HARVARD COLLEGE REVIEW OF ENVIRONMENT & SOCIETY

ENGINEERING OUR FOOD

A DISCUSSION OF GENETICALLY MODIFIED CROPS

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NECESSARY REGULATORY CHANGES TO IMPROVE THE FEDERAL GOVERNMENT'S OVERSIGHT OF GE CROPS

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In 2016, American farmers planted more varieties of genetically engineered (GE) crops than ever before on approximately 170 million acres of farmland (United States Department of Agriculture and National Agricultural Statistics Service, 2016). The National Academy of Sciences, Engineering, and Medicine released a thorough report, which found no evidence of harm from eating foods made from GE crops (The National Academy of Sciences, Engineering, and Medicine, 2016). However, many American consumers continue to believe that foods and ingredients from GE crops are not safe, and some food manufacturers are eliminating those ingredients from their food products and adding "non-GMO" label claims.

Is there a way to bridge the current divide between farmers and consumers? The federal government hoped to partially address those differing viewpoints by revising its *Coordinated Framework for the Regulation of Biotechnology* (The White House, 2017), and setting forth a *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (The White House, 2016). One of the goals of the 18-month process that produced those two government policies was to "increase consumer confidence" in both the regulatory system and the safety of products in commerce (Office of Science and Technology Policy, 2015). While the clarification and changes identified in those new policies will be helpful for many developers of crops and animals using modern biotechnologies, they will not change the tone or rancor of the societal debate about product safety, nor will they lead to greater consumer acceptance. The federal regulatory system needs basic changes before some consumers in the United States embrace the GE crops currently grown by farmers.

Current Consumer Perceptions about the Safety of Foods Made from GE Crops

In a 2015 poll conducted by the Pew Research Center, 88 percent of scientists researching GE foods said they believed foods from GE crops were safe, while only 37 percent of consumers believed the same (Pew Research Center, 2015). In a more recent 2016 Pew Research Center poll, 10 percent of consumers said GE ingredients were better for their health, 48 percent said they were no better and no worse, and 39 percent said they were worse. In addition, half of the people who said eating GE ingredients was worse for their health believed the risk from eating GE ingredients was high (Funk, 2016). Similarly, a 2016 Annenberg Public Policy Center poll found 27

percent of consumers disagreed with a statement that GE foods are safe, 39 percent agreed with the statement, and 30 percent stated that they neither agreed nor disagreed with the statement. The poll also found that 50 percent of consumers said they would avoid a food product containing GE ingredients (Annenberg Public Policy Center, 2016). Therefore, while there is a scientific consensus that foods and ingredients from GE crops are safe, many consumers don't yet believe in their safety.

FDA Must Review Each GE Crop and Determine it to be Safe for Human Consumption

The Food and Drug Administration (FDA) regulates food under the Federal Food, Drug, and Cosmetic Act (FFDCA). That statute only requires mandatory pre-market approval for "food additives." In 1992, FDA determined that adding new DNA into crops is not considered a "food additive" (US Food and Drug Administration, 1992). Instead, FDA set up a voluntary consultation process, by which GE crop developers can share food-safety data with FDA to allow for the identification of any deficiencies in the company's safety assessment of the GE crop. To date, approximately 150 GE crops have completed FDA's voluntary consultation process (US Food and Drug Administration, 2016). FDA concludes the process with a letter stating it has "no further questions about the safety of the GE crop," but it does not render an opinion about whether the GE crop is safe to eat.

FDA's review process for GE crops is inadequate because it is not mandatory, and when it is completed, FDA does not state its opinion about the safety of foods and ingredients made from the GE crop in question. Consumers want an independent agency like FDA to determine that foods and ingredients made from GE crops are safe to eat before those foods are marketed to them. To achieve a safety determination by FDA, Congress should amend the FFDCA to require a mandatory, pre-market approval process that is transparent and allows for public participation. Such a process would result in greater assurance of food safety and greater public confidence in GE crops. Improving public confidence is essential, since many consumers do not think GE foods are safe to eat.

USDA Must Establish a Science-Based Regulatory System to Address Potential Impacts from GE Crops

The United States Department of Agriculture (USDA) regulates GE crops to ensure that they don't harm agricultural interests and the environment. However, that regulatory system is not consistent with two important principles of an oversight system based on science and potential risk. The revised *Coordinated Framework* reiterates those principles, which are that: (1) oversight must be commensurate with risk, and (2) the government should regulate the final product, not the process by which it is made (The White House, 2017). However, USDA's current regulatory system for GE crops is inconsistent with those principles and needs to be changed.

"Consumers want an independent agency like FDA to determine that foods and ingredients made from GE crops are safe to eat before those foods are marketed to them"

USDA's regulatory system for GE crops is based on its oversight of "plant pests" in the *Plant Protection Act* (Code of Federal Regulations, 2017). USDA has identified a list of plant pests, which are organisms that can harm agricultural interests (United States Department of Agriculture,

2016). Under USDA's current regulations, a GE crop is considered a "potential" plant pest if any of its newly introduced DNA came from an organism on USDA's list of plant pests, or if the method of introducing DNA into the crop's genome involved an organism on USDA's list of plant pests (Code of Federal Regulations, 2017). For example, any GE crop using *Agrobacterium*-mediated transformation to introduce new DNA is considered to be a potential plant pest and subject to oversight. However, when that same DNA is introduced using the gene-gun method of transformation, USDA has no oversight over the GE crop – the difference being the use of *Agrobacterium*, which is a recognized plant pest.

"USDA should revise its oversight to only regulate GE crops that pose potential risks to agriculture and/or the environment. Such a system would no longer regulate based on the process of making the product or the inclusion of plant pest DNA"

The method used to create a new GE-crop variety – not whether the crop-trait combination poses potential risks or impacts to the environment or agriculture – currently determines USDA oversight. Currently, USDA could be wasting its resources regulating safe-crop varieties created using *Agrobacterium*, while potentially unsafe-GE varieties created using a gene gun go unregulated. To solve this problem and to create a regulatory system that is science-based, USDA should revise its oversight to only regulate GE crops that pose potential risks to agriculture and/or the environment. Such a system would no longer regulate based on the process of making the product or the inclusion of plant pest DNA.

A new regulatory system would allow developers and USDA to concentrate on potential impacts of GE crops, such as the development of resistant weeds and resistant pests, rather than analyzing whether adding one or two genes to a domesticated crop results in plant-pest characteristics. To date, USDA has reviewed over 125 GE crops, and never once has it found a GE crop to exhibit plant-pest characteristics (United States Department of Agriculture, 2017). If USDA cannot put this type of risk-based regulatory system in place using existing laws, then Congress should provide USDA with the legal authority to set up a science-based regulatory system.

Conclusion

If farmers are to continue growing GE crops, consumers must believe they are safe to eat and make a positive contribution to agriculture. The current regulatory oversight by FDA is unlikely to make consumers more comfortable with the safety of GE crops and foods and ingredients made from those crops. However, if FDA instituted a mandatory approval process for GE crops, public perception of GE crops could become much more favorable. In addition, if USDA used a science-based regulatory system to regulate GE crops and manage any potential environmental and agricultural impacts, GE crops would be able to better contribute to making agriculture sustainable. While such regulatory changes would require significant departures from current federal oversight and likely entail Congressional action, such actions are necessary to allow safe and beneficial GE crops to be planted, harvested, and accepted well into the future.

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