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The U.S. Department of Agriculture wants to reconsider how to regulate some genetically engineered crops. WAYNE STADLER/FLICKR (CC BY-NC-ND 2.0)

Trump's agriculture department reverses course on biotech rules

By **Kelly Servick**Nov. 6, 2017 , 5:32 PM

The U.S. Department of Agriculture (USDA) has withdrawn a plan to overhaul how it regulates biotechnology products such as genetically engineered (GE) crops.

The proposed rules, released in January as part of a broader update to federal biotech regulations, would have formally exempted some modern gene-edited plants from regulation, but industry and academic groups worried it would also add more onerous requirements for safety assessments early in the development of such products.

USDA's announcement and its **notice in the federal register** today provided little detail about the motivation for the reversal. The agency is taking another look at the rules to balance "regulatory requirements [that] foster public confidence" with a "review process that doesn't restrict innovation," Secretary of Agriculture Sonny Purdue said in a statement. USDA will now start fresh discussions with stakeholders to consider other approaches, the statement said.

It's a predictable move by President Donald Trump's White House to take another look at the policies of the previous administration, says Jennifer Kuzma, a social scientist who co-directs the Genetic Engineering and Society Center at North Carolina State University in Raleigh. "I expected them to eventually catch wind that this was something that USDA was doing, and reverse it."

The January proposal was in part **an attempt to clarify** whether and how the agency would oversee plants made through new genetic technologies such as CRISPR gene editing. Unlike older methods that insert a gene using the bacterial vector *Agrobacterium*, which USDA classifies as a "plant pest," CRISPR editing does not automatically trigger the agency's current premarket review process. (Last spring, USDA announced that **it would not regulate a CRISPR-edited nonbrowning mushroom** for that reason.) The proposed rules would have exempted certain gene-edited products from the GE definition—if they contained inserted DNA from a sexually compatible species, for example, or if their DNA changes could also have been achieved through older chemical or radiation-based methods.

But the proposal also gave the USDA's Animal and Plant Health Inspection Service (APHIS) the new responsibility of evaluating plants for their potential to become noxious weeds that could damage crops, livestock, agriculture, public health, or the environment. Under the proposal, the absence of bacterial DNA would no longer have

been enough to exempt a gene-edited product from regulation, Kuzma explains, and more products would fall "under the initial umbrella to analyze" for safety. "I see sticking with the status quo as less regulation," she says.

Industry and research groups also feared new risk assessment requirements. In June, more than 100 biotechnology and agriculture trade groups **submitted a letter** to USDA laying out their objections to the proposal. It would require a lengthy risk assessment simply to learn whether a GE product would be regulated, the signatories said, and would slow the early development of new crop varieties by creating a hurdle to even small-scale field trials.

I'm happy that [USDA is] taking a step back.

Harry Klee, University of Florida

The burden would be especially great for academic researchers and small companies, says Harry Klee, a molecular biologist who studies the genetics of tomato flavor at the University of Florida in Gainesville and is president of the American Society of Plant Biologists—one of the signatories on the letter. "I can't afford to … go through the processes for risk assessment the same way that a company like a Monsanto can do," he says. "I'm happy that [USDA is] taking a step back."

In January, the U.S. Food and Drug Administration also released a proposal to update the regulation of GE animals. Those rules would have swept such animals under the definition of a "new animal drug" and subjected them to the agency's approval process, even if they didn't contain DNA from another species, and even if their genome sequences could have been created with conventional breeding. Last month, lawmakers in the U.S. House of Representatives **wrote a letter** to Purdue, along with FDA Commissioner Scott Gottlieb and Environmental Protection Agency Administrator Scott Pruitt warning that the USDA's and FDA's approaches "offer deeply conflicting regulatory approaches" that "have sent inconsistent signals to our trade partners."

The public comment period for the FDA rules ended in June, but the agency has not finalized the proposal. "I would bet that [the administration] would probably pull back on that too, eventually," Kuzma says.

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