Agricultural biotechnology regulations are a mess — Here's how Trump can unshackle innovation

[The following is the first part of an Information Technology and Innovation Foundation report.]

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

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." 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. Not all of it has been followed yet, leaving numerous opportunities for improvement by the new administration. 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. 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.

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

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. 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)."

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. 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. It is noteworthy that based on their findings, independent academics and industry scientists reach identical conclusions. For these reasons, more than 275 scientific organizations have embraced the global scientific consensus on the safety of GM crops and foods. 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."

"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.

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. 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. The harshest condemnations of the failed European “precautionary” approach have come from Europeans.

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. Regulations first laid down in 1987 have been significantly adapted to experience only once, in 1992. Since then, the disparity between the level of risk and the degree of regulation has expanded dramatically. 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. 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.

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.

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:

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> “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.

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.

[Read the rest of the report here.]

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Val Giddings is Senior Fellow at the Information Technology & Innovation Foundation. He previously served as vice president for Food & Agriculture of the Biotechnology Industry Organization (BIO) and at the Congressional Office of Technology Assessment and as an expert consultant to the United Nations Environment Programme, the World Bank, USDA, USAID, and companies, organizations and governments around the world. Follow him on twitter @prometheusgreen.

For more background on the Genetic Literacy Project, read GLP on Wikipedia