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Adapting Federal Regulatory Approaches To Advances In Agricultural Biotechnology

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ADAPTING FEDERAL REGULATORY APPROACHES TO ADVANCES IN AGRICULTURAL BIOTECHNOLOGY

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Since it was first announced by the White House Office of Science and Technology Policy ("OSTP") in 1986, the Coordinated Framework for the Regulation of Biotechnology ("Framework") has sought to achieve "reasonable safeguards for the public" by regulating products of biotechnology across a network of agency jurisdictions using existing federal statutory authorities, as opposed to calling for the implementation of new legislation.[1] Working to achieve a balance between appropriate health and environmental safety regulations while maintaining sufficient flexibility to "avoid impeding the growth" of what was considered an "infant industry" at the time, the Framework was built on a foundational determination that the existing mosaic of existing federal laws, as currently implemented, would for the most part "adequately" address regulatory needs.[2]

One of the key challenges associated with formulating any federal approach to biotechnology regulation is the sheer diversity of products that can be developed with genetic engineering—including agricultural crops and livestock, pesticides, food, plants, human and animal drugs, and microorganisms with a range of industrial applications. These products are already regulated by a myriad of agencies, meaning a unitary statutory approach addressing all products of biotechnology would be challenging.[3] More than three decades after the Framework was first announced—and notwithstanding periodic controversy,[4] continued uneasiness with products of genetic engineering among sectors of the American public,[5] as well as

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1. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302 (June 26, 1986).

2. *Id.* at 23,303.

3. Although a number of federal agencies are involved in regulating products of biotechnology, this discussion focuses on the Environmental Protection Agency ("EPA"), Food and Drug Administration ("FDA"), and U.S. Department of Agriculture ("USDA").

4. *See, e.g.*, *Biotechnology, Genetic Engineering, and "GMOs:" Why all the Controversy?*, INST. OF FOOD TECHNOLOGISTS (Sept. 12, 2018), https://www.ift.org/career-development/learn-about-food-science/food-facts/food-facts-emerging-science-and-technologies/biotechnology-genetic-engineering-gmos.

5. *See* CARY FUNK & BRIAN KENNEDY, THE NEW FOOD FIGHTS: U.S. PUBLIC DIVIDES OVER FOOD SCIENCE, PEW RESEARCH CENTER 46 (2016), https://www.pewresearch.org/internet/wp-

groundbreaking advances in biotechnology that could hardly have been foreseen by the Framework's authors in 1986—OSTP's original decision to balance regulation and flexibility within existing statutory authorities has largely stood the test of time. Contemporary agency efforts to adapt regulatory approaches to novel advances in agricultural biotechnology, while remaining true to the Framework's decades-old intent and design, bear this out.

The Framework originally sought to cover the full spectrum of biotechnology applications by assigning jurisdiction over the commercial end-products of biotechnology based on each agency's experience with the review and regulation of similar products developed using conventional techniques. For example, the U.S. Department of Agriculture ("USDA") would be responsible for genetically engineered animal biologics, plant pests, seeds, animal pathogens, and meat, poultry, and eggs;[6] the U.S. Environmental Protection Agency ("EPA") was tasked with responsibility over genetically engineered microbial pesticides and intergeneric microorganisms;[7] and the U.S. Food and Drug Administration ("FDA") was assigned oversight for genetically engineered foods, food additives, human drugs, biologics and devices, and animal drugs.[8] In developing their coordinated but specific biotechnology regulatory programs, each agency was able to rely on authorities prescribed by an array of existing environmental laws and other statutes, including the Federal Plant Pest Act (superseded in 2000 by the Plant Protection Act ("PPA"));[9] the Federal Seed Act ("FSA");[10] the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA");[11] the Federal Food, Drug, and Cosmetic Act ("FFDCA");[12] the

content/uploads/sites/9/2016/11/PS_2016.12.01_Food-Science_FINAL.pdf (finding that 39% of Americans believe genetically modified food is harmful to consume).

6. *USDA's Role*, UNIFIED WEBSITE FOR BIOTECHNOLOGY REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about (last visited Feb. 11, 2021).

7. *EPA's Role*, UNIFIED WEBSITE FOR BIOTECHNOLOGY REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about (last visited Feb. 11, 2021).

8. *FDA's Role*, UNIFIED WEBSITE FOR BIOTECHNOLOGY REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about (last visited Feb. 11, 2021).

9. Federal Plant Pest Act, Pub. L. No. 85-36, 71 Stat. 31 (1957), *repealed by* Agriculture Risk Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 358.

10. Federal Seed Act, 7 U.S.C. §§ 1551–1611.

11. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y.

12. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399i.

Toxic Substances Control Act ("TSCA");[13] the Federal Meat Inspection Act ("FMIA");[14] and the Poultry Products Inspection Act ("PPIA").[15]

In 1992, OSTP released an update to the Framework reaffirming that federal oversight "focuses on the characteristics of the biotechnology product and the environment into which it is being introduced, not the process by which the product is created" and clarifying that the "[e]xercise of oversight in the scope of discretion afforded by statute should be based on the risk posed by the introduction and should not turn on the fact that [a biotechnology product] has been modified by a particular process or technique."[16] OSTP's continued emphasis on the evaluation of each end-product of agricultural biotechnology, irrespective of the genetic engineering process used in its development, has proved remarkably resilient even as scientific advancements over the last thirty years have progressed from introducing recombinant DNA ("rDNA") molecules through almost exclusive reliance on bacterial vectors (frequently plant pest organisms themselves) to, within just the last few years, the widespread use of revolutionary genome editing techniques like Clustered Regularly Interspaced Short Palindromic Repeats ("CRISPR") that allow developers to target specific genome mutations by inserting, deleting, or modifying DNA in living organisms.[17]

In 2017, OSTP published a second update to the Framework. While concluding that the current federal regulatory system for the products of biotechnology "effectively protects health and the environment," OSTP also observed that certain unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes limit the ability of technology developers to successfully navigate the regulatory process.[18] The 2017 update also acknowledged that regulatory complexities hamper the public's ability to easily understand how the safety of these products is assured.[19]

Consistent with a number of key recommendations expressed in the 2017 update, federal agencies have undertaken significant actions in recent

13. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2629.

14. Federal Meat Inspection Act, 21 U.S.C. §§ 601–695.

15. Poultry Products Inspection Act, 21 U.S.C. §§ 451–472.

16. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753, 6753 (Feb. 27, 1992).

17. *What is CRISPR?*, JACKSON LAB'Y, https://www.jax.org/personalized-medicine/precision-medicine-and-you/what-is-crispr# (last visited Feb. 12, 2021).

18. OFF. OF SCI. & TECH. POL'Y, WHITE HOUSE, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 1, 5 (2017), https://www.epa.gov/sites/production/files/2017-01/documents/2017_coordinated_framework_update.pdf.

19. *Id.*

years to clarify their respective roles, processes, and procedures under the Framework. These efforts have included USDA's statement that it does not regulate plants developed with genome-editing techniques (as long as they are developed without the use of a plant pest as the donor or vector, and they are not themselves plant pests);[20] and FDA's commitment to develop guidance explaining how its current regulatory policy for foods derived from new plant varieties applies to foods produced using genome editing.[21] In May 2020, USDA established comprehensive new regulations, known as the "SECURE rule," that represent an overhaul of longstanding regulatory requirements for genetically engineered organisms that pose plant pest risks.[22]

Efforts sparked by the 2017 update are ongoing. Recently, EPA proposed new regulations to exempt certain plant-produced substances developed using biotechnology (known as "plant-incorporated protectants," or "PIPs") from FIFRA and FFDCA requirements if those substances are otherwise found in plants that are sexually compatible with the recipient plant and meet certain other criteria.[23] Additional initiatives, such as EPA, FDA, and USDA's joint publication of a new "Unified Website for Biotechnology Regulation," reflect broader federal efforts to improve transparency and reduce uncertainty for the regulated community and the wider American public.[24]

Although science never remains static and future advances in genetic engineering will undoubtedly press agricultural biotechnology techniques to ever-expanding frontiers, agency regulations are necessarily framed around an understanding of commercially viable techniques in existence at a particular moment in time. Even so, the Framework's regulation-by-product approach has, for over thirty years, provided federal agencies with flexibility to adapt their respective regulatory programs under existing environmental statutory authorities to address scientific innovations as well as ongoing developments in the understanding of potential risks.

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20. Press Release, U.S. Dep't of Agric., Secretary Perdue Issues USDA Statement on Plant Breeding Innovation (Mar. 28, 2017), https://www.usda.gov/media/press-releases/2018/03/28/secretary-perdue-issues-usda-statement-plant-breeding-innovation.

21. U.S. FOOD & DRUG ADMIN., PLANT AND ANIMAL BIOTECHNOLOGY INNOVATION ACTION PLAN 1–3 (2018), https://www.fda.gov/media/119882/download.

22. Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29,790, 29,791 n.3 (May 18, 2020) (codified at 7 C.F.R. pt. 330, 340, 372).

23. Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived From Newer Technologies, 85 Fed. Reg. 64,308, 64,308 (proposed Oct. 9, 2020) (to be codified at 40 C.F.R. pt. 174).

24. *About the Coordinated Framework*, UNIFIED WEBSITE FOR BIOTECHNOLOGY REGUL., https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about (last visited Feb. 12, 2021).

Operating within the Framework, regulatory agencies have the ability to continuously reinforce their commitments to regulatory certainty and health and environmental safety, all of which are necessary to support industry innovation and consumer confidence in biotechnology-derived products. Looking ahead, there may be growing importance attached to this fundamental aspect of the Framework's approach, which encourages regular review and, as appropriate, updating agency policies and requirements to adapt to advances in biotechnology and management of associated risks.