New research reveals challenges in genetically engineered crop regulatory process

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A new innovation can completely reshape an industry-- inspiring both optimism and debate. The development of genetically engineered (GE) crops in the 1980's ignited a buzz in the agricultural community with the potential for higher crop yields and better nutritional content, along with the reduction of herbicide and pesticide use. GE crops grew to play a significant role in the U.S., with more than 160 million acres of farmland used to produce GE crops in 2011. However, the development of new GE crops has recently slowed to a trickle due to litigation over field testing and deregulation. University of Minnesota researchers Esther McGinnis, Alan Smith, and Mary Meyer set out to determine the cause of these litigation lulls responsible for slowing GE progress in the U.S.

Three federal agencies are responsible for regulating plant biotechnology in the United States. The Food and Drug Administration (FDA) oversees food and animal feed safety aspects of GE crops. The Environmental Protection Agency (EPA) is responsible for crops engineered to produce pesticidal substances. Lastly, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulates the planting of GE crops under the Plant Protection Act, introduced in 2000, to consolidate related responsibilities previously spread across various legislative statutes.

APHIS regulates GE crops if the donor organism, recipient organism, or vector or vector agent meets the plant pest definition or the APHIS administrator believes the organism to be a plant pest. The agency's

regulatory decisions have met much criticism in the last decade, inspiring the U of M research team to determine if and where APHIS may have gone wrong. The team used past lawsuits as case studies to determine whether APHIS failed to recognize the environmental impacts of GE crops and made legal errors in failing to comply with the sometimes strict procedures of U.S. environmental law.

After rising exponentially in the mid-1980s, the first commercially grown GE crop, the Flavr Savr tomato, was approved for sale in the U.S. in 1994. Many farmers since then, adopted GE crops as their own, excited by the prospects of scientific advancement and financial reward.

GE crop testing declined rapidly in 2003 in response to the first lawsuit. "Before that time, APHIS was dealing with a pretty heavy case load," says McGinnis. "Their compliance with NEPA may have slipped and left them vulnerable to lawsuits."

NEPA, the National Environmental Policy Act, is a U.S. national policy that was established in 1969 to promote environmental protection. NEPA requires environmental agencies to keep an in-depth administrative record of their actions that validates the agency's rationale in reaching regulatory decisions. The lack of transparency in creating these administrative records has been a point of criticism APHIS has faced in recent years.

McGinnis and her fellow researchers also pointed out that many of the lawsuits used in their study demonstrate that APHIS failed to differentiate between traditional GE crops, such as corn, soybeans, and cotton, and new GE crops presenting considerable regulatory challenges.

Take the genetic engineering of creeping bentgrass, for example. This weedy, wind-pollinated perennial raises unique gene flow concerns that aren't seen in more traditional herbicide-tolerant crops. APHIS has failed

to distinguish novel GE crops like this one and hold them to the rigorous evaluation standards required by environmental law, which has led to lawsuits that have grounded the GE crop regulatory process to a halt.

"APHIS needs to prioritize its resources. It needs to be spending more time regulating novel crops," says McGinnis. "I'm certainly not advocating more regulation of traditional agronomic crops. Really, it's about focusing on these novel crops that raise more issues."

APHIS has recently announced plans to streamline their regulatory review process of GE crops, and plans on implementing several efficiency improvements. These include executing more defined deadlines, better resource management, and earlier opportunity for public involvement.

"If APHIS can solicit public comment earlier in the regulatory process, it can more efficiently incorporate stakeholder concerns into either the environmental assessment or the environmental impact statement that it prepares in conjunction with its regulatory decision," says McGinnis.

While APHIS says it has already begun to apply new, more efficient process steps and more defined deadlines, changes to public engagement have yet to be implemented. The agency's complete set of revised procedures go into effect after the plans are published in the Federal Register.

More information: View the abstract at www.crops.org/publications/cs/articles/52/3/991

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