

## ENERGY &amp; ENVIRONMENT

# By 'Editing' Plant Genes, Companies Avoid Regulation

By ANDREW POLLACK JAN. 1, 2015

Its first attempt to develop genetically engineered grass ended disastrously for the Scotts Miracle-Gro Company. The grass escaped into the wild from test plots in Oregon in 2003, dooming the chances that the government would approve the product for commercial use.

Yet Scotts is once again developing genetically modified grass that would need less mowing, be a deeper green and be resistant to damage from the popular weedkiller Roundup. But this time the grass will not need federal approval before it can be field-tested and marketed.

Scotts and several other companies are developing genetically modified crops using techniques that either are outside the jurisdiction of the Agriculture Department or use new methods — like “genome editing” — that were not envisioned when the regulations were created.

The department has said, for example, that it has no authority over a new herbicide-resistant canola, a corn that would create less pollution from livestock waste, switch grass tailored for biofuel production, and even an ornamental plant that glows in the dark.

The trend alarms critics of biotech crops, who say genetic modification can have unintended effects, regardless of the process.

“They are using a technical loophole so that what are clearly genetically engineered crops and organisms are escaping regulation,” said Michael Hansen, a senior scientist at Consumers Union. He said the grass “can have all sorts of ecological impact and no one is required to look at it.”

Even some people who say the crops are safe and the regulations overly burdensome have expressed concern that because some crops can be left unregulated, the whole oversight process is confusing and illogical, in some cases doing more harm than good.

In November’s *Nature Biotechnology*, plant researchers at the University of California, Davis, wrote that the regulatory framework had become “obsolete and an obstacle to the development of new agricultural products.”

But companies using the new techniques say that if the methods were not labeled genetic engineering, novel crops could be marketed or grown in Europe and other countries that do not readily accept genetically modified crops.

Freedom from oversight could also open opportunities for smaller companies and university breeders and for the modification of less common crops. Until now, in part because of the costs associated with regulation, crop biotechnology has been dominated by Monsanto and a handful of other big companies working mainly on widely grown crops like corn and soybeans.

“It enables small companies to develop products, and even university start-ups,” said Luc Mathis, chief executive of Celerity Plant Sciences, which recently received a regulatory exemption for a potato it says will make French fries less unhealthy.

An industry-sponsored study said that the large companies spend an average of \$136 million on the development of a genetically engineered crop, including \$35 million in regulatory costs. The Agriculture Department once took two to five years to review applications, though it is trying to reduce that to 13 to 16 months.

Genetically engineered crops, popularly called genetically modified organisms or G.M.O.s, typically have genes from other organisms inserted into their DNA. The most popular ones, like Roundup-resistant soybeans and insect-resistant corn, use genes from bacteria.

Under a framework announced in 1986, oversight of the crops is shared by the Agriculture Department, the Environmental Protection Agency and the Food and Drug Administration. Rather than enact new laws for genetically engineered crops, the government covers them under existing statutes.

The Agriculture Department, which approves crops for commercial planting, is a case in point. Its authority stems from its responsibility for protecting American crops from plant pests, which typically are insects or pathogens.

That responsibility extends to certain G.M.O. crops because for many of them, the foreign gene is inserted through the use of a bacterium, or the inserted DNA contains a genetic “on” switch from a plant virus.

But companies can get around that oversight by avoiding components from plant pests. In Scotts’s newer grasses, for instance, the foreign genetic material comes only from other plants and is inserted with a gene gun rather than by the bacterium.

“If you take genetic material from a plant and it’s not considered a pest, and you don’t use a transformation technology that would sort of violate the rules, there’s a bunch of stuff you can do that at least technically is unregulated,” Jim Hagedorn, Scotts chief executive, told analysts in December 2013. He said the company nearly shut its biotech program after the previous mishap, until it hit upon the new strategy and created “a stunning array of products that are not regulated.”

The company recently started testing the grass on the lawns of its employees. But a spokesman said the grass was years from reaching the market.

A spokeswoman for the Agriculture Department said the agency was acting within the authority given to it by Congress and that even if it

did not have oversight of a particular crop, the F.D.A. or E.P.A. might still be involved.

Other companies, including Collectis, are using new genome-editing techniques that can change the plant's existing DNA rather than insert foreign genes. Cibus, a privately held San Diego company, is beginning to sell herbicide-resistant canola developed this way.

"With our technology, we can develop the same traits but in a way that's not transgenic," said Peter Beetham, chief executive of Cibus, using a term for a plant containing foreign genes.

Regulators around the world are now grappling with whether these techniques are even considered genetic engineering and how, if at all, they should be regulated.

"The technology is always one step ahead of the regulators," said Michiel van Lookeren Campagne, head of biotechnology research at Syngenta, a seed and agricultural chemical company.

Some researchers argue that using genome editing to inactivate a gene in a plant, or to make a tiny change in an existing gene, results in a crop no different from what could be obtained through natural mutations and conventional breeding, though it is achieved more quickly.

"Those are basically comparable to what you get from conventional breeding," said Neal Gutterson, vice president for agricultural biotechnology at DuPont Pioneer, a seed company. "We certainly hope that the regulatory agencies recognize that and treat the products accordingly."

The gene editing, they argue, is also more directed and precise than the existing technique of exposing plants to radiation or chemicals to induce random mutations in hopes of generating a desirable change. This technique has been used for decades and is not regulated, even though it can potentially cause unknown and unintended changes to crops.

But critics of biotech crops say the genome-editing techniques can make changes in plant DNA other than the intended one. Also, the gene editing is typically done on plant cells or plant tissues growing in a dish. The process of then turning those genetically altered cells or tissues into a full plant can itself induce mutations.

Another category that some researchers say should receive less scrutiny is so-called cisgenic crops, which are developed using conventional genetic engineering but with the inserted genes from the same species as the crop.

An example is a potato developed by the J. R. Simplot Company that resists bruising and makes a less unhealthy French fry. The Agriculture Department reviewed the Simplot potato before approving it recently.

Jennifer Kuzma, co-director of the Genetic Engineering and Society Center at North Carolina State University, said that there would soon be a flood of crops seeking regulatory exemptions and that there needed to be a public discourse about what should be regulated, in part to

allay possible consumer anxiety.

“It’s not that I think these are risky,” she said of the crops escaping regulation. “But the very fact that this is the route we are taking without any discussion is troubling.”

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