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Deepti A. Kulkarni

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THE AGE OF INNOVATION IN FOOD: IS OUR REGULATORY SYSTEM READY?

DEEPTI A. KULKARNI*

The United States is at the epicenter of a revolution in food innovation and food culture. Innovators are finding new ways to produce food more efficiently and with fewer impacts on our environment, using emerging and advanced technologies such as genome editing, synthetic biology, and animal cell culture technology. Consumer interests and expectations continue to rapidly evolve, and many consumers are looking for healthier, more sustainable, and diverse alternatives. At the same time, the world's population is growing exponentially and is estimated to reach over nine billion people in the next thirty years¹—meaning, we will have to produce more food, more efficiently, and with a much smaller footprint.

Against this backdrop, regulatory agencies are determining how to facilitate innovation that addresses many of these and other challenges, while protecting human health and the environment, and assuring that foods are appropriately labeled and otherwise compliant with current law.² Furthermore, it is expected that there will be a “profusion of new products” that could “overwhelm the U.S. regulatory system” within the next decade.³ Is our current regulatory system ready?

To answer this question, one must revisit the primary federal statutes governing foods, most of which were enacted over half a century ago, evaluate whether and how these laws can be *effectively* applied to new and emerging products, and then assess whether the current regulatory system does just that. Indeed, in a recent report by the National Academies of

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* Deepti A. Kulkarni is 2008 graduate of the University of Maryland Francis King Carey School of Law and a partner in the Food, Drug, and Medical Device Regulatory Practice Group at Sidley Austin, LLP. She thanks Jaclyn Fonteyne for her helpful contributions to this Essay.

1. *World Population Prospects 2019: Highlights*, UNITED NATIONS DEP'T OF ECON. & SOC. AFFAIRS 1 (2019), https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf.

2. See, e.g., Dennis Keefe, *FDA In Brief: FDA approves soy leghemoglobin as a color additive*, FDA (July 31, 2019), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-approves-soy-leghemoglobin-color-additive> (“We are in the midst of a revolution in food technology that in the next 10 years will likely lead to more innovations in food and ingredient production than there have been in the past half century. As these new products and ingredient sources come to the market, the FDA has a responsibility to provide the appropriate regulatory oversight to protect public health by ensuring that these new foods and food ingredients are safe.”).

3. NAT'L ACADS. OF SCIS., ENG'G, AND MED., *PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY* ix, 10 (2017).

Sciences, Engineering, and Medicine (“NASEM”)—addressing new types of biotechnology products and evaluation of these products under current regulatory frameworks—NASEM advised that the safe use of such products “requires rigorous, predictable, and transparent risk-analysis processes whose comprehensiveness, depth, and throughput mirror the scope, scale, complexity, and tempo of future biotechnology applications.”⁴ Such an approach, according to NASEM, also would increase “public confidence in the safety of products entering the marketplace.”⁵ NASEM cautioned that a regulatory paradigm “that is unnecessarily complex runs the risk of driving an ‘imitate not innovate’ mentality and may not scale to match the pace of biotechnology innovation.”⁶

The NASEM report was commissioned by the federal regulatory agencies with primary oversight of products developed using biotechnology, as part of a wide-ranging initiative to modernize the U.S. regulatory system that began in July 2015.⁷ These agencies include the Food and Drug Administration (“FDA”), Department of Agriculture (“USDA”), and Environmental Protection Agency (“EPA”). The federal regulatory policy describing the statutory authorities of each agency and how such authorities are applied to biotechnology products, particularly foods, is known as the Coordinated Framework for the Regulation of Biotechnology (“Coordinated Framework”).⁸

First established in 1986, and subsequently updated in 1992 and 2017, the Coordinated Framework describes the roles and responsibilities of FDA, USDA, and EPA in the regulation of biotechnology products under existing statutory authorities⁹ and sets forth key principles for the regulation of such

4. *Id.* at 11.

5. *Id.*

6. *Id.*

7. John P. Holdren, Administrator, Office of Information and Regulatory Affairs to Heads of the FDA, EPA, and USDA (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_regulatory_system_for_biotech_products_memo_final.pdf; see also *Modernizing the Regulatory System for Plant and Animal Biotechnology Products*, FDA (last updated Sept. 12, 2018), <https://www.fda.gov/safety/fdas-regulation-plant-and-animal-biotechnology-products/modernizing-regulatory-system-plant-and-animal-biotechnology-products>.

8. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, (June 26, 1986); see also *About the Coordinated Framework*, UNIFIED WEBSITE FOR BIOTECHNOLOGY REGULATION, <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/about> (last visited Feb. 28, 2021).

9. See generally Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986); Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992); EXEC. OFFICE OF THE PRESIDENT, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY (2017), <https://www.fda.gov/media/102658/download> [hereinafter *2017 Update*].

products.¹⁰ Under the Coordinated Framework, FDA regulates foods developed using biotechnology to “[e]nsure human and animal food is safe” and “properly labeled” pursuant to its expansive authority under the Federal Food, Drug, and Cosmetic Act (“FDCA”).¹¹ Historically, the vast majority of these foods have been derived from genetically engineered (“GE”) plants and microorganisms. FDA also has evaluated foods derived from GE animals, though to date has only approved two applications relating to such foods.¹² There are multiple statutes identified in the Coordinated Framework under which USDA, in theory, could exercise oversight relating to foods developed using biotechnology. Consistent with the actual use of biotechnology to develop foods, USDA, to date, primarily has regulated GE plants, particularly food crops, deemed “plant pests” pursuant to the agency’s interpretation and authority under the Plant Protection Act (“PPA”), “with a goal of protecting plants and plant products.”¹³ EPA generally has oversight

10. The key principles set forth in the Coordinated Framework serve as guidance for FDA, USDA, and EPA to help ensure the safety of biotechnology products. These principles provide, in relevant part, that: (1) each agency should apply its existing authorities “to ensure the safety of [] biotechnology products for their intended applications;” (2) “[u]nderlying statutes define the boundaries of the scope of oversight afforded to each agency;” (3) the agencies should apply their authorities to “regulate products based upon specific uses” to assure that “products with the same use are subject to the same types of [regulatory] oversight;” (4) “[i]t is the characteristics of the biotechnology product, the environment into which it will be introduced, and the application of the product that determine its risk (or lack thereof);” (5) “[e]xercise of agency oversight within the scope afforded by statutes should be commensurate with the risk posed” by the biotechnology product “and should not turn on the fact that it was created or has been altered by a particular process or technique;” (6) the regulatory system should be “risk-based;” (7) the agencies should “endeavor to operate their programs in an integrated and coordinated” manner; and (8) future scientific developments should “lead to further refinements of the Coordinated Framework . . . to reflect a more complete understanding of the potential risks involved.” *2017 Update* at 7–8.

11. *Id.* at 9. Notably, however, in 2016, Congress passed the National Bioengineered Food Disclosure Standard (“Disclosure Standard”), which directs USDA, rather than FDA, to establish a national disclosure standard for bioengineered foods, as defined in the law. Pub. L. No. 114-216, 130 Stat. 834 (2016) (codified as amended at 7 U.S.C. § 1639). USDA’s Agricultural Marketing Service promulgated regulations implementing the Disclosure Standard in 2018. *See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 65,814 (Dec. 21, 2018).

12. *See Animals with Intentional Genomic Alterations*, FDA (last updated Dec. 14, 2020), <https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/animals-intentional-genomic-alterations>. In November 2015, FDA approved a new animal drug application (NADA) concerning AquAdvantage Salmon, Atlantic salmon genetically engineered to reach market size “more rapidly than its non-GE farm-raised Atlantic salmon counterpart.” *AquAdvantage Salmon Fact Sheet*, FDA (last updated Apr. 15, 2020), <https://www.fda.gov/animal-veterinary/animals-intentional-genomic-alterations/aquadvantage-salmon-fact-sheet>. In December 2020, FDA approved an NADA for a “first-of-its-kind intention genomic alteration (IGA) in a line of domestic pigs, referred to as GalSafe pigs, which may be used for food or human therapeutics.” *FDA Approves First-of-its-Kind Intentional Genomic Alteration in Line of Domestic Pigs for Both Human Food, Potential Therapeutic Uses*, FDA (last updated Dec. 14, 2020), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-of-its-kind-intentional-genomic-alteration-line-domestic-pigs-both-human-food>.

13. *See 2017 Update*, *supra* note 9 at 23–24.

of pesticides produced through biotechnology, including those produced in food crops, pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), with the goal of protecting the environment and human health.¹⁴

Will these multiple and often overlapping federal regulatory statutes enable regulators to appropriately address the anticipated “profusion of new products” in a manner that facilitates critically important innovations?¹⁵ The short answer, of course, is that it depends. The statutes, themselves broadly define and encompass foods¹⁶ and potential technologies that may be used to modify plants, microbes, and animals to develop foods,¹⁷ or otherwise address potential risks arising from the development and commercialization of such foods.¹⁸ Accordingly, the statutory authorities should provide ample authority for comprehensive oversight. The question, thus, is whether the regulatory agencies have implemented policies pursuant to these authorities to appropriately regulate new products based upon risk and the best available

14. See *id.* at 10–11.

15. See NAT’L ACADS. OF SCIS., ENG’G, AND MED., *supra* note 3, at ix.

16. For example, under the FDCA, “food” is defined to mean “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” 21 U.S.C. § 321(f). “Food additives,” which are subject to FDA premarket review, are defined in relevant part as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food,” unless generally recognized as safe (“GRAS”) or otherwise exempt. *Id.* § 321(s).

17. For example, FDA takes the position that “[s]ubstances that are expected to become components of food products as a result of genetic modification of a plant and whose composition is such or has been altered such that the substance is not generally recognized as safe (GRAS) or otherwise exempt are subject to regulation as ‘food additives’” under the FDCA. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984–85 (May 29, 1992). Within the context of animals, FDA currently asserts that the use of genetic engineering or gene editing to modify an animal is subject to FDA’s new animal “drug” authorities. See *CVM GFI #187 Regulation of Intentionally Altered Genomic DNA in Animals*, FDA (last updated Sept. 18, 2018), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187-regulation-intentionally-altered-genomic-dna-animals>. In particular, FDA considers the “altered genomic DNA” of the animal to be a “drug” within the meaning of the FDCA “because such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the animal.” *Id.* at 7; see also 21 U.S.C. § 321(g) (defining a “drug” within the meaning of the FDCA).

18. For example, foods containing “unsafe” food additives, pesticide chemical residues, or new animal drugs, which in theory could include foods developed using biotechnology, are prohibited from introduction into interstate commerce and subject to various civil and criminal penalties under the FDCA. See 21 U.S.C. §§ 343(a)(2), 331(a), 332, 333, 334. In addition, the Plant Protection Act of 2000 (“PPA”) grants USDA the authority to prevent the introduction or control the dissemination of plant pests in the United States. 7 U.S.C. § 7711(a). Using this authority, USDA’s APHIS regulates certain genetically engineered plants as “plant pests” and requires review and permitting for movement of such products in interstate commerce. Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29,790 (May 18, 2020).

science and in a manner that is coordinated, predictable, efficient, and scalable.¹⁹

In some areas, the agencies have taken steps toward implementing such policies. For example, in May 2020, USDA's Animal and Plant Health Inspection Service ("APHIS") published a long-awaited final rule, amending its regulation of GE organisms under the PPA.²⁰ The amendments, among other things, seek to focus APHIS's approach to protecting plant health, spur innovation, and facilitate the availability of new crop varieties that are safe for plant health and not currently marketed, such as more sustainable varieties, or those with improved nutrient profiles.²¹ While the new regulations are still being implemented, the amendments indicate movement in a promising direction. Another example is oversight of animal cell culture technology. After a purported "turf battle" between FDA and USDA,²² the agencies issued a joint agreement in March 2019, announcing that they will jointly oversee such products, pursuant to longstanding and relatively well-understood policies and relevant expertise.²³ Although there are a number of open questions remaining, including those relating to requirements for labeling and inspection, the joint agreement provides much-needed clarity on the overarching regulatory framework for these products and generally has been embraced by a wide range of stakeholders.²⁴

In other areas, however, there remains significant uncertainty or lack of clarity. One example is the regulatory paradigm for GE animals, which is in a state of flux. On January 19, 2021, the last day of the Trump Administration, the U.S. Department of Health and Human Services finalized

19. See Holdren, *supra* note 7; NAT'L ACADS. OF SCIS., ENG'G, AND MED., *supra* note 3, at 11; see also *Modernizing the Regulatory System for Plant and Animal Biotechnology Products*, *supra* note 7.

20. Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg. 29,790 (May 18, 2020).

21. See *About the SECURE Rule*, USDA (last updated Feb. 19, 2021), <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision> (providing information and answers about the SECURE Rule).

22. See, e.g., Helena Bottemiller Evich, *Welcome to the turf battle over lab-grown meat*, POLITICO (June 15, 2018 6:12 PM), <https://www.politico.com/story/2018/06/15/lab-grown-meat-feds-turf-battle-629774>.

23. See *USDA and FDA Announce a Formal Agreement to Regulate Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, USDA (Mar. 7, 2019), <https://www.usda.gov/media/press-releases/2019/03/07/usda-and-fda-announce-formal-agreement-regulate-cell-cultured-food>; *Formal Agreement Between FDA and USDA Regarding Oversight of Human Food Produced Using Animal Cell Technology Derived from Cell Lines of USDA-amenable Species*, FDA (Mar. 7, 2019), <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>.

24. See, e.g., *USDA, FDA finalize cultured meat regulatory agreement*, AGRI-PULSE (Mar. 7, 2019 2:12 PM), <https://www.agri-pulse.com/articles/11978-usda-fda-finalize-cultured-meat-regulatory-agreement> (discussing positive reactions to the agreement from various stakeholders).

a “Memorandum of Understanding” (“MOU”) with USDA, shifting regulatory responsibility for certain GE animals intended for food and other agricultural purposes from FDA to USDA.²⁵ In response, then-FDA Commissioner, Dr. Stephen Hahn, maintained that “FDA does not support the Memorandum of Understanding” and “has no intention of abdicating [its] public health mandate.”²⁶ His predecessor, Dr. Scott Gottlieb, also denounced the MOU, calling it “an unprecedented usurping of FDA public health authority,” and calling for FDA to continue to “regulate animal biotech as part of its [public health] mandate.”²⁷ The Biden Administration has yet to articulate a clear position on its view of the MOU. Notably, however, on March 8, 2021, APHIS reopened the comment period for an Advance Notice of Proposed Rulemaking (“ANPR”), originally published in late 2020 before the release of the MOU, that proposes a framework for oversight governed by USDA rather than FDA, pursuant to USDA’s statutory authorities under the Animal Health Inspection Act, Federal Meat Inspection Act, and Poultry Product Inspection Act.²⁸ By reopening the comment period, the Biden Administration has signaled that it will consider overhauling the regulatory framework for GE animals as set forth in the ANPR, thereby indicating that the debate over regulatory reform will rage on. Another example is FDA’s approach to foods derived from genome-edited plants. In early 2017, FDA requested comments on the use of genome editing techniques to produce new plant varieties for human and animal foods and its approach to oversight.²⁹ In October 2018, FDA announced its intent to “develop guidance for industry explaining how [its] current regulatory policy for foods derived from new plant varieties applies to foods produced using genome editing” and to update its existing procedures “to reflect the FDA’s 25 years of experience with foods derived from biotechnology plants.”³⁰ Although a draft version of this guidance appears to have been under review by the Office of Management and Budget (“OMB”) during the final days of the Trump Administration, it

25. See *Memorandum of Understanding Between the United States Department of Agriculture and the Food and Drug Administration, Department of Health and Human Services*, FDA & USDA (Jan. 13, 2021), <https://www.aphis.usda.gov/biotechnology/downloads/mou-usda-fda.pdf>; *Secretary Perdue Statement on MOU on Animal Biotechnology*, USDA (Jan. 19, 2021), <https://www.usda.gov/media/press-releases/2021/01/19/secretary-perdue-statement-mou-animal-biotechnology>.

26. Stephen M. Hahn (@SteveFDA), TWITTER (Jan. 19, 2021 2:45 PM), <https://twitter.com/SteveFDA/status/1351616813705154562>.

27. Scott Gottlieb (@ScottGottliebMD), TWITTER (Jan. 19, 2021 3:08 PM), <https://twitter.com/scottgottliebmd/status/1351622618647027713>.

28. 86 Fed. Reg. 13,221 (Mar. 8, 2021); 85 Fed. Reg. 84,269 (Dec. 28, 2020).

29. Genome Editing in New Plant Varieties Used for Foods; Request for Comments, 82 Fed. Reg. 6564 (Jan. 19, 2017).

30. FDA, PLANT AND ANIMAL BIOTECHNOLOGY INNOVATION ACTION PLAN 5 (Oct. 2018), <https://www.fda.gov/media/119882/download>.

was subsequently withdrawn from OMB review and, to date, has not been finalized.³¹

Thus, the regulatory landscape is highly evolving and still taking new shape. There are signs indicating that the agencies are adapting their regulatory frameworks, based on existing law, science, and experience, to better address new products, but much remains to be seen and the revolution seems far from over.

31. See, e.g., Beth Wang, *OMB Withdraws 6 FDA Regs, Guides, FDA Yanks Tobacco Rules*, INSIDE HEALTHPOLICY (Jan. 22, 2021 6:21 PM), <https://insidehealthpolicy.com/daily-news/omb-withdraws-6-fda-regs-guides-fda-yanks-tobacco-rules>.