Conflict Over Cell-Based Meat: Who Should Coordinate Agencies in U.S. Biotechnology Regulation?

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ABSTRACT

The technology to create meat from cellular cultures has nearly arrived, with potential environmental, animal welfare, and nutritional benefits over traditional animal agriculture. However, considerable uncertainty over the regulatory framework for this emerging biotechnology arose throughout 2018, driven by overlapping statutory authority for the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) with insufficient guidance from the Coordinated Framework for Regulation of Biotechnology. While the FDA-USDA dispute has begun to stabilize, it reflects broader uncertainties over how to resolve jurisdictional disputes in the U.S. oversight of biotechnologies and who can or should coordinate these agencies. In the absence of a clear legal framework to answer these questions, this Article analyzes the strengths and weaknesses of varying public institutions in resolving jurisdictional disputes over novel biotechnologies. This Article assesses federal agencies, Congress, and the President with normative standards of transparency, predictability, and adaptability, considering the cell-based meat case and emerging biotechnologies broadly for insights on institutional mediation of interagency conflict.

INTRODUCTION

After decades of scientific promise and excitement, the technology to create meat from cellular cultures may soon yield marketable products.[1] Rather than harvesting meat from a slaughtered animal, cell-cultured meats would be grown from animal cells in a factory setting.[2] This food biotechnology promises to expand access to protein-rich foods while minimizing concerns over animal welfare and environmental impacts of traditional meat production.[3] Excitement has accelerated in the last several years, with strong momentum behind industry development and the price of production

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[1] NAT'L ACAD. SCI., PREPARING FOR FUTURE PRODUCTS OF BIOTECHNOLOGY 3, 54 (2017), https://www.nap.edu/read/24605/chapter/1 [hereinafter NAS].

[2] *See generally* Mark J. Post, *Cultured Meat from Stem Cells: Challenges and Prospects*, 92 MEAT SCI. 297 (2012).

[3] H. Charles J. Godfray et al., *Meat Consumption, Health, and the Environment*, 361 SCIENCE, no. 6399, July 20, 2018, at 1, 6.

falling.[4] Though the eventual viability of cultured meat depends on gaining consumer acceptance, industry experts project that cell-based meat products will arrive on the market in the next few years.[5]

While cultured meat technology may yield economically feasible products in the near-term, the regulatory framework these products will confront remains uncertain.[6] Oversight of food safety in the United States generally involves complex intersections between multiple administrative agencies at all levels of government.[7] For emerging food biotechnologies, the Coordinated Framework for Regulation of Biotechnology is charged with orchestrating how federal agencies constructively wield their existing regulatory authority in concert.[8] Adopted over thirty years ago, the Coordinated Framework represents a rulemaking effort by the executive branch to negotiate the jurisdictional boundaries between biotechnology agencies in the absence of new legislation from Congress.[9] Though the Coordinated Framework aims to mitigate jurisdictional ambiguities between agencies, its insular focus on genetically modified crops has provided insufficient guidance for authority over cell-cultured meat.

The Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) emerged as the likely regulatory bodies for cultured meat during 2018.[10] Stakeholders invoked meritorious legal and policy arguments for conferring primary or complete regulatory authority to either FDA or USDA, and both agencies have available oversight tools under existing federal law that could apply.[11] Decision-makers in the executive, legislative, and judicial branches became involved, representing the political and policy concerns of competing agricultural and technological constituencies. The conflict over cell-based meat stabilized following a compromise,[12] with the agencies agreeing to regulate different aspects of cell-based

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[4] Charlotte Hawks, *How Close Are We to a Hamburger Grown in a Lab?*, CNN (Mar. 8, 2018), https://www.cnn.com/2018/03/01/health/clean-in-vitro-meat-food/index.html [https://perma.cc/FZQ2-Z6L9]. In just six years, the price of cell-based beef has fallen from $1,200,000 per pound to approximately $50 per pound. Laura Riley, *From Lab to Table: Will Cell-Cultured Meat Win Over Americans?*, WASH. POST (May 3, 2019), https://www.washingtonpost.com/business/2019/05/03/lab-table-will-cell-based-meat-win-over-americans/?noredirect=on&utm_term=.950be2ccce8b [https://perma.cc/F6YS-XXGX].

[5] John Birdsall, *Is Lab-Grown Meat Ready for Dinner?*, WALL ST. J. (Oct. 16, 2018), https://www.wsj.com/articles/is-lab-grown-meat-ready-for-dinner-1539701100 [https://perma.cc/G9MR-2VM7].

[6] JOEL L. GREEN & SAHAR ANGADJIVAND, CONG. RES. SERV., REGULATION OF CELL-CULTURED MEAT 1–2 (Oct. 25, 2018), https://fas.org/sgp/crs/misc/IF10947.pdf [https://perma.cc/B4PA-SVLJ].

[7] RENÉE JOHNSON, CONG. RES. SERV., THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 1 (Dec. 16, 2016), https://fas.org/sgp/crs/misc/RS22600.pdf. *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-17-74, FOOD SAFETY: A NATIONAL STRATEGY IS NEEDED TO ADDRESS FRAGMENTATION IN FEDERAL OVERSIGHT 6–7 (2017), https://www.gao.gov/assets/690/682095.pdf. [https://perma.cc/7325-J5SN].

[8] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–03 (June 26, 1986) [hereinafter Coordinated Framework].

[9] *Id. See* NAS *supra* note 1, at 70–71.

[10] Rose Eveleth, *Should Lab-Grown Meat Be Called Meat?*, SLATE: FUTURE TENSE (July 11, 2018), https://slate.com/technology/2018/07/should-lab-grown-meat-be-called-meat.html [https://perma.cc/6L2W-5TJ3].

[11] Helena Bottemiller Evich, *Welcome to the Turf Battle Over Lab-Grown Meat*, POLITICO (June 15, 2018), https://www.politico.com/story/2018/06/15/lab-grown-meat-feds-turf-battle-629774 [https://perma.cc/K6U3-RHYU].

[12] Jacob Bunge, *Food Regulators Share Oversight of Cell-Based Meat*, WALL ST. J. (Nov. 16, 2017), https://www.wsj.com/articles/food-regulators-to-share-oversight-of-cell-based-meat-1542410292. *See* U.S.

meat production, but which institutions can or should decide how to allocate final regulatory authority remains largely unresolved.[13]

The regulatory debate over cell-based meat reflects broader uncertainties over how to resolve jurisdictional disputes in the oversight of biotechnologies. Existing mechanisms including the Coordinated Framework and its updates,[14] if they apply at all, leave unanswered questions about authority over emerging biotechnology products unanticipated by these arrangements. Who resolves the jurisdictional contours of cultured meat oversight will have implications for mediating future disputes and bridging gaps left by the Coordinated Framework. Determining which institutions can or should arbitrate jurisdictional bounds becomes critical, given the rapid rate of technological innovation and the inevitable appearance of new biotechnological products that will once again challenge existing interagency coordination apparatuses.[15]

This Article aims to characterize the relative strengths and shortcomings of engaging different political institutions to mediate jurisdictional conflicts over biotechnology products. The Article opens in Part I by sketching the technical, policy, and political contexts of cell-based meat that gave rise to the resulting jurisdictional debacle. Part II examines the conflict between FDA and USDA by assessing the legal landscape and failure of the Coordinated Framework to address the cell-based meat conflict. Part III deploys institutional and normative analysis to compare the role of agencies, Congress, and the President in resolving jurisdictional conflicts regarding cell-based meats and other emerging biotechnologies. Considering differences in the relative transparency, predictability, and adaptability of resolutions provided by each institution should illuminate and contextualize future conflicts between biotechnology agencies.

I. RISING EXCITEMENT FOR AND TENSIONS OVER CELL-BASED MEAT

The idea of producing meats from animal cells in the laboratory dates back decades,[16] though real excitement over the technology erupted after the first publicly-

Dep't Agric. and U.S. Food & Drug Admin., Memorandum of Understanding Over Cell Culture Technology (Mar. 7, 2019), https://www.fsis.usda.gov/wps/wcm/connect/0d2d644a-9a65-43c6-944f-ea598aacdec1/Formal-Agreement-FSIS-FDA.pdf?MOD=AJPERES [https://perma.cc/NVT6-R7BL].

[13] *See, e.g.*, Liz Crampton, *Cell-Based Meat Issue Could Still Be Settled on the Hill*, POLITICO (Nov. 20, 2018), https://www.politico.com/newsletters/morning-agriculture/2018/11/20/cell-based-meat-issue-could-still-be-settled-on-the-hill-422882 [https://perma.cc/RC8S-H7AC].

[14] Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introduction of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992) [hereinafter 1992 Update]; OFFICE OF SCIENCE AND TECHNOLOGY POLICY, MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY (2017) https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf [https://perma.cc/9YNJ-95XL] [hereinafter 2017 UPDATE].

[15] *See generally* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT (Gary E. Marchant, Braden R. Allenby & Joseph R. Herkert eds., 2011).

[16] Commentators often cite Winston Churchill's 1931 essay entitled "Fifty Years Hence" as an early example. Erik Jönsson, *Benevolent Technotopias and Hitherto Unimaginable Meats: Tracing the Promises of In Vitro Meat*, 46 SOC. STUD. SCI. 725, 731 (2016) ("[A] nascent in vitro meat canon [formed], where a quote from a 1931 Winston Churchill piece is repeated with incredible frequency," which reads "'[w]e shall

broadcasted tasting of a cultured beef patty in 2013.[17] In the subsequent years, a constellation of companies has emerged to form an industry committed to bringing cultured meats to market.[18] Some of these developers benefit from high-profile investing.[19] The technology behind cell-cultured meats has developed significantly and may allow for marketable products in 2021 or earlier.[20] Support and interest continue to swell, especially amidst intensifying concerns over the nutritional health and environmental impacts of animal agriculture and meat products.[21] Boosting its notoriety, the World Economic Forum recently recognized cultured meat in the top ten emerging technologies of 2018.[22]

The biotechnology behind cell-cultured meat developed over the last three decades into a complex multistep process, using existing work in medical tissue research as a platform.[23] The process begins by obtaining adult stem cells from the target animal, often through biopsy methods.[24] Animal cells are cultured in nutrient-rich media under highly controlled conditions in bioreactors.[25] Culturing the animal cells around edible scaffolds in the bioreactors enables greater control over the shape and growth of the tissue.[26] The adult stems cells undergo guided differentiation into muscle or other cell types using biochemical signals, supported by electrical or mechanical stimulation of

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escape the absurdity of growing a whole chicken in order to eat the breast or wing, by growing these parts separately under a suitable medium.'"). *See, e.g.*, PAUL SHAPIRO, CLEAN MEAT 8–9 (2018); Cor van der Weele & Johannes Tramper, *Cultured Meat: Every Village Its Own Factory?*, 32 TRENDS IN BIOTECHNOLOGY 294, 294 (2014).

17 Pallab Ghosh, *Lab-Grown Burger to Be Unveiled*, BBC NEWS (Aug. 5, 2013), https://www.bbc.com/news/science-environment-22885969 [https://perma.cc/8GQN-FB9B].

18 Several firms around the world are developing cultured beef, poultry, and seafood products.

19 *Tyson Foods Invests in Cultured Meat with Stake in Memphis Meats*, TYSON FOODS (Jan. 29, 2018), https://www.tysonfoods.com/news/news-releases/2018/1/tyson-foods-invests-cultured-meat-stake-memphis-meats [https://perma.cc/46J4-32AV].

20 *See* Birdsall, *supra* note 5.

21 *See, e.g.*, *Tackling the World's Most Urgent Problem: Meat*, U.N. ENV'T PROGRAMME (Sept. 26, 2018), https://www.unenvironment.org/news-and-stories/story/tackling-worlds-most-urgent-problem-meat [https://perma.cc/6KQW-TEV4]; *IARC Monographs Evaluate Consumption of Red Meat and Processed Meat*, INT'L AGENCY FOR RES. ON CANCER, (Oct. 26, 2015), https://www.iarc.fr/wp-content/uploads/2018/07/pr240_E.pdf [https://perma.cc/7MVG-3Q4T]. *See generally* Christine Parker, Fiona Haines & Laura Boehm, *The Promise of Ecological Regulation: The Case of Intensive Meat*, 59 JURIMETRICS J. 15 (2018).

22 Oliver Cann, *These Are the Top 10 Emerging Technologies of 2018*, WORLD ECON. FORUM (Sep. 14, 2018), https://www.weforum.org/agenda/2018/09/top-10-emerging-technologies-of-2018 [https://perma.cc/LGE5-TL8G].

23 Isam T. Kadim et al., *Cultured Meat from Muscle Stem Cells: A Review of Challenges and Prospects*, 14 J. INTEGRATIVE AGRIC. 222, 222–23 (2015).

24 Mark J. Post & Jean-François Hocquette, *New Sources of Animal Proteins: Cultured Meat*, *in* NEW ASPECTS OF MEAT QUALITY 425, 426 (Peter P. Purslow ed., 2017).

25 *See generally* Matilda S. M. Moritz, Sanne E. L. Verbruggen & Mark J. Post, *Alternatives for Large-Scale Production of Cultured Beef: A Review*, 14 J. INTEGRATIVE AGRIC. 208 (2015). The "self-organization" method of developing cultured meat products may present an alternative to using scaffolds, though may be more difficult to implement. Shruti Sharma, Sukhcharanjit Singh Thind & Amarjeet Kaur, *In Vitro Meat Production System: Why and How?*, 52 J. FOOD. SCI. TECH. 7599, 7600 (2015).

26 Zuhaib Fayaz Bhat & Hina Fayaz, *Prospectus of Cultured Meat—Advancing Meat Alternatives*, 48 J. FOOD SCI. & TECH. 125, 134–35 (2011). Scaffolds are commonly made from animal gelatins, but can also be derived from algae products. Javier Enrione et al., *Edible Scaffolds Based on Non-Mammalian Biopolymers for Myoblast Growth*, 10 MATERIALS (BASEL) 1404, 1405 (2017).

the growing tissue.[27] To generate products replicating the physical properties of meat, including taste and appearance, the technology has been honed to produce an appropriate balance of muscle, fiber, fatty, bone, and cartilage tissues.[28]

Ethical and environmental arguments may make cultured meat palatable to concerned groups while responding to the growing global demand for meat, especially in the developing world.[29] Cellular agriculture could boost access to meat while avoiding ethical issues with animal treatment and slaughter.[30] Relative to conventional meat agriculture, cultured meat promises to significantly reduce greenhouse gas emissions and the consumption of land, water, and feed by livestock.[31] Cultured ground beef may require as little as three weeks to produce, as opposed to months required for conventional meat.[32] Tissue engineering tools may further allow for improved nutritional quality over conventional meat or avoid antibiotics and growth-promoting hormones used in traditional meat production.[33]

Before cultured meat could provide its promised benefits, technical and social hurdles must still be overcome. Though estimates vary, producing the cultured burger showcased in 2013 may have cost approximately $300,000.[34] The price of production is falling, though further work remains, and industry actors seek to drop costs below

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[27] Neil Stephens et al., *Bringing Cultured Meat to Market: Technical, Socio-Political, and Regulatory Challenges in Cellular Agriculture*, 78 TRENDS FOOD SCI. & TECH. 155, 156 (2018); Muhammad Sajid Arshad et al., *Tissue Engineering Approaches to Develop Cultured Meat from Cells: A Mini Review*, 3 COGENT FOOD & AGRIC., 6–7 (2017).

[28] *See* Post, *supra* note 2, at 298–99.

[29] *See* Godfray et al., *supra* note 3, at 1, 6. *See also* Walter Willet et al., *Food in the Anthropocene: The EAT*-Lancet *Commission on Healthy Diets from Sustainable Food Systems*, 393 THE LANCET 447, 449–50 (2019), http://www.sciencedirect.com/science/article/pii/S0140673618317884 [https://perma.cc/E8WC-4MFU].

[30] G. Owen Schaefer & Julian Savulescu, *The Ethics of Producing In Vitro Meat*, 31 J. APPLIED PHIL. 188, 189 (2014).

[31] Hanna L. Tuomisto & M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, 45 ENVTL. SCI. & TECH. 6117, 6121–22 (2011). However, scaling up cultured meat production could require more energy consumption than originally predicted and environmental impact will depend on the source of electricity. *See* John Lynch & Raymond Pierrehumbert, *Climate Impacts of Cultured Meat and Beef Cattle*, 3 FRONTIERS SUSTAINABLE FOOD SYS., 2019, at 1 (2019); Carolyn S. Mattick et al., *Anticipatory Life Cycle Analysis of In Vitro Biomass Cultivation for Cultured Meat Production in the United States*, 49 ENVTL. SCI. & TECH. 11941, 11947 (2015). Reduced land use could allow for habitat restoration. Zuhaib Fayaz Bhat, Sunil Kumar & Hina Fayaz, *In Vitro Meat Production: Challenges and Benefits Over Conventional Meat Production*, 14 J. INTEGRATIVE AGRIC. 241, 244 (2015).

[32] Mark J. Post, *Cultured Beef: Medical Technology to Produce Food*, 94 J. SCI. FOOD & AGRIC. 1039, 1040 (2014).

[33] Mark Post & Cor van der Weele, *Principles of Tissue Engineering for Food*, *in* PRINCIPLES OF TISSUE ENGINEERING 1647, 1657 (Robert Lanza, Robert Langer, & Joseph P. Vacanti eds., 4th ed. 2013). Limiting antimicrobial use could strongly serve public health, as a recent Organization for Economic Co-operation and Development (OECD) report estimates 2.4 million mortalities from antimicrobial resistant pathogens between 2015-2050 in the Western world. ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, STEMMING THE SUPERBUG TIDE 15 (2018). Cell-based methods to reduce hazards associated with red meat, including cardiovascular disease, may further bolster public health and obviate proposals to tax meat products. *See Should There Be a Tax on Red Meat?*, BBC (Nov. 7, 2018), https://www.bbc.com/news/uk-46122227 [https://perma.cc/Q8Z4-A4QA].

[34] Regan Morris & James Cook, *Would You Eat Slaughter-Free Meat?*, BBC NEWS (Oct. 15, 2018), https://www.bbc.com/news/world-us-canada-45865403 [https://perma.cc/DY4H-C6J5].

$5 per pound.[35] Successfully scaling-up production may require deeper understanding of the underlying biological processes in culturing meat tissue and technical designs that can best leverage these processes.[36] An ethical concern remains over the use of fetal bovine serum in the cell culture procedures,[37] though newer techniques may obviate the need for animal serum in cultured meat preparation.[38] Consumer acceptance of cultured meat is not guaranteed and will require overcoming the "yuck" factor and perceived unnaturalness.[39] Consumer opinions and acceptance may vary across demographic groups and depend on the labels for cultured meat products.[40] The details of labeling and regulatory choices could yield critical differences in the perceived transparency and legitimacy of regulation for cell-based foods.[41]

Beyond technical and consumer factors, cultured meat products will emerge into a complex network of existing food safety oversight, involving multiple federal agencies and regulatory programs.[42] Cell-based meat presents a series of unresolved regulatory questions, from how to label products and if they can even be called "meat," to which food safety oversight framework and current FDA or USDA requirements will apply.[43]

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[35] Zara Stone, *The High Cost of Lab-to-Table Meat*, WIRED (Mar. 8, 2017), https://www.wired.com/story/the-high-cost-of-lab-to-table-meat [https://perma.cc/3AGH-8QN9]. Though the Good Food Institute predicts the first cell-based burgers sold to consumers may approach $50 each. *See* Jane Wakefield, *TED 2019: The $50 Lab Burger Transforming Food*, BBC NEWS (Apr. 17, 2019), https://www.bbc.com/news/technology-47724267 [https://perma.cc/5EFB-HF9J].

[36] *See* Elie Dolgin, *Sizzling Interest in Lab-Grown Meat Belies Lack of Basic Research*, NATURE (Feb. 6, 2019), https://www.nature.com/articles/d41586-019-00373-w [https://perma.cc/H4BK-MMP8].

[37] *See* Nick Thieme, *The Gruesome Truth About Lab-Grown Meat*, SLATE (July 11, 2017), http://www.slate.com/articles/health_and_science/science/2017/07/why_is_fetal_cow_blood_used_to_grow_fake_meat.html [https://perma.cc/W59R-ZKJU].

[38] These may include plant- or microbially-derived serum alternatives, potentially augmented with genome manipulation. Matt Reynolds, *The Clean Meat Industry Is Racing to Ditch Its Reliance on Foetal Blood*, WIRED (Mar. 20, 2018), https://www.wired.co.uk/article/scaling-clean-meat-serum-just-finless-foods-mosa-meat [https://perma.cc/KCB4-GYRA].

[39] Michael Siegrist, Bernadette Sütterlin & Christina Hartmann, *Perceived Naturalness and Evoked Disgust Influence Acceptance of Cultured Meat*, 139 MEAT SCI. 213, 218 (2018); *See generally* Charles W. Schmidt, *The Yuck Factor When Disgust Meets Discovery*, 116 ENVTL. HEALTH PERSP. A524 (2008).

[40] Walter Johnson, Andrew Maynard & Sheril Kirshenbaum, *Would You Eat "Meat" From a Lab? Consumers Aren't Necessarily Sold on "Cultured Meat"*, THE CONVERSATION (2018), http://theconversation.com/would-you-eat-meat-from-a-lab-consumers-arent-necessarily-sold-on-cultured-meat-100933 [https://perma.cc/GPJ4-AV9V]; *see also* Christopher Bryant et al., *A Survey of Consumer Perceptions of Plant-Based and Clean Meat in the USA, India, and China*, 3 FRONTIERS SUSTAINABLE FOOD SYS., Feb. 2019, at 1 (2019). Various rationales for consumer disinterest in cell-based meat have been observed including perceptions of cell-based meat as unnecessary, unnatural, disgusting, or harmful to farmers. *See* Matti Wilks, *Cultured Meat Seems Gross? It's Much Better than Animal Agriculture*, THE CONVERSATION (2019), https://theconversation.com/cultured-meat-seems-gross-its-much-better-than-animal-agriculture-109706 [https://perma.cc/ME6T-DC5D]. *See generally* Christopher Bryant & Julie Barnett, *Consumer Acceptance of Cultured Meat: A Systematic Review*, 143 MEAT SCI. 8 (2018).

[41] *See, e.g.*, Walter G. Johnson, *Lab-Grown Seafood and Lab-Grown Meat Aren't That Different*, SLATE: FUTURE TENSE (Oct. 23, 2018), https://slate.com/technology/2018/10/lab-grown-meat-seafood-usda-fda-labeling.html [https://perma.cc/8NZP-LJ7Q].

[42] Food safety regulation in the U.S. involves sixteen federal agencies which run different programs. *See* GOV'T ACCOUNTABILITY OFFICE, *supra* note 7, at 6–7.

[43] *See* Eveleth, *supra* note 10. Proposed names for the products include, but are not limited to, "cultured meat," "lab-grown meat," "clean meat," "in vitro meat," "artificial meat," "cell-culture products," and "cultured tissue." Sarah Zhang, *The Farcical Battle Over What to Call Lab-Grown Meat*, ATLANTIC

In February 2018, the U.S. Cattleman's Association brought attention to these questions by petitioning USDA to prohibit cultured meat from being labeled "meat,"[44] building on related tensions over labeling plant-based beverages as "milk."[45] Stakeholders and advocates of the ranching or cell-based meat industries wrestled over which administrative agency properly had jurisdiction over the cellular technology.[46]

Despite divided politics over regulatory jurisdiction, it remains clear that this novel food biotechnology will require adequate oversight to safeguard public health and provide assurances to consumers.[47] Food safety oversight for both conventional and cultured meat will involve monitoring for contamination throughout production.[48] Nevertheless, cultured meat may pose new safety concerns, including ensuring the safety of the cell lines, media, edible scaffolds, and bioreactor waste disposal protocols, as well as addressing any risks posed by genetically engineered cell cultures.[49] Cultured meat products may also require oversight to ensure an adequate nutritional profile for consumers.[50] Adequately addressing these food safety concerns will require resolving jurisdictional disputes between agencies to determine the applicable oversight framework.

II. JURISDICTIONAL UNCERTAINTY OVER CELL-BASED MEAT

Ensuring the safety of cultured meat products to safeguard public health will require a federal regulatory framework that adequately assesses known and potential food safety concerns. Historically, U.S. regulators have strived to examine new

(July 13, 2018), https://www.theatlantic.com/science/archive/2018/07/lab-grown-meat/565049 [https://perma.cc/978D-7QA6].

44 U.S. Cattleman's Association, *Petition for the Imposition of Beef and Meat Labeling Requirements: To Exclude Products Not Derived Directly from Animals Raised and Slaughtered from the Definition of "Beef" and "Meat"* (Feb. 9, 2018), https://www.fsis.usda.gov/wps/wcm/connect/e4749f95-e79a-4ba5-883b-394c8bdc97a3/18-01-Petition-US-Cattlement-Association020918.pdf?MOD=AJPERES [https://perma.cc/U36N-TJNH]. This was supported by comments submitted to USDA in May 2018. Consumers Union, National Consumers League & Center for Foodborne Illness Research & Prevention, *Comments on Petition to Establish Beef and Meat Labeling Requirements* (May 17, 2018), https://consumersunion.org/wp-content/uploads/2018/07/CU-cmmts-final-on-lab-grown-meat.5.17.18.pdf [https://perma.cc/CHN4-NZL2].

45 *See* Nellie Bowles, *Got Milk? Or Was That Really a Plant Beverage?*, N.Y. TIMES (Aug. 31, 2018), https://www.nytimes.com/2018/08/31/business/milk-nut-juice-plant-beverage-label.html [https://perma.cc/E449-4KND].

46 Jacob Bunge, *Lab-Grown Meat Raises Regulatory Questions*, WALL ST. J. (Oct. 3, 2018), https://www.wsj.com/articles/lab-grown-meat-raises-regulatory-questions-1538532420.

47 NAS, *supra* note 1, at 7. Representatives in Washington State have even proposed legislation to forbid the sale of cell-cultured meat based in part on safety concerns. *See* H.B. 1519, 66th Leg., Reg. Sess. (Wash. 2019).

48 *See* GREEN & ANGADJIVAND, *supra* note 6, at 2.

49 *See* Stephens et al., *supra* note 27, at 162–63; Bhat & Fayaz, *supra* note 26, at 133–34, 136. Some skeptics argue that insufficient evidence on cell-cultured meat exists to evaluate its safety. FRIENDS OF THE EARTH, FROM LAB TO FORK: CRITICAL QUESTIONS ON LABORATORY-CREATED ANIMAL PRODUCT ALTERNATIVES 11 (2018).

50 Jette F. Young et al., *Novel Aspects of Health Promoting Compounds in Meat*, 95 MEAT SCI. 904, 908–09 (2013).

biotechnological products within existing oversight programs,[51] without requesting more specialized legislation. Cultured meat is likely no exception, though this approach provides limited guidance for determining appropriate jurisdiction. Throughout 2018, USDA and FDA each postured themselves as the most appropriate regulatory body to address cultured meat and have existing oversight mechanisms that arguably could apply to the technology.[52]

USDA draws authority for its food safety operations for meat from a constellation of statutes. The Federal Meat Inspection Act confers authority to USDA over "meat food product" including "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats" and "food products of equines."[53] The Poultry Products Inspection Act, Egg Products Inspection Act, and 2008 Farm Bill respectively grant USDA control over "any poultry carcass" of "any domesticated bird,"[54] "any dried, frozen, or liquid eggs,"[55] and catfish.[56] These statutes charge USDA with preventing the sale of adulterated or misbranded meat, poultry, and eggs.[57] Within USDA, the Food Safety and Inspection Service (FSIS) administers these statutes with regulations and inspections designed to prevent and screen for microbial contamination during traditional meat production.[58]

The FDA oversees other meat products and seafood under the Federal Food, Drug, and Cosmetic Act.[59] The statutory scheme defines food broadly and empowers FDA with primarily post-market powers over adulterated or misbranded foods,[60] with preventative tools including setting good manufacturing and sanitation standards added by the FDA Food Safety Modernization Act.[61] Such authority may capture cultured meat given its sheer breadth and few express limitations. FDA also oversees "food additives," with premarket checks exempted when the additive is "generally

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[51] *See* Coordinated Framework, *supra* note 8, at 23,302.

[52] *See* Evich, *supra* note 11.

[53] Federal Meat Inspection Act, 21 U.S.C. § 601(j) (2018).

[54] Poultry Products Inspection Act, 21 U.S.C. § 453(e)–(f) (2018).

[55] Egg Products Inspection Act, 21 U.S.C. § 1033(f) (2018).

[56] Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, § 11016, 122 Stat. 1651, 2130–31 (2008) (adding catfish to the scope of the Federal Meat Inspection Act).

[57] 21 U.S.C. § 610 (2018); 21 U.S.C. § 458 (2018); 21 U.S.C. § 1037 (2018).

[58] *See* Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38806 (July 25, 1996) (codified in 9 C.F.R. pt. 304, 308, 310, 320, 327, 381, 416, and 417).

[59] 21 U.S.C. §§ 321–399i (2018). *See* U.S. Food & Drug Admin., *What We Do at CFSAN* (2018), https://www.fda.gov/about-fda/center-food-safety-and-applied-nutrition-cfsan/what-we-do-cfsan.

[60] 21 U.S.C. §§ 331–337a; U.S. Food & Drug Admin., *Compliance and Enforcement* (2018), https://www.fda.gov/food/complianceenforcement/default.htm [https://perma.cc/Z26H-3GN3] (listing post-market focused FDA food safety tools including inspection, sampling, recall power, seizure, injunction, and destruction).

[61] FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (defining preventative controls in § 103 as "those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified"). The FDA issued rules implementing these statutory provisions in 2015. *See* Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 Fed. Reg. 55907 (Sept. 17, 2015).

recognized as safe" (GRAS) by experts.[62] Under this framework, industry need not inform FDA of their internal GRAS determinations to bring an additive to market, but can informally consult with or voluntarily notify FDA for agency review.[63] The FDA approach of finding genetically modified crops as GRAS upon demonstrating their "substantial equivalence" to the traditional crop[64] may find applicability in cultured meat. Other existing FDA regulatory tools may apply, should genetic material be inserted into animal cells in cultured meat to enhance its properties, including the New Animal Drug pathway.[65]

The Coordinated Framework for the Regulation of Biotechnology intended to outline jurisdictional boundaries between FDA, USDA, and the Environmental Protection Agency (EPA).[66] However, the original 1986 policy primarily addressed genetically modified crops,[67] generating uncertainty about whether or how it applies to other biotechnologies.[68] The initial Framework discusses FDA's general authority over food and USDA statutes on meat and poultry.[69] Yet, the Framework only addresses food from genetically engineered animals, without considering cell-based products. The 2017 updated Coordinated Framework succeeds in contemplating cellular agriculture, but fails to offer more guidance than merely identifying FDA and USDA as the agencies requiring coordination.[70] Instead, the update again addresses primarily food products from genetically engineered animals without substantively considering jurisdictional divides in cell-cultured products and excluding other potentially relevant agencies.[71] Such omissions further cloud cell-cultured meat oversight, as USDA's lack of authority over seafood may produce bifurcated

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[62] 21 U.S.C. § 321(s) (2018); 21 C.F.R. §§ 170.30–170.38 (2018). *See* U.S. Food & Drug Admin., *Generally Recognized as Safe (GRAS)* (Sept. 26, 2018), https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras [https://perma.cc/R748-JE5K].

[63] 21 C.F.R. §§ 170.205, 170.265 (2018). *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-246, FOOD SAFETY: FDA SHOULD STRENGTHEN ITS OVERSIGHT OF FOOD INGREDIENTS DETERMINED TO BE GENERALLY RECOGNIZED AS SAFE (GRAS) 9 (2010), https://www.gao.gov/new.items/d10246.pdf [https://perma.cc/ZA2J-NA78].

[64] Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 HARV. L. REV. 526, 559 (2004); Stephanie Amaru, *A Natural Compromise: A Moderate Solution to the GMO & "Natural" Labeling Disputes*, 69 FOOD DRUG L.J. 575, 583 (2014).

[65] Jennifer Penn, *"Cultured Meat": Lab-Grown Beef and Regulating the Future Meat Market*, 36 UCLA J. ENVTL. L. & POL'Y 104, 121–22 (2018).

[66] Coordinated Framework, *supra* note 8, at 23,302–03.

[67] NAT'L RES. COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS 144–45 (2000), https://www.nap.edu/read/9795/chapter/1 [https://perma.cc/P5VR-VT7D].

[68] *See, e.g.*, Michael J. Donovan, *Genetically Modified Insects: Why Do We Need Them and How Will They Be Regulated?*, 17 MO. ENV'T L. & POL'Y REV. 62, 107 (2009); Albert C. Lin, *Mismatched Regulation: Genetically Modified Mosquitoes and the Coordinated Framework for Biotechnology*, 51 U.C. DAVIS L. REV. 205, 219–22 (2017).

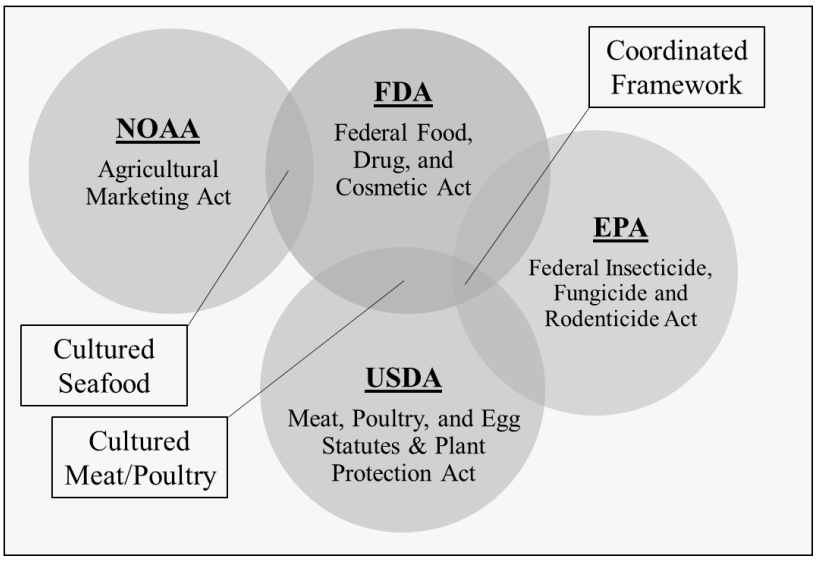
[69] *See* Coordinated Framework, *supra* note 8, at 23,311–13, 23,343–44. The 2017 update adds reference to the Egg Products Inspection Act. 2017 UPDATE, *supra* note 14, at 26.

[70] *See* 2017 UPDATE, *supra* note 14, at 30.

[71] The update again addresses food products from genetically engineered animals without addressing cell-cultured foods. *See* 2017 UPDATE, *supra* note 14, at 26–27. The update largely excludes the National Oceanic and Atmospheric Administration (NOAA) and its voluntary seafood inspection program. *See* 50 C.F.R. §§ 260.12–260.30 (2018); U.S. Nat'l Oceanic & Atmosphere Admin., *NOAA's Seafood Inspection Program* (2017), https://www.fisheries.noaa.gov/insight/noaas-seafood-inspection-program [https://perma.cc/39ZK-VB4L].

frameworks for cell-based meat and seafood (see Figure 1).[72] Additional jurisdictional confusion may arise should cell-based meat converge with other emerging biotechnologies, including genome editing[73] or de-extinction.[74]

Figure 1. Complex Jurisdictional Overlaps in Cell-Based Products



Against this unclear backdrop, stakeholders asserted various legal and policy arguments for USDA or FDA oversight of cultured meat throughout 2018. Arguments for USDA alleged that cultured meat falls under the Department's statutory authority, wielding a broad interpretation of the definition of "meat," and calling for FSIS to prevent adulteration and "mislabeling" of cell-based meat.[75] Traditional meat stakeholders argued that USDA's robust inspection infrastructure and expertise indicated FSIS oversight would be the most efficient option.[76] Others countered that cultured meat could not be a meat food product, as USDA's jurisdiction appears

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[72] Johnson, *supra* note 41.

[73] *See* Stephens et al., *supra* note 27, at 162.

[74] Lily Hay Newman, *Yum: This Lab-Grown Meat Cookbook Includes Recipes for Dodo Nuggets*, SLATE: FUTURE TENSE (Oct. 14, 2014), https://slate.com/technology/2014/10/the-in-vitro-meat-cookbook-created-in-the-the-netherlands-has-50-recipes-for-lab-grown-meat.html [https://perma.cc/2RZ5-MMNY]. *See generally* Jacob S. Sherkow & Henry T. Greely, *What If Extinction Is Not Forever?*, 340 SCIENCE 32 (2013).

[75] *See* U.S. Cattleman's Association, *supra* note 44, at 3–7 (citing 21 U.S.C. § 601(n)(2)–(3), (7)). USDA would also have a duty to prevent misbranding in poultry and eggs, as well as adulteration in all three classes of food products. *See* 21 U.S.C. § 601(m); 21 U.S.C. § 453(g)–(h); 21 U.S.C. § 1033(a), (l).

[76] American Farm Bureau Federation et al., *Letter to President Trump on Regulation of Cell-Cultured Products* (July 26, 2018), http://www.beefusa.org/CMDocs/BeefUSA/Barnyard%20Letter%20RE%20Cell%20Cultured%20Meat%207.26.18.pdf [https://perma.cc/4E8S-G2Q3]. Notably, USDA does receive greater congressional appropriations for its food safety operations than FDA, though this trend may be changing. *See* JOHNSON, *supra* note 7, at 8–9.

connected to slaughtered animal "carcasses."[77] Instead, FDA could manage cell-based meat with its expansive definition of food and history of regulating cellular biotechnology in food, arguably promoting food safety and innovation.[78] Seeking a middle path, other cultured meat advocates argued both entities could collaborate in a scheme of FDA premarket approval and USDA post-market inspections.[79]

Exacerbating the uncertain legal landscape, both FDA and USDA in 2018 claimed jurisdiction over cell-based meat. In early 2018, USDA Secretary Sonny Perdue referred to USDA's longstanding role in meat regulation and asserted the Department would oversee any product labeled as meat.[80] Two months later, then-FDA Commissioner Scott Gottlieb issued a statement claiming broad jurisdiction over cell-based meat and announced a public meeting without USDA staff.[81] Ultimately, FDA and USDA called a joint public meeting in October 2018 to address stakeholder concerns and announced that they would co-regulate cell-based meats.[82] The next month, the agencies clarified that FDA would regulate "cell collection, cell banks, and cell growth and differentiation," while USDA would oversee "production and labeling."[83] The resulting March 2019 memorandum of understanding (MOU) added

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[77] Amaru Sanchez, *Laws and Regulations Concerning Cell-Cultured Meat and Cellular Agriculture*, UPDATE MAGAZINE (2018), https://www.fdli.org/2018/02/update-laws-regulations-concerning-cell-cultured-meat-cellular-agriculture/ [https://perma.cc/95U4-FWMS]; *see also* NAS, *supra* note 1, at 90.

[78] *See* 21 U.S.C. § 321(f) (2018); Kelly Servick, *As Lab-Grown Meat Advances, U.S. Lawmakers Call for Regulation*, SCIENCE (May 10, 2018), http://www.sciencemag.org/news/2018/05/lab-grown-meat-advances-us-lawmakers-call-regulation [https://perma.cc/4V3J-GFRK]. Cooperhouse et al., *RE: Docket No. FDA-2018-N-2155 for Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments* (Sept. 25, 2018) https://www.gfi.org/files/policy/fda-comments-2018-09-25.pdf. However, others argue cell-based meat might fall outside the scope of FDA authority for food additives. Taylor A. Mayhall, *The Meat of the Matter: Regulating a Laboratory-Grown Alternative*, 74 FOOD & DRUG L.J. 151, 166 (2019).

[79] Memphis Meats & North American Meat Institute, *Letter to President Trump on Regulation of Cell-Based Meat and Poultry Products* (Aug. 23, 2018), https://www.meatinstitute.org/index.php?ht=a/GetDocumentAction/i/148176 [https://perma.cc/YBH3-YVRD]. *See also* Zachary Schneider, Comment, *In Vitro Meat: Space Travel, Cannibalism, and Federal Regulation*, 50 HOUS. L. REV. 991, 1016–19 (2013) (arguing the most prudent framework would combine FDA food additive and new drug oversight with USDA oversight).

[80] *Hearing Before the H. Subcomm. on Agriculture, Rural Development, FDA, and Related Agencies to consider FY2019 Budget Request for USDA Programs*, 115th Cong. (2018) (statement of Sonny Perdue, Sec'y, U.S. Dep't Agric.) ("meat and poultry has been the sole purview of USDA. We would expect any product that expects to be labeled as meat would come under that same inspection criteria.").

[81] *Statement from FDA Commissioner Scott Gottlieb, M.D. and FDA Deputy Commissioner Anna Abram on Emerging Food Innovation, "Cultured" Food Products*, U.S. FOOD & DRUG ADMIN. (June 15, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm610869.htm [https://perma.cc/J3YZ-4M94]. After the FDA released its statement, a spokesperson for USDA was quoted expressing frustration at FDA's broad and possibly exclusive jurisdictional claim. *See* Evich, *supra* note 11.

[82] Joint Public Meeting on Use of Animal Cell Culture Technology to Develop Products Derived from Livestock and Poultry, 83 Fed. Reg. 46,476, 46,476–78 (Sept. 13, 2018). *See* Brian Sylvester, *Building the Regulatory Conversation on Cellular Agriculture*, LAW360 (Oct. 30, 2018), https://www.law360.com/lifesciences/articles/1096770/building-the-regulatory-conversation-on-cellular-agriculture [https://perma.cc/V36Z-CA7P].

[83] *Statement from USDA Secretary Purdue and FDA Commissioner Scott Gottlieb on the Regulation of Cell-Cultured Food Products from Cell Lines of Livestock and Poultry*, U.S. DEP'T AGRIC. (Nov. 16, 2018), https://www.usda.gov/media/press-releases/2018/11/16/statement-usda-secretary-perdue-and-fda-commissioner-gottlieb [https://perma.cc/MC5P-VUUT] [hereinafter USDA/FDA Statement].

some detail to this division of oversight activities, expressly providing that regulatory authority passes from FDA to USDA after harvesting cultured cells.[84]

The jurisdictional debacle over cell-based meat ultimately yielded a compromise, but only after months of uncertainty and clashes between stakeholders and regulators. Though the FDA-USDA agreement represents a temporary point of stability, conflict could still return during implementation of the oversight scheme, given the nonbinding nature of the MOU.[85] Additional instability could result should stakeholders or lawmakers raise challenges to the FDA-USDA agreement.[86] While these policy and political conflicts over cell-based meat jurisdiction may reflect the historically divergent constituencies and missions of FDA and USDA,[87] such observations alone do not identify methods of defusing tension over regulatory boundaries. The Coordinated Framework, as the key instrument for orchestrating federal agencies around biotechnology,[88] failed to prevent the clashes over cell-based meat and will likely offer little assistance for mitigating any future friction over jurisdiction for these products. In the future, avoiding vexing and resource-intensive interagency conflicts may require new insights on creating novel coordination schemes for biotechnology agencies.

III. POSSIBLE DECISIONMAKERS IN RESOLVING JURISDICTIONAL DISPUTES

The jurisdictional uncertainties over cell-based meat reflect broader issues in coordinating regulatory agencies with authority over biotechnologies when new products arise in defiance of existing jurisdictional boundaries. With numerous emerging biotechnologies on the horizon[89] and poor guidance from existing coordination tools, future conflicts resembling the one over cell-based meat between FDA, USDA, EPA, or other agencies in this space appear likely. The U.S. regulatory landscape for biotechnological products exemplifies governance challenges that can arise when multiple agencies with conflicting goals occupy a "shared regulatory space."[90] Congress frequently assigns agencies authority and responsibilities that

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[84] U.S. Dep't Agric. and U.S. Food & Drug Admin., *supra* note 12, at 2–3.

[85] *See id.* at 4.

[86] For example, one month after the FDA-USDA MOU was formalized, Senator Cindy Hyde-Smith introduced a bill that would funnel substantially more regulatory authority to USDA than the agencies had previously agreed to in their MOU. S.1056, 116th Cong. (2019). *See also* Press Release, Office of Sen. Hyde-Smith, Hyde-Smith Moves to Codify Oversight, Regulation of Lab-Grown Meat & Poultry (Apr. 10, 2019), https://www.hydesmith.senate.gov/content/hyde-smith-moves-codify-oversight-regulation-lab-grown-meat-poultry [https://perma.cc/96JZ-B6TY].

[87] *See* Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 82–84 (2000) (describing the history of President Roosevelt removing FDA from USDA in 1940).

[88] *See* NAS, *supra* note 1, at 98–99.

[89] *Id.* at 4–5.

[90] Jody Freeman & Jim Rossi, *Agency Coordination in Shared Regulatory Space*, 125 HARV. L. REV. 1131, 1145–46 (2012) (describing situations where multiple agencies have overlapping or adjacent authority over a common set of goods or services).

overlap in substantive areas.[91] Scholars list various reasons for this phenomenon,[92] often arguing that the overlap offers benefits in effectiveness, interagency accountability, and avoiding stagnation.[93] The resulting system often requires coordinating the agencies' regulatory activities to fill out the jurisdictional contours of statutes and create clear oversight standards.[94]

Successfully coordinating agencies can create regulatory transparency and predictability in biotechnology that is critical for enabling the regulated industry to comply effectively and for building public trust in biotechnological oversight.[95] Predictability in coordination can be defined here as the ability of the regulated industry to reasonably anticipate the shape of the eventual oversight scheme and how regulators will ultimately treat their products or services.[96] Transparency instead serves to render regulatory activity accountable and responsive to stakeholders and the public, infusing a degree of public participation into the oversight system.[97] Accordingly, predictability and transparency have served as guiding principles in coordinating biotechnology agencies, including while updating the Coordinated Framework.[98]

The rapidly evolving nature of biotechnological products creates a unique case for oversight in a shared regulatory space. New biotechnological products not only fall

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[91] U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-318SP, OPPORTUNITIES TO REDUCE POTENTIAL DUPLICATION IN GOVERNMENT PROGRAMS, SAVE TAX DOLLARS, AND ENHANCE REVENUE 5–7 (2011), https://www.gao.gov/assets/320/315920.pdf [https://perma.cc/5KWQ-FJE8]. *See generally*, Jacob E. Gersen, *Overlapping and Underlapping Jurisdiction in Administrative Law*, 2006 SUP. CT. REV. 201 (2006).

[92] *See, e.g.*, Michael Doran, *Legislative Organization and Administrative Redundancy*, 91 B.U. L. REV. 1815, 1820–21 (2011) (proposing overlap reflects, in part, the fragmentation and politics within Congress); Todd S. Aagaard, *Regulatory Overlap, Overlapping Legal Fields, and Statutory Discontinuities*, 29 VA. ENVTL. L.J. 237, 273–85 (2011) (suggesting vague legislative delegations, interagency accountability, agencies expanding their own purview, and inherent substantive overlap in regulated industries as possible explanations).

[93] *See* Anne Joseph O'Connell, *The Architecture of Smart Intelligence: Structuring and Overseeing Agencies in the Post-9/11 World*, 94 CAL. L. REV. 1655, 1676–78 (2006); Neal Kumar Katyal, *Internal Separation of Powers: Checking Today's Most Dangerous Branch from Within*, 115 YALE L.J. 2314, 2317 (2006).

[94] Jason Marisam, *Duplicative Delegations*, 63 ADMIN. L. REV. 181, 185, 214 (2014).

[95] *See* Alison Peck, *Re-Framing Biotechnology Regulation*, 72 FOOD & DRUG L.J. 314, 323–24 (2017) (discussing difficulties of small companies in complying with the labyrinth created by the Coordinated Framework); Jennifer Kuzma, Pouya Najmaie & Joel Larson, *Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms*, 37 J.L. MED. & ETHICS 546, 579 (2009) (reporting an expert's observation that the "public has low confidence in regulations [of genetically modified crops]. This is because the process is not transparent.").

[96] Definitions of regulatory predictability frequently focus on providing stability for stakeholders such that they can act and plan without fear of significant changes in oversight. *See e.g.*, U.K. DEP'T FOR BUS. INNOVATION & SKILL, PRINCIPLES FOR ECONOMIC REGULATION 5 (Apr. 2011), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/31623/11-795-principles-for-economic-regulation.pdf.

[97] Lindsay Stirton & Martin Lodge, *Transparency Mechanisms: Building Publicness into Public Services*, 28 J.L. & SOC. 471, 475–76 (2001).

[98] Transparency and predictability were key objectives in updating the Coordinated Framework. JOHN P. HOLDREN ET AL., OFFICE OF SCI. AND TECH. POLICY, MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONMENTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE 1 (July 2, 2015) https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizingtheregsystemforbiotechproductsmemofinal.pdf [https://perma.cc/K7QA-39M4] [hereinafter OSTP Memo].

into (or sometimes outside of) overlapping delegations to agencies, but novel products may blur once clear lines between statutes.[99] Cell-based meat represents one such unanticipated product, challenging the very definition of "meat" and upsetting existing jurisdictional boundaries between FDA and USDA. Disentangling which agency has or should have regulatory authority over products based on emerging biotechnologies therefore becomes an ongoing process.[100] Adaptability then becomes another critical component to any agency compromise, enabling the collaborative approach to flex without breaking when new technologies arise.[101] However, the flexibility inherent in adaptable oversight systems can reduce consistent regulatory outcomes and perceived equal treatment of stakeholders, conflicting with predictability and transparency norms.[102]

In cell-cultured meat, FDA and USDA have clearly overlapping statutory authority. Such jurisdictional conflicts are often resolved by the regulatory bodies involved or by the political branches, often precipitated by pressure from the regulated industry.[103] In the case of cell-based meat then, which entity should decide how to allocate regulatory authority between FDA and USDA? With no concrete legal answer available, this question becomes a normative and functional one. Setting aside the issue of how to effectively structure coordination itself, the analysis below compares institutional decision-makers' ability to resolve jurisdictional disputes based on normative metrics of transparency, predictability, and adaptability, given their unique importance in cell-based meat and biotechnology more broadly (summarized in Table 1). Generally, interagency resolution in the biotechnology space can offer reasonable transparency, particularly when conducted through formal notice and comment procedures,[104] though the flexibility resulting from these solutions and ongoing technological advances promote high adaptability and low predictability. Instead, congressional resolution comes with low adaptability as Congress tends to legislate slowly outside of a clear policy window,[105] though slower processes afford transparency through stakeholder participation and statutes can provide clearly delineated jurisdictional boundaries for higher predictability. Resolution through the President can offer a degree of adaptability through prioritizing coordination efforts within the administration, but the availability of closed-door coordination efforts can undermine transparency and rushed coordination at the close of an administration may diminish predictability.

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[99] *See* Marisam, *supra* note 94, at 216–17 (regarding challenges posed by GMOs in the 1980s).

[100] This is particularly true given that Congress infrequently updates key statutes granting regulatory authority over technology. *See* Jody Freeman & David B. Spence, *Old Statutes, New Problems*, 163 U. PA. L. REV. 1, 2, 5–6 (2014).

[101] *See* Daphna Renan, *Pooling Powers*, 115 COLUM. L. REV. 211, 239–40 (2015) ("technological change creates or exacerbates pressures for high-speed governance and more flexible administration").

[102] Peter J. May, *Performance-Based Regulation and Regulatory Regimes: The Saga of Leaky Buildings*, 25 L. & POL'Y 381, 387–88 (2003).

[103] Marisam, *supra* note 94, at 215, 216 (describing how "[p]ressure to avoid duplication—initiated by regulated entities—ultimately led [FERC and Interior] to find ways to divide the regulatory tasks").

[104] *See* Freeman & Rossi, *supra* note 90, at 1189–91.

[105] *See* JOHN W. KINGDON, AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES 166–94 (2d ed. 1995).

Table 1. Relative Normative Metrics for Institutions Resolving Biotechnology Jurisdiction[106]

	Interagency	Congress	President & EOP
Transparency	Moderate	Moderate	Low
Predictability	Low	High	Moderate
Adaptability	High	Low	Moderate

A. Resolution By Administrative Agencies

Administrative agencies have multiple tools at their disposal to coordinate amongst themselves, including agreements, consultations, and collaborative rulemaking.[107] These processes can be voluntary or mandated by the political branches.[108] Agencies regulating biotechnology have traditionally operated through these instruments in a largely voluntary manner, demonstrated by the Coordinated Framework and subsequent interagency efforts.[109] In cell-cultured meat, FDA and USDA have coordinated themselves through taking public comments together and collaborating on the eventual joint oversight framework.[110]

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[106]This Article does not consider the capacity of the federal judiciary to address agency jurisdictional disputes over biotechnology for two reasons. First, the administrative coordination literature identifies courts as an institution that primarily enforces coordination, and legal limitations on coordination, rather than providing initial decisions. *See*, *e.g.*, Freeman & Rossi, *supra* note 90, at 1203; Jason Marisam, *Interagency Administration*, 45 ARIZ. ST. L.J. 183, 229–30 (2013). Second, a gap in the literature and case law exists over the role of courts where agencies wielding separate statutory authorities dispute over a novel regulatory field, rather than interpreting a joint statute differently or acting on a longstanding regulatory field. *See, e.g.*, Gersen, *supra* note 91, at 208–09 (contemplating legal issues arising only from agencies with a single, shared statute); Marisam, *supra* note 94, at 208–10 (illustrating how courts can resolve agency disputes arising from separate statutory authority, but only when one agency has a long history of regulating an existing space and the other agency attempts to break into that space); Gillian E. Metzger, *Embracing Administrative Common Law*, 80 GEO. WASH. L. REV. 1293, 1365 (2012) (describing a dearth of case law substantively considering how courts should address agency coordination issues). This gap is directly implicated in emerging biotechnology regulation, as the Coordinated Framework explicitly recognizes agency authority over future and novel regulatory spaces as arising from separate organic statutes. *See* Coordinated Framework, *supra* note 8, at 23,303. Future work should address this gap, but it falls outside the scope of this Article.

[107]*See* Freeman & Rossi, *supra* note 90, at 1157–73.

[108]*Id.* at 1155–56.

[109]The Coordinated Framework itself was a use of joint policymaking, coordinated by OSTP, and the 2017 update promotes interagency consultations and agreements as needed. *See* 2017 UPDATE, *supra* note 14, at 36–38.

[110]U.S. Dep't Agric. and U.S. Food & Drug Admin., *supra* note 12. *See* USDA/FDA Statement, *supra* note 83.

Resolving jurisdictional lines for genetically modified (GM) insects used for public health[111] offers another case study of biotechnology regulators coordinating themselves around a novel technology with the Coordinated Framework providing insufficient guidance.[112] USDA has approved environmental releases for GM insects in the past.[113] In 2009, officials directed the developer Oxitec to submit materials for their GM mosquitos to USDA, but USDA determined that it lacked statutory authority over the technology in late 2011.[114] Instead, FDA took control of the approval process, though the National Academies noted the statutory basis for FDA's move was nonobvious.[115] By late 2017, FDA effectively passed the regulatory baton to EPA by clarifying that the definition of "drug" did not include "articles intended to function as pesticides."[116] Despite a commitment to rapid review, EPA extended its public comment period in May 2018 and has not yet finalized its decision.[117]

Failures in predictability from agency mediated jurisdiction solutions exist for both technologies. Months passed while FDA and USDA argued over jurisdiction in cell-based meat and have yet to clarify the details of how they will allocate regulatory responsibility, despite deciding to collaborate.[118] For GM insects, agencies passing off authority has kept Oxitec and concerned health and environmental stakeholders in limbo for years.[119] This unsteady ground offers no predictability to cultured meat or GM insect developers, who cannot determine the path to regulatory approval until agencies finalize their approach. Nor does it provide transparency for stakeholders who remain apprehensive about the technology and concerned about safety.[120] That cell-based meats involve FDA and USDA fighting for jurisdiction while GM insects

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[111]*See generally* Kenneth A. Oye et al., *Regulating Gene Drives*, 345 SCIENCE 626 (2014); Anusha Panjwani & Anthony Wilson, *What Is Stopping the Use of Genetically Modified Insects for Disease Control?*, 12 PLOS PATHOGENS, no. 10, Oct. 6, 2016.

[112]*See* Lin, *supra* note 68, at 219–22.

[113]NAT'L ACAD. SCI., ENG'G & MED., GENE DRIVES ON THE HORIZON: ADVANCING SCIENCE, NAVIGATING UNCERTAINTY, AND ALIGNING RESEARCH WITH PUBLIC VALUES 156 (2016), https://www.nap.edu/read/23405/chapter/1 [https://perma.cc/P7E6-XFPX] [hereinafter NASEM].

[114]Emily Waltz, *A Face-Lift for Biotech Rules Begins*, 33 NATURE BIOTECH. 1221, 1221 (2015).

[115]*See* NASEM *supra* note 113, at 155–57.

[116]U.S. FOOD & DRUG ADMIN., NO. 236, CLARIFICATION OF FDA AND EPA JURISDICTION OVER MOSQUITO-RELATED PRODUCTS: GUIDANCE FOR INDUSTRY 4–6 (2017), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf [https://perma.cc/LN98-2PF2]. Reconfiguring regulatory authority has previously occurred within the Coordinated Framework when EPA obtained authority over insect resistant crops. *See* NAT'L RES. COUNCIL, *supra* note 67, at 26, 32.

[117]*EPA Reopens Public Comment Period on Application for Experimental Use Permit to Combat Mosquitos*, U.S. ENVTL. PROT. AGENCY (May 10, 2018), https://www.epa.gov/pesticides/epa-reopens-public-comment-period-application-experimental-use-permit-combat-mosquitoes [https://perma.cc/B8R7-SCS2].

[118]*See* Bunge, *supra* note 12.

[119]Megan Molteni, *When Is a Mosquito Not an Insect? When It's a Pesticide*, WIRED (Oct. 17, 2017), https://www.wired.com/story/oxitecs-genetically-modified-mosquitoes-are-now-the-epas-problem [https://perma.cc/B26B-ME5Q].

[120]*See* John Carey, *The Race to Extinguish Insect Pests by Enlisting Their Own Kind*, 115 PROC. NAT'L ACAD. SCI. 7839, 7841–42 (2018); *Tell the EPA No Genetically Modified Mosquitos!*, CHANGE.ORG, https://www.change.org/p/tell-the-epa-no-to-gmo-mosquitoes [https://perma.cc/R92T-DKU9].

depict agencies trying to give up authority makes no difference on these normative observations, as both led to failures in predictability and transparency.

Jurisdictional resolutions mediated by agencies themselves may instead offer adaptability to biotechnology oversight. In GM insects, FDA released regulatory control over the Oxitec mosquitos after several years of delays in regulatory approval, and EPA appears better suited to making more timely decisions.[121] Despite the additional time for approval for Oxitec specifically, this FDA-EPA interaction suggests that agency-mediated jurisdictional solutions come with flexibility to change, with relatively few procedural constraints, when the current allocation is not functioning properly. For cell-based meats, the FDA and USDA collaboration offers the possibility of a scheme flexible enough to address known and novel risks by relying on the expertise of both agencies. Agencies are incentivized to assist each other by the promise of exchanging needed resources, such as staff for influence over regulatory areas of interest,[122] which should promote ongoing collaboration and shared expertise between FDA and USDA in an area of mutual interest like cell-based meat. Additional time and implementation will be required to determine the adaptability of this scheme.

Transparency benefits may result when the public has an opportunity to comment on proposed regulatory allocations and agencies publicly respond to stakeholder concerns. The FDA-USDA joint meeting on cell-based meats and multiple public comment opportunities[123] have enabled agencies to signal their attitudes towards cell-based meat to stakeholders, even if not providing predictability in the final oversight scheme. EPA's public comment period on Oxitec similarly provides opportunities for transparency[124] now that regulatory control has changed hands. Some degree of transparency may also result merely by knowing which agencies will or will not have primary roles in regulation, as their attitudes towards regulation and existing programs can signal to stakeholders how oversight may proceed.[125]

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[121]John J. Cohrssen & Henry I. Miller, *Current FDA Approach to Genetically Engineered Animals Is Flawed*, HILL (Nov. 6, 2017), https://thehill.com/opinion/healthcare/358893-current-fda-approach-to-genetically-engineered-animals-is-flawed [https://perma.cc/7MRW-5ANZ]; Emily Waltz, *US Government Approves 'Killer' Mosquitos to Fight Disease*, NATURE (Nov. 6, 2017), https://www.nature.com/news/us-government-approves-killer-mosquitoes-to-fight-disease-1.22959 [https://perma.cc/39D8-RLDX].

[122]Marisam, *supra* note 106, at 189–91 (stating that "an acting agency benefits from interagency contributions by saving resources that would otherwise go to building the expertise and infrastructure necessary to perform the outsourced tasks").

[123]U.S. Food Safety & Inspection Serv., *Petition Submitted by U.S. Cattleman's Association on Beef and Meat Labeling Requirements* (Apr. 12, 2018), https://www.regulations.gov/docket?D=FSIS-2018-0016 [https://perma.cc/CY78-SJBY]; U.S. Food & Drug Admin., *Foods Produced Using Animal Cell Culture Technology; Public Meeting; Request for Comments* (June 18, 2018), https://www.regulations.gov/docket?D=FDA-2018-N-2155 [https://perma.cc/Z2WE-HGDD]; U.S. Food Safety & Inspection Serv., *Joint Public Meeting on the Use of Cell Culture Technology to Develop Products Derived from Livestock and Poultry* (Sept. 12, 2018), https://www.regulations.gov/document?D=FSIS-2018-0036-0001 [https://perma.cc/R3UY-EDY3] [hereinafter Joint Public Comment].

[124]U.S. Envtl. Prot. Agency, *Pesticide Experimental Use Permits; Applications: Oxitec, Ltd.* (May 8, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPP-2017-0756-0435 [https://perma.cc/B9D5-Y5E8].

[125]*See, e.g.*, Zahra Meghani & Jennifer Kuzma, *Regulating Animals with Gene Drive Systems: Lessons from the Regulatory Assessment of a Genetically Engineered Mosquito*, 5 J. RESPONSIBLE INNOVATION S203, S203, S210–11, S217 (2018).

B. Congressional Resolution

Congress has remained relatively silent on cell-based meats and has not called hearings on its regulation. However, in May 2018, the House Committee on Appropriations approved a draft bill that would definitively fix regulation and labeling jurisdiction for cell-based meats with USDA.[126] The jurisdiction provision regarding "products made from cells . . . grown under controlled conditions for use as human food" was later removed,[127] but illustrates how Congress can use its legislative powers to expressly allocate authority to certain agencies or to use appropriations and other mechanisms to influence jurisdiction.[128] Lawmakers could instead require agencies to negotiate jurisdiction using the tools available to them.[129] Congress can also pressure the President to act; for example, four representatives wrote a letter to the U.S. Office of Management and Budget (OMB) calling for coordination in cell-based meat after FDA's July 2018 public meeting without USDA.[130] Following the FDA-USDA agreement to share jurisdiction on cell-based meat, several members of Congress expressed willingness to intervene depending on the outcome,[131] suggesting that Congress could still act on cultured meat.

Congress recently revised agency jurisdiction over the labeling of GM crops. In 2016, Congress enacted a statute preempting GM crop labeling and delegating authority to USDA only to create federal labeling requirements.[132] This decision surprised some stakeholders, who previously regarded FDA as having longstanding authority and expertise in GM crop labeling.[133] Lawmakers passed the statute in three weeks, following the enactment of a Vermont law that would have imposed state-

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[126]H.R. 115, 115th Cong., § 736 (2018), https://docs.house.gov/meetings/AP/AP01/20180509/108287/BILLS-115HR-SC-AP-FY2019-Agriculture-SubcommitteeDraft.pdf [https://perma.cc/BRB3-J6B8].

[127]Act of Sept. 28, 2018, Pub. L. No. 115-245, 132 Stat. 2981.

[128]*See* Gersen, *supra* note 91, at 211–12.

[129]*See* Eric Biber, *Too Many Things to Do: How to Deal with the Dysfunctions of Multiple-Goal Agencies*, 33 HARV. ENVTL. L. REV. 1, 41–42 (2009) (illustrating Congress's ability to require agencies to interact).

[130]Letter from Rep. Robert Aderholt et al. to Mick Mulvaney, Director, OMB (July 11, 2018), https://foodpolitics.com/wp-content/uploads/2018_0712-FDA-USDA-CellBasedMeatLtr.pdf [https://perma.cc/47E5-WR2F] [hereinafter Letter].

[131]*See* Crampton, *supra* note 13. More recently, Congress directed FDA and USDA to promptly delineate the specifics of their regulatory roles over cell-based meat, though this does not preclude future congressional intervention. *See* STAFF OF H. COMM. ON APPROPRIATIONS, 116TH CONG., JOINT EXPLANATORY STATEMENT REGARDING H.J. RES. 31: CONSOLIDATED APPROPRIATIONS ACT, 2019 (2019), https://docs.house.gov/billsthisweek/20190211/116hrpt9-JointExplanatoryStatement-u1.pdf [https://perma.cc/H73Q-G92Q].

[132]To reauthorize and amend the National Sea Grant College Program Act, and for other purposes, Pub. L. No. 114-216, 130 Stat. 834 (2016).

[133]Since 1996, FDA had operated a voluntary labeling system where industry consulted with the agency. U.S. FOOD & DRUG ADMIN., *Consultation Process Under FDA's 1992 Statement of Policy—Foods Derived from New Plant Varieties* (1997).

specific labeling requirements.[134] USDA proposed labels in May 2018,[135] though some stakeholders strongly disapproved of the regulatory deliverable.[136]

The genetically modified organism (GMO) labeling and cell-based meat cases demonstrate that a congressional resolution of biotechnology jurisdiction could provide predictability for stakeholders, but at the cost of adaptability. Using statutes to reallocate authority can provide certainty about which agency will lead oversight, as the GMO labeling statute expressly did and the provision on cell-based meat would have done. However, this approach may fail to offer full predictability when Congress grants responsibility to an agency with limited expressed views or experience on a topic, indicated by the response to USDA's proposed GMO labels.[137] Moreover, the rapid legislative action limited the transparency of the decision by restricting time for stakeholders and constituents to comment.

Statutes may serve as blunt instruments in dividing jurisdiction, as FDA was entirely removed from GMO labeling and could have been removed from cell-based meat.[138] Legislatively prohibiting or discouraging one agency from participating in regulation may limit administrative adaptability, as USDA and FDA would have limited ability to renegotiate jurisdiction absent further legislation, even in response to new developments in technology or risk profiles. Downstream adaptability may be possible should agencies influence each other by less formal mechanisms[139] or drift away from legislative structures,[140] though Congress rarely intends this later result. Further, legislation becomes difficult to revisit, especially in the near-term, once a policy window has closed.[141] The stability provided by a statute could cause a poor jurisdictional compromise to be locked-in, wasting resources and increasing costs for regulators and stakeholders by requiring agencies to build or discard expertise.

The GM labeling case demonstrates that legislation on agency jurisdiction need not be slow, potentially limiting the transparency of decisions, though this likely represents a special case. Regarding cell-based meat, a Missouri statute went into effect in August 2018 prohibiting labeling cell-based products as "meat,"[142] similarly impacting interstate commerce. Congress did not respond this time, perhaps disincentivized by litigation challenging the statute.[143] Congress generally appears

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[134]Dan Charles, *Congress Just Passed a GMO Labeling Bill. Nobody's Super Happy About It*, NPR (July 14, 2016), https://www.npr.org/sections/thesalt/2016/07/14/486060866/congress-just-passed-a-gmo-labeling-bill-nobodys-super-happy-about-it [https://perma.cc/QBN5-59QA].

[135]*See* National Bioengineered Food Disclosure Standard, 83 Fed. Reg. 19860 (May 4, 2018).

[136]Merrit Kennedy, *USDA Unveils Prototypes for GMO Food Labels, and They're . . . Confusing*, NPR (May 19, 2018), https://www.npr.org/sections/thesalt/2018/05/19/612063389/usda-unveils-prototypes-for-gmo-food-labels-and-theyre-confusing [https://perma.cc/5PHP-4YL2].

[137]*Id.*

[138]*See supra* notes 126–27, 132 and accompanying text.

[139]*See* Keith Bradley, *The Design of Agency Interactions*, 111 COLUM. L. REV. 745, 748 (2011).

[140]*See* Mathew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J.L. ECON. & ORG. 243, 246–47 (1987).

[141]*See* KINGDON, *supra* note 105, at 166–94.

[142]S.B. 627, 99th Leg., 2d Reg. Sess. (Mo. 2018) (codified as MO. REV. STAT. § 265.494(7) (2018)) ("Misrepresenting the cut, grade, brand or trade name, or weight or measure of any product, or misrepresenting a product as meat that is not derived from harvested production livestock or poultry[.]").

[143]Turtle Island Foods v. Richardson, No. 18-cv-4173 (W.D. Mo. filed Aug. 27, 2018); *see* Amie Tsang, *What, Exactly, Is Meat? Plant-Based Food Producers Sue Missouri Over Labeling*, N.Y. TIMES

slow to legislate on biotechnology oversight,[144] limiting its ability to facilitate adaptability in agency jurisdiction. However, Missouri or other state legislation perceived as imminently threatening interstate commerce, as was the Vermont GMO statute,[145] could precipitate another swift congressional response. With more states introducing legislation in early 2019 to define cell-based products out of the term "meat,"[146] Congress may choose to respond.

C. Presidential Resolution and the Executive Office of the President

Rather than agencies organizing themselves around novel biotechnologies, the President could facilitate or require interagency negotiations on jurisdiction with various tools, including executive orders or through the Executive Office of the President (EOP).[147] EOP agencies, including the Office of Management and Budget and the Office of Science and Technology Policy (OSTP), have a central role in issues at the intersection of multiple agency delegations.[148] Though current administrative law leaves unanswered the degree to which a President can force a decision on agencies,[149] Presidents and the EOP can communicate policy objectives and desired outcomes and provide deadlines to prompt action.[150]

The Trump Administration has been largely silent on the conflict over cell-based meats, though an EOP agency quietly held a meeting between FDA and USDA following the FDA-only public meeting in July 2018.[151] The 2017 update to the Coordinated Framework offers another recent example of EOP resolution. In 2015, the OSTP called for an update to the Coordinated Framework with the intention of resolving jurisdictional issues over novel biotechnologies.[152] An update provided an

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(Aug. 29, 2018), https://www.nytimes.com/2018/08/28/us/missouri-meat-law-tofurky.html [https://perma.cc/9GZB-4J3M].

[144]Few legislative changes have expanded the statutes underpinning the Coordinated Framework since its promulgation, despite criticisms of insufficient agency authority under existing legislation. *See* Alison Peck, *supra* note 95, at 315–16.

[145]*See* Niraj Chokshi, *Vermont Just Passed the Nation's First GMO Food Labeling Law. Now It Prepares to Get Sued.*, WASH. POST (May 9, 2014), https://www.washingtonpost.com/blogs/govbeat/wp/2014/04/29/how-vermont-plans-to-defend-the-nations-first-gmo-law/?utm_term=.1e13d32190e4 [https://perma.cc/2ZA4-K8WP].

[146]Nathaniel Popper, *You Call That Meat? Not So Fast, Cattle Ranchers Say*, N.Y. TIMES (Feb. 9, 2019), https://www.nytimes.com/2019/02/09/technology/meat-veggie-burgers-lab-produced.html [https://perma.cc/VKP7-G29K]. *See, e.g.*, H.B. 1407, 92d Gen. Assemb., Reg. Sess. (Ark. 2019); H.B. 2604, 54th Leg., 1st Reg. Sess. (Ariz. 2019); H.B. 1519, 66th Leg., Reg. Sess. (Wash. 2019).

[147]Jason Marisam, *The President's Agency Selection Powers*, 65 ADMIN. L. REV. 821, 826, 849 (2013).

[148]HAROLD C. RELYEA, CONG. RES. SERV., THE EXECUTIVE OFFICE OF THE PRESIDENT: AN HISTORICAL REVIEW 1 (2008), https://fas.org/sgp/crs/misc/98-606.pdf [https://perma.cc/YNQ4-382F]. *See* OFFICE OF MANAGEMENT AND BUDGET, https://www.whitehouse.gov/omb/ (last visited July 23, 2019); OFFICE OF SCIENCE AND TECHNOLOGY POLICY, https://www.whitehouse.gov/ostp/ (last visited July 23, 2019).

[149]*See* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2327 (2001).

[150]*See* Freeman & Rossi, *supra* note 90, at 1175.

[151]*See* Letter, *supra* note 130.

[152]*See* OSTP Memo, *supra* note 98, at 3 (calling for an update "to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology").

opportunity to establish a coordinated regulatory approach for cultured meat oversight, but ultimately failed to substantively change the existing framework.[153] The Obama Administration requested that the National Academies consider upcoming biotechnologies relevant for the revised policy.[154] Though the eventual National Academies report covered cultured meat,[155] the final update was released several months prior during the final days of the Administration,[156] undercutting the predictability of the EOP's coordination outcome by reducing its capacity to address unanswered questions such as on cell-based meat jurisdiction.

Presidential resolution of agency conflict over biotechnology offers mixed results for adaptability, transparency, and predictability. For cell-based meats, the EOP meeting called between FDA and USDA demonstrates the capacity for rapid response that could increase adaptability in coordinating agencies around new technical and social developments in biotechnological products.[157] After the EOP meeting between the agencies, FDA and USDA called their joint public meeting and opened a joint public comment opportunity.[158] The joint public meeting and resulting announcement of joint regulation increased transparency in how the agencies might cooperate, though the EOP encouraged rather than conducted the public joint meeting. Instead, the results of the EOP meeting itself remain unpublished and no formal announcement of the mediation occurred,[159] limiting the transparency of this tool in the EOP's coordination process. In general, the EOP's ability to conduct behind-closed-door coordination activities can reduce transparency,[160] especially when forgoing intentional efforts at transparency such as notice and comment procedures used by OSTP with the Coordinated Framework.[161]

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[153]Tracey Tomlinson, *A Crispr Future for Gene-Editing Regulation: A Proposal for an Updated Biotechnology Regulatory System in an Era of Human Genomic Editing*, 87 FORDHAM L. REV. 437, 459 (2018).

[154]Emily Waltz, *CRISPR-Edited Crops Free to Enter Market, Skip Regulation*, 34 NATURE BIOTECH. 582 (2016).

[155]NAS, *supra* note 1, at 7. Creating further uncertainty for cultured meat, the confusing distinctions in practice between product-based and process-based approaches to oversight in emerging biotechnologies remains unresolved by the update. *See* 1992 Update, *supra* note 14, at 6753 ("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").

[156]Robbie Barbero et al., *Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System* (Jan. 4, 2017), https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory [https://perma.cc/RS8M-LLP9].

[157]*See* Marisam, *supra* note 147, at 873–74.

[158]*See* Joint Public Comment, *supra* note 123.

[159]Journalism, instead, provides the only evidence that the meeting took place. Helena Bottemiller Evich, *Lab-Grown Meat's Washington Moment Is Now*, POLITICO (July 12, 2018), https://www.politico.com/story/2018/07/12/lab-grown-meat-fda-679951 [https://perma.cc/DZ36-ML5J] (stating that "The White House has . . . worked to bring USDA and FDA together on the issue . . . .").

[160]*See* Kathryn A. Watts, *Controlling Presidential Control*, 114 MICH. L. REV. 683, 686 (2016).

[161]Coordinated Framework, *supra* note 8. The OSTP also used notice and comment procedures to announce work towards updating the Coordinated Framework in 2015, increasing transparency using those tools. *See* Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology, 80 Fed. Reg. 60,414 (Oct. 6, 2015).

Generally, the President may also be well suited to build adaptability into coordination by weighing regulators' expertise, missions, and regulatory approaches.[162] The 2017 Coordinated Framework update reflects this potential capacity, as it sought to consider how new technologies and risk considerations might require reallocating jurisdiction.[163] However, the Coordinated Framework case also reveals that predictability and adaptability offered by presidential reallocation of authority is inherently limited by shifting political tides, which may only afford a small window of time to make substantive decisions on jurisdiction.[164] As a highly technical matter, updating agency collaboration in biotechnology requires substantial time and expertise,[165] demonstrated by the call for a National Academies report to assist in the process. Yet, the efforts to update the Coordinated Framework were largely abandoned and left unfinished prior to an expert report, upon the election of a deregulatory President and Congress during the update process.[166] Outgoing Administrations may have incentives to conclude coordination projects to insulate their policy objectives from new decision-makers,[167] potentially jeopardizing predictability of the resulting regulatory scheme by leaving unanswered questions, including jurisdictional boundaries. A rushed presidential resolution may also limit transparency, as commentators criticized the Coordinated Framework update process for not substantively including stakeholders or experts.[168]

CONCLUSION

Facilitating appropriate regulation of cell-based meat is vital given the transformative potential of the technology.[169] Yet, uncertain oversight has burdened the cell-based meat space, with conflicts between FDA and USDA arising over which agency properly holds regulatory authority. Though conflict between the two agencies has begun to stabilize with a co-regulatory scheme, the considerable uncertainty created by their jurisdictional dispute exemplifies struggles faced by emerging biotechnologies that fail to fit easily into existing regulatory programs.

Agency disputes over regulatory authority in biotechnology provoke questions about which entities should make final decisions on dividing that authority, requiring institutional and normative consideration. Interagency resolution offers the greatest

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[162]*See* Marisam, *supra* note 94, at 238–39.

[163]*See* OSTP Memo, *supra* note 98, at 3–5 (including a goal of "identifying changes to authorities . . . that could improve agencies' abilities to assess expeditiously the potential impacts and risks arising from future products of biotechnology").

[164]FREDRICK M. KASIER, CONG. RES. SERV., INTERAGENCY COLLABORATIVE ARRANGEMENTS AND ACTIVITIES: TYPES, RATIONALES, CONSIDERATIONS 25 (2011) (listing shifting political contexts as one key factor in the success of coordination).

[165]*See* Jennifer Kuzma, *A Missed Opportunity for U.S. Biotechnology Regulation*, 353 SCIENCE 1211, 1211–12 (2016).

[166]*See* Tomlinson, *supra* note 153.

[167]Patrick A. McLaughlin, *The Consequences of Midnight Regulations and Other Surges in Regulatory Activity*, 147 PUB. CHOICE 395, 397 (2011).

[168]*See* Kuzma, *supra* note 165, at 1212.

[169]Carolyn Mattick & Brad Allenby, *The Future of Meat*, 30 ISSUES SCI. & TECH., Fall 2013, at 69 ("factory meat is perhaps best understood as a planetary engineering technology, and to pretend otherwise can become just a subtle way of avoiding ethical responsibility for the consequences of our own creations").

potential for a flexible and transparent outcome, at the cost of predictability in the final oversight scheme. Congressional intervention may provide substantially higher predictability, but it limits the adaptability of the resulting agency jurisdictional map. Presidential resolution of jurisdictional disputes offers a middle level of adaptability and predictability, subject to changes in administration, but may lack in transparency. Each institution provides a unique set of strengths and weaknesses that should be considered during uncertainty over dividing authority. As the regulatory framework for cell-based meats solidifies, other emerging biotechnologies will inevitably create new jurisdictional questions calling for new decisions that can be informed by these insights around institutional resolution of interagency conflict.