some honey bee samples, including acetamiprid, coumaphos, fluvalinate, permethrin and phosmet, and the fungicide, thiabendazole.

The Runoff

- **China has approved three strains of GM** soy beans and one GM corn variety for import, says Agrentina's Ag Minister Norberto Yauhar. Yauhar won the agreement after traveling to Beijing to meet with Chinese officials. The approved varieties include Monsanto Intacta soy beans, one oy seed resistant to imidazolinone and one resistant to glufosinate.
- The European Food Safety Authority (EFSA) has set a July 30 deadline for comments on **new risk assessment methodologies for plant protection products**. The draft guidance covers clustering and ranking of emissions of active substances.
- DuPont Thursday warned that profits will be affected by the cool wet spring that has **farmers returning unused seed**. Demand from food producers is also down, further putting downward pressure on sales, the company forewarned.
- The Central Tuber Crops Research Institute in Thiruvanthapuram, India, says it has successfully developed to biopesticides to be used **against banana pseudo stem weevil**. Both Nanma and Menma tested successfully on crops at the Sanghamythri Farmers Producer Co., officials say.

Around the Country

Montana: Montana State University extension officials are encouraging adoption of state-of-the art nozzles to reduce drift. The threat to crops in neighboring fields is especially acute this year because the unusually wet spring is causing growers to mix herbicides that normally applied in sequence.

Delaware: Residents are being warned by state ag officials to ask for commercial applicator licenses before agreeing to have their grounds treated by third parties. The Pesticide Management division also says the name of the company, as well as its telephone and license numbers must be prominently displayed on all trucks and vehicles used in their work.

Kansas: Multiple cases of crop damage caused by drift are reported in the state, including to field corn, vegetables, trees and bushes in a state park and plantings on a college campus. Ag officials are warning applicators to read labels and comply with all details cited therein.

Minnesota: Minnesota Public Radio recently broadcast a lengthy story featuring beekeeper Steve Ellis who has joined with NGOs to sue the EPA in U.S. District Court in Northern California, asking for injunctive relief from neonicotinoid pesticides. Ellis told the station that people say to him, "Oh, you're up against the ag-chem industry and the government? And they go, well, you're screwed. But the problem is we're all screwed." The story is one of a growing number in the general press giving greater traction to the narrative critical on neonicotinoid pesticides.

Nebraska: University of Nebraska extension officials warn that the wet spring has disrupted the normal sequence of herbicide applications. They warn that mixing herbicides to make up for time lost can result in unintended consequences. Especially important is whether specific herbicides are appropriate to crop and weed stages.

EPA

EPA to OK 14 Cyazypyr-based insecticides

By Andy Beer

EPA has proposed the registration of DuPont's anthranilic diamide insecticide, cyantraniliprole (trade-marked as Cyazypyr), alone and in combination with Syngenta's neonicotinoid insecticide, thiamethoxam. The planned approvals cover ten single active ingredient products for a range of crop and non-crop applications and four combination products. The EPA has determined that cyantraniliprole should be accorded reduced-risk status and proposes that the approvals be unconditional.

The agency intends to approve a 100 g/liter oil dispersion formulation of cyantraniliprole, Benevia, for use on tree nuts, oilseeds (including cotton) and certain vegetables. A 100 g/liter suspo-emulsion formulation, Exirel, is for citrus, stone and pome fruit, bush berries, tree nuts and various vegetable crops. A 200 g/liter suspension concentrate formulation, Verimark, is for citrus fruit and certain vegetables.

Dermacor Z-103 is a 624 g/liter flowable concentrate seed treatment for use on rapeseed and mustard seed. Two other 600 g/liter seed treatments, listed as A17960A and A179060B, are recommended for use on potatoes and sunflowers. The Canadian authorities recently proposed the approval of these seed treatments as Fortenza and Fortenza Colorless, respectively, as seed piece treatments on potatoes.

Four single active ingredient products are intended for non-crop use. They include a fly control bait for use in and around residential and commercial and agricultural structures and a 200 g/litre suspension concentrate listed as SC Insect Control for indoor and outdoor use. Two more 200 g/litre suspension concentrates, T&O Insect Control and GH&N Insect Control, are for use on turf and ornamentals.

Only one of the four combination products is for agricultural use. Listed as A169101B (Minecto Duo in Canada), it is a water-dispersible granule formulation of cyantraniliprole (20%) and thiamethoxam (20%) for use on various vegetable crops. A similar combination, Mainspring, is for use on vegetables and ornamentals in greenhouses and nurseries. Two more combinations with the same proportions of active ingredients, A16901B Residential and A16901B Turf, are for outdoor residential ornamentals and turf, respectively.

The proposed maximum single application rate for liquid or granular formulations of cyantraniliprole is 0.42 lb ai/acre (0.5 kg/ha) and 0.69 active ingredient/acre for seed treatments. The proposed registrations are open to public comment until July 6.

Research

New papers bring neonic risk assessments into question

By Martin Zook

Two new papers question the validity of risk assessment methodologies widely accepted by regulators while registering neonicotinoid pesticides, commonly accepted to be a significant contributor to the widespread die-off of honeybees.

The papers point toward new research to better understand the complexities of determining the role pesticides play in the bees' mortality, both directly and indirectly. For instance, some experts question anecdotal evidence about why some bees exposed to neonicotinoids apparently do not show the concerning mortality rates that other bees do when exposed to the toxins.

The recently published papers point to the need to better understand the molecular action of the pesticides on the bees and how different routes of exposure affect their health.

A more valid way of measuring the impact of neonicotinoids on honeybees and other pollinators would be to measure the effect of pesticides over time at low doses typically encountered in the field, according to *The Molecular Basis of Simple Relationships Between Exposure Concentration and Toxic Effects With Time,* published *by Toxicology*.

"The mechanism of toxic ation has important implications for risk assessment." – The Molecular Basis of Simple Relationships Between Exposure Concentration and Toxic Effects With Time

Field studies measuring the mortality rate of hives in an agricultural setting where neonicotinoids are applied and contrasting that with a control group, could be the basis of a more meaningful assessment of the risk to honeybees, according to authors Henk Tennekes and Francisco Sánchez-Bayo.

The authors maintain in their paper that neonicotinoids bind tightly to receptors in the honey bees, which means the toxins accumulate over time as the exposure to toxins is prolonged.

They advocate for prolonged field studies to observe "chemicals showing irreversible or slowly reversible binding to specific receptors will produce cumulative effects with time of exposure, and whenever the effects are also irreversible they are reinforced over time; these chemicals have time-cumulative toxicity.

"The mechanism of toxic action has important implications for risk assessment. Traditional risk approaches cannot predict the impacts of toxicants with time-cumulative toxicity in the environment," the authors maintain.

"Neonicotinoid insecticides show reinforcement of lethal effects over time of exposure … The toxicity pattern of imidacloprid and thiacloprid suggests that these and other neonicotinoid compounds have irreversible binding to their nicotinic acetylcholine receptors," the authors write.

Widely accepted risk assessment

Neonic ► 5

Neonic ◄ 4

methodologies over-emphasize dose, as opposed to chronic exposure, the authors say. Much of the dispute over current research centers on doses used in laboratory studies. The authors' advocacy for field testing at low doses would address that concern.

A similar recommendation was made to *Pesticide & Chemical Policy* early this year by apiculturist and University of California extension official Eric Mussen. He suggested that Europes restrictions on the applications of neonicotinoids offers a good opportunity to set up a study similar to that recommended by Tennekes and Sánchez-Bayo.

However, he and others also say setting up such a study would be difficult because of the challenge of finding an environment free of neonicotinoid exposure needed for a control group.

"The interaction of a toxicant with the specific receptors that lead up to an effect is essential to understand the mechanisms of toxicity. Toxicokinetic and toxicodynamic models must be based on a molecular approach that considers the mechanisms of action of chemicals. Only then they will be able to explain the time-dependent effects observed in toxicity testing, and predict environmental impacts with reasonable accuracy," Tennekes and Sánchez-Bayo conclude.

Exposure route challenges

The second paper, *Neonicotinoids, Bee Disorders and the Sustainability of Pollinator Services*, reviews data from previous studies to trace neonicotinoids' path from application to leaching in the soil, making its way into water, or infiltrating hives exposing honeybees to the toxins throughout the year, as well as through more periodic exposures such as drift, or pollen. Current studies are overly focused on exposure associated with the various pollinating seasons.

The six authors also extrapolate the molecular action of neonicotinoids in concluding that sublethal exposure to neonicotinoids could play a significant role in what many expect are multiple causes of morbidity, including the Varroa mite.

The "wide application [of neonicotinoids], persistence in soil and water and potential for uptake by succeeding crops and wild plants make neoicotinoids bioavailable to pollinators at sublethal concentrations for most of the year," the authors write.

Exposure to neonicotinoid residues leads to a delayed development of honeybee larvae... This can favor the development of the Varroa destructor parasite." Neonicotinoids, Bee Disorders and the Sustainability of Pollinator Services

They also point out that insects' nervous systems makes them particularly vulnerable to neonicotinoids.

The persistence of the neonicotinoids means they accumulate in the environment. For seed treatments, the authors estimate no more than 20% of the insecticide is absorbed by the plant, the rest going into the environment where persistence from a single soil drench application has been measured in blossoms six years after the fact.

"It is however not the quantity that is relevant but the potency to cause harm, which results from toxity, persistence and bioavailability," the authors write.

Honeybees and other pollinators are exposed to the persistent toxins through six paths: ingestion, nesting material, direct contact through drift, contamination (soil, water, plants), cooling water in the hive, and inhalation of contaminated air.

In addition to the threat posed by commercial agricultural operations, foraging honeybees are exposed to suburban applications of pesticides, which frequently are not applied according to directions.

The authors also link neonicotinoids to honey bee susceptibility to the Varroa mite, commonly blamed by the pesticide industry as the primary cause of bee die-offs.

"Exposure to neonicotinoid residues leads to a delayed development of honeybee larvae, notably in the early stages. This can favor the development of the Varroa destructor parasitic mite within the colony. Likewise, the life span of adult bees emerging from the exposed brood proved to be shorter," the authors say.

Risk assessments questioned

The two papers signify a strategic shift in research that is bringing into question the way pesticides are reviewed during registration by questioning risk assessment methodologies.

The *Neonicotinoids, Bee Disorders* study is funded by a group of global environmental organizations that includes the Triodos Foundation's Support Fund for Independent Research on Bee Decline and Systemic Pesticides and donations from environmental groups such as Adessium Foundation (The Netherland), Act Beyond Trust (Japan), Zukunft Stiftung Landwirtschaft (Germany) and private citizens.

In addition to more research now in the pipeline that environmentalists hope will yield ammunition to their cause, NGOs are attacking EPA's registration procedures as inadequate and incomplete in determining the risk associated with registering neonicotinoids in two important suits now in U.S. district courts.

In one suit, the Center for Food Safety, Beyond Pesticides, other environmental groups and a handful of beekeepers allege EPA failed to adequately assess environmental threats when it registered neonicotinoid pesticides.

In the second suit, the Center for Biological Diversity has refiled its suit (see story page X) against the EPA in U.S. District Court of Northern California, at least in part over complaints that the regulator failed to follow procedures to adequately determine the risk posed to listed species under the Endangered Species Act.

USDA

APHIS extends comments on GE varieties resistant to old herbicides

By Stephen Clapp

USDA's Animal and Plant Health Inspection Service (APHIS) is extending the comment periods by 30 days for biotech crop varieties resistant to the controversial old herbicides 2,4-D and dicamba.

Stakeholders now have until July 17 to comment, based on notices published by APHIS in Monday's *Federal Register* (*http://1.usa.gov/19ijV3i*).

Virtual public meetings also have been scheduled for June 26-27, details for which are available at *www.aphisvirtualmeetings.com*.

The crop varieties at issue emerged in response to increasing resistance by weeds to the popular herbicide glyphosate, which is marketed by Monsanto as Roundup. Glyphosate-tolerant crops with added tolerance to 2,4-D and dicamba would enable farmers to cope with so-called "super weeds" no longer killed by Roundup.

APHIS says in a May 16 *Federal Register* notice (*http://1.usa.gov/13pqHwC*) that it plans to prepare two separate environmental impact statements (EIS) "to better inform decision-making regarding the regulatory status" of the controversial crop varieties. "If approved, these GE plants would provide farmers the flexibility for new applications of these herbicides, while also offering farmers additional crop planting options," the agency notes.

The agency identifies the following potential environmental issues for consideration in the EIS for dicamba-resistant crops:

- What are the impacts of weeds, herbicide-resistant weeds, weed management practices, and unmet weed management needs for crop cultivation, and how may these change with the approval of these petitions for non-regulated status of these herbicide-resistant crops?
- In which weeds would the approval of the two petitions likely contribute to controlling the spread of biotypes that are resistant to more than one herbicide mode of action, and how will that control influence weed management strategies in cropland or managed non-cropland?
- What weeds are currently resistant to dicamba herbicide and what is their natural frequency and occurrence in soy and cotton crops, other crops, and in non-crop ecosystems?
- Would the increased use of dicamba associated with the approval of these two petitions cause an acceleration of the selection and spread of dicamba-resistant biotypes? Are there weeds that are more likely to be difficult to control if they become resistant to dicamba?
- In which crops or non-cropland weeds would the selection and spread of dicamba-resistant biotypes be most problematic in terms of available alternate weed management strategies and agronomic production?
- In which weeds would the approval of the two petitions likely contribute to the selection and spread of biotypes that are resistant to more the one herbicide mode of action, and which would be most problematic for weed management strategies in cropland or managed non-cropland?
- What are the potential changes in agronomic practices, including crop rotation and weed management practices (e.g., herbicide use, tillage), for control of weeds in rotational crops that may occur with the use of these herbicide-resistant crops? What are the current and potentially effective strategies for management of herbicide-resistant weeds in crops? What are the costs associated with these practices and strategies?

EDC

BPA regulation comes under regulatory pressure

By Martin Zook

Pressure mounted last week to tighten regulation of bisphenol A in food packaging on both sides of the Atlantic.

In the U.S. Congress, Sen. Diane Feinstein (D-Calif.), who previously supported restrictions banning BPA's use in sippy cups but not baby formula containers, introduced the *BPA in Food Packaging Right to Know Act of 2013*. On June 4, Rep. Ed Markey, (D-Mass.) reintroduced legislation that would ban BPA from use in food containers. In Europe, BPA faces a ban in food containers in the fall.

FDA is weighing tighter regulations for BPA and for the second time this year clarified its position.

Regardless of legislative solutions, FDA is weighing tighter regulations for BPA and for the second time this year clarified its position on continued use of the chemical in food containers.

Feinstein's bill, which lacks bipartisan support, would require all food containers that include BPA to disclose, "This food packaging contains BPA, an endocrine-disrupting chemical."

"Scientific evidence continues to mount that BPA exposure is a risk to human health, especially for children. Therefore, it is essential that consumers know what chemicals are in the products they purchase," said Feinstein in a written statement. "Our children should not be used as guinea pigs by chemical companies when their parents are left in the dark about these harmful products."

While the proposed labeling language sounds innocuous enough, it

BPA wrap ► 7

EDC

BPA wrap ◄ 6

potentially could open a Pandora's Box that would require similar disclosure for other EDC, such as phthalates and polychlorinated biphenyls. The exact number of EDC are unknown, but some estimate the number to be well into the hundreds.

Feinstein's bill also would direct the Department of Health and Human Services to conduct a safety assessment of food containers with BPA.

On the House side, Markey's reintroduced Ban Poisonous Additives Act (*http://1.usa.gov/ZLip6A*), which would prohibit the use of bisphenol A in all food and beverage containers can claim 19 co-sponsors and the endorsement of 23 advocacy groups. But it does not enjoy a bright future in the Republican-dominated House.

Markey, in the midst of a re-election campaign, has been pushing to restrict the use of BPA in food packaging since 2008, including a bill that directed FDA to evaluate potential health threats posed by the controversial container sealant.

Markey's legislation would:

- Bar BPA from reusable food containers;
- Provide for FDA to issue one-year waivers if no alternative chemical is available;
- Require manufacturers receiving a waiver to submit a plan to FDA detailing how they plan to comply; and
- Mandate FDA review of chemicals already approved for food packaging and limit use of materials that pose a health threat.

FDA doesn't at this time support banning BPA, although the agency indicates it is moving toward tighter restrictions. FDA recently altered its stance on BPA to assure the public that restrictions enacted, in July 2012, against use in baby bottles and cups, but not formula packaging, is adequate protection for now.

Markey, in the midst of a re-election campaign, has been pushing to restrict the use of BPA.

The agency says it is "supporting the industry's actions to stop producing BPA-containing baby bottles and infant feeding cups, facilitating the development of alternatives to BPA for the linings of infant formula cans, and supporting efforts to replace BPA or minimize BPA levels in other food can linings."

Also, on its website (*http://1.usa.gov/KzXAh*) FDA says it is "supporting a shift to a more robust regulatory framework for oversight of BPA."

But, for now, consumers are safe using food from packaging that complies with current restrictions, the FDA adds on its website.

The wording on FDA's site, edited last Tuesday, reflects a more nuanced statement of FDA's stance. Previously, language added in the spring declared BPA safe for now but also said the regulator was working toward further restricting exposure risks.

Trade associations and other supporters of BPA took that language out of context to say the agency is reversing itself and giving BPA a clean bill of health.

In addition to FDA's efforts to work with industry groups, California added BPA to the Prop 65 list as a reproductive toxicant, but the state was forced to remove it by court order that granted the American Chemistry Council injunctive relief (see *FCN* April 26, 2013, Page 19)

In Europe, BPA faces a potential ban in food packaging. European Health Commissioner Tonio Borg said June 3 whether the European Commission pursues the ban depends on the recommendation by the European Food Safety Authority expected in the fall.

EFSA is reviewing recent BPA studies to determine whether regulation of BPA should be tightened. The studies under review include several that conclude BPA poses several threats to reproductive and neural systems in people.

Litigation

Environmentalists take second swing at pesticide ESA 'megasuit'

By J.R. Pegg

Environmentalists have filed an amended complaint in the pesticide "megasuit" alleging EPA has run afoul of the Endangered Species Act (ESA) by failing to assess how an array of registered pesticides could harm listed species, a move they hope will clear the legal hurdles that doomed their original challenge.

The revised complaint still fits the term "megasuit," but it is leaner than the original, which alleged EPA had registered some 382 pesticides without assessing the potential impacts to 214 listed species.

U.S. Magistrate Joseph Spero dismissed the first complaint in April on procedural grounds, ruling the complaint was too vague and concluding the plaintiffs failed to present specific allegations for each individual pesticide (see *P&CP* April 26, 2013, Page 1).

The new filing from the Center for Biological Diversity and Pesticide Action Network North America covers roughly 50 pesticide active ingredients. It alleges EPA failed to consult with the National Marine Fisheries Service and/or the U.S. Fish and Wildlife Service over the potential impacts to 112 endangered and threatened species, including the Florida panther, California condor and the black-footed ferret.

The new complaint makes the "same arguments we made before but with additional information," says Justin Augustine, an attorney with the Center for

ESA megasuit ► 8

Litigation

ESA megasuit ◄ 7

Biological Diversity. "It provides a better picture of how the pesticide regulatory process plays out."

The scaling back of the number of pesticides and species is a bid to get "some action on these more quickly," he adds. "We are still concerned about all of the pesticides cited in the original complaint, but we wanted the focus on some of the ones we are most concerned about, like diazinon, atrazine and 2,4-D."

The pesticides cited in the complaint fall into two categories. One includes pesticides for which EPA has indicated concentrations found in the environment may exceed levels of concern for listed species or may cause indirect effects on endangered species by altering habitat or food sources. The second category includes pesticides that are "highly acutely toxic" or "very highly acutely toxic" to one or more taxa groups.

The complaint notes that the "vast majority of pesticides have undergone no ESA analysis of impacts to listed species," and there have been only a few completed consultations between EPA and the wildlife agencies in the past 20 years regarding pesticide impacts, other than those imposed by court order.

For the pesticides in question, EPA has either failed to initiate or reinitiate consultation regarding its registration and reregistration actions since 1989.

Like the original, the amended complaint seeks a court order compelling EPA to start and complete the consultation process for the pesticides and species identified. It also asks the court to bar EPA from allowing label uses that might lead to pesticides entering designated critical habitat of listed species until the consultation process has been completed.

When asked if the plaintiffs had filed the amended complaint in a bid to get EPA to settle some of the claims and agree to a consultation timetable, Augustine said that was not the direct intent.

"We will have to wait and see if EPA is interested in settlement discussions," he tells *Pesticide & Chemical Policy*. "It is still early in the game, and it depends on how things go, but we are certainly open to that and wouldn't rule it out."

"It is a bit surprising that the complaint is as muddled as it is because district court gave them a pretty clear road map." - Attorney familiar with the refilled suit

Doubting lawyers

An attorney familiar with the case suggests settlements are the likely aim of the amended complaint, casting doubts that the plaintiffs will be able to satisfy the jurisdictional and procedural challenges that prompted Spero to dismiss the original complaint.

"It is a bit surprising that the complaint is as muddled as it is because district court gave them a pretty clear roadmap," the attorney tells *P&CP*.

Another attorney tracking the case calls the new complaint "voluminous" and "thinly researched."

"I don't expect this to be well received by the judge," the attorney tells *P&CP*.

Spero's reaction remains unknown, but he has previously voiced reservations the plaintiffs will be able to meet the legal requirements to succeed with their case.

"Plaintiffs must bring a separate ESA claim in connection with the EPA's affirmative act with regard to each individual pesticide in order to invoke [the ESA's] consultation requirement," Spero wrote in his April 22 ruling.

The judge offered the plaintiffs the opportunity to refile their claims, but noted that such separate claims face significant jurisdictional barriers and would likely have to be filed in an appeals court with 60 days of the underlying EPA action.

A key issue relates to the "ongoing agency action" that triggers consultation the amended complaint repeats statements in the original complaint that EPA's ongoing jurisdiction and discretionary control over pesticide registration is akin to such action.

That could be a problem for plaintiffs, says Tim Backstrom, a senior attorney with Bergeson & Campbell.

"That theory was decisively and unequivocally rejected by the district court's opinion," he explains. "There has to be a specific agency action with respect to which the plaintiffs are seeking relief. It can't be based on continued regulatory authority or ongoing discretionary control."

The issue of jurisdiction could also prove difficult for the plaintiffs.

In his April dismissal, Spero also questioned whether the subject matter of the complaint belongs in district court.

He determined the plaintiffs' "core objections" were not related to the ESA but to pesticide registrations and thereby governed by FIFRA, concluding they fell under the provision of the pesticide law that calls for review in district court.

Such review is afforded to a decision for which there was not a public hearing, though such a review is generally limited to a six-year statute of limitations. Under applicable precedent, actions for which EPA provided notice and comment are deemed to be actions for which there was a public hearing.

The EPA actions cited in the new complaint may not be able to clear that hurdle, Backstrom tells *P&CP*.

"The problem is that many of the cited actions are registration actions that implemented or effectuated a reregistration eligibility decision which was in fact taken after notice and comment," says Backstrom, a former attorney in EPA's Office of General Counsel.

The plaintiffs disagree and have not "let go of some of our legal positions," Augustine says, but still believe the amended complaints may convince Spero of their case.

"We hope he will get past the procedural issues and rule on the substance on and the merits," he tells *P&CP*.

Preemptive lawsuit by growers against Monsanto rejected

By Stephen Clapp

A federal appeals court, in Washington, D.C., on Monday affirmed a lower court's ruling to dismiss what's been described as a preemptive lawsuit to prevent Monsanto from suing farmers if traces of its patented genes are found in organic or other non-biotech crops.

Originally filed in March 2011, the lawsuit (*Organic Seed Growers and Trade Association (OSGATA) et al v. Monsanto et al*, No. 1:11-cv-2163-NRB) aims to protect farmers "from being accused of patent infringement should their crops ever become contaminated by Monsanto's genetically modified seed."

OSGATA and the other plaintiffs asserted that they suffered economic loss by restricting cultivation of their crops, because they feared a patent-infringement lawsuit in the event Monsanto's transgenic traits entered their fields inadvertently through cross-pollination or other means.

However, in her 24-page opinion dismissing the lawsuit, in February 2012, U.S. Judge Naomi Buchwald, said the plaintiffs engaged in a "transparent effort to create a controversy where none exists." She noted that Monsanto hadn't taken any action or even suggested taking any action against any of the plaintiffs.

And in a 24-page opinion issued by a three-judge panel Monday (*http://1.usa.gov/12Dg7bo via PACER*), the U.S. Court of Appeals for the Federal Circuit, in Washington, D.C., says the organic growers must rely on Monsanto's assurances that it won't sue them as long as the biotech traces are inadvertent. "Monsanto's binding representations remove any risk of suit against the appellants as users or sellers of trace amounts (less than one percent) of modified seed," the court states in its opinion.

> **"The appellants have alleged no concrete plans...The appellants therefore lack an essential element of standing." – U.S. Judge Naomi Buchwald**

"The appellants have alleged no concrete plans for activities to use or sell greater than trace amounts of modified see, and accordingly fail to show any risk of suit on that basis," the opinion continues. "The appellants therefore lack an essential element of standing."

Applauding the court's decision, Monsanto says in an email statement, "The assertion that Monsanto would pursue patent infringement against farmers that have no interest in using the company's patented seed technology was hypothetical from the outset -- the plaintiffs were unable to point to a single act of patent enforcement by Monsanto directed at any plaintiff. The appellate court quoted established precedent that parties "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm."

Plaintiffs declare "partial victory"

In a news release, the plaintiffs' attorney, Dan Ravicher of the Public Patent Foundation (PUBPAT), views the decision as a "partial victory" and says the plaintiffs are considering an appeal to the Supreme Court.

"Before this suit, the Organic Seed plaintiffs were forced to take expensive precautions and avoid full use of their land in order to not be falsely accused of patent infringement by Monsanto," Ravicher says. "The decision today means that the farmers did have the right to bring the suit to protect themselves, but now that Monsanto has bound itself to not suing the plaintiffs, the Court of Appeals believes the suit should not move forward."

While the court is relying on Monsanto's promise not to sue farmers for unintentional contamination, a growing number of America's farmers and consumers are concerned about "genetic contamination of our food supply by Monsanto's transgenic crops," the news release continues. "While this lawsuit seeks to protect contaminated farmers from being accused of infringing Monsanto's patents, the decision today allows farmers who are contaminated to sue Monsanto and Monsanto's customers for the harm caused by that contamination, without fear of a retaliation patent infringement claim against them by Monsanto."

Ravicher notes that the plaintiffs still have the right to ask the Supreme Court to review the appeals court's decision and "are considering doing so."

Court derails chlorine industry's challenge of rail safety rule

By J.R. Pegg

A federal appeals court has rejected the Chlorine Institute's bid to throw out a rule that tightens security and safety requirements for rail shipments of hazardous materials, concluding the industry group failed to show its members will be harmed by the regulation.

The rule in question was issued by the Federal Railroad Administration (FRA) as part of the agency's effort to implement the Rail Safety Improvement Act of 2008. It requires rail carriers to install "positive train control" (PTC) systems by Dec. 31, 2015 on certain tracks used for transporting "poison inhalation hazard" (PIH materials) such as chlorine.

Chlorine ► 10

Litigation

Chlorine ◄ 9

FRA issued the interim rule governing these requirements in January 2010, establishing 2008 as the baseline for determining which rail lines would be affected. It permitted railroads to request an exclusion from the requirements if it made routing changes to cease PIH traffic, setting up a two-part test that included an alternative route analysis as well as a residual risk analysis to show that shifting the PIH traffic to other routes did not increase the risk of accidents.

The Association of American Railroads challenged the rule, leading to a settlement with FRA that committed the agency to rework the rule and consider abandoning the use of the 2008 baseline as well as the two-part test for excusion/removal from the PTC requirements.

FRA issued a new final rule in May 2012 that met those demands, explaining that failure to do so "could potentially require PTC system implementation at a great cost to the railroads on lines that will not carry PIH traffic as of December 31, 2015."

The rule prompted the Chlorine Institute to file suit in the U.S. Court of Appeals for the D.C. Circuit. It contends the FRA's decision to eliminate the 2008 baseline and the two-part test was "arbitrary and capricious" and contrary to congressional intent.

> **"At this point, we do not know how routing may change." – U.S. Judge Karen LeCraft Henderson**

The industry group argued that its members were directly injured by the revision of the rule, suggesting it gives the railroads added power and incentive to restrict or eliminated chlorine transportation by rail.

But the court was unconvinced and determined it lacked jurisdiction because the challenge was not ripe for review.

The Chlorine Institute's "described impact is -- at most -- speculative," writes Judge Karen LeCraft Henderson.

It is unclear which track segments will be fitted with PTC, "much less whether any Institute member's ability to ship PIH will be significantly affected," Henderson writes in the 12-page opinion.

Although FRA acknowledged that eliminating the two-part test will cause more rerouting of PIH traffic than under the 2010 rule, the modification does "not necessarily" limit or eliminate the ability of a chlorine shipper to send its product by rail, Henderson adds.

"It simply requires a different shipping route be used," she explains. "At this point, we do not know how routing may change — or whether the additional rerouting under the 2012 Final Rule will affect — an Institute member's ability to transport chlorine."

As the 2012 rule is implemented and its "impact becomes clearer, such an injury may indeed emerge and the Institute's challenge may thereby ripen," Henderson concludes. "It is not ripe now."

REACH

REACH compliance costs threat to business

The costs of complying with the REACH regulation could force some companies, particularly small firms, off the market by the 2018 registration deadline, a chemical industry representative recently warned.

Chris Scott-Wilson, of the European Chemical Industry Council (Cefic), spoke out at a June 4 meeting of the European Parliament Intergroup on Climate change, biodiversity and sustainable development on 'REACH: Ensuring environmental protection and European competitiveness.'

Scott-Wilson said that there were two dimensions to REACH, environmental protection and competition, "which turns into costs," and that the two were seen as in conflict with each other. He said that one side (environmentalists) want protection at any price; the other side (industry) asked who was going to pay for it.

He noted that REACH was "certainly the most expensive legislation in the world."

Scott-Wilson reported that Cefic was "hearing a lot of squeals" from Eastern European members that if the costs continue, small and medium-sized (SMEs) firms will not continue after 2018 – when the third REACH registration deadline falls for substances produced or imported in quantities over 10 metric tons a year per producer or importer and which will affect many small firms.

Scott-Wilson said he was hearing some smaller companies were already winding down operations ahead of the May 2018 deadline. However, he admitted that he had no hard evidence for this, it was just "jungle drums."

Fee cuts for SMEs not the answer

The Cefic representative went on to say that compliance with the REACH process was not necessarily easier for big companies as they still had to bear significant costs.

Scott-Wilson said that the solution favoured by the Commission of "simply tipping the balance" so that SMEs pay less and big firms much more, was "not the solution, it is better to reduce the costs for all."

Francis Peters of tire maker Michelin also suggested that reducing fees for SMEs was not the answer since this was not where the problem costs lay for small firms, rather it was in the costs of letters of access to shared data generated through the Substance Information Exchange Fora (SIEFs).

Peters said that letters of access were "very expensive," pointing as an example to the one for carbon black which was "something like €180,000." He said that this was hard on SMEs.

The high costs would mean some historical production will end up going outside Europe, Peters warned.

Michal Kubicki of the European Commission's DG Enterprise agreed that cutting fees was not necessarily

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the solution. He argued industry needed to move on the important question of how the costs of letters of access are better distributed, "so we in the Commission would not have to overreact with fees."

However, Henrik Laursen of DG Environment pointed out that letters of access were not just an administrative cost but were about the cost of generating the information needed to prove a chemical can be used safely.

Substitution not easy

Scott-Wilson further claimed that it was easy to say "take out harmful substances and replace them", which was something that everyone could agree on, but it was difficult to identify not only how harmful a particular substance is, but also how harmful a potential replacement is as well as whether it can deliver the same benefits and costs.

He underlined that substitution was a "complex scientific process that should not be underestimated," adding, "when you talk about substitution don't think it is easy, it is not."

While industry has embraced REACH, Scott-Wilson admitted there had been "teething problems" particularly when it came to dossier quality and nanomaterials.

NGOs keen to see 'Monsanto' rider die on the vine

By J.R. Pegg

Critics of a temporary provision that limits the ability of federal courts to halt the planting of genetically modified crops are hoping they have convinced lawmakers to allow the law, commonly known as the "Monsanto protection act," to expire this fall.

At issue is language inserted in the Continuing resolution signed into law in late March. The "Farmer Assurance" provision requires the USDA to allow the continued sale and planting of GM crops even if a federal court has invalidated or vacated the regulation that approved them. It permits the sale and planting of the affected crop until USDA completes any environmental impact analysis or consultations required by a court order.

Proponents argue the language is necessary to bring certainty to farmers of GM crops who face disruption from litigation filed against GM crop regulation.

Major grower groups, seed manufacturers and other biotech advocates have weighed in with support, including the American Farm Bureau Federation, National Corn Growers Association, American Soybean Association and Biotechnology Industry Organization.

But it has drawn the ire of NGOs and some Democrats in Congress, who see it as unwarranted.

"This provides absolutely no assurance to farmers and will actually create more concern and confusion in rural America," says Colin O'Neil, director of government relations for the Center for Food Safety. "It seeks to assure that Monsanto, Dupont and others will be able to continue to sell their seeds."

The recent discovery of an unauthorized Monsanto strain of GM wheat in an Oregon field has helped fuel opposition to the measure, O'Neil adds.

> **"This provides absolutely no assurance to farmers and will actually create more concern and confusion in rural America." – Colin O'Neil, director, government affairs, Center for Food Safety**

"It shows we need to be really looking at the inadequacies of the field trial system, not at expanding loopholes in the regulatory system," he tells *Pesticide & Chemical Policy*.

USDA Secretary Tom Vilsack has also suggested the rider is unnecessary, telling the Senate appropriators last month that the provision is confusing and interferes with the regulatory and legal processes.

"It doesn't necessarily do anything that I can't already do," he said during testimony May 9. "So my view of this is 'why stir up the pot if you don't have to?'"

Sen. Jeff Merkeley (D-Ore.), who proposed an amendment to the Farm Bill to repeal the rider, echoed that view last week on the Senate floor and alluded to the GM wheat controversy.

The situation in Oregon "underscores the fact that poorly regulated GMO cultivation can pose a significant threat to farmers who are not cultivating GMO crops," he told colleagues. "Equally troubling to the policy rider's allowance of unrestricted sale and planting of GMO seeds is the fact that the Monsanto protection act instructs the seed producers to ignore a ruling of the court, thereby raising profound questions about the constitutional separation of powers and the ability of our courts to hold agencies accountable."

Merkeley also criticized the inclusion of the measure within a must-pass spending bill, adding that he is keen to ensure an extension of the provision is "not tucked into subsequent legislation in a manner that bypasses full committee examination and Senate debate."

Republicans blocked consideration of Merkeley's amendment Sen. Roy Blunt (R-M.) said critics were misreading the impact of the provision that he authored, reportedly with help from Monsanto.

"This language doesn't require USDA to approve biotech crops," Blunt said during Senate debate on the Farm Bill last month. "It doesn't prevent individuals from suing the government over a biotech crop approval. Ultimately, this language simply codifies the authority the Secretary believes he had."

But opposition to the measure appears to be growing and critics gained a key Democratic ally in the fight during discussion of the Farm Bill, namely Senate agriculture committee Chair Debbie Stabenow (Mich.).

During a colloquy with Merkeley last week on the Senate floor, Stabenow said

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she agrees that the provision should not be extended behind closed doors.

"I think it would be inappropriate for that language to be adopted in a conference committee or otherwise adopted in a manner designed to bypass open debate," she told the *Oregon Democrat*. "I will do my best to oppose any effort to add this kind of extension in the conference committee on this Farm Bill or to otherwise extend it without appropriate legislative examination."

O'Neil says there are signs that the House is also losing its luster for the provision. House Republicans did not add an extension to the rider to their version of the USDA appropriations bill, which was passed by the House appropriations subcommittee on agriculture last week.

This may reflect the influence of Senate Appropriations Committee Chair Barbara Mikulski (D-Md.), who has promised to block an extension of the rider via any appropriations bill, O'Neil says, adding that public opposition is playing a role as well.

"Members of Congress have heard from a lot of constituents on this issue," he says. "It is the first time the food movement has been so vocal."

Pigs fed GE corn and soy developed health issues, study suggests

By Stephen Clapp

Pigs fed genetically engineered feed rations by an Iowa farmer showed significant increases in severe stomach inflammation and thickening of the uterus, a team of Australian scientists and Iowa farmers report in a 17-page study published in this month's issue of the *Journal of Organic Systems* (*http://bit.ly/12jxMnj*).

But the biotechnology industry already is questioning the credibility of the study.

Gilles-Eric Séralini, a molecular biologist at the University of Caen, in France, caused much uproar and controversy in September when he published the results of his two-year study of rats fed GE food, finding higher rates of certain tumors, and liver and kidney problems. The study has been rejected as being of poor scientific quality by the European Food Safety Authority (EFSA) and other risk assessment bodies worldwide.

However, biotech opponents now say a new, peer-reviewed study performed in the United States by a group of eight scientists and farmers "reinforces" the concerns raised by Séralini.

A research team, led by Judy Carman, an organic chemist with the Institute of Health and Environmental Research, in Kensington Park, Australia, and Howard Vlieger, president of Verity Farms, in Maurice, Iowa, reportedly examined 84 pigs fed double and triple-stacked varieties of GE corn and soy under commercial production conditions over a 22.7 week period -- the normal lifespan of a commercial pig from weaning to slaughter -- and compared them to a control group of 84 pigs fed conventional corn and soy, the GE-fed pigs showed significant increases in severe stomach inflammation and thickening of the uterus.

The group reports finding no differences between the pigs fed the GM and non-GM diets in relation to feed intake, weight gain, mortality, and routine blood biochemistry measurements. However, the "GM-fed pigs had uteri that were 25% heavier than non-GM fed pigs" and "GM-fed pigs had a higher rate of severe stomach inflammation with a rate of 32% of GM-fed pigs compared to 12% of non-GM-fed pigs." For male pigs, the rate of severe stomach inflammation was four times higher for GE-fed males to non-GE fed males, and for females, the rate was more than two-fold higher.

These effects "are a red flag and deserve further study," says Michael Hansen, senior scientist for the Consumers Union, the advocacy arm of *Consumer Reports*, in a press release issued Tuesday to bring attention to the study. "We also believe this study underlines the need for labeling of GE food, since there is still much to learn about their health effects." He urges state legislatures, as well as Congress and FDA, to require labeling of GE foods.

There have been very few animal feeding studies of GE food to date, and extremely few that lasted longer than 90 days, Hansen notes.

"The results indicate that it would be prudent for GM crops that are destined for human food and animal feed, including stacked GM crops, to undergo long-term animal feeding studies preferably before commercial planting, particularly for toxicological and reproductive effects," he says.

The Washington, D.C.-based Biotechnology Industry Organization (BIO), as might be expected, isn't impressed. In a news release issued Tuesday evening, BIO says it reviews all new feeding studies involving GMOs, "as assertions of food safety [risks] have been made previously, but none have been found to be credible. There are several aspects of this report that deserve further scrutiny."

BIO describes the study's lead authors, Carman and Vlieger, as "veteran anti-biotech campaigners" and notes that their study was published in "an obscure online journal. It reaches conclusions that are diametrically opposed to the great preponderance of the scientific evidence gathered over hundreds of independent food and feed safety studies that found no difference in between animals fed GMO or non-GMO diets."

It's true that Vlieger and Carman can be found numerous times on the Internet, expressing their views about the dangers of consuming GE foods prior to the publication of their study, including this radio interview (*http://bit.ly/11vYN0P*).

BIO continues: "In reporting observations that pigs fed GMOs had severely inflamed stomachs, the authors note that pigs fed non-GMO diets also had inflamed stomachs, but failed to mention in their conclusion that there were more pigs with inflamed stomachs that had eaten the non-GMO diet. Such inflammation is common in animals with high feed intake or feed that has been finely ground.

"Moreover, without important information about the setting of the experiments, other non-feed related factors could account for the observed results. Accordingly, these data cannot be critically analyzed."

Chinese indecision jeopardizes Intacta RR2 seed sales in Brazil

By Steven Lewis

Anticipated Brazilian sales of Intacta RR2 soybean seeds may dissipate during the upcoming growing season if Chinese food safety officials don't approve the biotech variety for importation.

With the soybean planting season only a few months away, a team of Brazilian agriculture sector leaders headed to Beijing last month in order to get a reading on China's willingness to purchase Intacta RR2 soybeans. However, the team shed little light on China's stance.

"I must admit that when I returned to Brazil, I had more unanswered questions than when I left," Sen. Blairo Maggi conceded in a trip report issued May 24.

He goes on to explain that Chinese officials gave no reason for the delay in approving commercial transactions involving Intacta RR2 soybeans or the 19 other varieties of genetically engineered crops still under review.

Similar frustration is voiced by Glauber Silveira, president of the Brazilian Association of Soybean Producers (Arposoja), who returned from the trip without the information needed to advise member growers on whether to purchase Intacta RR2 seeds.

"Unless we get the green light from the world's largest soybean importing nation, Brazilian farmers won't be in a position to plant Intacta RR2 seeds," Silveira laments in a statement to members.

He expresses concern that, if China doesn't approve the technology prior to September, it will be necessary to find another market for three million sacks of Intacta RR2 soybean seeds earmarked for planting in Brazil this year.

The same scenario played out on a smaller scale last growing season, when China's indecision forced farmers to give up plans for adopting the new seed technology.

Brazilian farmers are showing increasing signs of frustration at their inability to plant new technology seeds that achieved higher yields with fewer applications of agricultural chemicals during recent field tests.

The number of farmers who engaged in experimental plantings of the Intacta RR2 seeds under the Ground Breakers program increased 58% year-on-year during the 2012-2013 growing season. This jump in planting creates the challenge of ensuring that soybeans derived from the experimental plantings don't commingle with older technology soybean shipments destined for China.

There is a growing consensus among key players in Brazil's soybean sector that China is abusing its power as the world's leading grain importer by destabilizing the market.

However, he predicts that China will eventually approve the new seed technology, because Chinese importers are in no position to give up purchases of GE soybeans from their three main suppliers in the Americas: Argentina, Brazil, and the United States.

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"The lab technician unquestionably creates something new when cDNA is made," Thomas says.

Middle ground

The mixed ruling reflects the view put forth by the Obama administration during oral arguments in April.

U.S. Solicitor General Donald Verrilli rejected the notion that human genes can be patented, but pressed the court to limit the scope of its ruling and ensure that DNA that has been modified or manipulated for a use not found in nature can be patent protected.

As a conceptual matter, synthetic DNA is "patent eligible," Verrilli told the justices on April 15.

The court's agreement with that middle ground has left both sides claiming at least partial victory.

Myriad highlighted the court's ruling on the cDNA in its reaction to the decision, opting not to comment on the core of the decision.

"We believe the court appropriately upheld our claims on cDNA, and underscored the patent eligibility of our method claims, ensuring strong intellectual property protection for our BRACAnalysis test moving forward," says Peter D. Meldrum, company president and chief executive.

The chief of the Biotechnology Industry Organization (BIO) also hones in on the cDNA portion of the ruling.

"cDNA is the commercially most important form of DNA used in biotechnology," says Jim Greenwood, president and CEO of the industry group, in a statement, "Today's decision offers urgently needed certainty for research-driven companies that rely on cDNA patents for investment in innovation."

But Greenwood does caution that the decision to invalidate the BRCA patents is "troubling" and could impede development of a broader range of biotechnology inventions.

Companies who use biotech to produce vaccines, renewable fuels, industrial enzymes, as well as pest and disease resistant crops "have long relied on patents on preparations of DNA molecules and other biological chemicals in order to bring innovative, socially beneficial products to the marketplace," Greenwood says. "BIO will continue its efforts to ensure that these companies and our partners in research universities around the globe can secure the patent protection necessary to continue our common mission to help fuel, feed and heal the world."

Plaintiffs pleased

The head of Breast Cancer Action, one of the plaintiffs, says the ruling "ends Myriad's monopoly" and will dramatically lower the costs for testing to identify the two genes.

"One of the single greatest barriers to breast cancer research, improved testing, new diagnostic tools and targeted therapies related to the BRCA genes was today struck down," says BCA executive director Karuna Jaggar. "Women will now have access to new tests, at lower cost, and will be able for

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the first time to get second opinions."

The court has confirmed "once and for all that all genes are part of the natural world and cannot be patented," says Andrew Kimbrell, executive director of Center for Food Safety. "This groundbreaking decision is a victory for all of us that have long argued that nature and humanity should not and cannot be owned and controlled by corporations."

Kimbrell's group contends the ruling invalidates patents on some 15,000 genes that have been approved by the Patent and Trade Office.

These patents range from "microbes to mice to monkeys," adds Jaydee Hanson, policy director of the International Center for Technology.

The ruling "means someone who wants to do research with one of those genes that may have been owned by a seed company, for example, doesn't have to get permission to do research on that gene," he tells *Pesticide & Chemical Policy*.

Companies and individuals "can't go and discover something in nature and claim they have a patent on it," Hanson explains. "You can't patent a whole plant. For someone trying to make safer pesticides, that means you have the whole plant to look at."

Hanson and other supporters of the plaintiffs, however, are frustrated the court ruled that synthetic DNA may be patentable.

"We urge the court to revisit the issue," he says. "This kind of copying of DNA should be no more patentable than a photocopy of a Picasso should be sold as a new work of art."

Maine bill ◄ 1

But for the Maine law to be enacted, four states from the region (New York, New Hampshire, Vermont, Massachusetts, New Jersey, and Pennsylvania) must approve similar legislation. Even David Murphy, founder of Food Democracy Now, is not sanguine about chances for labeling this year outside of Washington State, whose voters will decide the issue in a fall referendum.

"It's not likely at this point a bill is going to pass (this year)," he concedes.

In fact, the contingency in the Maine bill is even tougher to clear than contingencies included in Connecticut's bill approved two weeks ago (see *P&CP*, June 7, 2013, page 1). The tougher contingency was introduced to get the votes of labeling opponents and assure them that the law will not be enacted.

Of the six contingent states referenced in the Maine bill, passage of labeling is certain in none of them. There was a hearing last week in Massachusetts on three bills, and two others have yet to be taken up, creating a logjam that makes passage unlikely this year. Murphy holds out qualified hope for labeling in New Jersey, where there is strong opposition from grocers. In the eyes of many, it was food retailer's threat of higher food prices for labeled food that sent Prop 37 down to defeat in California last year.

Labeling was defeated in committee two weeks ago in New York. Vermont's adjourned legislature cannot consider until 2014 labeling legislation that passed the house earlier this year. Labeling legislation in Pennsylvania remains bottled up in committee and faces seemingly insurmountable opposition from farmers.

In 16 other states that considered labeling of GM foods this year, the issue is considered dead for this year, or state legislators, including Colorado and Hawaii, say they are deferring to Congress or the FDA.

And that's the same path that Murphy and NGOs see. Passage of any legislation at the state level this year is seen as "groundbreaking," he says. By gaining support state by state activists hope to force the hand of Congress, or the FDA, to require labeling of GM food, says Murphy, who is lobbying for labeling in a number of state legislatures.

Looking forward to the end of the year, the brightest hope for passage of legislation is in the state of Washington, where voters will decide the issue in a referendum in the fall.

Also next year, NGOs will support reintroduction of legislation in states that either defeated labeling bills this year, or let them die on the vine, again with the aim of building pressure on federal officials.

State bills need work

Labeling GM food is a complex subject that demands expertise generally not available at the state level and the bill passed in Maine reflects that lack of sophistication. The Maine bill includes a definition of "genetically engineered" food that could pose problematic based on Europe's experience with labeling GM foods.

There is no definition of GM food in Maine's bill. Instead, it defines the process of engineering food: "'Genetically engineered' means the application of in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."

While this definition defines the process, it does not describe the end result, food. For instance, many foods contain genetically engineered parts, but themselves are not the product of the process described in Maine's legislation.

Honey is such a food and European Union officials are wrestling with the question of whether pollen from genetically modified plants in honey makes it GM.

The four-page Maine bill does go to considerable length, however, to exempt foods. For instance, the bill attempts to exempt a person who unknowingly produces food from ingredients derived from genetically engineered products.

This raises the thorny question about what food producers knew about the components they use in manufacturing their final products. In Europe, legislators are asking whether a beekeeper can claim ignorance that honey produced from hives near fields planted with GM seed can claim they didn't know their honey contains GM ingredients.

Animals in the Maine bill are not considered GM food if their diet includes modified feed. It's not clear, but this would seem to indicate that honey with GM pollen in it is not subject to labeling requirement.

Processed foods are not subject to labeling requirements if the total weight of GM ingredients is less than 0.9% of the total weight. This may not be as clear as it sounds. Again, using the example of honey, most of the bee byproduct sold in stores is considered processed because it is heated and filtered to remove ingredients, including pollen. But raw honey, advocated for its health benefits by the National Honey Board, is not processed and presumably subject to labeling in Maine.

OPP Comments

Comments directed at EPA's Office of Pesticide Programs can be sent:

- *By mail* to Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, EPA, 1200 Pennsylvania Ave., NW, Washington, D.C. 20460
- *In person or by courier* to Public Information and Records Integrity Branch, Information Resources and Services Division (7502P), Office of Pesticide Programs, EPA, One Potomac Yard (South Building), Room S-4400, 2777 S. Crystal Drive, Arlington, Va. 22202
- *Electronically* via the Internet at: *www.regulations.gov.*

FIFRA/FFDCA

Tolerance Actions

Proposal issued to convert time-limited tolerances for tetrachlorvinphos

In the June 12 *Federal Register* (78 *FR* 35189), EPA issued a proposal to amend §180.252 by converting into permanent tolerances the existing time-limited interim tolerances for the combined residues of the insecticide **tetrachlorvinphos**, (Z)-2-chloro-1-(2,4,5-trichlorophenyl) vinyl dimethyl phosphate, including its metabolites, 1-(2,4,5-trichlorophenyl)-ethanol (free and conjugated forms), 2,4,5-trichloroacetophenone, and 1-(2,4,5-trichlorophenyl)-ethanediol, in or on the following commodities:

- cattle and hog fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*) at 0.2 ppm;
- cattle and hog kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 1.0 ppm;
- cattle and hog liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.5 ppm;
- cattle and hog meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*) at 2.0 ppm;
- cattle and hog meat byproducts, except kidney and liver at 1.0 ppm;
- egg (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.2 ppm;
- milk, fat (reflecting negligible residues in whole milk and of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.05 ppm;
- poultry, fat (of which no more than 7.0 ppm is tetrachlorvinphos *per se*) at 7.0 ppm;
- poultry, liver (of which no more than 0.05 ppm is tetrachlorvinphos per se) at 2.0 ppm;
- poultry, meat (of which no more than 3.0 ppm is tetrachlorvinphos *per se*) at 3.0 ppm; and
- poultry, meat byproducts, except liver, at 2.0 ppm.

EPA issued a proposal March 6 to extend the expiration/revocation date for the time-limited tolerances to Aug. 18. A final rule issued March 13 finalized the extension of the expiration/revocation date.

Comments identified by Docket No. EPA-HQ-OPP-2011-0360 must be received on or before Aug. 12.

Exemption Actions

Exemptions issued for 1,3-propanediol, *Bacillus pumilus* strain BU F-33

On June 12 (78 *FR* 35143), EPA issued a final rule amending: (1) §180.910 by establishing an exemption from the requirement of a tolerance for residues of **1,3-propanediol** (CAS Reg. No. 504-63-2) when used as an inert ingredient (solvent, co-solvent, diluent or freeze-point depressant) in pesticide formulations applied to growing crops and to raw agricultural commodities and (2) §180.940 by establishing an exemption from the requirement of a tolerance for residues of **1,3-propanediol** when used in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment and food-processing equipment and utensils.

EPA announced Jan. 16 that DuPont Tate & Lyle BioProducts, LLC, Loudon, Tenn., had petitioned for the exemptions. No comments were received in response to the filing notice.

The regulation is effective June 12. Objections and requests for hearings identified by Docket No. EPA-HQ-OPP-2012-0921 must be received on or before Aug. 12.

Also on June 12 (78 *FR* 35147), EPA issued a final rule amending §180.1322 by establishing an exemption from the requirement of a tolerance for residues of ***Bacillus pumilus*** **strain BU F-33** in or on all food commodities when applied to elicit induced systemic resistance in plants and when used in accordance with both label directions and good agricultural practices.

In a notice issued Sept. 28, 2012, EPA announced that Becker Underwood, Inc., Ames, Iowa, had petitioned for the exemption. No comments were received in response to the filing notice.

The regulation is effective June 12. Objections and requests for hearings identified by Docket No. EPA-HQ-OPP-2012-0264 must be received on or before Aug. 12.

Registration Actions

Requests received to voluntarily cancel certain pesticide registrations

On June 12 (78 *FR* 35265), EPA issued a notice announcing the receipt of requests by registrants to voluntarily cancel 54 pesticide product registrations.

EPA intends to grant these requests at the close of the comment period unless substantive comments are received that would merit further review or unless the registrants withdraw their requests.

For a complete list of the cancellation requests, visit the FR website at: *http://www.gpo.gov/fdsys/pkg/FR-2013-06-12/html/2013-13817.htm*

Comments identified by Docket no. EPA-HQ-OPP-2010-0014 must be received on or before Dec. 9.

Also on June 12 (78 *FR* 35268), EPA issued a notice announcing the receipt of requests by registrants to voluntarily cancel 45 pesticide product registrations.

EPA intends to grant these requests at the close of the comment period unless substantive comments are received that would merit further review or unless the registrants withdraw their requests.

For a complete list of the cancellation requests, visit the FR website at: *http://www.gpo.gov/fdsys/pkg/FR-2013-06-12/html/2013-13978.htm*

Comments identified by Docket no. EPA-HQ-OPP-2009-1017 must be received on or before July 12.

Federal Register

OPP Comments

Comments directed at EPA's Office of Pesticide Programs can be sent:

- *By mail* to the Document Control Office (7407M), OPPT, EPA, 1200 Pennsylvania Ave., N.W., Washington, D.C. 20460-0001
- *In person or by courier* to OPPT Document Control Office (DCO), EPA East Building, Room 6428, 1201 Constitution Ave., N.W., Washington, D.C.
- *Electronically* via the Internet at: *www.regulations.gov.*

TSCA Actions

PMN, TME update issued

On June 14 (78 *FR*), EPA issued a status report on the receipt of premanufacture notices (PMNs) or applications for a test marketing exemption (TMEs), as well as the receipt of notices of commencement (NOCs) to begin the manufacture of these chemicals. Federal regulations require that any person intending to manufacture, including import, of a new chemical not on the TSCA inventory, is to notify the agency and to comply with the statutory provisions pertaining to the manufacture of a new chemical.

This notice covers the time period from March 11, 2013 – April 19, 2013 and provides the required notice and status report for the PMNs and TMS, both pending and expired, and the NOCs to manufacture a new product.

Comments identified by both EPA Docket No. EPA-HQ-OPPT-2013-0229 and the specific PMN or TME number must be received on or before July .

Federal Dockets

Federal Dockets

Pesticide & Toxic Chemical Dockets: Comments Due June 17 – August 12

Subject	Title/Description	Docket No.	Due
Methanol	Comment period	EPA-HQ-ORD-2009-0398-0031	June 17
Propiconazole	Tolerance	PA-HQ-OPP-2012-0246-0003	June 18
Azoxystrobin	Tolerances	EPA-HQ-OPP-2012-0283-0004	June 24
Bacillus mycoides isolate J	Time-Limited Exemption from the Requirement of a Tolerance	EPA-HQ-OPP-2012-0397-0004	June 24
Glyphosate	Tolerances	EPA-HQ-OPP-2012-0132-0009	July 1
Cyantraniliprole	New Active ingredient	EPA-HQ-OPP-2011-0668-0006	July 6
Spirotetramat	Tolerances	EPA-HQ-OPP-2012-0107-0006	July 15
Streptomycin	Emergency Exemptions	EPA-HQ-OPP-2011-0852-0007	July 16
Sulfoxaflor	Tolerances	EPA-HQ-OPP-2010-0889-0402	July 16
Difenzoquat	Tolerances	EPA-HQ-OPP-2012-0441-0005	July 29
Guar hydroxypropyltrime thylammonium chloride	Exemptions from Tolerance Requirements	EPA-HQ-OPP-2012-0558-0003	July 29
Triforine	Tolerances	EPA-HQ-OPP-2011-0780-0004	July 29
Diisopropyl adipate	Tolerances	EPA-HQ-OPP-2012-0469-0003	Aug 5
Propamocarb	Tolerances	EPA-HQ-OPP-2008-0887-0004	Aug 5
Bacillus pumilus strain BU F-33	Tolerances	EPA-HQ-OPP-2012-0264-0005	Aug 12
1,3-Propanediol	Tolerances	EPA-HQ-OPP-2012-0921-0003	Aug 12
Tetrachlorvinphos	Tolerances	EPA-HQ-OPP-2011-0360-000	Aug 12

Editor's note: To access regulatory and supporting documents or to file a comment, enter the Docket Number at *www. regulations.gov.*

The Shifting Status of BPA under California's Proposition 65

With legislation introduced in both chambers of Congress this week to outlaw the use of bisphenol A (BPA), including one bill offered by Sen. Dianne Feinstein (D-Calif.) (see p.6), you might be interested in reading this thorough analysis from one of the food industry's top packaging regulatory experts regarding an effort, in California, to add this chemical sealant to the state's Prop 65 list of reproductive toxicants. -- J. Huffman

By George G. Misko

The California Environmental Protection Agency's (Cal/EPA) Office of Environmental Health Hazard Assessment (OEHHA) just does not want to give up on trying to include bisphenol A (BPA) on the state's Proposition 65 list of reproductive toxicants.

After its Developmental and Reproductive Toxicant Identification Committee (DART-IC) voted unanimously in 2009 *against* the inclusion of BPA on the state's Proposition 65 list of reproductive toxicants, the office tried earlier this year to include BPA by way of another listing mechanism. However, OEHHA was thwarted once more, as the Sacramento County Superior Court, on April 19, issued a preliminary injunction ordering removal of the listing pending its final determination in a case brought by the American Chemistry Council (ACC) (see *FCN* April 26, 2013, Page 19).

It's hard enough to stay on top of all the federal regulatory issues related to food packaging, much less issues that arise in different states. But here's how it all went down, starting with a quick explanation of how an already under-fire starting material for epoxy resins and polycarbonate plastics could get on California's Proposition 65 list and what that might mean to packaging made with it.

The Law

Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, requires the governor of California to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. Among other things, the law prohibits a person from knowingly exposing any individual to a listed chemical without first providing a "clear and reasonable warning" to such individual.

Violations of Proposition 65 are subject to hefty civil penalties of up to $2,500 per day for each violation.

The law requires these warnings to be provided for consumer product, workplace, and environmental exposure unless "the person responsible can show that the exposure [to a listed carcinogen] poses no significant risk assuming lifetime exposure at the level in question," or, for a listed reproductive toxin, "will have no observable effect assuming exposure at 1,000 times the level in question," what OEHHA refers to as a Maximum Allowable Dose Level (MADL). Warning requirements go into effect for a given chemical one year after the chemical is officially listed.

Violations of Proposition 65 are subject to hefty civil penalties of up to $2,500 per day for each violation. Injunctive relief is also available. Proposition 65 may be enforced by the California Attorney General, local district and city attorneys, or "bounty hunters" -- private citizens permitted to bring enforcement actions if the state declines to do so or does not act within 60 days after it is notified of an alleged violation.

A chemical may be added to the Proposition 65 list in one of several ways. One of the more common is for OEHHA to seek the advice of its Science Advisory Board, which it did in this case in 2009. Another way is to propose a listing based on the conclusions of one or more "authoritative bodies," which have concluded that a particular chemical is a carcinogen or reproductive toxicants.

The BPA Saga

The latest twist in this saga began when OEHHA announced on Jan. 25, that it intended to add BPA to the state's Proposition 65 list of reproductive toxicants under the authoritative bodies mechanism based on the conclusions reached by the National Toxicology Program (NTP).

In particular, OEHHA cited a 2008 report issued by the NTP's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR), titled, *"NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A."* The NTP-CERHR report cited several studies that found developmental effects in laboratory animals at high levels of exposure to BPA.

OEHHA concluded that NTP's finding of "clear evidence" of adverse effects on development in laboratory animals at high doses of BPA met the criteria required to list BPA under the authoritative bodies provision. At the

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View from the Field

BPA and Prop 65 ◄ 17

same time, OEHHA also proposed the adoption of a MADL of 290 micrograms per day for exposures to BPA.

Not everyone agreed with OEHHA's reading of the NTP report, and shortly after OEHHA announced its intent to list BPA, the ACC filed a lawsuit in Sacramento County Superior Court challenging the action.

Surprisingly, just two weeks after the comment period on OEHHA's proposed listing of BPA ended, the office announce its final decision to add BPA to the Proposition 65 list of chemicals known to the state to cause reproductive toxicity The decision was announced on April 11.

Acting on the motion of ACC, Judge Raymond M. Cadei issued the preliminary injunction on April 19, ordering BPA to be removed from the Proposition 65 list pending a final resolution in the lawsuit, *American Chemistry Council v Office of Environmental Health Hazard Assessment et al*.

Reasonable Probability of Prevailing on the Merits

In granting the preliminary injunction, the court determined that there was a reasonable probability that ACC would prevail on the merits at trial. One of the points raised by ACC in the lawsuit was that OEHHA circumvented its own scientific process, since the DART-IC had already voted against the inclusion of BPA, after having extensively reviewed the NTP's 2008 report on BPA -- the sole document cited by OEHHA -- to justify its decision to list BPA.

ACC also argued that the NTP report did not identify BPA as causing reproductive toxicity. According to

The court "agreed with [the American Chemistry Council] and pointed out that when a consumer becomes aware of a [Prop 65] listing, he or she will choose not to purchase such products, thereby resulting in the very irreparable harm that an injunction is supposed to avoid."

ACC, the report merely concluded that "the possibility that [BPA] may alter human development cannot be dismissed." ACC further pointed to several excerpts from the report to support its argument, noting NTP's use of terms such as, "insufficient evidence," "[n]egligible concern," "[m]inimal concern," and "[s]ome concern" in describing the myriad of effects that have been alleged.

This, along with expert testimony that the report "cannot be treated as a conclusion that BPA causes reproductive toxicity," seemed enough to convince the court that ACC had met its burden of showing a reasonable probability of success at trial.

To obtain the injunction, however, ACC also needed to show that allowing the listing to stand pending trial would result in irreparable harm to its members, others in the chemical industry, and consumers. ACC pointed out that no government agency has ever found BPA to be a reproductive health concern, and that the listing would result in "widespread and irreversible consumer deselection of products made with BPA."

OEHHA had argued that granting the injunction would delay providing the public with information that could be important to public health. However, the court again agreed with ACC and pointed out that OEHHA's argument implied that when a consumer becomes aware of a listing, he or she will choose not to purchase such products, thereby resulting in the very irreparable harm that an injunction is supposed to avoid.

OEHHA acted on the judge's order the following week, removing the listing of BPA just two short weeks after it had been added. Now, it appears that OEHHA will have to convince the judge that, in fact, NTP's conclusion is what they represent it to be. That might be a tall order, indeed.

ABOUT OUR AUTHOR

George Misko (*misko@khlaw.com*) is a partner at Keller and Heckman, where he is one of the firm's Food and Drug Practice Group leaders. He has extensive experience counseling clients on regulatory requirements relating to chemical substances, plastics and food products in the U.S. and other jurisdictions, including Canada, the European Union, Latin America and the Pacific Rim. His practice also includes environmental concerns, pesticide regulation, right-to-know laws and toxic substance control regulations.

Also online...

THIS WEEK IN FOOD CHEMICAL NEWS GUIDE

Chemicals updated this week:

- ***Bacillus pumilus* strain BU F-33**
- **mica-based pearlescent pigments**
- **1,3-propanediol**

U.S. Pesticide Patent Roundup

Recently Issued Patents

For more details on the following patents, enter the patent number at: *http://patft.uspto.gov/netahtml/PTO/srchnum.htm.*

DIG-5 insecticidal Cry toxins (8,461,422, Dow Agrosciences) DIG-5 Cry toxins, polynucleotides encoding such toxins, use of such toxins to control pests, and transgenic plants that produce such toxins are disclosed.

Toxin genes and methods for their use (8,461,421, Athenix Corp.) Compositions and methods for conferring pesticidal activity to bacteria, plants, plant cells, tissues and seeds are provided. Compositions comprising a coding sequence for a delta-endotoxin polypeptide are provided. The coding sequences can be used in DNA constructs or expression cassettes for transformation and expression in plants and bacteria. Compositions also comprise transformed bacteria, plants, plant cells, tissues, and seeds. In particular, isolated delta-endotoxin nucleic acid molecules are provided. Additionally, amino acid sequences corresponding to the polynucleotides are encompassed, and antibodies specifically binding to those amino acid sequences. In particular, the present invention provides for isolated nucleic acid molecules comprising nucleotide sequences encoding the amino acid sequence shown in SEQ ID NO:61-121 and 133-141, or the nucleotide sequence set forth in SEQ ID NO:1-60, 124-132, and 142-283, as well as variants and fragments thereof.

AXMI-192 family of pesticidal genes and methods for their use (8,461,415, Athenix Corp.) Compositions and methods for conferring pesticidal activity to bacteria, plants, plant cells, tissues and seeds are provided. Compositions comprising a coding sequence for a toxin polypeptide are provided. The coding sequences can be used in DNA constructs or expression cassettes for transformation and expression in plants and bacteria. Compositions also comprise transformed bacteria, plants, plant cells, tissues, and seeds. In particular, isolated toxin nucleic acid molecules are provided. Additionally, amino acid sequences corresponding to the polynucleotides are encompassed, and antibodies specifically binding to those amino acid sequences. In particular, the present invention provides for isolated nucleic acid molecules comprising nucleotide sequences encoding the amino acid sequence shown in SEQ ID NO:28-62, or the nucleotide sequence set forth in SEQ ID NO:1-27, as well as variants and fragments thereof.

Plants having enhanced yield-related traits and a method for making the same (8,461,413, CropDesign N.V.) The present invention relates generally to the field of molecular biology and concerns a method for enhancing various economically important yield-related traits in plants. More specifically, the present invention concerns a method for increasing seed yield in plants by increasing expression in a plant of a nucleic acid sequence encoding a Dwarf1 (DWF1) polypeptide. The present invention also concerns plants having increased expression of a nucleic acid sequence encoding a DWF1 polypeptide, which plants have increased seed yield relative to control plants. The invention also provides constructs useful in performing the methods of the invention.

Fungicidal active substance combinations containing trifloxystrobin (8,461,349, Bayer CropScience AG) What are described are novel active compound combinations comprising a known oxime ether derivative (trifloxystrobin) and imidacloprid, which combinations are highly suitable for controlling phytopathogenic fungi and insects.

Enantiomerically enriched aryloazol-2-yl cyanoethylamino compounds, method of making and method of using thereof (8,461,176, Merial Limited) The present invention relates to novel aryloazol-2-yl-cyanoethylamino derivatives substantially enriched in an enantiomer of formula (I): ##STR00001## and compounds of formula (IH) ##STR00002## wherein R.sub.3, R.sub.4, R.sub.5, R.sub.6, R.sub.7, R.sub.13a, R.sub.13b, R.sub.14a, R.sub.14b, P, Q, V, W, X, Y, Z and a are as defined in the description, compositions thereof, processes for their preparation and their uses as pesticides.

Pteridines and their use as agrochemicals (8,461,164, Dow AgroSciences) The present disclosure relates to 1- or 2-(4-(aryloxy)-phenyl) ethylamino-, oxy- or sulfanyl)pteridines and 1- or 2-(4-(heteroaryloxy)-phenyl)ethylamino-, oxy- or sulfanyl)pteridines and their use as agrochemicals and animal health products. More specifically, the invention provides new compounds of the formula (I-A): ##STR00001## wherein: R is H, CH.sub.3, phenyl, or a heterocycle comprising a 5 or 6 membered single ring or a fused ring system comprising at least one 5 or 6 membered heterocycle optionally substituted with H, halo, lower alkyl, lower alkoxy, benzyloxy, lower alkenyl, lower alkynyl, haloalkyl, haloalkoxy, NO.sub.2, CN, lower alkoxycarbonyl, lower alkylcarbonyl, lower alkyl-SO.sub.q, and aldoximes and lower alkyloximes, optionally substituted on oxygen by lower alkyl. Z is H, a C--C single bond, CH.sub.2, NH, O, S, CN, CH.sub.2O, OCH.sub.2, CH.sub.2CH.sub.2O, or OCH. sub.2CH.sub.2: m is 4; p is 0 or 1; q is an integer from 0 to 2; R.sup.1 is independently H, halo, lower alkyl, lower alkenyl, lower alkynyl, hydroxy, lower alkoxy, haloalkyl, haloalkoxy, NO.sub.2, CN, lower alkylcarbonyl, lower alkoxycarbonyl, mercapto, lower alkylthio, aldoximes and lower alkyloximes, optionally substituted on oxygen by lower alkyl; Y is a C--C single bond, C(R.sup.5.sub.n)O or C(R.sup.5.sub.n); n is 2.

Bioherbicide from Festuca spp (8,461,085, Cornell Research Foundation) The present invention relates to methods of using m-tyrosine compounds from Festuca species for inhibiting weed growth and enhancing growth of non-weed plants. The present invention also relates to methods of identifying plants having herbicidal properties.

Herbicidal mixture, comprising an imidazolinone herbicide and an adjuvant (8,461,084, BASF Aktiengesellschaft) A herbicidal mixture, comprising a) a herbicidally effective amount of an imidazolinone herbicide selected from the group consisting of imazamox, imazapic, imazapyr; b) an adjuvant comprising at least one of the following components: a partial phosphoric ester or a partial sulfuric ester of a monohydroxy-functional polyalkyl ether and optionally c) a further additive.

Herbicidal compounds (8,461,083, Syngenta) The present invention relates to novel herbicidal [1,8]-naphthyridines of Formula (Ia) or (Ib), or an agronomically acceptable salt of said compound wherein R.sup.2, R.sup.3, R.sup.4, R.sup.5, R.sup.6, R.sup.7, R.sup.8, n, m, X and Q are as defined herein. The invention further relates to processes and intermediates for the preparation of the [1,8]-naphthyridines, to compositions which comprise the herbicidal compounds, and to their use for controlling weeds, in particular in crops of useful plants.

Important Subscriber Announcement

Pesticide & Chemical POLICY

Important Subscriber Announcement

Dear Subscribers,

We recently announced some exciting changes to your *Pesticide & Chemical Policy* subscription. In case you missed it, your subscription will soon become part of *Agrow World Crop Protection News*, offering you the complete view of the global pesticide and chemical industry.

To ensure you are up to date with all the developments as they happen and to avoid risk, we are also launching a new website that will provide you with a quicker source of information.

As part of our drive towards instant digital news reporting to help keep our subscribers ahead of their competitors, we will be going online only with the current *Pesticide & Chemical Policy* service and the last printed hardcopy will be sent to you on Friday, June 28. After that you will have access to all of your current content and more through the new *Agrow* website, providing you with:

Easier navigation:

- A clearer layout means it's quicker for you to find the information you need.

More customisable content:

- Top stories will be highlighted on the homepage to save you time.
- Daily news alert emails will highlight top stories and relevant content.

While continuing to provide you with your usual *Pesticide & Chemical Policy* information and access to the *Pesticide Chemical News Guide* database through the new website, we will also be enhancing our coverage of U.S. pesticide chemical regulation news. This is in addition to the *Agrow World Crop Protection News* content you will now be able to access.

Your new enhanced subscription package will include:

- Access to *Pesticide Chemical News Guide* database;
- Access to *Pesticide & Chemical Policy* news and analysis;
- Access to the new *Agrow* website with easier navigation and customisable content;
- *Agrow Plant Biotech* Database;
- *Agrow Intelligence;* and
- The latest issue of *Agrow*, available as online PDF with issue archive and search.

We hope you agree that these significant enhancements to your subscription will provide you with a more complete and timely view of the global crop protection industry. Look out for further communication over the coming weeks, including more in depth information about *Agrow* and its content.

If you have any questions regarding these changes to your subscription, please contact ***client.support@informa.com*** or call **(+1) 888-732-7070 – option 1**.

If you do not currently have an online username and password, please contact us today by emailing ***onlineaccess@informa.com*** – be sure to include your customer number. This will ensure that you receive full access to all of the new online features on the website.

Yours sincerely,

Pesticide & Chemical Policy