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Streamlining USDA Regulation of Gene Editing to Benefit US Agriculture

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Executive Summary

Feeding a growing world population and adapting agricultural production to a changing climate is a significant challenge that can be mitigated through the use of new gene-editing technologies in crops. However, current regulatory processes are overly burdensome and confusing, have limited scientific innovation, and prevent the widespread production of genetically engineered (GE) crops. To address this, we propose the consolidation of federal regulatory communication into the USDA, a regulatory exemption of GE plants that have a previously-reviewed trait and mechanism of action, and a unified and detailed web platform for applications for commercial approval.

I. Gene Editing: An Emerging Technology That Could Feed the World

Agricultural production is increasingly strained by changing climate and population growth. With the global population expected to reach 9.8 billion by 2050, farmers will have to grow about 70% more food than current production.¹ Meeting this challenge will require scientific advances that bridge the gap between conventional techniques and new technologies in plant breeding.

Selective breeding has been used for thousands of years in the domestication of crops to artificially select desired traits in foods. More recent breeding techniques have used chemicals to induce random DNA mutations, hoping that one of these mutations is involved in a trait of interest and spending decades attempting to remove unwanted random mutations through breeding. Because these techniques do not introduce foreign DNA into a plant, they are not considered to be genetically engineered.

¹ "Fast Facts About Agriculture & Food." American Farm Bureau Federation. <https://www.fb.org/newsroom/fast-facts>. Accessed 13 Apr. 2020.

In the past decade, efforts to select for desirable plant traits have drastically increased with new biotechnology to more quickly and precisely introduce changes at the genetic level.² New gene-editing techniques like CRISPR-Cas9 have revolutionized the field, allowing plant breeders to target traits of value with greater speed and precision. This revolution has also allowed smaller, non-traditional groups to enter the market. While the creation of GE crops was previously done by research universities and industrial agriculture companies, it is increasingly undertaken by small to mid-sized innovators.

As a net exporter of agricultural products, particularly to developing countries, the US could see significant economic benefits from growth in the agricultural sector.³ Despite the fact that the US plants the largest acreage of GE crops in the world (40% of the global total), the development of GE crops in the US has not been able to reach its full potential.⁴ This is primarily due to costs associated with the complicated regulatory process.

It is expensive to bring a GE crop from the laboratory bench to commercial distribution, averaging \$130 million and 7 years (13 years including R&D) for a single crop in the US.⁵ For this reason, GE research has focused on staple crops like corn and wheat. However, the US exports a much larger variety of crops--in California alone, the grape, almond, and pistachio markets are significant contributors to the state's multibillion-dollar agriculture economy.^{3,6} The proliferation of new, cheaper gene-editing techniques that can be applied to these crops and the rapid growth in developers have therefore raised issues around the regulation of genetically modified plants.

II. Existing Federal Policy Framework

GE plant regulatory policy is primarily created and implemented by three federal agencies: the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA). These agencies regulate different types and features of GE crops, depending on the specific use of the crop and how it was produced. Their responsibilities regarding GE crops are outlined by the 2017 Update to the Coordinated

² Kuzma, J. "Regulating Gene-Edited Crops." Issues in Science and Technology. 2018. <https://issues.org/regulating-gene-edited-crops/>. Accessed 12 Apr. 2020.

³ Kraybill, D., Mercier, S., Glauber, J. "How the United States Benefits from Agricultural and Food Security Investments in Developing Countries." The Association of Public & Land-grant Universities. <https://www.aplu.org/library/how-the-united-states-benefits-from-agricultural-and-food-security-investments-in-developing-countries/file>. Accessed 13 Apr. 2020.

⁴ James, C. "Global Status of Commercialized Biotech/GM Crops: 2014." The International Service for the Acquisition of Agri-biotech Applications. 2014. <https://isaaa.org/resources/publications/briefs/49/toptenfacts/default.asp>. Accessed 12 Apr. 2020.

⁵ "What does it take to bring a new GM product to market?" <https://gmo.geneticliteracyproject.org/FAQ/what-does-it-take-to-bring-a-new-gm-product-to-market/>. Accessed 13 Apr. 2020.

⁶ Kuzma, J. "Regulating Gene-Edited Crops." Issues in Science and Technology. 2018. <https://issues.org/regulating-gene-edited-crops/>. Accessed 30 May. 2020.

Framework for the Regulation of Biotechnology⁷ and the 2019 Executive Order 13874 (EO13874).⁸

Here, we focus on the role of the USDA in biotechnology regulation as it is the agency with the most recent updated regulations in response to EO13874. Within the USDA, the Animal and Plant Health Inspection Service (APHIS) is the main agency responsible for regulating GE crops and other biotechnology products that may pose a risk to agricultural plant and animal health. For example, in November 2018, APHIS decided that a *Pichia kudriavzevii* mutant manufactured by Lygos, Inc. should be regulated.^{9,10} This was in accordance with APHIS' mission to regulate potential plant pests; *P. kudriavzevii* is a fungus known to cause disease in citrus and grapes.

APHIS proposed an updated regulatory policy in June 2019: the Movement of Certain Genetically Engineered Organisms.¹¹ While still in review (as of March 12, 2020),¹² this rule aims to reduce "regulatory burden for developers of organisms that are unlikely to pose plant pest risks". One key element is allowing developers to self-determine exemption for their GE plant by comparing it to all plants with completed regulatory reviews, with the option to request written confirmation from APHIS. To support accurate self-determinations, APHIS proposes creating a publicly-accessible database containing the results of all completed regulatory status reviews, including each reviewed combination of plant, trait, and mechanism of action (MOA, or the way a trait is expressed).

While recent federal actions have sought to clarify and modernize regulation, significant barriers to scaling up the production of GE products still exist. Together, the 2017 Coordinated Framework Update and EO13874 outline the need for a unified and straightforward process for the approval of new biotechnologies, but the specifics of such a process are weakly defined at present. While EO13874 calls for the creation of a Unified Biotechnology Web-based Platform, the current iteration is a website with internal redundancies and links to a confusing web of

⁷ "2017 Update to the Coordinated Framework for the Regulation." https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf. Accessed 12 Apr. 2020.

⁸ "Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products." 11 Jun. 2019, <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>. Accessed 12 Apr. 2020.

⁹ "Am I Regulated CBI-Deleted Copy, 18-208-01." USDA APHIS. 17 Oct. 2018, https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-208-01_a3_air_cbidel.pdf. Accessed 12 Apr. 2020.

¹⁰ "Am I Regulated Response, 18-208-01." USDA APHIS. 29 Nov. 2018, https://www.aphis.usda.gov/biotechnology/downloads/reg_loi/18-208-01_air_response_signed.pdf. Accessed 12 Apr. 2020.

¹¹ "Movement of Certain Genetically Engineered Organisms." 6 Jun. 2019, <https://www.federalregister.gov/documents/2019/06/06/2019-11704/movement-of-certain-genetically-engineered-organisms>. Accessed 13 Apr. 2020.

¹² "Updating Biotechnology Regulations." USDA APHIS. 12 Mar. 2020, <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision>. Accessed 12 Apr. 2020.

regulations, leaving the user frustrated and with limited additional information. Updated regulation is in flux, with the relevant agencies still developing their updated approach.

III. Policy Recommendations

We recommend several measures that can be taken by the USDA to address the above shortcomings and provide a clear path to safely and efficiently bring GE crops to market.

First, the USDA must update federal regulations to clarify and consolidate communication regarding the GE plant approval process. The current APHIS proposal, albeit improved, fails to simplify the regulatory process in a way that makes it accessible to small to medium sized innovators who have no previous experience with regulation. Federal agencies should coordinate their response to inquiries in addition to improvement of the aforementioned unified web platform. Since the USDA is currently the designated funder of the consolidated web-based platform (by EO13874), we propose assigning coordination to the USDA. This agency is best poised to oversee regulations by using its EO13874-mandated appropriations to develop and manage a clearinghouse for all GE-related inquiries. The USDA would thereby serve as a liaison between all three federal regulators and innovators, benefitting innovators and the agencies alike.

Second, while we support APHIS' creation of a database of all completed regulatory reviews to help developers make self determinations, we argue that the proposed use does not go far enough. APHIS states that developers whose GE plant has the same plant-trait-MOA combination as a previously-reviewed organism could easily self determine non-regulation by APHIS.¹³ Developers must request a review or permit if their GE plant has not been previously reviewed and does not fit into another exempted category. We argue that this exemption for previously-reviewed plant-trait-MOA combinations applies to few GE plants and provides no significant relief of regulatory burden. Instead, we propose that APHIS extend this exemption to GE plants with a previously-reviewed trait-MOA combination that is combined with a new plant. If a trait-MOA combination is reviewed in one plant and determined to cause no plant pest risk, then it is unlikely to cause a plant pest risk in a different plant. This is consistent with APHIS' attempt to create more risk-based regulation and reduce regulatory burden.

Third, the federal government, led by the USDA, should push an agenda that supports implementation of clarifying web-based platforms. EO13874's recommended Unified Biotechnology Web-Based Platform provides the foundation for improvement, but does not go far enough. The platform should contain more than just descriptions for the regulatory roles of

¹³ "Movement of Certain Genetically Engineered Organisms." 6 Jun. 2019, <https://www.federalregister.gov/documents/2019/06/06/2019-11704/movement-of-certain-genetically-engineered-organisms>. Accessed 14 Apr. 2020.

the USDA, FDA, and EPA as it does now.¹⁴ While the site also allows users to contact the agencies with questions regarding regulation, a far better use of the platform would be an avenue to submit an application for commercial approval of a biotechnology product. The web platform currently states that “[each] regulatory agency has its own specific application procedures” but does little more than offer links to each website.¹⁵ If the goal of the current regulatory modernization is to streamline and clarify the process of GE plant approval, then the unified web platform should serve as a tool to help small and midsize producers begin the process of product approval.

IV. Potential Limitations

By simplifying the GE regulatory requirements, the process of taking a GE crop to market will be more transparent and navigable for small to medium sized companies. However, a policy that extends exemptions will also benefit established companies with proprietary traits that have already undergone federal inspection and are better poised to scale up those traits into new crops. This may make it harder for small innovators to succeed in the market.

If new proposals are implemented, the USDA will absorb new roles for the overall efficiency of the regulatory process. However, the agency will also have a greatly decreased regulatory burden since many new gene-edited crops will be exempt from USDA regulation. Still, the USDA may not have sufficient capacity to handle requests without a corresponding increase in funding to hire personnel to manage these new roles.

V. Conclusion

We recommend the regulatory exemption of GE plants with a previously-reviewed trait-MOA combination, a unified and detailed web platform for applications for commercial approval, and the consolidation of federal regulatory communication to the USDA. If implemented, our proposals will reduce regulatory burdens on companies and researchers seeking to bring new products to market without eliminating meaningful safety and consumer protection standards. An extension of the regulatory exemption to more GE plant products will likely bring the greatest benefit to large firms, since it will be easier for them to adjust their techniques to bring the same trait to different plants. It will also allow the USDA more time to focus on regulation of novel GE crops, which have completely new traits or mechanisms of action. Meanwhile, the proposals to consolidate oversight and implement regulations in a clear way will accommodate smaller firms and researchers, who do not have legal staff or experience with handling federal regulations. These stakeholders will face lower financial and time constraints.

¹⁴ “The Unified Website for Biotechnology Regulation.” USDA, FDA, and EPA. <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home>. Accessed 10 Apr. 2020.

With a clearer and more streamlined process, the US will see a proliferation of GE crops. Small to mid-sized innovators may find niche markets in editing crops that lag in breeding efficiency. These benefits will be particularly fruitful for specialty crops like grapes, almonds, and pistachios that are ripe for rapid advancements. The US agricultural sector also awaits innovations that will increase adaptation to the worsening threats of climate change such as fire, drought, and flooding. If federal policy keeps up with these advancements by streamlining and demystifying regulations, the United States will benefit from crops that are safer, cheaper, and more resilient.