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How the Biden Administration Can Accelerate Prosperity by Fixing Agricultural-Biotech Regulations

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The Biden administration has a rare opportunity to accelerate agricultural innovation and spur broad and lasting economic growth by taking a handful of discrete regulatory actions that would update longstanding policy that has enjoyed strong bipartisan support.

KEY TAKEAWAYS

- With bipartisan support, U.S. biotech regulations since 1986 have enabled innovation to flourish, leading a global revolution in agricultural productivity and sustainability that has benefitted farmers, consumers, and the environment.
- Yet regulations have not been modernized to keep pace with scientific innovation, and they have strayed from relying on science and data. This has impeded further biotech innovation that could improve safety and solve pressing societal problems.
- USDA has made some progress updating and streamlining regulations, but data and experience show it needs to move farther and faster. EPA and FDA have become obstacles to progress and safety advances and urgently need to correct course.
- The Office of Science and Technology Policy should work with the Office of Management and Budget to ensure updates take place quickly. This will stimulate innovations in agricultural biotechnology across multiple sectors of the economy.

INTRODUCTION

Agriculture provides the foundation of our economy—indeed of civilization—and few areas of public sector investment provide greater returns.[1] The Biden administration can seize a rare conjunction of opportunities to accelerate agricultural innovation and thus promote broad economic growth. The denouement of new technologies for genetic improvement in plants, animals, and microbes offers innovative solutions to many of the most urgent and challenging problems facing humanity, including sustainable agriculture and climate change.

Yet policies to enable and encourage solutions tapping into this potential have lagged behind and languished for decades, encumbered by the strangler figs of unduly burdensome regulations, backed by anti-innovation voices.[2] The unprecedented opportunities of the moment follow from a history of bipartisan support for an ongoing, strong push for continued scientific advances and a rational, pragmatic set of science-based policies and regulations to enable safe progress. Some background will clarify.

The Biden administration can seize a rare opportunity to accelerate agricultural innovation and promote broad economic growth by fixing biotech regulations.

"Civilization has been built on genetically modified plants," said Nina V. Fedoroff, science advisor to Secretary of State Hillary Clinton and member of the National Academy of Sciences.[3] For tens of thousands of years, plant and animal breeders have been modifying crops and livestock to improve their value to humans.[4] Recent advances—first genetic engineering and now gene editing—have been unprecedented in scope and magnitude.[5] The contributions to human and environmental health and public welfare around the globe have been dramatic.[6] And the safety of the innovative products developed with these new technologies has been exemplary.[7] Nevertheless, some special interest groups, predictably, have exploited unfamiliarity with the new and dissatisfaction with downsides of some past agricultural innovations (most considerably remediated by the more recent innovations) to foment fear and spread an illusion of broad opposition.[8]

But the positive impacts of these innovations have been substantial and widespread, disproportionately blessing the small farmers who make up more than 90 percent of those growing biotech crops worldwide.[9] These biotech-improved crop varieties have been particularly beneficial to the women who make up the majority of small farmers in developing countries, alleviating the drudgery of weeding and injecting significant cash influxes, benefitting rural families and local economies.[10] Farmers are eager for access to biotech improved seed varieties, so much so that they have launched large-scale civil disobedience campaigns in countries where government approvals have lagged behind or been stymied by special interest "green" politics.[11] European NGOs (nongovernmental organizations) have been key players in this eco-imperialism.[12]

Countries around the world have taken starkly different approaches to safety regulations for these innovations, which can be divided into two categories: the European "precautionary" approach (severely criticized by scientists worldwide, nowhere more harshly than in Europe), and the more pragmatic, science-driven tack taken by the United States, Australia, Canada, Japan, Korea,

Bangladesh, and a few more nations.[13] But even in the latter nations, including the United States, existing regulations or their applications all too often are overly precautionary and limit innovation, with no additional safety or environmental benefits.

The drag on innovation created by regulations that are poorly implemented or unscientific is significant, and wildly out of step with the needs of the day.[14] With a handful of specific moves, the Biden administration could correct this, and unleash the innovative potential humanity desperately needs. There are opportunities to re-align U.S. regulations with reason at each of the major regulatory agencies: the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA). Perhaps the most important of these rests with the FDA. But it is important, first, to revisit how the U.S. regulatory system is supposed to work in order to make it clear that the remedies we propose are not radical but rather only a restoration of the status quo ante.

BIOTECHNOLOGY PRODUCT REGULATION IN THE UNITED STATES: THE COORDINATED FRAMEWORK

Recombinant DNA technologies were derived from advances in molecular biology that took place in the early 1970s.[15] As the power of recombinant DNA technology became clear, scientists leading the research considered how best to ensure their work could go forward safely.[16] Politicians noticed, and vigorous public exchanges at many levels took place over more than a decade, including several years of congressional hearings.[17] The result was the promulgation in 1986 of a policy statement by the Office of Science and Technology Policy (OSTP) of the Executive Office of the President, known since as the "Coordinated Framework."[18]

This policy aimed to coordinate regulatory actions by the major federal agencies with jurisdiction: USDA, EPA, and FDA. The policy was predicated on two major findings extracted from years of scientific deliberation, public conversations, vast media attention, and Congressional hearings. First, no novel hazards had emerged as being associated with the use of recombinant DNA techniques, and exposure to the kinds of hazards with which we were already familiar created risks such as those resulting from classical plant breeding and conventional mutagenesis with radiation or chemicals. Second, in the absence of novel hazards and new types of risk, existing regulatory authorities through which Congress had charged agencies with responsibility for public safety were sufficient to the task and fit for purpose.

OSTP directed the agencies to develop regulations to apply their preexisting authorities to (primarily) agricultural products developed with the new techniques. Because recombinant DNA processes introduced no novel hazards and involved only familiar risks, the regulations were to focus not on the processes of generating the new products but rather on their qualities and characteristics—in other words, the phenotypes, the suite of observable traits through which all risks would be manifest. Regulations were required to be based on products, not process.

USDA was first out of the gate with new regulations in 1987, followed by the first major update and revision based on experience in 1992. EPA and FDA followed, and products began to find their way to market, particularly through the regulatory regime set up by USDA. Ultimately, field-trials took place at tens of thousands of research plots around the country, with new varieties field-tested thousands of times under permits, and crop varieties improved through biotechnology rapidly becoming the new standard for conventional agriculture. Adoption was less swift for

products reviewed by EPA and FDA, while those agencies struggled to bring the vision of the Coordinated Framework to life. Perhaps the biggest gap between expectation and achieved results was at FDA.

THE FOOD & DRUG ADMINISTRATION

The FDA should cede authority over bioengineered animals to USDA. The most important opportunity to unshackle agricultural innovation lies with the FDA, not because of its importance as the overseer of some 20 percent of the national economy, but because, of all the regulatory agencies, it has strayed farthest from the policies laid down in the 1986 Coordinated Framework and explicitly reaffirmed by every administration since.[19] With strong and broad authority under the Federal Food, Drug, and Cosmetic act (FFDCA) to ensure the safety of the nation's food supply, FDA controls the narrowest bottleneck on the path an idea must travel, from inception to the marketplace.[20] But with products of biotechnology, instead of starting with hazard identification and then developing proportional risk-based regulatory scrutiny for genetically engineered and gene-edited animals, FDA has taken a "guilty until proven innocent" approach. This presupposes, with no basis in fact, that they carry significant hazard, and demands massive amounts of data to prove the safety even of items indistinguishable from things found in nature.[21] Having previously commented at length on how misguided and divorced from science and longstanding policy the approach FDA applies to both animals and plants is, the Information Technology and Innovation Foundation (ITIF) has outlined a more coherent, science-based, streamlined approach the agency should take.[22] The remedies we suggest are both valid and applicable, and (where not rendered moot by other developments) should be taken on board by the agency at the earliest opportunity in order to restore FDA's alignment and compliance with longstanding U.S. policy.[23]

To summarize, FDA should exercise its regulatory discretion and not routinely recommend (much less require) consultation from developers of gene-edited animals. It should instead invite public comment to help define categories of intentional genomic alterations likely to be hazardous that could present unreasonable risks sufficient to justify consultation and regulatory action. This approach would be reasonable, consistent with experience, as well as our most up-to-date understanding of modern molecular biology—and is defensible as policy, unlike the approach FDA has proposed.[24] FDA's proposal with respect to gene-edited plants is similarly defective and can be repaired in like manner.[25]

FDA has, however, shown little inclination to correct its mistakes in these regards. This has galvanized major segments of agricultural industry to demand that jurisdiction for gene-edited animals be shifted from FDA to USDA.[26] A Memorandum of Understanding to accomplish this was one of the final acts of the outgoing Trump administration.[27]

It is tempting to view this as an example of inappropriate political interference in regulatory policy, but a closer look suggests otherwise. FDA has been out of sync with longstanding, bipartisan U.S. policy in this space for the past several administrations, ignoring mandates to correct this from the last two. The action taken by the outgoing administration in January adheres to the preexisting and longstanding mandate that bioengineered and gene-edited animals be regulated on the basis of science, data, and sound hazard identification, risk assessment, and management. FDA has had two decades and multiple administrations to get it right—and the agency has fallen short. It has instead taken a precautionary approach,

unsupported by data or experience, and disincentivized innovation without providing any commensurate benefit to human, animal, or environmental health.[28] As USDA takes up this responsibility, it can hardly do worse, but nevertheless should be watched closely to make sure it does not push the pendulum too far in the wrong direction.

Meanwhile, public misunderstanding of these new technologies and the role of regulatory agencies continues to be widespread. After decades of failure by agencies to educate the public on these topics, Congress stepped in and mandated FDA and USDA take action to educate the public—and the results represent a step in the right direction.[29] These results are praiseworthy and should be expanded.

THE ENVIRONMENTAL PROTECTION AGENCY

Arguably no agency involved with regulating products of agricultural biotechnology has more-consistently betrayed the public good by choosing to ignore the science in order to expand its authority. EPA has broad jurisdiction to regulate pesticides and related compounds under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA), and to set allowable residue-level limits for pesticides in food under the FFDCA. EPA has deployed these authorities to regulate biotechnological innovations in agriculture.[30] When EPA proposed in 1998 to finalize multiple proposals from prior years to expand its authority over "plant pesticides" (now called "plant incorporated protectants" or PIPS), it was harshly criticized by the scientific community.[31] Eleven scientific societies united to condemn the proposal, stating:

> EPA's proposed rule sends a signal to the world that the United States views its own genetically modified plants as hazardous to people or the environment.... No evidence exists that these plants produce any hazard, and it is scientifically indefensible to regulate them as though they were synthetic chemical pesticides.[32]

In light of their concerns, EPA promised to return with an additional explanation and justification, which have yet to appear. In 2011, more than 60 members of the U.S. National Academy of Sciences came together to condemn a subsequent proposal by EPA to expand its regulations in this space further.[33] They reminded EPA that under the 1986 Coordinated Framework,

> [It remains U.S. policy that] there is no scientific basis to single out plants produced by a transgene insertion for a special regulatory review, nor to distinguish these products from others on the basis of the process used to create them. There is now abundant evidence that the most appropriate regulatory approach would be to require review only of truly novel traits introduced into plants without regard to the methods used for their introduction... It is most troubling that EPA is also proposing to increase its regulation to cover matters which are still not deemed to be threats even after years of study.[34]

These concerns were similarly not taken on board by EPA.

In August 2020, EPA proposed to update its regulation of PIPs by creating exemptions for certain kinds of plants improved through gene editing to resist certain insect pests.[35] Before this proposal, EPA had in effect subjected both genetically engineered and gene-edited products to heightened scrutiny based not on the degree of hazard they carry or the risk they present but

rather primarily on the process used to create them. This was and remains inconsistent with the Coordinated Framework and impossible to justify on the basis of science, data, or experience.[36] With its recent proposal, EPA is moving, at least cosmetically, to repair this.[37]

EPA proposes to exempt from regulation plants containing certain PIPs made through biotechnology "if they 1) pose no greater risk than PIPs that meet EPA safety requirements, and 2) could have been created through conventional breeding."[38] Under this proposal, EPA would require developers to submit a "self-determination letter" or a request for EPA to confirm that their PIP meets the criteria for exemption, or both. This would be a major improvement over a policy that presumes, with no basis, all gene-edited PIPs to be so hazardous as to require full-scale review—and has already been widely welcomed by those creating such innovations.[39] Comments from these scientific bodies note, however, that EPA's proposed exemptions are too narrowly drawn—encumbered with requirements that contradict EPA's past rationales for regulatory exemptions—and lack an evidentiary basis. The EPA proposal, for example, requires for putatively exempt gene-edited PIP-containing plants that notification to EPA be mandatory and accompanied by a data package in support, despite EPA's admission:

> EPA, nonetheless, recognizes that plant breeding in the United States has a good record of providing a safe food supply and that plant breeders employ accepted standards of practice to maintain this record. This good record provides support to the Agency's determination that it can exempt plant-incorporated protectants derived through conventional breeding from sexually compatible plants from almost all regulatory oversight, relying only on the post-market reporting of adverse effects.[40]

EPA's recent proposal to exempt certain gene-edited plants from regulation is commendable, and overdue—but the proposal is too narrowly drawn.

Additionally, EPA's proposed exemptions rely on distinctions drawn between "native" genes or alleles from within the edited species' own gene pool and other sources, through which genes have long been introduced via, for example, embryo rescue, with a safety record no different than from "conventional breeding," or from mutagenesis. But the lesson from nature is that hinging any hazard identification on the provenance of the genetic material is dubious, as the origin of a gene has no necessary connection or relationship with the presence of a hazard or the existence of a risk, as the U.S. National Academy of Sciences and authoritative bodies around the world have repeatedly found and reaffirmed.[41]

It would be more consistent with the considerable body of experience and safety data if EPA instead were to stipulate that novel phenotypes resulting from gene editing outside the realm of what could be derived from conventional plant breeding would remain under existing PIP regulations. Meanwhile, the agency should solicit public input to help identify phenotypic categories for products derived from whatever mechanisms that would present sufficient hazard to justify pre-market regulation, as opposed to simply being subject to an after-market adverse event-reporting requirement. If EPA can correct these defects in a plan that otherwise takes significant steps in the right direction, it would deliver a major benefit to the environment and U.S. citizens.

EPA has also proposed to update its oversight and regulation of the use of PIPS in order to manage the evolution of resistance in target pest populations.[42] This is perhaps less a matter of safety than of mitigating product obsolescence, and it could be argued that it thus falls outside EPA's jurisdiction. But if one accepts that pest susceptibility to the newer generation of less-toxic pesticides is a public good, or commons, to be managed for societal benefit, and given the courts' deference to agencies' interpretation of their own authorities, then EPA's proposals for improved pest-resistance management are meritorious.

EPA proposes to mandate prompt reporting of cases wherein PIPs may have failed to protect crops against pest damage, on the rationale that such events may be presumed to signal an eruption of pest resistance that could potentially be mitigated by prompt action. Previously, growers and companies were allowed to delay reporting until they had completed sometimes-lengthy testing to confirm whether resistance had in fact emerged.[43] This change will allow more-effective stewardship of the pest-resistance traits and should be welcomed.

The lesson from nature is that hinging hazard identification on the provenance of genetic material is dubious, as the origin of a gene has no necessary connection or relationship to hazard.

EPA also proposes to phase out the use of PIP crops that carry genes that encode for only one pesticidal protein or mode of action at a time. Such phenotypes represent the easiest selection pressure for pests to adapt to and overcome; again, such a proposal would enhance good stewardship, and thus is worthy of support. EPA also proposes changes to the refugia requirements that set aside areas or portions of a planting (e.g., 10 percent of a field or of a bag of seed) in order to sustain threshold levels of susceptible pests so as to help forestall the emergence of resistance. These proposals have been welcomed by academia and industry, are consistent with data and lived experiences, improve stewardship, and are deserving of support.[44] The Biden administration should move them forward to final adoption with alacrity.

THE DEPARTMENT OF AGRICULTURE

USDA was the first agency to promulgate regulations to assess and manage risks associated with crops improved through biotechnology, which they did in 1987.[45] These regulations were updated and improved in 1992. Despite several attempts, no further significant updates have taken place until the "Am I Regulated?" process was put in place in 2011, which was a major innovation and improvement.[46] This was superseded recently by the Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient (SECURE) rule, which entered into force on August 17, 2020.[47]

USDA's stated purpose for the SECURE rule is to establish "a clear, consistent, and risk-based regulatory framework for products developed using genetic engineering that provides regulatory relief and better focuses regulatory resources on potential areas of risk."[48] The rule formalizes categories of genetically engineered or edited plants that are exempt from regulatory oversight, and a consultation process through which responsible individuals can seek guidance as to whether their innovation meets the exemption criteria or must be looked at more closely. It also provides a permitting process through which regulated articles not qualifying for exemption can be reviewed pursuant to a field-trial permit. These changes do update and streamline the

regulatory process, but they continue to fall short of being truly science based and consistent with the bedrock principles of the Coordinated Framework.

Under the SECURE rule's provisions:

> [C]ertain categories of modified plants are exempt from the regulations because they could otherwise have been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. These exemptions apply only to plants because the long history of plant breeding provides us extensive experience in safely managing any associated plant pest risks. In addition, plants that have a plant-trait-mechanism of action combination that is the same as in a plant that has been determined by APHIS to be unlikely to pose a plant pest risk and therefore to be not regulated are exempt from the regulations.[49]

USDA's recent changes update and streamline the regulatory process but continue to fall short of being truly science based and consistent with the Coordinated Framework.

But the exemption process, indeed the entire SECURE rule, singles out products of genetic engineering and editing for special focus and differential treatment. It does so without having identified any unique hazards associated with the use of these techniques. On the other hand, strong scientific evidence supported by vast experience has shown no such novel and unique hazards have been identified despite decades of energetic efforts. It must be repeated, yet again, that any and all hazards manifest by any new plant (or animal, or microbial) variety, however generated, are mediated by phenotype. These hazards are made real and worthy of regulation only if the phenotype creates problems upon exposure, which is the definition of risk. And again, any given hazardous phenotype can be generated in many different ways, none of which have ever been shown to bear any causal relationship with risk. The SECURE rule, like every other regulatory regime that has seriously attempted to adhere to science and respect data, tries to approximate credibility by focusing on the characteristics of the organism (its phenotype) rather than the process by which it came about. But in applying risk-assessment and management measures solely to genetically engineered and edited organisms, it presumes them to be hazardous without having ever demonstrated any hazard. In so doing, USDA continues to stigmatize and disincentivize the most modern, precise, and safest methodologies in the history of plant and animal breeding. This works against human and environmental health by increasing the time and expense of developing new products at a moment in modern human history when the need has never been greater or more urgent.

Just as we recommend for FDA, USDA should build on the improvements delivered by the SECURE rule, though imperfect, by soliciting public input to identify hazardous phenotypes that may create undue risks to human health or the environment regardless of how they are generated. A focused effort of this sort would either identify such classes, or it would not. If it does, the existing regulatory mechanisms can be adapted to identify, manage, and mitigate the risks. If no such classes of hazards unique to products of genetic engineering or gene editing are identified, then no process-specific regulatory regime aimed at them could be justified, and existing regimes should be set aside as wasteful and counterproductive.

THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Overarching U.S. policy for regulating the products of biotechnology in agriculture was first laid out in 1986 by OSTP of the Executive Office of the President.[50] At the time, it was welcomed by many as a commendably science-based approach, though viewed with some skepticism since it presumed an unprecedented degree of coordination among sometimes competing regulatory agencies. Although such fears were not realized, the course of events delivered a more pernicious outcome as implementation drifted away from its science-based foundations and in a more precautionary direction.

OSTP is good at designing policy, but less so at seeing it implemented. OSTP must follow up and work closely with OMB/OIRA to see that regulatory agencies implement policy as directed and in a timely manner.

The Obama administration in 2015 tried to rectify this with renewed guidance and instructions to regulatory agencies, directing a return to first principles and updating of regulations in accord with ongoing policy.[51] OSTP created an interagency working group tasked with developing a "National Strategy for Modernizing the Regulatory System for Biotechnology Products," which was published in September 2016.[52] It specifically reaffirmed:

> [T]he policy of the United States Government is to seek regulatory approaches that protect health and the environment while reducing regulatory burdens and avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers, [further stipulating that EPA should] clarify its approach to pesticidal products derived from genome editing techniques.[53]

The Trump administration took similar steps to address the same concerns, issuing in June 2019 an "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products."[54] This was the direct impetus for the EPA revisions to the PIPs regulation previously discussed, as well as the USDA actions on gene-edited plants. It is thus made starkly apparent that the vision, goals, and policy objectives for agricultural biotechnology are bipartisan and transcend administrations.

One could be forgiven for wondering, then, why this hasn't happened yet.

OSTP is good at designing policy, but less so at seeing it implemented. The Biden administration could fix this. OSTP should reaffirm these long-standing policy objectives as a matter of urgency, tasking FDA, EPA, and USDA with correcting and repairing the deficiencies identified herein with alacrity. OSTP must then follow up and work closely with the Office of Management and Budget (OMB)/Office of Information and Regulatory Affairs (OIRA) both to put agencies on notice as to what is expected and to apply rapid timelines (consistent with the Administrative Procedure Act) for delivering the mandated outcomes.

Moreover, as the Senate reviews Biden administration nominees for these related agencies and divisions, it should press nominees for their views on these issues, working to ensure that they support the United States continuing its leadership in agricultural innovation.

If the administration takes the handful of steps we've outlined, it will reaffirm that the most effective means for ensuring environmental and human health is policies strongly grounded in science and informed by experience. The effect of this would be to stimulate and enable a vast wave of innovations spanning multiple sectors of the U.S. and global economies, accelerating delivery of innovative solutions to urgent problems.

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ENDNOTES

1. Julian M. Alston, Philip G. Pardey, and Xudong Rao, *The Payoff to Investing in CGIAR Research*, Supporters of Agricultural Research Foundation (October 16, 2020), https://supportagresearch.org/assets/pdf/Payoff_to_Investing_in_CGIAR_Research_final_October_2020.pdf; Neal F. Lane, "Science is the Key to Growth," *New York Times* (October 28, 2012), https://www.nytimes.com/2012/10/29/opinion/want-to-boost-the-economy-invest-in-science.html.
2. Fred L. Smith, "Biotechnology Flirts with the Regulators," Competitive Enterprise Institute (October 31, 1988), https://cei.org/opeds_articles/biotechnology-flirts-with-the-regulators/.
3. Paul Recer, "Ancient farmers modified corn genes," NBC News Science News (Nov. 13, 2003), https://www.nbcnews.com/id/wbna3475915.
4. Nina V. Fedoroff, "Food in a Future of 10 Billion," Agriculture and Food Security 4 (11) (2015), https://agricultureandfoodsecurity.biomedcentral.com/articles/10.1186/s40066-015-0031-7; Noel Kingsbury, *Hybrid; The History and Science of Plant Breeding*, University of Chicago Press, November 15, 2011; Stephen Budiansky, *The Covenant of the Wild: Why Animals Chose Domestication*, Yale university Press (April 10, 1999); Tim Flannery, *The Future Eaters: An Ecological History of the Australasian Lands and People* (Grove Press, New York, 1994), ISBN 0-8021-3943-4.
5. Jennifer Doudna and Samuel H. Sternberg, *A Crack in Creation: Gene Editing and the Unthinkable Power to Control Evolution*, Mariner Books (August 21, 2018), https://www.goodreads.com/book/show/30971755-a-crack-in-creation.
6. Graham Brookes and Peter Barfoot, "GM crop technology use 1996–2018: farm income and production impacts," GM Crops & Food, 11(4):242–261, (2020), DOI: 10.1080/21645698.2020.1779574; International Service for the Acquisition of Agri-biotech Applications, "Global Status of Commercialized Biotech/GM Crops in 2017," ISAAA Brief 53-2017 (June 26, 2018), https://www.isaaa.org/resources/publications/briefs/53/download/isaaa-brief-53-2017.pdf.
7. Alison L. Van Eenennaam and A. E. Young, "Prevalence and impacts of genetically engineered feedstuffs on livestock populations," J Anim Sci 92(10):4255–78 (October, 2014), doi: 10.2527/jas.2014-8124; Alessandro Nicolia et al., "An overview of the last 10 years of genetically engineered crop safety research," Critical Reviews in Biotechnology 34(1):77–88 (September 16, 2013), https://doi.org/10.3109/07388551.2013.823595.
8. Calestous Juma, *Innovation and Its Enemies: Why People Resist New Technologies,* Oxford University Press (Cambridge, 2016), ISBN 978-0-19-046073-6.
9. ISAAA, "Global Status of Commercialized Biotech/GM Crops in 2017," (2018).
10. Marnus Gouse et al., "Genetically Modified Maize: Less Drudgery for Her, More Maize for Him? Evidence from Smallholder Maize Farmers in South Africa," World Development 83:27–38 (July, 2016), https://www.sciencedirect.com/science/article/pii/S0305750X16000498; John Agaba, "African women are leading biotechnology's advance across the continent," Cornell Alliance for Science (July 13, 2020), https://allianceforscience.cornell.edu/blog/2020/07/african-women-are-leading-biotechnologys-advance-across-the-continent/; Joseph Opoku Gakpo, "African farmer Patience Koku: 'Give us the chance to use ag biotech'," Cornell Alliance for Science (August 1, 2019), https://allianceforscience.cornell.edu/blog/2019/08/african-farmer-patience-koku-give-us-chance-use-ag-biotech/; Cornell Alliance for Science, "Women farmers take lead in India's pro-GMO 'seed satyagraha' movement" (June 25, 2019), https://allianceforscience.cornell.edu/blog/2019/06/women-farmers-take-lead-indias-pro-gmo-seed-satyagraha-movement/; Mactilde Mbenywe, "Farmers' joy as new cotton seeds boost harvest," Nairobi Standard (September 18, 2020), https://www.standardmedia.co.ke/nyanza/article/2001386775/farmers-joy-as-new-cotton-seeds-boost-harvest.
11. T.V. Jayan and Radheshyam Jadhav, "Maharashtra farmers defy ban to plant GM cotton," The Hindu Business Line (June 10, 2019), https://www.thehindubusinessline.com/news/maharashtra-farmers-

defy-ban-to-plant-gm-cotton/article27766300.ece; Shruti Rajagopalan, "The Impartial Spectator, Opinion: A farmer satyagraha for permission-less innovation," Mint (June 11, 2019), https://www.livemint.com/opinion/online-views/opinion-a-farmer-satyagraha-for-permission-less-innovation-1560192197896.html; L. Val Giddings, "Indian Farmers Launch Civil Disobedience Campaign to Secure Access to GM Seeds," The Innovation Files (June 14, 2019), https://itif.org/publications/2019/06/14/indian-farmers-launch-civil-disobedience-campaign-secure-access-gm-seeds; Vishwa Mohan, "Tests confirm illegal cultivation of Bt Brinjal in Haryana district," *Times of India* (May 11, 2019), http://timesofindia.indiatimes.com/articleshow/69276147.cms; "Pro-GM seed movement spreads to 11 districts in Maharashtra, bail of Buldana farmer rejected," *Times of India* (June 25, 2019), http://timesofindia.indiatimes.com/articleshow/69932768.cms; Joseph Opoku Gakpo, "Ghana's scientists, farmers reject claim that GMO crops aren't needed," Cornell Alliance for Science (March 20, 2019), https://allianceforscience.cornell.edu/blog/2019/03/ghanas-scientists-farmers-reject-claim-gmo-crops-arent-needed/; John Agaba, "African farmers want GMO seeds to help weather climate change," Cornell Alliance for Science (March 12, 2019), https://allianceforscience.cornell.edu/blog/2019/03/african-farmers-want-gmo-seeds-help-weather-climate-change/.

12. Margaret Karembu, "How European-Based NGOs Block Crop Biotechnology Adoption In Africa," Genetic Literacy Project (February 23, 2017), https://geneticliteracyproject.org/2017/02/23/european-based-ngos-block-crop-biotechnology-adoption-africa/; Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, Harvard University Press (Cambridge, MA, 2008), ISBN 13:978-0-674-02973-6; *Food Politics: What Everyone Needs to Know*, Oxford University Press (Oxford, U.K., 2010), ISBN 978-0-19-538960-9; "Opinion: Europe Is Sinking Biotech—Again; Scientifically groundless regulations could undercut the potential of gene-edited crops, much as they have with GMOs," The Scientist, (February 1, 2021), https://www.the-scientist.com/reading-frames/europe-is-sinking-biotechagain-68339; Jon Entine (ed.), *Let Them Eat Precaution*, AEI Press (Washington, D.C., 2006), ISBN 0-8447-4200-7.
13. European Commission Scientific Advice Mechanism (SAM) Group of Chief Scientific Advisors, "A scientific perspective on the regulatory status of products derived from gene editing and the implications for the GMO Directive," Publications Office of the EU (November 13, 2018), https://op.europa.eu/en/publication-detail/-/publication/a9100d3c-4930-11e9-a8ed-01aa75ed71a1/language-en; N. G. Halford, "Legislation governing genetically modified (GM) and genome edited crops in Europe: The need for change," *Journal of the Science of Food and Agriculture* 99:8-12 (2019), doi: 10.1002/jsfa.9227; Rothamstead Research, "Defra Gene Editing Consultation: List of questions" (March 10, 2021), https://www.rothamsted.ac.uk/news/rothamsted-submits-evidence-defra-gene-editing-consultation, https://www.rothamsted.ac.uk/sites/default/files/Defra_GE_consultation_questions_Rothamsted_Research.pdf.
14. L. Val Giddings, Robert D. Atkinson, and John Wu, "Suppressing Growth: How GMO Opposition Hurts Developing Nations," ITIF white paper (February 28, 2016), http://www2.itif.org/2016-suppressing-innovation-gmo.pdf.
15. James Watson et al., *Molecular Biology of the Gene*, 4th ed., Benjamin Cummings (Menlo Park, CA, 1965), ISBN 0-8053-9612-8.
16. Paul Berg, et al., "Potential Biohazards of Recombinant DNA Molecules," Science 185:303 (July 26, 1974).
17. James Watson and John Tooze, *The DNA Story: A Documentary History of Gene Cloning*, W.H. Freeman and Company (San Francisco, 1981), ISBN 0-7167-1292-X.
18. Office of Science and Technology Policy (OSTP), Executive Office of the President, "Coordinated Framework for Regulation of Biotechnology," 51 FR 23302 (June 26, 1986), ttps://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

19. OSTP, Executive Office of the President, "Coordinated Framework for Regulation of Biotechnology," 51 FR 23302 (June 26, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf; OSTP, "Update to the Coordinated Framework" (OSTP, 1992, 57 FR at 6753); Food and Drug Administration Fact Sheet: FDA at a Glance – FDA-regulated products and facilities (November, 2020), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance#; OSTP, "Coordinated Framework for Regulation of Biotechnology," Executive Office of the President (OSTP, June 26, 1986, 51 FR 23302), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf; "Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products," Executive Office of the President, Office of Science and Technology Policy, July 2, 2015, https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.
20. Food and Drug Administration, "Federal Food, Drug, and Cosmetic Act (FD&C Act)," https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.
21. Alison Van Eenennaam, "Regulation of Genetically Modified Animals Part #1," https://biobeef.faculty.ucdavis.edu/2020/12/28/regulation-of-genetically-modified-animals-part-1/; "Regulation of Genetically Modified Animals Part #2," https://biobeef.faculty.ucdavis.edu/2020/12/28/regulation-of-genetically-modified-animals-part-2/; "Regulation of Genetically Modified Animals Part #3," https://biobeef.faculty.ucdavis.edu/2020/12/28/regulation-of-genetically-modified-animals-part-3/; "Regulation of Genetically Modified Animals Part #4," https://biobeef.faculty.ucdavis.edu/2020/12/28/regulation-of-genetically-modified-animals-part-4/; BioBeef Blog (December 28, 2020); Office of Science and Technology Policy (OSTP), "Update to the Coordinated Framework" (OSTP, 1992, 57 FR at 6753).
22. L. Val Giddings, "FDA Must Revise Current Regulatory Proposal for Gene-Edited Animals," letter providing comments to Docket No. FDA-2008-D-0394 (April 17, 2017), http://www2.itif.org/2017-fda-comments.pdf; "FDA's Proposals for Gene Edited Plants are Ill-considered and Counterproductive," letter providing comments to Docket No. FDA 2016-N-4389 (June 14, 2017), http://www2.itif.org/2017-fda-ge-plants.pdf.
23. OSTP, Executive Office of the President, "Coordinated Framework for Regulation of Biotechnology," 51 FR 23302 (June 26, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf; "Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products" (July 2, 2015), https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.
24. L. Val Giddings, letter providing comments to Docket No. FDA-2008-D-0394 (April 17, 2017), http://www2.itif.org/2017-fda-comments.pdf; J.D. Murray and E.A. Maga, "Opinion: A new paradigm for regulating genetically engineered animals that are used as food," PNAS 113 (13) 3410-3413 (March 29, 2016), https://doi.org/10.1073/pnas.1602474113.
25. L. Val Giddings, letter providing comments to Docket No. FDA 2016-N-4389 on "Genome Editing in New Plant Varieties Used for Foods" (June 14, 2017), http://www2.itif.org/2017-fda-ge-plants.pdf.
26. National Pork Producers Council, "US Pork calls for level playing field as FDA makes regulatory land grab" (July 12, 2018), https://nppc.org/u-s-pork-calls-for-level-playing-field-as-fda-makes-regulatory-land-grab/; "Oversight for gene-edited livestock should be under USDA, not FDA, Iowa pork producer tells Congress" (March 12, 2020); American Soybean Association, "ASA Pleased with Move to Allow USDA to Lead Animal Biotech" (ASA Press Release, January 19, 2021), https://soygrowers.com/news-releases/asa-pleased-with-move-to-allow-usda-to-lead-animal-biotech/;

Jenny Splitter, "Who Wants To Deregulate GE Animals? Maybe not the opponents of fake meat," The Feed (January 28, 2021), https://jennysplitter.substack.com/p/who-wants-to-deregulate-ge-animals.

27. U.S. Department of Agriculture, "Secretary Perdue Statement on MOU on Animal Biotechnology" (January 19, 2021), https://www.usda.gov/media/press-releases/2021/01/19/secretary-perdue-statement-mou-animal-biotechnology; Steve Davies, "Despite FDA objections, MOU aims to give USDA authority over GE animals," AgriPulse (January 19, 2021), https://www.agri-pulse.com/articles/15175-new-mou-aims-to-give-usda-authority-over-ge-animals; Dan Flynn, "Perdue exits the building after getting USDA jurisdiction over gene-edited livestock," Food Safety News (22 January, 2021), https://www.foodsafetynews.com/2021/01/perdue-exits-the-building-after-getting-usda-jurisdiction-over-gene-edited-livestock; Alison Van Eenennaam, "Regulation gone wrong: A critique of the FDA's nonsensical animal gene editing rules, Genetic Literacy Project" (January 13, 2021), https://geneticliteracyproject.org/2021/01/13/regulation-gone-wrong-a-critique-of-the-fdas-nonsensical-animal-gene-editing-rules/.
28. Alison L. Van Eenennaam and A.E. Young, "Prevalence and impacts of genetically engineered feedstuffs on livestock populations," Journal of Animal Science 92 (10): 4255–78, (October 2014), https://pubmed.ncbi.nlm.nih.gov/25184846/; Reid Wilson, "How scientists saved Trump's FDA from politics," The Hill (February 16, 2021), https://thehill.com/policy/healthcare/538898-how-scientists-saved-trumps-fda-from-politics#.YCur6Yzi77E.twitter.
29. USFDA, "FDA Launches 'Feed Your Mind' to Help Consumers Better Understand the Science Behind Foods Derived from Genetic Engineering," Constituent Update (March 4, 2020), https://www.fda.gov/food/cfsan-constituent-updates/fda-launches-feed-your-mind-help-consumers-better-understand-science-behind-foods-derived-genetic; L. Val Giddings, letter providing comments to Docket No. FDA-2017-N-5991, "Agricultural Biotechnology Education and Outreach Initiative; Public Meetings; Request for Comments," (November 12, 2017), http://www2.itif.org/2017-fda-outreach-comments.pdf.
30. United States Environmental Protection Agency, "Regulation of Biotechnology under TSCA and FIFRA," https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra (last accessed 18February, 2021).
31. Roger Beachy et al., "Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests: A scientific review of a policy proposed by the U.S. Environmental Protection Agency, Plant Pesticides subject to FIFRA and FFDCA," in Cook, R. J., and C. O. Qualset (Eds), "Appropriate oversight for plants with inherited traits for resistance to pests" (Institute of Food Technologists, 1996).
32. Institute of Food Technologists, "Science-Based Decision Guide May Be Answer to EPA's Controversial Rule," press release (December 14, 1998).
33. Nina V. Fedoroff et al., "Letter to the Honorable Lisa P. Jackson" (July 5, 2011).
34. Fedoroff et al., ibid.
35. USEPA, "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived From Newer Technologies," Federal Register 85(197): 64308-64344 (October 9, 2020), https://www.govinfo.gov/content/pkg/FR-2020-10-09/pdf/2020-19669.pdf.
36. OSTP, Executive Office of the President, "Coordinated Framework for Regulation of Biotechnology," 51 FR 23302 (June 26, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.
37. USEPA, "Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies" (August 31, 2020), https://www.epa.gov/sites/production/files/2020-09/documents/10014-10-prepub-fr-doc-admin_esignature2020-08-31.pdf.
38. Ibid.
39. American Society of Agronomy, Crops Science Society of America, Soil Science Society of America, "Comments to EPA Re: Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs)

Derived From Newer Technologies" (December 8, 2020), https://www.crops.org/files/science-policy/letters/2020-12-08-acs-epa-pip-rule-comments.pdf.

40. USEPA, "Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides)," FR 66 (133): 37772 (July 19, 2001) (Amending 40 CFR § 152 and 174), https://www.govinfo.gov/content/pkg/FR-2001-07-19/html/01-17981.htm; Naglaa A. Abdallah, Channapatna S. Prakash, and Alan G. McHughen, "Genome editing for crop improvement: Challenges and opportunities," GM Crops Food 6(4):183–205 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5033222/.
41. U.S. National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key Issues,* National Academy Press, (1987); *Field Testing Genetically Modified Organisms: Framework for Decisions,* National Academy Press, (1989); *Genetically Modified Pest-Protected Plants: Science and Regulation*, National Academy Press, (2000); *The Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation,* National Academy Press, (2002); *The Safety of Genetically Engineered Foods*, National Academy Press, (2004); *Genetically engineered crops : experiences and prospects*, National Academy Press, (2016), ISBN 9780309437387; Organization for Economic Cooperation and Development, *Recombinant DNA Safety Considerations* (Paris: OECD, 1986), ISBN 92-64-12857-3; *Agricultural and Environmental Policies: Opportunities for Integration* (Paris, OECD, 1989); *Safety Considerations for Biotechnology* (Paris: OECD, 1992), ISBN 92-64-13641-X; *Biotechnology, Agriculture and Food* (Paris: OECD, 1992), ISBN 92-64-13725-4; *Traditional Crop Breeding Practices: An Historical Review to Serve as a Baseline for Assessing the Role of Modern Biotechnology* (Paris: OECD, 1993), ISBN 92-64-14047-6; *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles* (Paris: OECD, 1993), ISBN 92-64-13859-5.
42. USEPA, "Proposal to Improve Lepidopteran Resistance Management for Bt Plant-Incorporated Protectants," Federal Register 85(55448) (September 8, 2020), https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0682/document.
43. USEPA, "Insect Resistance Management for Bt Plant-Incorporated Protectants," EPA website, last accessed February 19, 2021, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/insect-resistance-management-bt-plant-incorporated.
44. Emily Unglsebee, "How to Save Bt: EPA Proposes New Bt Crop Regulation to Slow Insect Resistance," Progressive Farmer (September 15, 2020), https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/09/10/epa-proposes-new-bt-crop-regulation; "ASA, CSSA, and SSSA Submit Comments on EPA Rule on Plant Gene Editing" (December 8, 2020), https://www.soils.org/files/science-policy/letters/2020-12-08-acs-epa-pip-rule-comments.pdf.
45. Code of Federal Regulations, "Introduction of Organisms and Products Altered or Produced through Genetic Engineering Which Are Plant Pests or Which There is reason to believe are" (June 16, 1987), https://www.ecfr.gov/cgi-bin/text-idx?node=pt7.5.340&rgn=div5.
46. USDA, "'Am I Regulated?' Process" (December 29, 2020), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated; "Regulated Article Letters of inquiry" (October 21, 2020), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry.
47. USDA, "SECURE rule" (February 19, 2021), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about; Chris Clayton, "New Biotech Rule Finalized: USDA to Deregulate Certain Genetically Engineered Crops," Progressive Farmer (May 14, 2020), https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/05/15/usda-deregulate-certain-genetically.
48. Ibid.

49. USDA, “Secure Rule.”
50. OSTP, “Coordinated Framework for Regulation of Biotechnology,” Executive Office of the President (OSTP, June 26, 1986, 51 FR 23302), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.
51. OSTP, Executive Office of the President of the United States, “Modernizing the Regulatory System for Biotechnology Products” (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.
52. OSTP, Emerging Technologies Interagency Policy Coordination Committee, Biotechnology Working Group, *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (September 2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.
53. Ibid.
54. Executive Office of the President, “Modernizing the Regulatory Framework for Agricultural Biotechnology Products,” Executive Order 13874 (June 14, 2019), https://www.federalregister.gov/documents/2019/06/14/2019-12802/modernizing-the-regulatory-framework-for-agricultural-biotechnology-products.