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THE MODERNIZATION OF BIOTECHNOLOGY REGULATIONS: WILL THE THIRD TIME BE THE CHARM?

[Agriculture \(/full-blog/category/Agriculture\)](#)

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When people hear about the use of genetic engineering or biotechnology in the agriculture industry, many think of it as a recent development employed by the industry within the last few years. However, biotechnology in the agriculture industry has been around for decades and has been regulated by the federal government since 1986.^[i] Agricultural biotechnology is a variety of tools utilized by farmers to manage and optimize production.^[ii] These tools consist of genetically engineering or altering living organisms to make or modify products, plants, or animals to become more resilient towards diseases and pests.^[iii]

In 1986, the federal government developed the Coordinated Framework for the Regulation of Biotechnology "to provide regulatory oversight of organisms derived through genetic engineering."^[iv] There are three principal agencies that are responsible for ensuring that crops produced through genetic engineering are tested properly and studied thoroughly to ensure they pose no significant risk towards consumers.^[v] These three agencies are the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).^[vi]

With decades old biotechnology regulations and new approaches in gene editing (e.g., CRISPR) taking over the scientific community by storm and proving to be a powerful tool for the agriculture industry,^[vii] the agencies have made multiple attempts to modernize the regulations of biotechnology within the past decade.^[viii] The USDA first proposed a regulatory update in 2008, but withdrew that iteration in 2015.^[ix] The first official attempt at updating the regulations was made in 2015, when the Executive Office of the President (EOP) directed the agencies to update the regulations.^[x] Per the EOP, the agencies clarified their roles and responsibilities in the regulatory process and assessed a long-term strategy to ensure that the regulatory system was prepared for future products of biotechnology.^[xi] The agencies' second attempt at an update was with the release of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology ("2017 Proposal"), closely following the heels of the 2015 attempt.^[xii]





http://www.shulmanrogers.com/assets/htmlimages/53627992_s.jpg

However, since the unveiling of the 2017 Proposal, the agencies are starting anew and making their third attempt at modernization.^[xiii] The question on every biotech companies', environmentalists', and farmers' mind is whether this third attempt at modernization will be the "charm." Although the steps these agencies have taken signify noteworthy progress towards modernizing decades old biotechnology regulations into a future ready regulatory system,^[xiv] this third attempt at modernizing will not be the agencies' last attempt and should not be their last. As noted by Agriculture Secretary Sonny Perdue, the regulatory system needs to "foster public confidence and empower American agriculture while also providing [the] industry with an efficient and transparent review process that doesn't restrict innovation."^[xv]

Currently, the 2017 Proposal is not the regulatory system described by Secretary Sonny Perdue, not yet at least. The 2017 Proposal continues to cause uncertainty for developers due to a risk of innovation restrictions, and it fosters concerns from the public regarding the relaxation of the regulations.^[xvi] This uncertainty is due to the ever-advancing technology in genetic engineering and the transparent benefits and unknown harm associated with such technology.^[xvii] For instance, the agencies remain uncertain on the scope and approach they wish to take in regulating new genetic sequencing and editing (i.e., a wide scope with a regulate first, analyze later approach or a narrow scope with an approach that regulates products of biotechnology and not biotech techniques).^[xviii] This uncertainty will continue to exist until the agencies have collected and analyzed all available data—the findings of the ongoing independent study by the National Academy of Sciences (NAS) on future biotechnology products, along with the 203 comments submitted by the public in response to the 2017 Proposal—to make informed regulatory updates regarding the potential future products of biotechnology.^[xix] In my opinion, biotechnology regulations will be a regulatory system that will continue to receive regulatory updates due to what the regulations regulate, an ever-advancing field of science—biotechnology.^[xx]

[i] *Biotechnology FAQs*, U.S. Dep't of Agric., <https://www.usda.gov/topics/biotechnology/biotechnology-frequently-asked-questions-faqs> (last visited Nov. 20, 2017); *Regulation of Biotech Plants*, U.S. Dep't of Agric., <https://www.usda.gov/topics/biotechnology/how-federal-government-regulates-biotech-plants> (last visited Nov. 20, 2017).

[ii] *Biotechnology FAQs*, *supra* note i.

[iii] *See id.*

[iv] *Biotechnology FAQs*, *supra* note i.

[v] *Id.*

[vi] *See* Robbie Barbero et al., *Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System*, White House: Blog (Jan. 4, 2017, 1:20 PM), <https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory>; *Biotechnology FAQs*, *supra* note i; *Modernizing the Regulatory System for Biotechnology Products*, U.S. Evtl. Protection Agency, <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/modernizing-regulatory-system-biotechnology-products> (last visited Nov. 20, 2017).

[vii] See *Gene Editing: What Can it Deliver for Agriculture?*, Future Farming: Smart Farmers (Sept. 15, 2017), <https://www.futurefarming.com/3079/gene-editing-can-deliver-agriculture/>.

[viii] See Chuck Abbott, *USDA Will Try Again on Update of Biotechnology Regulations*, Successful Farming (Nov. 7, 2017), <https://www.agriculture.com/news/crops/usda-will-try-again-on-update-of-biotechnology-regulations>.

[ix] *Id.*

[x] See *Id.*; Barbero, *supra* note vi; *Modernizing the Regulatory System for Biotechnology Products*, *supra* note vi.

[xi] Barbero, *supra* note vi; *Modernizing the Regulatory System for Biotechnology Products*, *supra* note vi.

[xii] See *Id.*; Abbott, *supra* note viii.

[xiii] See Abbott, *supra* note viii.

[xiv] See Barbero, *supra* note vi.

[xv] Abbott, *supra* note viii.

[xvi] See *Id.*

[xvii] *Id.*

[xviii] *Id.*

[xix] See *Id.*; See also Barbero, *supra* note vi.

[xx] See Barbero, *supra* note vi.

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