How the Trump Administration Can Unshackle Innovation in Agricultural Biotechnology

BY L. VAL GIDDINGS | APRIL 2017

Fears of the new have led to calls for "precautionary" regulation, which risks stifling agricultural innovation without any showing of need or benefit. There is a better way. The time is long past due for significant regulatory rollback.

New techniques for improving plants and animals promise to reshape virtually every aspect of the relationship between humans and our environment for the better. Safer and more sustainable crops have already made enormous contributions to the economy and the environment, and genetically improved livestock and companion animals are close behind. Discovery of more precise, predictable, and easily used techniques derived directly from nature is dramatically accelerating this progress. But fears of the new have led to calls in many nations for "precautionary" regulation, which risks stifling agricultural innovation without any showing of need or benefit. There is a better way.

This report discusses proposals for updating policies and regulations for agricultural biotechnology products in the United States to ensure they safeguard public and environmental health and animal welfare without discouraging needed innovations. An authoritative review of 10 years' worth of academic literature has found that the scientific research conducted so far "has not detected any significant hazards directly connected with the use of [genetically engineered] crops."[1] This experience is evidence that the time is long past due for significant regulatory rollback in this field around the world. Good advice has already been offered as to the best ways for updating these regulations.[2] Not all of it has been followed yet, leaving numerous opportunities for improvement by the new administration.[3] This report recommends the following reforms:

- The Trump administration should enforce the mandate from the Office of Science and Technology Policy that agencies update their regulations and policies for innovative agricultural-biotechnology products, and that the revised regulations

must be effective in preventing unreasonable risks while encouraging and enabling innovation.

- The Animal and Plant Health Inspection Service (APHIS) should set aside its proposal for process-based regulations.
- The Food and Drug Administration (FDA) should enforce the federal law prohibiting misleading food labels.
- The FDA should revise its current proposal for regulating gene-edited animals, withdraw its proposal for gene-edited plants, and develop new proposals to exercise its discretion in preventing unreasonable risks.
- The Environmental Protection Agency (EPA) should not prematurely obstruct gene-silencing technologies.
- The Fish and Wildlife Service should immediately withdraw the prohibition on planting biotech-improved seeds on national refuge lands.
- The Trump administration should pursue efforts through the World Trade Organization to hold China and the European Union accountable for continuing to discriminate against crops improved through biotechnology, despite being obligated otherwise.

BACKGROUND

The single biggest obstacle slowing the wider dissemination of the considerable benefits from agricultural biotechnology innovations is unwarranted regulatory burdens across the world.[4] The disparity between the degree of hazard or risk associated with these innovations and the regulatory hurdles they must clear has widened everywhere over the past three decades from a gap to a chasm. This has happened even while experience has shown that early safety concerns were unfounded, and that the predictability and safety associated with these innovations has been shown to be unmatched by the products of any other production method.

What Is "Agricultural Biotechnology" and Why Should We Care?

Innovations in agriculture are being delivered today through a host of different techniques referred to with a baffling array of labels: recombinant DNA, genetically modified organisms (GMOs), genetic modification (GM), gene editing, CRISPR, TALENs, Zinc Fingers, meganucleases, advanced breeding, new breeding technologies, precision agriculture, big data, remote sensing, and more. There is some overlap among these terms both vis-à-vis the subject matter they cover and the ways in which they are used, but misunderstanding is widespread, and scientific justification for some of these terms is lacking or altogether absent.[5]

When scientifically nonsensical terms are used as the foundation of discriminatory regulations, without due regard for hazard or risk, the resulting policies do not advance the protection of public and environmental health. This is the case for any and all regulations that single out "GM" processes or "GMOs" for regulatory scrutiny. Scientists and policy mavens spent years examining these issues in the late 1970s and early 1980s. They reached consensus that the "process" of genetic modification tells regulators nothing useful about any possible hazards of the resulting product, or the risks associated with different levels of exposure; these require consideration of the final characteristics and qualities of a product—its phenotype. To use an example from manufacturing, a product's safety does not depend on how a chemical is made, but rather on its chemical composition and structure. The same is true for food, feed, fiber, and animal products.

Yet, for ideological or political reasons unsupported by data or experience, many nations' regulators have adopted explicitly process-based regulations. Even countries that have avoided this fundamental error have drifted in that direction through uncritical implementation of otherwise less flawed regulations that slow ag-biotech innovation. These different developments have combined to create the gross disparity between and within nations regarding risk and regulatory burden as manifested in regulatory proposals we examine here.

"GM" Food Is Safe

The foundation of confidence in the safety of agricultural products produced through biotechnology, no matter what breeding method was used, lies in a concept known as "substantial equivalence." This is based on the work of an international expert group at the Organization for Economic Cooperation and Development (OECD), which published a series of landmark policy papers in the 1980s and 1990s.[6] The concept of substantial equivalence emerged from the recognition that plants and animals we have long used for food provide a familiar baseline for comparison and for the evaluation of novel traits as we consider their safety. A number of factors are important, including:

- "[T]he composition and characteristics of the traditional or parental product or organism;

- "[T]he characteristics of the new component(s) or trait(s) derived, as appropriate, from information concerning: the component(s) or trait(s) as expressed in the precursor(s) or parental organism(s); transformation techniques (as related to understanding the characteristics of the product) including the vector(s) and any marker genes used; possible secondary effects of the modification; and the characterization of the component(s) or trait(s) as expressed in the new organism; and

- "[T]he characteristics and composition [i.e. the amount of the component(s) or the range(s) of expression(s) of the new trait(s)] as compared with the conventional counterpart(s) (i.e. the existing food or food component)."[7]

The U.S. National Academy of Sciences explicitly endorsed this approach in its first paper on this topic, and reaffirmed it in 11 subsequent reports, which corroborated the safety of products produced with these methods.[8] The safety of these products was reaffirmed in a comprehensive review of more than 1,700 peer-reviewed papers from the scientific literature over a decade, published in 2013, adding to a database of more than 2,000 such papers compiled by independent academics.[9] It is noteworthy that based on their findings, independent academics and industry scientists reach identical conclusions.[10] For these reasons, more than 275 scientific organizations have embraced the global scientific consensus on the safety of GM crops and foods.[11] The European Union has summarized the safety issue thus:

> "Indeed, the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects—none have appeared as yet—these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear."[12]

"Process-Based" Regulation Doesn't Work

In the early 1980s, when the potential of recombinant DNA techniques to deliver solutions to problems in agriculture was first widely noted, two main schools of thought emerged on the best way to ensure their safety without discouraging innovation. Expert bodies around the world repeatedly found no unique or novel hazards associated with crops, livestock, microbes, or foods improved through biotechnology. They found that the foreseeable risks were similar to those with which we were long familiar with from classical plant and animal breeding throughout 10 millennia of domestication and agriculture. As a result, the United States, Canada, and Australia aimed to base regulations on experience and scientific data. U.S. policymakers, for example, concluded that existing regulations for risk assessment and management were sufficient, and determined to move forward with products of agricultural biotechnology under close scrutiny, with a watchful eye for surprises. This was attended by the expectation that regulations would be adapted regularly as knowledge and understanding accrued.[13]

European politicians chose a different approach, and crafted new, process-specific regulations unrelated to any concrete demonstration of real hazards or actual risks, based instead on hypothetical potential harms. Following this lead, a number of other countries have also taken this "precautionary" approach and subordinated the findings of scientific risk assessment and experience to political and ideological interests.[14] The results have been clear and dramatic; innovative products have rapidly swept to market dominance in countries that have chosen science-based approaches, while European farmers have become increasingly uncompetitive as innovators have fled the continent.[15]
The harshest condemnations of the failed European "precautionary" approach have come from Europeans.[16]

But despite this reasoned approach early on, regulations in the United States more recently have not evolved to match our accumulated experience and the dramatic growth in our understanding.[17] Regulations first laid down in 1987 have been significantly adapted to experience only once, in 1992.[18] Since then, the disparity between the level of risk and the degree of regulation has expanded dramatically.[19] This led the White House Office of Science and Technology Policy in 2015 to call for an updating of regulatory agencies' responsibilities under the Coordinated Framework, the 1986 roadmap set forth to guide regulators into the new landscape.[20] The new Trump administration's directive that each new regulation must be accompanied by repeal of two already in place is, in this arena at least, a step in the right direction.[21]

The Purpose of Regulation Is to Manage Risk

Regulations exist for a purpose: to manage and mitigate risks. Reasonable and effective regulations will also incorporate a consideration of economic costs and dynamic innovation effects. Thus, under the 1986 Coordinated Framework, the Animal and Plant Health Inspection Service is charged with managing risks that crops improved through biotechnology may present to American agriculture; the Environmental Protection Agency with ensuring that pesticides are used safely to manage pests and protect human and environmental health; and the Food and Drug Administration with ensuring that food and feed derived from crops or animals improved through biotechnology are as safe to consume as other food and feed.

Regulations exist for a purpose: to manage and mitigate risks.

But much of the oversight applied to crops improved through biotechnology in the United States has lost sight of the fundamental principle for determining risk, expressed in the equation: risk equals hazard times exposure. If there is no prospect for exposure to a hazard, then the hazard, no matter how great, presents no risk. If there is no hazard, or if it is present only at very low levels, then even high levels of exposure may be entirely irrelevant to human or environmental health. But in the regulatory systems now in place there is no relationship among the presence of a hazard, the level of exposure, and the degree of regulatory scrutiny applied. If innovation is to be enabled, much less encouraged, that must be remedied.

But the importance of one other objective driving the adoption of regulations to deal with biotechnological innovations in agriculture cannot be overstated:

> "In response to public concern … [t]he goal in developing the 'Coordinated Framework' was to explain to the American public that, for questions involving the products of 'biotechnology' (more specifically, organisms derived from recombinant-DNA technology), human health and the health of the environment were of paramount concern and were adequately protected.[22]

There is no denying the virtuous intent of that sentiment, for if consumers are not convinced that biotech foods are safe they will not buy them. But in fact, the promulgation of regulations in advance of any confirmed finding of hazard or demonstration of risk has not assuaged public concerns. Nor has the subsequent confirmation of safety led to a

reduction in regulatory oversight or regulatory delays in the deployment of innovative technologies and products. In fact, entrenched opposition from the very beginning has taken every emplacement of regulation as confirmation of the need for yet more stringent regulation, driven by the unfounded assertion of unique and technology-specific hazards.

This discordance between the degree of regulatory oversight and the actual hazards and risks confirmed by experience has only grown over the years, exacerbated by the emergence of regulation for the purpose of litigation-avoidance by the agencies. Special interest groups have brought a significant number of procedural lawsuits against USDA for approving specific crops improved through biotechnology, leading to lengthy delays in the dissemination of new products.[23] The ephemeral success of these lawsuits hinged on deficiencies noted by the courts in the documentation of USDA's decision-making process. In no case have they identified any genuine hazard, and, after USDA repaired the paper record for its decision making, the products are now on the market. But the opportunity costs, both economic and environmental, imposed by the delays remain on the ledgers.

NEEDED U.S. REGULATORY REFORMS

There are a number of areas in which regulatory reforms are amply justified, and in some cases long overdue. The White House Office of Science and Technology Policy (OSTP) recently concluded an extensive analysis to identify ways in which regulatory agencies might better coordinate, and it has reaffirmed fundamental principles. USDA has proposed significant changes to its regime for regulating innovations derived through agricultural biotechnology, but these proposals suffer from major flaws. Existing law intended to ensure that food labels inform consumers without misleading them are robust, but FDA needs to enforce them to stem a surge in deceptive marketing. FDA proposals to oversee plants and animals modified with the most recent gene-editing techniques (and others yet to emerge) are flawed and need of substantial revision. EPA proposals to manage the risks associated with products of the new technologies are not ready for prime time and must be set aside until they have been shown to have practical value. The Interior Department's Fish and Wildlife Service must set aside positions that violate long-standing policy guidance and that undermine its own mission. And finally, the administration should hold U.S. trading partners accountable when they violate trade rules by discriminating against crops improved through biotechnology. We will take each of these in turn.

OSTP Should Reaffirm the Mandate That Agencies Update Regulations for Agricultural-Biotech Products

On January 4, 2017, the White House published its latest plans for updating the Coordinated Framework in two parts: a document titled "Update to the Coordinated Framework for the Regulation of Biotechnology" along with another presented as a "National Strategy for Modernizing the Regulatory System for Biotechnology Products."[24] These documents reaffirm the fundamental principles laid down in 1986, make adjustments to improve interagency coordination, and map a plan to address anticipated challenges in the foreseeable future. These represent the culmination of an effort launched on July 2, 2015 to update and modernize the U.S. regulatory system. OSTP and the

regulatory agencies are to be commended for taking up this complicated challenge, which was long overdue. But these documents fail to deliver the reforms that are most needed, and while the "National Strategy" provides a sound vision for the future, the companion and derivative documents do not accomplish that vision.

By some standards, regulation under the Coordinated Framework could be argued as having been a success. The United States now has a robust agricultural-biotechnology industry that has added over $150 billion of value to the world economy, improved the livelihood of more than 18 million farmers and billions of consumers worldwide, while substantially improving the sustainability and reducing the environmental impacts of modern production agriculture.[25] All this has been accomplished without a single example of a negative impact on human health or the environment stemming from the biotech-derived source of the innovation, an enviable record.[26]

This success, however, is dwarfed by the unrealized potential. The biotech-improved seeds commercially available today make up but a small fraction of those crops that were field tested in the early years of the Coordinated Framework.[27] Many innovations have languished in laboratories or the frustrated imaginations of innovators because of the high costs and onerous burden of meeting regulatory requirements for approval of field trials and commercialization.[28]

Much of the regulation presently applied to crops improved through biotechnology has lost sight of the fundamental principle that risk results from exposure to a hazard. If there is no hazard and no harm, then there is no justification for regulation.

The passage of time has seen an increase in the volume and kinds of information requested by regulators on the innovations developers seek to bring to market. It is difficult to see how most of this requested information could be used to help shape a decision to approve or reject a new product. In other words, while it might be "nice to know," it is evidently not something regulators really "need to know" to make a sound decision on the safety of a product. It is for this reason, above all, that the White House directed regulatory agencies to review regulations for biotechnology products with an eye to reducing regulatory burdens that serve no purpose.[29]

The January 2017 update to the Coordinated Framework does not meet the criteria reaffirmed in 1992 that regulations must "achieve a balance … to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation." More specifically, it does not:

- Describe "a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment";
- "[F]ocus … on the characteristics of the biotechnology product and the environment into which it is being introduced, [rather than] the process by which the product is created";
- Describe a review process in which "[e]xercise of oversight in the scope of discretion afforded by statute [is] based on the risk posed by the introduction [that does] not turn on the fact that [a biotechnology product] has been modified by a particular process or technique"; and

- "[E]nsure that limited federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, [guaranteeing] oversight will be exercised only where the risk posed by the introduction is unreasonable."[30]

The 2017 update does note that:

> "[I]n some cases unnecessary costs and burdens associated with uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have arisen. These costs and burdens have limited the ability of technology developers, particularly those in small and midsized companies and in academic research institutions, to navigate the regulatory process and have limited the ability of the public to understand easily how the safety of these products is assured. Accordingly, the costs and burdens have the potential to hamper economic growth, innovation, and competitiveness."[31]

But it leaves the main vehicle of these negative outcomes essentially unchanged. It leaves untouched the process-driven regulatory focus on the products of the newest, most precise, predictable, and safest techniques. It ignores the chasm between the familiar (and small to non-existent) risks they pose and the degree of regulatory scrutiny applied to these products, and ignores the perverse incentive thus created, which discourages these innovations, unnaturally prolonging reliance on obsolete technologies that have no safety advantages and that are dramatically less sustainable.

The OSTP documents delve into the details of which agencies regulate what, under which authorities, providing a useful primer to those new to this arena. But they give short shrift to the central questions: Are the regulations being applied proportional to the hazards they seek to mitigate and the risks they aim to manage? Do they succeed in preventing unreasonable risks while enabling and encouraging innovation? Clearly, they do not.

The specific failings of the individual agency proposals to meet the stipulated criteria are documented in the sections below, but the strategic failure of the OSTP's revisions requires a qualitatively different remedy.

Most of what OSTP proposes in these documents can be accepted. But the content must be built upon with further guidance from OSTP to the agencies as they are directed to set aside the present, counterproductive proposals and replace them with others that are fit for the intended purpose. New agency proposals must make it clear that their intent is not to deliver against a standard of zero risk, but rather to prevent unreasonable risks. This requires recognition that the appropriate standard is one of relative risk –the risks of innovative products (regardless of their production method) must be compared with the risks of products presently being used, and the opportunity costs of continuing with the status quo rather than the proposed innovation.

The "National Strategy" document is essentially sound, and provides much of the kind of guidance needed. It should be reduced to three or four pages of distilled guidance, and the agencies should be challenged to demonstrate that their proposals are consistent with this guidance.

All proposals that do not closely align regulatory burdens with the alleviation of demonstrated risks, and that do not create significant regulatory relief for the existing product pipelines, should be rejected. Agencies should be enjoined from proposing any expansion of their regulatory authority or oversight without a clear and convincing demonstration of hazard, and a level of risk sufficient to justify proportional regulation to manage or mitigate significant potential for harm to human or environmental health.

USDA Should Set Aside Process-Based Regulatory Proposals

APHIS has shown that most genetically engineered plants do not present any plant pest risk.

On January 19, 2017, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) proposed changes to the regulations governing "[i]mportation, interstate movement, and environmental release of certain genetically engineered organisms."[32] This was in follow up to an earlier proposal inviting public comment on the stated intent "to prepare a programmatic environmental impact statement [EIS] in connection with potential changes to the regulations [at 7 CFR 340] regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms."[33] The purpose of this proposal is clearly stated:

> "to update the regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by genetically engineered (GE) organisms, thereby reducing burden for regulated entities whose organisms pose no plant pest or noxious weed risks."[34]

To justify the proposal, APHIS invokes the bedrock principles for regulation under the Coordinated Framework.[35] APHIS also refers to a significant body of experience accrued under the regulations put in place in 1987:

> "APHIS has issued more than 18,000 authorizations for the environmental release of GE organisms in multiple sites, primarily for research and development of improved crop varieties for agriculture. Additionally, APHIS has issued more than 12,000 authorizations for the importation of GE organisms, and nearly 12,000 authorizations for the interstate movement of GE organisms.… APHIS has granted 124 determinations of nonregulated status.…"

This vast body of experience has led APHIS to conclude that "t]he Agency's evaluations to date have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk."

The agency then devotes 30 pages of dense and convoluted prose to outline a new scope for regulating things they've determined pose no risks and therefore do not need regulating, as

well as similar products produced with the latest generation of techniques that are even more precise, manageable, and predictable than anything that has gone before.

The crux of the matter is this:

> "[T]he proposed regulations would not apply to organisms that are created using techniques that APHIS does not consider to constitute genetic engineering or that fall outside the scope of GE organism.… By genetic engineering, APHIS would mean techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome."

APHIS would unilaterally abandon more than three decades of U.S. policy and move directly, immediately, and explicitly to a process-based regulation. In view of the conspicuous failure of such regulation everywhere it has been tried, this is difficult to understand.

APHIS focuses the proposed new regulation squarely on innovations developed with "genetic engineering" as it arbitrarily defines it, leaning heavily on the "intent to create or alter a genome" without regard to the results. With this language, APHIS would unilaterally abandon more than three decades of U.S. policy and move directly, immediately, and explicitly to a process-based regulation. In view of the conspicuous failure of such regulation everywhere it has been tried, this is difficult to understand.

Even if APHIS had the independent authority to take such a move, such a departure from the status quo would need to be justified with a substantial argument showing that such changes are required to safeguard the public good against unreasonable risks, and that they cannot be achieved through less disruptive means. But the agency's own words document the massive data and experience showing the proposed regulations to be incapable of achieving the desired objectives.

Some observers have praised the APHIS proposal because it does exempt some items from this regulatory scrutiny:

> "APHIS would exclude from the definition of *genetic engineering* traditional breeding techniques (including, but not limited to, marker assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation based mutagenesis. APHIS would do so because the Agency has never considered such techniques to constitute genetic engineering.… APHIS would also exclude, from its definition of *GE organism,* certain organisms that are created using techniques that fall within the scope of *genetic engineering,* but that could otherwise have been produced using traditional breeding techniques or chemical or radiation based mutagenesis. Such organisms are essentially identical, despite the method of creation, because while there may be small genetic differences, those differences are not phenotypically observable and these types of changes occur naturally in all organisms."

APHIS states further that:

> "GE plants as a class, which constitute the vast preponderance of GE organisms to date, pose no greater plant pest or noxious weed risk than their counterparts developed through traditional breeding techniques or chemical or radiation based

> mutagenesis. Moreover, it is both impracticable and unnecessary to regulate plants created through traditional breeding techniques or chemical or radiation based mutagenesis for plant pest or noxious weed risk."

And then APHIS offers the following exculpatory defense for its proposed exclusions, while noting but setting aside the fact that it applies equally to crops improved through biotechnology:

> "Such regulations would also fail to take into consideration the usual purpose of applying traditional breeding techniques or chemical or radiation based mutagenesis to a plant: To introduce desirable phenotypic traits into the organism or remove phenotypically undesirable traits from the organism. Additionally, it would fail to take into adequate consideration that phenotypic traits that could increase the plant pest or noxious weed risk posed by a plant tend to also adversely impact its vitality, uniformity, or commercial viability. For example, a mutation caused by chemical or radiation based mutagenesis could render a plant more susceptible to certain viroids or pathogens and able to transfer this increased susceptibility to sexually compatible relatives, and thus increase the plant pest risk associated with the plant. However, it would also directly adversely affect the plant's vitality."

With these statements APHIS has not even attempted to argue that items not exempted pose greater hazards and higher risks than those exempted, as the law and policy requires. In fact, as APHIS has shown, all data and experience point in the opposite direction.

The proposed new definition of biotechnology is arbitrary and incoherent, departing in significant ways from established usage and scientific understanding, and its focus is overtly and impermissibly process based. And although it exempts a series of techniques and measures clearly understood by the world to be encompassed in the term, the clear meaning of the term captures not only these excluded methods, but numerous processes and phenomena that are ubiquitous among living organisms in the natural world. And it does all this with a definition that lacks even the most remote connection with any indicators of hazard or risk. We have above cited the numerous studies by the National Academy of Sciences, the Organization for Economic Cooperation and Development, and authoritative bodies worldwide confirming that hazard is a function of the characteristics of a product and is unrelated to the process by which it is produced. This proposal therefore provides no basis for any improvement in the existing U.S. Department of Agriculture regulatory paradigm and is at odds with the 2015 OSTP mandate as well as the 1986 Coordinated Framework.

Further, if APHIS sincerely intends to rely on the argument that "certain organisms" should be exempted from regulatory scrutiny if they could be produced through other methods or if any differences would be "not phenotypically observable," then APHIS would be on firm ground establishing broad phenotypic categories for exemption from regulatory scrutiny that would include, for example, all herbicide-tolerant and insect or

disease-resistant plants, among others. Numerous examples abound in nature of all these phenotypes, and APHIS has not provided a single concrete example of an intentional genetic modification that would impart through these phenotypes any novel threat to agriculture.

If the fatal defects described above are insufficient to compel the new administration to set aside the APHIS proposal in its entirety, there are more. APHIS also argues for a significant expansion of its authority to regulate "GE plants" under its existing authority to regulate noxious weeds. In the course of marshaling this argument, APHIS states that:

> "Historically, there has not been a significant need for such a noxious weed evaluation of GE plants. Most of the GE plants that APHIS regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as 'noxious weeds.' This is because most GE plants to date have been agricultural crops, and most agricultural crops are not biologically weeds prior to modification. Indeed, in order to domesticate a plant for crop production, farmers often had to deliberately eliminate weedy traits, such as seed shattering, thorns, and seed dormancy, from the plant using traditional breeding techniques. Moreover, the phenotypic traits that have historically been introduced into crops through genetic engineering do not confer weediness. Because the plants have not been weeds prior to genetic engineering, and genetic engineering has not introduced weediness, evaluating the plant solely for plant pest risk has not been problematic."

APHIS goes on to argue that some plants now being adapted for agriculture, e.g., switchgrass for use as a biofuel crop, do have some weedy characteristics that could, in principle, be exacerbated by modifications to improve their biofuels utility. But it still fails to articulate (though it asserts otherwise) any hazard that could not be encompassed under their existing plant-pest risk trigger, much less one that poses an unreasonable risk sufficient to justify being regulated. Instead, they claim that "under the [Plant Protection Act's (PPA's)] definition of *plant pest,* a plant must be parasitic in order to be considered a plant pest." But the PPA states that:

> "The term 'plant pest' means any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product:
> (A) A protozoan.
> (B) A nonhuman animal.
> (C) A parasitic plant.
> (D) A bacterium.
> (E) A fungus.
> (F) A virus or viroid.
> (G) An infectious agent or other pathogen.
> (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs."[36]

The APHIS argument is plainly without merit. The fundamental challenge APHIS faces in the effort to update its regulations is that they are focused on DNA from certain sources as being potential vehicles for hazards and risks that could threaten U.S. agriculture. But APHIS has correctly concluded from three decades of experience that this approach has not been fruitful; the energies expended to date in evaluating genetically engineered plants have not identified any novel risks stemming from their modification through genetic engineering, much less unreasonable ones. Furthermore, many of the improvements imparted through genetic engineering are indistinguishable in kind from traits developed through other methods like radiation or chemical mutagenesis, or intrinsic to plants (nearly all plants are tolerant to one or more herbicides, which is why agronomists have developed multiple different herbicides). In other words, no matter how acquired by a plant, a DNA sequence is, at best, an imperfect marker of hazard, and of no value as a predictor of risk. It follows logically, then, that DNA sequences provide no basis for rational regulation.

No matter how it is acquired by a plant, a DNA sequence is, at best, an imperfect marker of hazard, and of no value as a predictor of risk. It follows logically, then, that DNA sequences provide no basis for rational regulation.

APHIS nevertheless goes on at length in an effort to justify a fundamentally unsound approach. APHIS proposes "a new risk analysis process to determine which organisms would require a permit." Yet, in this second attempt to push these suggestions forward, APHIS still fails to share sufficient information about this "new risk analysis process" to enable one skilled in the art to understand, much less test it. It offers, instead, empty boilerplate:

> "[T]he GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis related that is expected to cause plant disease symptoms, or if it was evaluated and found to represent plant pest or noxious weed risks."

This is not only tautological, but perpetuates dependence on a regulatory trigger that APHIS has already conceded is without value or utility.

APHIS further asserts that:

> "[I]f the developer believes that it possesses sufficient information to demonstrate that the organism presents no plant pest or noxious weed risk, and wished to release it into the environment, it would have to submit this information to APHIS and request that APHIS conduct an evaluation of such risk. The process for submitting such a request, as well as the possibilities for how APHIS would act on that request, is set forth in proposed § 340.4."

This is an assumption of "guilty until proven innocent" based on a presumption of hazard that APHIS has already shown is unfounded. While such approaches may be appropriate under Napoleonic Code-based jurisprudence, they are not here.

APHIS nowhere provides any concrete example of the questions they would ask to evaluate the regulated article; nor what the answers would have to look like to ensure a positive decision by regulators. Nor do they inform as to why APHIS would want to waste time asking these questions and reviewing answers for categories for which no realistic hazard has been identified (e.g., herbicide-tolerant plants). What is the basis for presuming a degree of hazard for genetically engineered or gene-edited plants greater than those known to be associated with conventionally bred plants? Where is any empirical basis for a presumption of hazard that vast experience and rigorous scientific review to date have failed to document? How is this consistent with the 1986 Coordinated Framework requirement that agencies abjure process-based regulation, and reserve regulation for cases of unreasonable risk? This proposal suggests a lamentable disregard for evidence-based decision-making.

Throughout all of this baroque argumentation, APHIS repeatedly sidles up to the recognition (without ever openly naming and embracing it) that the tool of utility to regulators here would be to identify categories of phenotypes that present hazards leading to risk that would be manageable by regulation.

The proposed APHIS regulations offer an assumption of "guilty until proven innocent" based on a presumption of hazard that APHIS has already shown to be unfounded. While such approaches may be appropriate under Napoleonic Code-based jurisprudence, they are not here.

APHIS should set aside the present proposal entirely, and abandon any effort to advance regulatory proposals based on the inheritance or genetics of a regulated article. Instead, APHIS should identify classes of hazards of concern, and develop a catalog of the phenotypes of regulated articles that would be vehicles for associated unreasonable risks, regardless of the techniques by which they came to be. APHIS should develop regulations for addressing such risks in a manner that is based on data and experience, and whereby the regulatory burdens are proportionate to the risks thus mitigated or managed. It should be an overarching mandate that these regulations not discourage or discriminate against innovation without evidence of actual hazards leading to unreasonable risks.

FDA Should Enforce Law Against Misleading Food Labels

Few issues relating to "GMOs" have generated more heat, less light, and seen more wasted money than food labels. For more than a decade, professional campaigners have pushed a well-funded special interest agenda calling for mandatory labels designed to stigmatize foods derived from crops or livestock improved through biotechnology.[37] Gaining no traction at the federal level, they shifted tactics and pursued ballot initiatives at the state level, where they launched a series of raucous, expensive contests in states including California, Oregon, Washington, and Colorado. Despite repeated, major defeats, they persisted until their first, small successes came in New England, after years of effort and tens of millions of dollars spent. Maine and New Hampshire straddled the fence by passing laws that would require GMO labels only after a population threshold had been met by passage of similar laws in nearby states. But Vermont went whole hog, passing a law exceeded in its lack of wisdom only by its lack of coherence.[38] It purported to require labels for foods derived through biotechnology, but it conveniently exempted categories important to Vermont producers who also happened to be vocal proponents and supporters of the campaign effort (such as the local dairy industry and Ben & Jerry's) and

asserted a host of untruths about nonexistent safety issues as justification. Immediately challenged in court, the case dragged on until food companies felt compelled by a looming date for entry into force to find some way to comply while minimizing the unavoidable negative consequences. But the primary fruit of the Vermont law was to irritate the food companies enough that they finally sought and won federal action to make it go away: Congress passed legislation that reaffirms federal authority over food labels and explicitly preempts state actions.[39] And while the dust from that fight is still settling, the 800-pound gorilla that remains is that consumers continue to be misled by the same well-funded propaganda campaign from brazen and unapologetic special interests working to grow their market share by fomenting unfounded fears regarding competitors' products.

Federal law requires that food labels be accurate, informative, and not misleading. This federal law, upheld by court challenges that overturned earlier laws requiring labels designed to mislead consumers, applies directly to the way in which the Non-GMO Project and other absence-claim labels are being deployed today.[40]

FDA should enforce the law by advising parties marketing foods based on misleading absence claims, or on implications of health or safety differences between foods produced through different seed improvement technologies where none exist, to cease and desist.

FDA Should Revise Current Regulatory Proposal for Gene-Edited Animals

On January, 19, 2017, FDA published and invited comment on a document titled "Guidance for Industry, Regulation of Intentionally Altered Genomic DNA in Animals, Draft Guidance." FDA described it as "a revision of Guidance #187, 'Regulation of Genetically Engineered Animals,' … revised to update information concerning the products of different technologies used to produce such animals."[41] FDA states it "is intended to clarify our requirements and recommendations for producers and developers … of animals with intentionally altered genomic DNA" and that:

> "[It] addresses animals whose genomes have been intentionally altered using modern molecular technologies, which may include random or targeted DNA sequence changes including nucleotide insertions, substitutions, or deletions, or other technologies that introduce specific changes to the genome of the animal. This guidance applies to the intentionally altered genomic DNA in both the founder animal in which the initial alteration event occurred and the entire subsequent lineage of animals that contains the genomic alteration."

FDA states clearly that this guidance is intended to cover the spectrum of so-called "gene-editing" technologies that has exploded in recent years, specifically including CRISPR, but also noting that "other technologies intended to alter genomic DNA will arise over time" and will also be captured.

FDA grounds their authority in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) language concerning new animal drugs:

> "The term 'new animal drug' means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective.…"

That broad definition makes it clear that Congress intended to give FDA expansive authority, and with the established precedent of courts deferring to agencies in their construction of their authorities, it is likely that FDA's authority to advance this proposal would be upheld if challenged. It therefore appears that the FDA proposal is within its statutory authority. Whether or not it is wise, and whether or not it meets the criteria laid down by OSTP in 2015, and is consistent with the 1986 Coordinated Framework, requires a closer look.

FDA does clarify that "in certain circumstances, based on the risk(s) they pose, we intend to exercise enforcement discretion with regard to … requirements for certain of these animals" and to require premarket approval. Exempted categories include non-food producing animals that are regulated by other agencies (like insects regulated by APHIS), animals used for research in contained facilities, as well as "other kinds or uses of animals based on our evaluation of risk factors." This seems reasonable. But FDA then lays out a process for review and approval of organisms whose genomes have been "intentionally altered" with newer breeding technologies (or, in fact, by any means whatsoever). This is not so reasonable.

This proposal may be consistent with FDA's authorities, but to exercise this authority over a category that bears no demonstrable or meaningful relationship to hazard or risk is a fundamental departure from long-standing U.S. policy. In the absence of any finding of hazard and elevated risk associated with the regulated categories vs. others not captured, the imposition of far reaching regulatory control measures, as the revised guidance described above would impose, is not justified. To justify such a radical departure from fundamental principles, FDA would have to provide a persuasive case for the existence of hazards that would otherwise lead to significant danger to human or environmental health. This they have not demonstrated.

A concrete example illuminates the problem. Some cattle have horns, while others do not. Both traits are widely distributed among bovine lineages. Dairy cattle, selected for millennia to be optimal milk producers, generally have horns. This adds a counterproductive element of hazard to dairy operations, and so the practice of de-horning dairy cattle is widespread. The resulting reduction in risk to humans is significant, but the animal welfare costs are non-trivial, and many dairy farmers would love to find a better way to dispense with horns. Gene editing has provided a solution that is widely lauded as superior and urgently needed.[42] While the usual opponents of agricultural innovation remain hostile, there is little doubt it would be welcomed by dairy farmers.[43] Independent academics, however, were dismayed at FDA's proposed rule, which creates unjustified

impediments to such innovations despite the fact that all the DNA and proteins involved have been part of the human food chain since the dawn of civilization, and there is no plausible hypothesis of risk.[44] Widely reported as a "crackdown" on new animal breeding technologies, objections to this absurdity have been immediate and widespread.[45] As animal biotechnology expert and U.C. Davis Professor Alison Van Eenennaam notes, FDA proposes to require that "each specific genomic alteration is considered to be a separate new animal drug subject to new animal drug approval requirements."[46] What does this mean? She explains that:

> "[E]very [single nucleotide polymorphism] is potentially a new drug, if associated with an intended alteration.… To put this in perspective, in one recent analysis of whole-genome sequence data from 234 taurine cattle representing 3 breeds, >28 million variants were observed, comprising insertions, deletions and single nucleotide variants. A small fraction of these mutations have been selected owing to their beneficial effects on phenotypes of agronomic importance. None of them is known to produce ill effects on the consumers of milk and beef products, and few impact the well-being of the animals themselves."

By contrast to FDA's proposal, guidance that would be consistent with three decades of U.S. policy and the 2015 OSTP mandate to review and update regulations could have asserted its jurisdiction as they have done, but announced that, in keeping with long-standing policy, they would exercise discretion and not routinely recommend (much less require) consultation from developers. They then would have had a strong basis to invite public comment to help in defining categories of intentional genomic alterations of potential concern that might justify consultation, and even possibly further regulatory action. This would have been reasonable, consistent with millennia of experience as well as our most up to date understanding of modern molecular biology, and defensible as policy.[47] It is not too late to get it right.

By contrast, in the matter of gene-edited mosquitoes intended to address diseases such as Zika, Dengue, Chikungunya, and others carried by their primary insect vector, *Aedes aegypti,* FDA has prudently stepped back from regulating and deferred to EPA.[48] This mosquito species appears to play an essential role in no ecosystem on earth, and in the Americas it is an invasive, colonizing species.[49] Its role as a vector of numerous human diseases and apparent lack of any signal virtues has led to calls for its extirpation as the deadliest animal on the planet.[50] This is the animal for which the term "pestilential" was coined.

As FDA made clear in its guidance document, the gene-edited mosquito developed to assist in suppressing the disease-carrying mosquito clearly meets the definition of "animal drug." But in declining to regulate the gene-edited variety developed to suppress human disease transmission, FDA has merely deferred to congressional intent, which defines it as a pesticide when "the product is intended to reduce the population of mosquitoes and does not make a disease prevention claim." So the real credit for this flash of sanity must be

chalked up to Congress. It will be important to track this closely to make sure that EPA does not stifle this innovation.

FDA should revise the present proposal and develop a new iteration to lay out its authority to regulate, and invite comment on the intention to exercise discretion for the products of modern genome modification techniques. FDA should invite comments to help define phenotypic categories of intentionally modified animals that represent potentially elevated hazard to human health or animal welfare; these may be appropriate subjects of regulatory oversight, based on data and experience. Congress and the public should follow EPA closely to ensure that the use of gene-edited mosquitoes to suppress human disease transmission of mosquito-borne diseases like Zika is not impeded.

FDA Should Withdraw Current Regulatory Proposal for Gene-Edited Plants

FDA also has a separate proposal to regulate gene-edited plants. In it, FDA asks: "Are there categories of genome edited plant varieties for which there are scientific bases to conclude that foods from such categories are unlikely to present food safety risks different from or greater than those for traditional plant breeding?"[51]

This turns the principles underlying the Coordinated Framework on their heads. For three decades, U.S. policy has been predicated on the finding, robustly corroborated by a mass of accumulated data and experience, that the hazards associated with crops and foods improved through biotechnology are not different from those with which we are familiar from other products of domestication and agriculture. For FDA to frame the question on the unsupported assertion that such hazards exist, and justify such a significant departure from long-standing policy, demands a demonstration of hazard it has not provided. The rest of the agency's proposal for gene-edited plants is similarly unfounded, at odds with long-standing policy, and specifically the mandate from OSTP, and subject to the same kinds of defects and illogic underlying its proposal with regard to gene-edited animals.

It is ironic that FDA should publish such draconian proposals for premarket review of gene-edited plants and animals even as the National Academy of Sciences was concluding a study highlighting the value of gene-editing technologies and their potential to improve human welfare through medical applications, including germline applications.[52] An interesting contrast is seen in the European Union, which has postponed yet again their review of the topic in an effort to avoid coming to a hasty, but ill-considered conclusion.[53]

FDA should withdraw the present proposal and develop a new proposal to lay out its authority to regulate, and invite comment on their intention to exercise discretion for the products of modern genome modification techniques in plants. FDA should invite comments to help define phenotypic categories of novel plants that represent potentially elevated hazard to human health or animal welfare that may be appropriate subject of regulatory oversight, based on data and experience.

EPA Should Not Prematurely Impede Gene-Silencing Technologies

Of all the agricultural biotechnology innovation fronts under EPA's stewardship, the one perhaps at highest risk of being drowned at birth is an ancient and wholly natural phenomenon known as RNAi. This refers to certain kinds of small RNA molecules, ubiquitous in nature, that play a role in regulating gene expression.[54] Scientists' understanding of the role and mechanisms by which these RNAi molecules function has increased to the point that they have begun to develop ways to use them to solve problems in agriculture, mainly by precisely shutting down the expression of specific genes. Like the other biotechnology-based approaches, this is very much in line with Rachel Carson's hopeful prediction in the last chapter of Silent Spring that specialists representing myriad disciplines across "the vast field of biology" would contribute their collective knowledge and creative inspirations to "a new science of biotic controls."[55]

Instead of focusing on whether regulators have access to the information they need to make sound decisions regarding safety, EPA's Scientific Advisory Panel repeatedly indulged interesting but essentially irrelevant diversions into topics about which it might be nice to know, but which would contribute little or nothing to the understanding and management of risk.

Scientific meetings on the topic have been held around the world, including several devoted to the specific challenge of identifying any unique risks associated with these technologies.[56] In considering the potential hazards of products of RNAi technology it is worth noting several salient facts: No proteins are produced, novel or otherwise; it is highly dependent on specific nucleic acid sequences; and there may or may not be a "donor organism" as is common with conventional transgenics.

At least two overarching areas of general agreement have emerged from scientific examinations of these issues: 1) No plausible risk hypotheses have been identified that are unique to RNAi mechanisms vs. other plants with similar phenotypes; 2) The same tests and protocols that are used for evaluating other genetically engineered plants will be sufficient for testing RNAi plants.

Of course, regulators have been close behind. EPA convened a Scientific Advisory Panel (SAP) in 2014 to look at these technologies and make recommendations.[57] They reached conclusions consistent with those summarized above. But EPA revisited the area in the context of specific product approvals in September 2016.[58] Its stated focus was:

> "[T]o seek guidance on the natural processes in the environment and within non-target organisms that serve to reduce or eliminate exposure; the importance of the potential for unexpected effects of dsRNA PIPs and RNAi in non-target organisms; and additional testing that EPA may require to reduce uncertainties in risk estimates and risk conclusions."

The outcome of this SAP was largely consistent with the two overarching scientific conclusions indicated above. And despite having "concurred with the Agency's human health risk assessment and considered it as robust and complete," panel members "suggested some 'omics' studies in order to address unknown sequence signatures or secondary dsRNA as a result of introducing intended RNAi" and "recommended the use of in vivo studies and experimental evidence to be performed at all times in the overall assessment in order to validate the 'omics' derived in silico results since in silico studies are not singularly conclusive."

The SAP repeatedly affirmed the adequacy of EPA's data analysis and preliminary findings of no unacceptable levels of risk. Despite the failure to identify any genuine hazard, or any plausible hypothesis of risk, the panel nevertheless repeatedly prescribed collection of more detailed data and analyses that might be appropriate if the objective were omniscience rather than hazard identification, risk assessment, and, where appropriate, risk management or mitigation. But instead of focusing on whether or not regulators have access to the information they need to make sound decisions regarding safety, SAP repeatedly indulged interesting but essentially irrelevant diversions into topics about which it might be nice to know, but which would contribute little or nothing to the task at hand.

The suggestion to incorporate "omics" methods into risk assessment is akin to recommending that a piano tuner abandon the use of a tuning fork to calibrate pitch, and instead generate reference tones by leaning with both forearms on the keyboard of a pipe organ. "Omics" represent rapidly growing and extremely exciting fields of science. But to understand the data they create, much less harness it for predictive utility in risk assessment, requires understanding and disentangling tens of thousands of complex, confounding, interacting variables affecting multiple imperfectly understood metabolic pathways at once. This is an idea that is years, perhaps decades away from being ready for prime time, as had been shown by one recent, ill-considered foray into this new landscape.[59]

The suggestion to incorporate "omics" methods into risk assessment is akin to recommending a piano tuner abandon the use of a tuning fork to calibrate pitch, and to generate reference tones instead by leaning with both forearms on the keyboard of a pipe organ.

Having said that, it remains true that while "current knowledge may well be sufficient to conduct case-specific risk assessments, it is clear that our current understanding of the susceptibility of organisms to environmental exposure to dsRNA, as well as the parameters which influence the likelihood of off-target gene effects are not complete. Additional research addressing these areas is warranted…."[60]

Traits already under development using these techniques include modified ripening, modified plant oil composition, improved potato starch composition, decaffeinated coffee, reduced lignin alfalfa (also applicable to trees for pulp or paper), improved nutritional value, and disease and pest resistance.[61] It does not appear that any rise to the level of presenting hazards that would justify regulatory measures beyond those already in place.

It is clear that for RNAi plants, USDA will continue to consider those containing DNA sequences from plant pests to be regulated articles; EPA will continue to have authority (under the Federal Insecticide, Fungicide, and Rodenticide Act) over plants with pesticidal properties; and FDA will continue to have authority to ensure food safety. This is appropriate and reasonable, and it is not at all clear that anything further is required.

EPA should set aside, for the foreseeable future, any notion of requiring "omics"-based data or analysis in risk assessments of any sort before appropriate baselines have been developed and robust and predictive risk assessment methodologies brought into practice. Further, EPA should set aside any proposals to regulate RNAi products until and unless a predictive, robust categorization of phenotypes of concern have been compiled, and categories of products within EPA's stewardship that would require risk management have been

demonstrated. The administration, through OSTP, should remind EPA that "precautionary" regulations based on hypothetical hazards unsupported by demonstrated risk are specifically proscribed by policy.

The Fish and Wildlife Service Should Adopt Science-Based, Wildlife-Friendly Stewardship Policies

If one set out to assemble a list of federal agencies that should favor innovations and technologies that benefit the environment, the Fish and Wildlife Service at the Department of the Interior would probably wind up near the top of that list. After all, the first of their "guiding principles" reads, "We are land stewards, guided by Aldo Leopold's teachings that land is a community of life and that love and respect for the land is an extension of ethics. We seek to reflect that land ethic in our stewardship and to instill it in others."[62]

With huge responsibilities, and hampered by years of inadequate funding, few agencies have more to gain from the remarkable biological advances of the last half century. Yet remarkably, and against the evidence, on July 17, 2014, the Chief of the National Wildlife Refuge System ignored existing U.S. policy and unilaterally proclaimed a prohibition on the use of neonicotinoid pesticides anywhere in the refuge system, and announced the phase out, to be completed by 2016, of any and all planting of crops improved through biotechnology. The illogic of this diktat has been noted.[63] These moves were unjustified and unsupported by data and experience then, and remain so today. It is time for them to be set aside and replaced by a positive vision based on data, experience, and reason.

The Fish and Wildlife Service should immediately withdraw the prohibition on biotech-improved seeds, consider the biotech innovations available to agriculture today, those likely to become available within the foreseeable future, and identify where there may be opportunities for further improvements in environmental stewardship through their application to reserve lands. The blanket prohibition on the use of neonicotinoid seed treatments should be set aside immediately, and the Fish and Wildlife Service should identify where their use might raise concerns for threatened or endangered species and prepare a comparative analysis of the potential relative impacts of the use of neonics versus their alternatives. This would provide a basis for case by case determinations going forward.

USTR Should Hold Trading Partners Accountable for Violating Trade Rules

A number of U.S. trading partners (customers) have a record of discriminating against crops improved through biotechnology in ways that are inconsistent with their obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures under the World Trade Organization (WTO).[64]

The United States, joined by Argentina, Australia, Brazil, Canada, Chile, China, Chinese Taipei, Colombia, El Salvador, Honduras, Mexico, New Zealand, Norway, Paraguay, Peru, Thailand, and Uruguay, led the effort to bring Europe back to the ranks of nations that honor their treaty obligations in their regulation of agricultural-biotechnology innovations. The EU lost the case, but implementation of the settlement agreement has not resulted in a WTO-compliant regulatory regime in Brussels and EU member states.[65]

The Office of the U.S. Trade Representative should launch formal conversations in Geneva with the EU to remedy this.

China has put in place a regulatory regime that falls short of its WTO obligations in a host of ways. [66] China has animated a system designed to manipulate global markets for parochial benefit and to disadvantage foreign trading partners. These transgressions are most often revealed to derive from parochial politics, or an evident intention to gain a preferential advantage by disrupting market forces to one party's advantage.[67] The United States has pursued diplomatic conversations with Beijing in search of resolution, but with no satisfaction to date. The United States recently initiated WTO challenges to China's agriculture subsidy programs and tariff-rate quota administration practices but has not yet used WTO leverage to help resolve biotech regulatory problems. The strategic benefits of bringing China into compliance will flow not only to The United States, but also to China and its other trading partners.[68]

The new administration should initiate consultations in Geneva with Beijing to identify and pursue measures to bring China's biotechnology regulatory regime into compliance with its WTO obligations. The administration should also renew conversations in Geneva aimed at overcoming European Union recalcitrance with regard to their own regime's failures to live up to their WTO obligations and the agreed-upon dispute resolution. If these talks fail, countermeasures should be implemented.

CONCLUSION

Innovations brought to agriculture through biotechnology have improved the lives of farmers around the world, enhanced their stewardship of the land, and benefitted consumers and the global environment. The principle obstacle to even greater and more widespread benefits is regulatory hurdles that benefit only a handful of special interests. Setting these barriers aside will unshackle the ability of innovators to solve challenges impeding our ability to meet the food, feed, and fiber needs of a growing population while reducing undesirable environmental impacts. The proposals in this paper provide a number of practical and easy ways this can be enabled. The time to act is now.

ENDNOTES

1. Alessandro Nicolia et al., "An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research," *Critical Reviews in Biotechnology* (March 2014): 77-88, DOI: 10.3109/07388551.2013.823595.
2. L. Val Giddings and Bruce M. Chassy, "Igniting Agricultural Innovation," *Science Progress* (July 1, 2009), https://scienceprogress.org/2009/07/igniting-agricultural-innovation.
3. Robert D. Atkinson and L. Val Giddings, "Clarifying Certain 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; Request for Information" (Comments to Docket No. FDA-2015-N-3403, November 5, 2015), http://www2.itif.org/2015-modernizing-cf-filing.pdf.
4. Clive James, "20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015" (ISAAA Brief No. 51, 2015), http://isaaa.org/resources/publications/briefs/51/default.asp.
5. Giovanni Tagliabue, "The EU Legislation on 'GMOs' Between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choices," *GM Crops & Food 8*, no. 1 (December 21, 2016), http://dx.doi.org/10.1080/21645698.2016.1270488.
6. Organization for Economic Cooperation and Development, "Recombinant DNA Safety Considerations" (Paris: OECD, 1986), ISBN 92-64-12857-3; OECD, "Safety Considerations for Biotechnology" (Paris: OECD, 1992), ISBN 92-64-13641-X; OECD, "Biotechnology, Agriculture and Food" (Paris: OECD, 1992), ISBN 92-64-13725-4; OECD, "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; OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" (Paris: OECD, 1993) ISBN 92-64-13859-5.
7. OECD, "Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles" (Paris, 1993), ISBN 92-64-13859-5.
8. L. Val Giddings, "U.S. National Academy of Science Reaffirms Safety of GMOs for 11th Time, But Confuses the Story on Yields," *Innovation Files,* June 3, 2016, http://www.innovationfiles.org/u-s-national-academy-of-science-reaffirms-safety-of-gmos-for-11th-time-but-confuses-the-story-on-yields.
9. A. Nicolia, et al., "An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research;" Jon Entine and JoAnna Wendel, "With 2000+ Global Studies Affirming Safety, GM Foods Among Most Analyzed Subjects in Science," Genetic Literacy Project, October 8, 2013, https://www.geneticliteracyproject.org/2013/10/08/with-2000-global-studies-confirming-safety-gm-foods-among-most-analyzed-subject-in-science; William Saletan, "Unhealthy Fixation—The War Against Genetically Modified Organisms is Full of Fearmongering, Errors, and Fraud. Labeling them Will Not Make You Safer," *Slate*, July 15, 2015, http://www.slate.com/articles/health_and_science/science/2015/07/are_gmos_safe_yes_the_case_against_them_is_full_of_fraud_lies_and_errors.html.
10. Marc Brazeau, "Research by Independent and Industry Scientists Reaches the Same Conclusions: GM Food is Safe According to Independent Studies", *Cosmos*, 15 September, 2014, https://cosmosmagazine.com/biology/gm-food-safe-according-independent-studies.
11. Daniel Norero, "More than 275 Organizations and Scientific Institutions Support the Safety of GM Crops," *Si Quiero Transgenicos*, November 1, 2016, http://www.siquierotransgenicos.cl/2015/06/13/more-than-240-organizations-and-scientific-institutions-support-the-safety-of-gm-crops.
12. European Commission, "Announcing the Release of 15 Year Study Incl 81 Projects/70M Euros, 400 Teams," press release, October 8, 2001, http://ec.europa.eu/research/fp5/eag-gmo.html and http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf.

13. David T. Kingsbury, "Regulation of Biotechnology: A Perspective on the US 'Coordinated Framework,'" in *Introduction of Genetically Modified Organisms Into the Environment*, ed. Harold A. Mooney and Giorgio Bernardi (SCOPE 44, John Wiley & Sons, New York, 1990), chapter 14.

14. European Union Council Directive 90/220/EEC on the Deliberate Release Into the Environment of Genetically Modified Organisms, EUR-Lex, April 23, 1990, http://eur-lex.europa.eu/legal-content/SK/TXT/?uri=CELEX:31990L0220; Robert Paarlberg, "The Politics of Precaution: Genetically Modified Crops in Developing Countries" (International Food Policy Research Institute, 2001), http://www.tinyurl.com/mpa98uz; Jon Entine (ed.), *Let Them Eat Precaution: How Politics Is Undermining the Genetic Revolution in Agriculture*, (Washington, D.C.: AEI Press, 2006, ISBN0-8447-4200-7), 203.

15. James, "20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015."

16. John Davison & Klaus Ammann,"New GMO Regulations for Old: Determining a New Future for EU Crop Biotechnology" *GM Crops & Food 8,* no. 1 (February 8, 2017), http://dx.doi.org/10.1080/21645698.2017.1289305; United Kingdom Advisory Committee on Releases to the Environment (ACRE), "Report by the Advisory Committee on Releases to the Environment Examining the EU Framework for Controlling Genetically Modified Organisms, Towards an Evidence-Based Regulatory System for GMOs," August 27, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239839/an-evidence-based-regulatory-system-for-gmos.pdf; "Why a Modern Understanding of Genomes Demonstrates the Need for a New Regulatory System for GMOs," August 27, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239852/genomes-and-gm-regulation.pdf; Giovanni Tagliabue, "The EU Legislation on 'GMOs' Between Nonsense and Protectionism: An Ongoing Schumpeterian Chain of Public Choices", *GM Crops & Food 8*, no. 1 (December 21, 2016), http://dx.doi.org/10.1080/21645698.2016.1270488.

17. Gregory Conko et al., "A Risk-Based Approach to the Regulation of Genetically Modified Organisms," *Nature Biotechnology* 34 (May 6, 2016): 493–503, http:dx.doi.org/10.1038/nbt.3568; L. Val Giddings and Bruce M. Chassy, "Igniting Agricultural Innovation" (*Science Progress*, July 1, 2009), https://scienceprogress.org/2009/07/igniting-agricultural-innovation/.

18. Office of Science and Technology Policy (OSTP), "Update to the Coordinated Framework" (OSTP, 1992, 57 FR at 6753).

19. Gregory Conko et al., "A Risk-Based Approach to the Regulation of Genetically Modified Organisms," *Nature Biotechnology* 34 (May 6, 2016): 493–503, http:dx.doi.org/10.1038/nbt.3568; L. Val Giddings and Bruce M. Chassy, "Igniting Agricultural Innovation" (*Science Progress*, July 1, 2009).

20. Office of Science and Technology Policy (OSTP), The White House, "Coordinated Framework for Regulation of Biotechnology," (51 FR at 23302-23303, 1992 Update to the Coordinated Framework at 57 FR at 6753, June 26, 1986), https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

21. The White House, Office of the Press Secretary, "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," news release, January 30, 2017, https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling.

22. Kingsbury, "Regulation of Biotechnology."

23. "Lawsuit Involving Roundup Ready Alfalfa," Monsanto Company, accessed March 20, 2017, http://www.monsanto.com/newsviews/pages/roundup-ready-alfalfa-supreme-court.aspx.

24. "Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System" (Washington, D.C.: OSTP, January 4, 2017), https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory; "Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology" (Washington, D.C.: OSTP, 2017),

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf; "National Strategy for Modernizing the Regulatory System for Biotechnology Products" (Washington, D.C.: OSTP, September 2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

25. Wilhelm Klümper and Matin Qaim, "A Meta-Analysis of the Impacts of Genetically Modified Crops," *PLoS ONE 9*, no. 11 (November 2014), http:dx.doi.org/10.1371/journal.pone.0111629; Clive James, "Global Status of Commercialized Biotech/GM Crops" (ISAAA Brief No. 51, 2015), http://isaaa.org/resources/publications/briefs/51/executivesummary/default.asp.
26. Opponents cite numerous supposed examples of harms. Without exception, they either fail under scrutiny, or result from factors unrelated to the biotech-derived origin of the phenotype involved.
27. Steven H. Strauss, et al., "Strangled at Birth? Forest Biotech at the Convention on Biological Diversity," *Nature Biotechnology 27,* no. 6 (2009): 519-527, http:dx.doi.org/10.1038/nbt0609-519; L. Val Giddings, "Transgenic Plants on Trial in the USA," *Current Opinion in Biotechnology 7,* (1996): 275-280.
28. Agnes E. Ricroch and Marie-Cécile Hénard-Damave, "Next Biotech Plants: New Traits, Crops, Developers and Technologies for Addressing Global Challenges," *Critical Reviews in Biotechnoly*, (February 2, 2015), http:dx.doi.org/10.3109/07388551.2015.1004521; Phillips McDougall, "The Cost and Time Involved in the Discovery, Development and Authorisation of a New Plant Biotechnology Derived Trait," *A Consultancy Study for Crop Life International*, September 2011, at https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf.
29. "Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture: Modernizing the Regulatory System for Biotechnology Products," (Washington, D.C.: OSTP, July 2, 2015), https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_me mo_final.pdf; Nicholas Kalaitzandonakes, Julian M. Alston, and Kent J. Bradford, "Compliance Costs for Regulatory Approval of New Biotech Crops," *Nature Biotechnology 25* (2007): 509-511, http:dx.doi.org/10.1038/nbt0507-509.
30. "Food for Human Consumption and Animal Drugs, Feeds, and Related Products; Foods Derived from New Plant Varieties; Policy Statement," Food and Drug Administration, *Federal Register 57*, no. 104 (May 29, 1992): p. 22984, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm.
31. Ibid.
32. "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms," Animal and Plant Health Inspection Service, *Federal Register 82*, no. 12 (January 19, 2017): pp. 7008-7039, https://www.regulations.gov/document?D=APHIS-2015-0057-0001.
33. "Environmental Impact Statement; Introduction of the Products of Biotechnology: Extension of the Comment Period" Animal and Plant Health Inspection Service, *Federal Register 81*, no. 44 (March 7, 2016): p. 11738, https://www.regulations.gov/#!documentDetail;D=APHIS-2014- 0054-0023.
34. "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms," Animal and Plant Health Inspection Service, *Federal Register 82*, no. 12 (January 19, 2017): pp. 7008-7039, https://www.regulations.gov/document?D=APHIS-2015-0057-0001.
35. The purpose of regulation is to mitigate or manage the risk of exposure to hazards. The degree of regulation must be proportional to the level of hazard being managed. Hazards that may be associated with biotechnology products are not different in kind from those of other production methods with which we are familiar. Regulation must therefore focus on the qualities of a product that may lead to exposure to a hazard rather than the process used to produce the product, which is irrelevant to hazard. Existing regulatory authorities are generally adequate to capture the hazards of new products in

agriculture, biomedicine, and research and development in various spheres; "Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms" (Animal and Plant Health Inspection Service).

36. Plant Protection Act of 2000, Pub. L. No. 106-224, 114 Stat. 438 (2000) Sec. 403. Definitions at https://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/PPAText.pdf.
37. "Right to Know Center," Just Label It Campaign, accessed March 17, 2017, http://www.justlabelit.org/right-to-know-center; "Why Consumers Pay More for Organic Foods? Fear Sells and Marketers Know It." *Academics Review*, April 7, 2014, http://academicsreview.org/2014/04/why-consumers-pay-more-for-organic-foods-fear-sells-and-marketers-know-it; Bruce Chassy et al., "Organic Marketing Report," *Academics Review*, April 7, 2014, http://academicsreview.org/wp-content/uploads/2014/04/AR_Organic-Marketing-Report_Print.pdf.
38. L. Val Giddings, "Mandatory 'GMO' Labeling Proposals Are Failing Despite Unprecedented Efforts and Expenditures," *Innovation Files*, March 10, 2015, http://www.innovationfiles.org/mandatory-gmo-labeling-proposals-are-failing-despite-unprecedented-efforts-and-expenditures.
39. L. Val Giddings, "Our Long, National GMO Labeling Nightmare Is Over," *Innovation Files*, July 14, 2016, http://www.innovationfiles.org/our-long-national-gmo-labeling-nightmare-is-over.
40. Karen Daynard, "Labelling of Non-GMO Products Shamefully Ignores Reality," *Troy Media*, March 7, 2017, http://www.troymedia.com/2017/03/02/labelling-of-non-gmo-products-shamefully-ignores-reality; Trevor Charles, "Despite What the Marketing Department Says, the Non-GMO Label IS a Declaration of Opposition to GMO Science," February 27, 2017, https://medium.com/@trevorcharles/despite-what-the-marketing-department-says-the-non-gmo-label-is-a-declaration-of-opposition-to-gmo-c2e7c822b548.
41. "Regulation of Intentionally Altered Genomic DNA in Animals Draft Guidance," (U.S. Food and Drug Administration, Guidance for Industry no. 187, January 15, 2009), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf.
42. Daniel F. Carlson et al., "Production of Hornless Dairy Cattle from Genome-Edited Cell Lines," *Nature Biotechnology 34* (May 6, 2016): 479–481, http:dx.doi.org/10.1038/nbt.3560.
43. Kat McGowan, "This Scientist Might End Animal Cruelty—Unless GMO Hardliners Stop Him," *Mother Jones,* September/October, 2015, http://www.motherjones.com/environment/2015/07/fahrenkrug-genetic-modification-gmo-animals.
44. Alison Van Eenennaam, "FDA Seeks Public Comments on Regulation of Genetically Altered Animals," *BioBeef Blog*, January 22, 2017, http://biobeef.faculty.ucdavis.edu/2017/01/22/fda-seeks-public-comments-on-regulation-of-genetically-altered-animals.
45. Kristen V. Brown, "The FDA's Newly Proposed GMO Rules Are Nonsense," *Gizmodo*, January 24, 2017, http://gizmodo.com/the-fdas-newly-proposed-gmo-rules-are-nonsense-1791519749; Ron Bailey, "Scientifically Absurd Proposed FDA Regulations on Genetically Improved Livestock Should Be Withdrawn Immediately," *Reason*, January 25, 2015, https://reason.com/blog/2017/01/25/scientifically-absurb-proposed-fda-regul; Amy Maxmen, "Gene-Edited Animals Face US Regulatory Crackdown," *Nature News*, January 19, 2017, http://www.nature.com/news/gene-edited-animals-face-us-regulatory-crackdown-1.21331.
46. Alison Van Eenennaam, "FDA Seeks Public Comments on Regulation of Genetically Altered Animals," *BioBeef Blog*, January 22, 2017, http://biobeef.faculty.ucdavis.edu/2017/01/22/fda-seeks-public-comments-on-regulation-of-genetically-altered-animals/.
47. Werner Arber, "Genetic Engineering Compared to Natural Genetic Variations," *New Biotechnology 27,* no. 5 (2010): 517–521, http:dx.doi.org/10.1016/j.nbt.2010.05.007.
48. "Mosquito Borne Disease," Oxitec, Ltd., accessed March 14, 2017, http://www.oxitec.com/mosquito-borne-disease.

49. Sir S. Rickard Christophers, "Aedes Aegypti (L.)," in *The Yellow Fever Mosquito: Its Life History, Bionomics, and Structure* (NY: Cambridge University Press, 1960), pp. xii, 739.

50. Bill Gates, "The Deadliest Animal in the World," *GatesNotes*, April 25, 2014, https://www.gatesnotes.com/Health/Most-Lethal-Animal-Mosquito-Week; Daniel Engber, "Let's Kill All the Mosquitoes," *Slate*, January 29, 2016, http://www.slate.com/articles/health_and_science/science/2016/01/zika_carrying_mosquitoes_are_a_global_scourge_and_must_be_stopped.html.

51. "Genome Editing," Food and Drug Administration, *New Plant Federal Register 82*, no. 12 (January 19, 2017): pp. 6564-6566, https://www.federalregister.gov/documents/2017/01/19/2017-00840/genome-editing-in-new-plant-varieties-used-for-foods-request-for-comments.

52. U.S. National Academy of Sciences, *Human Genome Editing: Science, Ethics, and Governance* (2017), https://www.nap.edu/catalog/24623/human-genome-editing-science-ethics-and-governance.

53. Jackie Bird, "EU Admits More Delay on Rules for New Plant Breeding Techniques," *Agrow*, February 9, 2017, https://www.agra-net.com/agra/agrow/markets-regulatory/europe/eu-admits-more-delay-on-rules-for-new-plant-breeding-techniques--1.htm; "Gene Editing in Legal Limbo in Europe," *Nature 542*, February 23, 2017, http:dx.doi.org/10.1038/542392a.

54. Gregory J. Hannon, "RNA Interference," *Nature 418* (2002): 244–251, http:dx.doi.org/10.1038/418244a; Andrew F. Roberts, "Risk Assessment and Regulation of RNAi Pesticides in the Context of GE Plants and the Regulation of Novel Plant Breeding Techniques in the United States," Center for Environmental Risk Assessment, September 19, 2013, http://www.cera-gmc.org/files/cera/uploads/roberts_2.pdf.

55. Rachel Carson, *Silent Spring* (New York: Houghton Mifflin, 1962), Chapter 17 ("The Other Road"): "A truly extraordinary variety of alternatives to the chemical control of insects is available. Some are already in use and have achieved brilliant success. Others are in the stage of laboratory testing. Still others are little more than ideas in the minds of imaginative scientists, waiting for the opportunity to put them to the test. All have this in common: they are biological solutions, based on understanding of the living organisms they seek to control, and of the whole fabric of life to which these organisms belong. Specialists representing various areas of the vast field of biology are contributing—entomologists, pathologists, geneticists, physiologists, biochemists, ecologists—all pouring their knowledge and their creative inspirations into the formation of a new science of biotic controls."

56. "Problem Formulation for the Environmental Risk Assessment of RNAi Plants" (Center for Environmental Risk Assessment, Proceedings of the Conference on Problem Formulation for the Environmental Risk Assessment of RNAi Plants, Washington, D.C.: June 1-3, 2011), http://cera-gmc.org/docs/cera_publications/pub_08_2011.pdf; Roberts, "Risk Assessment and Regulation of RNAi Pesticides."

57. U.S. Environmental Protection Agency (EPA), Meeting Materials for the January 28, 2014, Scientific Advisory Panel, https://www.epa.gov/sap/meeting-materials-january-28-2014-scientific-advisory-panel.

58. EPA, FIFRA Scientific Advisory Panel Minutes No. 2016-02, "A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding: RNAi Technology: Human Health and Ecological Risk Assessments for SmartStax PRO" (FIFRA Scientific Advisory Panel Meeting Held at EPA Conference Center, September 27-28, 2016), https://www.researchgate.net/publication/312479395_RNAi_Technology_Human_Health_and_Ecological_Risk_Assessments_for_SmartStax_PRO.

59. Alison Van Eenennaam, "I Would Appreciate Your Comment on a Recently Published Study," *BioBeef Blog,* January 3, 2017, http://biobeef.faculty.ucdavis.edu/2017/01/03/i_would_appreciate_your_comments, critique of Robin Mesnage et al., "Multiomics Reveal Non-Alcoholic Fatty Liver Disease in Rats Following Chronic Exposure to an Ultra-Low Dose of Roundup Herbicide," *Scientific Reports* 7, no. 39328 (2017), http:dx.doi.org/10.1038/srep39328.

60. Roberts, "Risk Assessment and Regulation of RNAi Pesticides."

61. Ibid.

62. "Mission Statement," National Wildlife Refuge System, Fish and Wildlife Service, U.S. Department of the Interior, accessed February 20, 2017,https://www.fws.gov/refuges/about/mission.html.

63. L. Val Giddings, "GMOs, Neonicotinoids, and Aldo Leopold's Land Ethic: The Fish & Wildlife Service Brings a 'Whole Foods' Approach to Wildlife While Shooting Itself in Our Foot," *Innovation Files*, October 21, 2014, http://www.innovationfiles.org/gmos-neonicotinoids.

64. L. Val Giddings, "The Price of Folly – Trade Disruptions Caused by Flawed Agricultural Biotechnology Regulations," *Innovation Files*, December 15, 2016, https://itif.org/publications/2016/12/15/price-folly-trade-disruptions-caused-flawed-agricultural-biotechnology.

65. World Trade Organization Dispute Settlement, DS 291, "European Communities — Measures Affecting the Approval and Marketing of Biotech Products" (January 17, 2008), https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

66. Nicholas, L Kalaitzandonakes. et al., "The Impact of Asynchronous Approvals for Biotech Crops on Agricultural Sustainability, Trade, and Innovation" (Council for Agricultural Science and Technology [CAST]. 2016, *Commentary QTA2016-2*, CAST: Ames, Iowa), http://www.cast-science.org/download.cfm?PublicationID=284473&File=1e308085783bb68d27aec1a20553345703c6TR.

67. Robert Paarlberg, *Food Politics: What Everyone Needs to Know,* (Oxford University Press, 2010), 218.

68. "United States Files Dispute Challenging Chinese Agricultural Subsidies," World Trade Organization, September 14, 2016, https://www.wto.org/english/news_e/news16_e/ds511rfc_14sep16_e.htm; Robert D. Atkinson, Nigel Cory, and Stephen Ezell, "Stopping China's Mercantilism: A Doctrine of Constructive, Alliance-Backed Confrontation" (Information Technology and Innovation Foundation, March 2017), https://itif.org/publications/2017/03/16/stopping-chinas-mercantilism-doctrine-constructive-alliance-backed.

ACKNOWLEDGMENTS

The author wishes to thank the following individuals for providing input to this report: Klaus Ammann, Wayne Parrott, C.S. Prakash, and Bruce Chassy. Any errors or omissions are the author's alone.

ABOUT THE AUTHOR

L. Val Giddings is a senior fellow at ITIF with three decades of experience in science and regulatory policy relating to biotechnology innovations in agriculture and biomedicine. He is also president and CEO of PrometheusAB, Inc., providing consulting services on biotechnology issues to governments, multilateral organizations, and industry clients. Before founding PrometheusAB, he served eight years as vice president for food and agriculture at the Biotechnology Industry Organization and a decade as a regulatory official with the U.S. Department of Agriculture. Giddings received his Ph.D. in genetics and evolutionary biology from the University of Hawaii in 1980.

ABOUT ITIF

The Information Technology and Innovation Foundation (ITIF) is a nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized as one of the world's leading science and technology think tanks, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress.

FOR MORE INFORMATION, VISIT US AT WWW.ITIF.ORG.