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New GMO potato avoids USDA regulation

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A new potato that's engineered with gene deletion doesn't have to be regulated by USDA.

The USDA's deregulation of J.R. Simplot's genetically engineered potatoes recently generated much publicity, but another biotech potato was quietly cleared for commercialization without undergoing that regulatory process.

Cellectis Plant Sciences, a subsidiary of a French pharmaceutical company, has genetically modified potatoes to experience less sugar buildup during cold storage, thereby helping to preserve their quality. The crop also contains less of a potentially cancercausing compound.

These traits are similar to Simplot's "Innate" potato but Cellectis' product wasn't subject to the same environmental assessments and public notice and comment requirements.

The difference is that Simplot used agrobacterium, a plant pest, to transfer genes from wild and cultivated potatoes, which causes the Innate variety to fall under USDA's regulatory purview.

Under the USDA's interpretation of federal law, which has been upheld in court, the agency's authority over genetically engineered crops is limited to those that are potential plant pests.

In the case of Cellectis' potato, the company did rely on a protein from a blight-causing bacteria to remove unwanted genetic material from the variety.

However, that bacterial protein wasn't incorporated into the potato's genes, which convinced the USDA that the variety isn't a plant pest and doesn't require a permit for field release or interstate movement, according to documents recently released by the agency.

"We knocked out DNA sequences that inactivated a gene," said Dan Voytas, chief science officer for Cellectis.

Cellectis hopes the variety will gain broader market acceptance than previous genetically engineered varieties that were deregulated by USDA because the technology simply removes genetic material, rather than inserting it from other species, he said.

Roughly 10-15 percent of potatoes are lost during storage due to sugar buildup, and the company hopes to significantly cut that waste, Voytas said.

Before it can make actual claims about waste reduction, Cellectis must first conduct large-scale tests that are now possible due to USDA's decision, he said.

The company expects it will take several years before enough of its potatoes are available for commercial production, and it still plans to clear the variety with the U.S. Food and Drug Administration and the Environmental Protection Agency, he said.

Also, Cellectis will seek regulatory approval in foreign countries that import U.S. potatoes, Voytas said. "There's still quite a bit of effort in front of us."

The Center for Food Safety, a non-profit that's critical of genetic engineering, is nervous about the USDA's position on the Cellectis potatoes.

"I think it's really jumping the gun for the USDA to be removing it from regulatory oversight," said Doug Gurian-Sherman, director of sustainable agriculture for the group. "This speaks to real irresponsibility by the agency."

Scientists still don't fully understand the unintended consequences of gene editing, so it's inappropriate for regulators to give such a crop a "clean bill of health" without further study, he said.

The USDA basically washes its hands of regulating any biotech crop that's not a plant pest, which is defined very narrowly by the agency, Gurian-Sherman said.

The agency could expand its oversight over biotech crops under its statutory power to regulate noxious weeds but it choses not to, he said. "That, to me, is shirking its responsibility to protect the public and the environment."

The plight of the honeybee eludes simple solutions

Specialists at a Maine conference agree there are no easy answers for curing colony collapse disorder and other threats. BY TOM ATWELL

Honeybees are in trouble – in Maine, all over the place. Just about everyone agrees.

The disagreement comes about what is causing the problems and, more than that, what should be done.



A honeybee on a marigold. Most of the food we eat requires pollination, and bees do most of that work. Shutterstock.com

A daylong conference earlier this fall sponsored by the University of Maine Cooperative Extension Service and the Maine Department of Agriculture, Conservation and Forestry looked into those questions.

The conference, held in South Portland, was prompted by a bill introduced in the Maine Legislature two years ago to place a moratorium on the use of neonicotinoid pesticides, which work by drawing insect-killing substances into the tissue of plants. Although that initial legislation was withdrawn (the sponsor consulted with the Maine State Beekeepers Association, which found flaws), a rewritten version that would allow use of the pesticides by commercial farmers is expected to be introduced in the coming session.

Why all the attention to honeybees? Because most of the food we eat requires pollination, and honeybees carry out most of that work. The bees are a \$25 billion industry in the United States, John Skinner of the University of Tennessee said in remarks at the start of the conference.

As anybody who hasn't lived in a cave for the last five-plus years knows, the biggest problem honeybees face is colony collapse disorder, in which hives mysteriously die or disappear. The disorder got its name in 2006, but there were instances of it before then, and European honeybees had problems for decades earlier.

Honeybees face a variety of difficulties, all of which may be contributing to colony collapse disorder. They are attacked by mites, both tracheal mites and varroa mites. They get infections, including foulbrood and nosema. They are overworked, their hives hauled from place to place to pollinate crops, which can cause stress – like people who work 80-hour weeks. Bees who eat pollen solely from the crops that humans want pollinated, say blueberries, can suffer from malnutrition; healthy bees need food from many different plants, not a monoculture. And interbreeding may be weakening the bee gene pool.

On top of all that, many pesticides kill bees.

"We are dealing with a complex issue," Maine state apiarist Tony Jadczak summed up for the 250 attendees after some seven hours of presentations from professors, scientists and government officials. "Banning one class of insecticides will not fix this problem." That said, neonicotinoids have come in for a lot of criticism. The European Union recently enacted a moratorium on their use. The EU was supposed to develop a monitoring program on how the moratorium is affecting the honeybees, said David Epstein of the U.S. Department of Agriculture Office of Pest Management Policy. "They are not doing that, and to me that is really frustrating."

Nancy Ostiguy of the Penn State Department of Entomology presented a lot of detailed technical information about pesticides, but here's how she began: "The big conclusion of what I have to say is that we don't have a clue about what is going on."

For example, people have assumed that herbicides – which kill plants – are safe for animals, she said, but that is not necessarily true. One complication is that most research is done when a pesticide kills insects immediately because researchers can more easily connect cause and effect; less research exists on chronic effects that may build up over years, gradually harming insects, she said.

Pesticide mixing is also insufficiently researched. For example, when fungicides mix with neonics, the result may be much more toxic than either one used separately, Ostiguy said.

Several speakers expressed concerns about a new pesticide being considered for release, flupyradifurone. It is similar to neonicotinods in that it is a systemic, but it is in a different class (because it kills insects in a different way). Field studies show that flupyradifuron is less toxic to bees; Ostiguy has her doubts.

Epstein said he is concerned that Bayer, which developed the pesticide, won't have to prove beyond doubt that it is safe over the long term before introducing it.

Many at the conference also expressed concern that a lot of these pesticides are used on ornamental gardens – designed simply to please the eye – rather than on farms, which produce the food we need to live. No matter the activity, people always must consider benefits versus risks, Ostiguy noted. "It matters a lot who is asking the question," she said. "The beekeeper, the grower, the farmer and the homeowner all have different perceptions and different benefits and risks."

Despite the criticism leveled at neonicotinoids, several speakers said that they have been shown to be less harmful to humans and to pollinators than the pesticides they replaced:

organophosphates, carbamates and pyrethroids. They also agreed that when pesticides are applied by professionals – whether for food production or ornamental gardens – they are usually less harmful than when applied by homeowners, who tend to neither read nor follow label instructions.

And finally, they agreed that the debate will continue for a long time to come.

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http://www.pressherald.com/2014/12/09/lyme-disease-digging-in-as-battle-revs-up/

Lyme disease digging in as Maine mounts fight against it

A new research lab will help with treatment, and public education efforts have intensified, but cases of the debilitating illness may fall just short of a state record this year.

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Rebecca Nelson poses for a photograph with her dog Dalton on her property in Scarborough. Nelson raises turkeys, chickens (both laying and broilers) and cattle to provide much of the meat her family eats, as apart of her diet to combat symptoms of Lyme disease. Whitney Hayward/Staff Photographer

With the number of Lyme disease cases in Maine this year approaching the record set in 2013, a voterapproved plan to build an \$8 million laboratory to test ticks and do other research comes at a critical juncture in the fight against the debilitating disease.

More than 1,000 Lyme disease cases have been reported annually in Maine since 2011, five times the number reported a decade ago, according to the Maine Center for Disease Control and Prevention. In 2013, Maine set a record with 1,376 cases of the bacterial infection, which is spread in the Northeast by

deer tick bites. The National Wildlife Foundation has said that global warming has expanded tick habitat, leading to more Lyme disease.



This year will be at least the second-highest on record for

Lyme disease in Maine

The new lab, scheduled for completion at the University of Maine in 2017, will accelerate the process of identifying infected ticks and provide information to doctors more quickly, speeding up the diagnosis and therefore the successful treatment of Lyme cases.

That's important to people like Rebecca Nelson of Scarborough, who finally tested positive in January for Lyme, a disease she believes she contracted decades ago. Nelson wants people to recognize the severity of Lyme and to increase awareness among doctors and the public.

"It was a relief" when she was diagnosed, said Nelson, 39. "I finally knew what was wrong with me. I had gotten so tired of people thinking that I was crazy." She described symptoms ranging from chronic fatigue, pain and insomnia to anger and short-term memory problems.

"They sound like such generic symptoms," she said. "I don't think people believe it's as debilitating an illness as it really is."

LYME CASES JUMP IN RECENT YEARS

The Maine CDC has reported 1,231 Lyme infections in the state through November, on track for this year to have the second-highest number of cases on record. The cases spike in the summer when ticks are most active – more than half of 2014's reported infections came in July, August and September.

Lyme disease has spread across much of the eastern United States, especially the Northeast. Nationally, cases have increased exponentially over the past few years, according to the federal Centers for Disease Control and Prevention. More than 25,000 cases were reported in 2013.

Although the UMaine lab that voters approved Nov. 4 also will research animal and plant diseases and other insect-borne infections, a major component of its mission will be to identify ticks and test them for Lyme. The testing will help researchers determine the scope of the problem and get information on infected ticks more quickly to doctors, increasing the effectiveness of treatments, said James Dill, pest management specialist at the University of Maine Cooperative Extension.

The waiting period for Lyme test results – ticks are currently tested out of state – should decrease from several weeks to about 48 hours, Dill said.

Lyme is notoriously difficult to diagnose, in part because the symptoms – which include joint pain, chronic fatigue and inflammation – mimic other diseases, and many people don't realize they've been bitten by a tick.

Because Lyme is often misdiagnosed, scientists believe the number of actual cases is 10 times greater than reported, said Susan Elias, a researcher with the Maine Medical Center Research Institute.

EFFECTS TAKE TOLL ON DAILY LIFE

Nelson, the Scarborough woman with Lyme, has been seeing doctors for years with complaints about various pains and problems. She tested negative for Lyme in 2007 – she said it was a false negative – and positive for Lyme this year.

The treatment and recovery have been slow, she said, with improvement over the summer but backsliding this fall.

"I don't know what (feeling) normal is. I don't remember normal," Nelson said.

She said the physical effects of the disease are difficult to describe. "The feeling is like when you have the flu and you're tired and achy and that all you want to do is go to bed. That's the way I feel much of the time. Your best day is when you feel like you're almost over the flu," she said.

Nelson owns a horse stable and gives riding lessons to students, so doctors would often attribute her pain to muscle strains from working on the farm, or fatigue from having young children around the house. But Nelson said she would have pains even when she didn't strain her muscles, and she later discovered the problem was caused by inflammation from Lyme.

DEBATE IN MEDICAL COMMUNITY

Nelson's physician, Dr. Keelyn Wu, a Falmouth doctor who specializes in Lyme treatment, has about 50 patients with the disease and had to turn away new Lyme patients because the demand was more than he could handle.

If Lyme is caught early, the treatment is straightforward, with patients taking a course of antibiotics to clear up the infection. But when not diagnosed within a few months of the tick transmitting the bacteria, diagnosis and treatment become messy.

Wu said there's controversy in the medical community on everything from what constitutes a positive test to how to treat the disease, and even what to call a long-term Lyme diagnosis.

"There are still some doctors who do not believe chronic Lyme disease exists," Wu said. He concluded after reviewing research that chronic Lyme is real and needs specialized treatment.

"It's a very individualized disease. No two cases are completely alike," he said.

Because of a lack of understanding and awareness, the medical community is mostly unprepared for the influx of Lyme cases, Wu said, noting that there are only a dozen doctors statewide with in-depth Lyme expertise.

"There are not enough physicians out there who are able to treat Lyme," he said. "They don't know where to start, how to address it or where to refer (patients) to. The testing is often unreliable, a lot of false negatives."

INDIVIDUAL TREATMENT TAKES TIME

Wu said most primary care practices are not set up to treat people with a long-term Lyme illness – Lyme consultations can take up to two hours, follow-ups at least 30 minutes, and treatment plans are individualized. Compare that to the caseloads of many primary care doctors, who schedule 15 minutes for patient consultations and are dealing with diseases, such as diabetes or asthma, that have a well-known course of treatment, Wu said.

For patients who were initially not diagnosed and have long-term Lyme disease, treating with antibiotics alone is insufficient, he said. So he advocates dietary changes and over-the-counter nutritional supplements in addition to medications. It often takes a lot of mixing and matching before hitting on the correct treatment that eases symptoms.

Nelson takes five prescription medications, including anti-anxiety drugs, and six over-the-counter supplements, including dietary, detox and herbal supplements. Out-of-pocket, she pays about \$4,000 to \$5,000 per year to treat her symptoms. She said she felt "great" for about 10 weeks in summer and early fall, but started struggling again with pain and fatigue in recent weeks.

IDEAS FOR COMBATING LYME

Dr. Phillip Baker, executive director of the Connecticut-based American Lyme Disease Foundation, said that even in Connecticut, where Lyme disease was discovered, some doctors are not as well-versed in the disease as they could be.

Baker said the federal CDC has an effective training tool on its website about Lyme that counts toward physicians' continuing education requirements, so promoting the site or other training would be helpful. Baker said the 10 northeastern states where Lyme disease is most common should work together on regional strategies to help combat Lyme.

He said a Lyme vaccine developed for mice "looks promising," and could be an environmental way to control the problem and reduce the percentage of ticks carrying Lyme.

Although deer carry the ticks that transmit Lyme to humans, the ticks contract the Lyme bacteria from mice, so Baker said vaccinating mice by baiting them in the wild could prove effective. When the mice become vaccinated and produce antibodies to destroy the Lyme bacteria, fewer ticks would become carriers.

A human vaccine for Lyme was available in the late 1990s and early 2000s, but was pulled from the market after some patients complained of arthritis. Although one pharmaceutical company, Baxter International, was researching a new human vaccine, that research is now on hold.

Baker said he doesn't have much hope that a new human vaccine will be brought to market soon.

STATE STRESSING PUBLIC EDUCATION

In addition to the UMaine bond issue, which Gov. Paul LePage supported, the Maine CDC has intensified its public education efforts about Lyme disease over the past few years, said agency spokesman John Martins.

Public health officials attend events, and the administration promotes May as Lyme Disease Awareness Month. The state also hosts an annual poster contest for students in grades K-8.

For Nelson, the goal is to get through every day with enough energy to operate her business and help around the house. Taking Wu's advice, she has cut most processed food from her diet, her family now raises more than 50 chickens, 30 turkeys and a cow for home-grown meat, and she has doubled the size of the vegetable garden. She said eating better has helped, or it has at least slowed the progression of the disease.

"I can't think long-term. It's too overwhelming," Nelson said. "I'm just taking it day by day."



American Lyme Disease Foundation, Inc.

P.O. Box 466, Lyme, CT 06371

Home '4-Poster' Deer Treatment Bait Station

'4-Poster' Deer Treatment Bait Station







Before Treatment



After Treatment

NOTE: Some states have approved the pesticide used in this device, but some also have regulations against the feeding of deer and other wildlife. Please check with your individual state as to current rules and regulations.

What is the Problem?

Tick populations of both the lone star tick, *Amblyomma americanum* and the 'deer tick', *Ixodes scapularis*, continue to spread geographically throughout much of the country, due in large part to a continued increase in deer herds throughout most of the United States. As tick populations increase so does disease risk, and there are currently ten known major tick-borne infections in the country affecting humans, most of which are carried by species of ticks which feed on deer. One published study has estimated that Lyme disease alone may cost society over two billion dollars a year. It is now apparent that controlling tick populations is a highly effective way to reduce local disease risk.

What is the '4-Poster' Deer Treatment Bait Station?

United States Department of Agriculture (USDA) - Agricultural Research Service (ARS) - Office of Technology Transfer (OTT) has granted an exclusive license of the ARS patented '4-Poster' Deer Treatment Bait Station to the American Lyme Disease Foundation, Inc. (ALDF). The device was developed by researchers J. Mathews Pound, J. Allen Miller, and Craig A. LeMeilleur of the United States Department of Agriculture (USDA) - Agricultural Research Service (ARS) and patented on November 29, 1994 under United States patent number 5367983.

The '4-Poster' device is specifically designed to kill species of ticks that feed on white-tailed deer and especially those for which white-tailed deer are keystone hosts for adult ticks. In this regard, two primary target species for '4-Poster' technology in the U.S. are the deer tick, *Ixodes scapularis*, that transmits agents causing Lyme disease, anaplasmosis, and human babesiosis, and the lone star tick, *Amblyomma americanum*, that transmits the agent causing human monocytic ehrlichiosis (HME). New tick-borne agents of infection have been identified, and the existence of yet others is suspected.

How does the '4-Poster' work?

The '4-Poster' basically consists of a central bin containing clean whole kernel corn used as a bait and two application/feeding stations located at either end of the device. As deer feed on the bait, the design of the device forces them to rub against pesticide-impregnated applicator rollers. The rollers in turn apply tickicide to their ears, heads, necks, and shoulders where roughly 90% of feeding adult ticks are attached. Through grooming, the deer also transfer the tickicide to other parts of the body. Studies (see below) have shown that use of '4-Poster' technology has resulted in the control of 92 to 98% of free-living tick populations in areas around the devices after three years of use.

What are basic requirements for maximum efficacy?

For maximum efficacy in areas where both deer and lone star ticks are found together, the '4-Poster' device should be maintained essentially on a year-round basis. An exception would be if temperatures remained below freezing for extended periods of time. In areas where only deer ticks are found, the devices should be maintained continuously from September through May to impact the entire adult feeding/breeding season. However, adult ticks are not active during prolonged periods of snow cover or below 45° F air temperature. Where only lone star ticks are found, maintenance of the devices from late January or early February through mid to late September will significantly impact both immature (larvae and nymphs) and adult stages on deer.

What have been the research results with the '4-Poster'?

Two studies have been completed, and data are currently being collected and compiled from a third larger study that involves sites in five states in the northeast. Sites that are deer-fenced or where movement of deer is otherwise 'controlled' have better results than 'unrestricted sites,' where deer are able to come and go as they please. Unfenced deer pick up ticks outside the immediate study area and thus are able to reintroduce ticks to treated areas. This is especially true for adult deer ticks during the fall when deer (especially bucks) often expand their normal territorial range, and tick feeding activity is at its peak. Results may also vary depending upon the tickicide used.

Site one: Located near Kerrville, TX at the Kerr Wildlife Management Area, two 96-acre deer-fenced wooded plots were used to test efficacy of the '4-Poster' technology in controlling free-living populations of lone star ticks. A single corn-baited '4-Poster' was placed in each pasture, but only the device in one pasture was treated with an oily formulation of the tickicide amitraz. After three years, a 92 to 97% reduction in tick numbers was observed in the plot where deer were allowed to passively treat themselves at the device. Lone star ticks in this region of Texas characteristically have a one-year life cycle. In contrast, deer ticks have a two or three-year life cycle, and hence a meaningful level of control may take longer to appear.

Site two: Located at the Goddard Space Flight Center in Maryland (a single 600+ acre deer-fenced facility) an exceptional 96 to 98% reduction in free-living nymphal deer ticks was noted after three years of treatment using permethrin (tickicide).

Sites in five Northeastern States:

Data is currently being compiled after five years of study at sites in MD, NJ, NY, CT and RI. Treatment was terminated in the spring of 2002, but tick sampling will continue through 2004 because the tick's two-year life cycle necessitates observing efficacy of treatment for two additional years.

4-Poster 'Tickicide'

The EPA has approved a specially formulated 10% permethrin based tickicide for use in treating ticks on deer. As with any pesticide, labels regarding its safety are included with its shipment to the Licensed Pesticide Operator.

For additional information contact: Dandux Outdoors 3451 Ellicott Center Drive Ellicott City, Md 21043 Phone: 800.933.2638 (extension: #481) Fax: 410.461.2987 Email: info@crdaniels.com (info@crdaniels.com)

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