POLICY FORUM

BIOTECH REGULATION

Community-led governance for gene-edited crops

A post–market certification process could promote transparency and trust

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In August 2020, the U.S. Department of Agriculture (USDA) began implementing new regulations for genetically engineered (GE) organisms, the SECURE (sustainable, ecological, consistent, uniform, responsible, efficient) rule (*1*). SECURE marks the first comprehensive reform of U.S. genetically modified (GM) crop oversight since the agency's initial approach in 1987 (and after several unsuccessful attempts to update its regulations over the past two decades) [see (*1*) for definitions of GE and GM crops]. The USDA estimates that under this substantial departure from its prior approach, 99% of GM plants will be exempt from premarket field testing and data-based risk assessment requirements (*2*). This rule has potential implications for international trade as the European Union (EU) is taking a more stringent approach to regulating gene-edited crops and will track them in the marketplace (*3*). We are also concerned that developers of gene-edited and GM (i.e., biotech) crops, who largely support the SECURE approach (*4*), are reconstituting the same conditions that led to public rejection and mistrust of the first generation of GM foods (*3*). To earn greater public trust and transparency, as well as enhance the ability to track gene-edited plants entering the marketplace, we therefore propose a "community-led and responsible governance" (CLEAR-GOV) coalition and certification process for biotech crop developers based on transparent information sharing about current and anticipated market uses of biotech crop varieties.

REGULATION OF BIOTECH CROPS

After a series of stakeholder meetings, the USDA Animal Plant Health Inspection Service (APHIS) proposed the new SECURE rule in mid-2019 and finalized the rule in May 2020. SECURE substantially changes the approach adopted by USDA-APHIS to regulating biotech crops. Because earlier generations of GM plants were engineered using plant-pest DNA sequences from *Agrobacterium*, the use of these sequences provided a regulatory basis for the USDA under its plant-pest regulatory authorities. But because this is no longer the only method used to genetically engineer plants, several plants have in the past decade gone unregulated by the USDA. SECURE recenters the regulations on "plant-pest risk" (defined as "the potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest"), as opposed to the mere presence of plant-pest sequences. We view this as positive, as many DNA fragments from plant pests have little to do with environmental or agricultural risk. Another positive attribute of SECURE is that if a plant contains a combination of a plant-trait–mechanism of action (MOA) that has already been reviewed by the USDA, the new product would be exempt from review. This allows the agency to expend limited resources on new biotech crops rather than variations of previous ones.

However, the SECURE rule has several shortcomings. First, in comparison to a proposed 2017 rule, it abandons a focus on noxious weed risks under the Plant Protection Act. A demonstrated category of risks from the first generation of GE crops centered around the evolution of resistant weeds (*5*). Although the USDA will review the "weedy impacts of the plant and its sexually compatible relatives" during its regulatory status review (RSR), if the crop does not pose an increased plant-pest risk, it is not subject to regulation [(*1*), p. 29835].

Second, it puts forth several regulatory exemptions based on whether the genetic change could conceivably have been achieved through conventional breeding, and these exemptions are not necessarily risk-based (*6*). Some gene-edited crops with single point mutations—or other changes from gene editing that could conceivably be found in the biotech crop's gene pool—may pose substantial risk. For example, small DNA mutations can lead to changes in the amounts of plant chemicals that are harmful to nontarget insects or human health (*7*). A 2016 report by the U.S. National Academies of Science, Engineering, and Medicine (NASEM) suggested screening both conventionally bred and GM crops for potential risks (6). Another NASEM report justified a closer look at GM crops in regulation given public concern and our shorter history with consuming them (*8*). Regulating new gene-edited crops makes sense from risk-based and public-legitimacy standpoints.

Third, and most important for our vision of CLEAR-GOV, most biotech crops will not go through regulatory pathways that require formal risk assessment, and opportunities for peer-review and public input are lacking. For example, developers will be able to self-determine whether their GE crop falls into an exempt area with no USDA-APHIS review or by requesting a letter of confirmation from USDA-APHIS. The USDA describes the confirmation process as "functionally equivalent to" the existing "Am I Regulated?" (AIR) process that has exempted over 100 GM crops, including many gene-edited crops, from USDA-APHIS regulation [(*1*), p. 29801]. Neither the AIR nor the new SECURE process provides opportunities for public, stakeholder, or expert input.

If a biotech crop is not exempt through the self-exemption or USDA confirmation process, it will undergo an RSR, a key decision point for whether a new biotech crop is regulated. This involves a scientific review of what is known about the host, its modification, and the environment to determine whether there is a potential plant pest risk. This is a crucial screening stage, yet it will not require publication of any risk or environmental assessment for notice and comment in the *Federal Register*. The USDA will, however, maintain a list of biotech crops that undergo the first step of the RSR process by plant, trait, and general MOA on its website [unless claimed as confidential business information (CBI) and thus kept out of public view].

If there is a potential plant-pest risk that is indicated from the RSR, USDA-APHIS will conduct a pest risk assessment in the second phase of the RSR (which overlaps with the agency's past permitting process) and publish it for comment in the *Federal Register*. After the plant-pest risk assessment, a determination will be made

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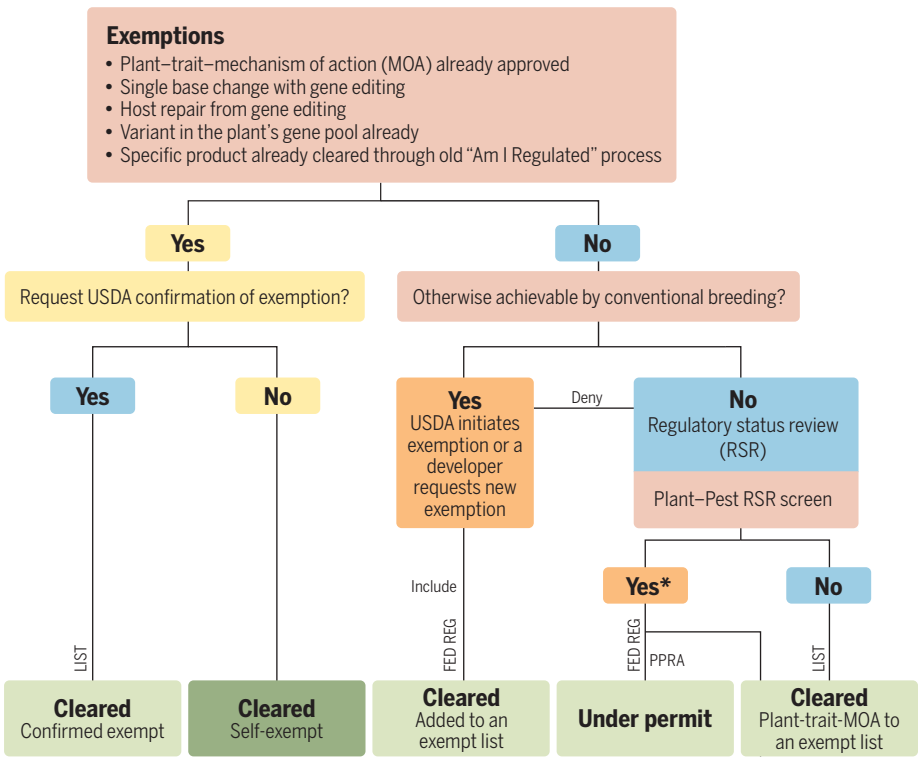
USDA SECURE regulatory pathways for GE plants

This schematic depicts regulatory pathways and places for public information or input. It shows the general process and does not contain details for every step. The U.S. Department of Agriculture (USDA) may put forth new categories of exemptions owing to achievability by conventional breeding. These will also undergo public posting and a comment period before a potential plant–pest risk determination is made, however.



Issues considered by USDA to make a decision about which regulatory pathway applies

USDA makes a determination

Product developer makes a self-determination

USDA shares written assessments with the public in the Federal Register ("FED REG") for public comment prior to decision-making

USDA will keep a public record ("LIST") of some form on its website of the genetically engineered (GE) plant products cleared for the market (although the information on the LIST may be limited by confidential business information, or for confirmed exemptions may omit the phenotype and gene function)

No information will be required to be made publicly available

*If a potential plant–pest risk is identified, the developer has a choice to immediately apply for a permit or ask USDA for plant–pest risk assessment (PPRA). After assessment, USDA may determine a low likelihood of plant–pest risk and put the GE plant-trait-MOA on an exempt list, or require permitting conditions. SECURE, sustainable, ecological, consistent, uniform, responsible, efficient; GE:genetically engineered.

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whether a permit is needed to limit environmental release in some way (e.g., to certain geographic regions). If no restrictions are put in place under a permit, the crop would be cleared for commercial use and interstate commerce.

COMMUNITY-LED RESPONSIBLE GOVERNANCE

The lack of information about biotech crops that will be exempt, as well as the deficit of opportunities for peer and public review of the basis for initial RSR decisions, is likely to exacerbate low levels of public trust (*9*). For example, according to the USDA's informational webinar on 5 August 2020, developers do not need to submit information about the function of the gene or the plant phenotype through the confirmation process, and the USDA will allow CBI to be removed under the same policy as with the AIR process. Furthermore, allowing developers with a clear conflict of interest to self-determine exemptions is likely to promote public skepticism, not confidence, as well as have potential implications for international trade. Therefore, we propose to augment formal government oversight of biotech crops with a voluntary certification process that will bolster transparency and increase the availability of public information and the ability to track gene-edited plants. The process that we suggest will also make possible external scientific peer review because of greater public information about the presence and use of GM crops.

In contrast to previous cooperative governance models for gene-edited crops that center on decision-making for environmental release (*10*), we focus on the sharing of basic information in pursuit of transparency, which is a cornerstone of responsible governance. As a starting point for community discussion about the content and structure of a CLEAR-GOV approach, we propose the following.

CERTIFICATION

To incentivize biotech developers' participation in greater information sharing, there should be rewards. Biotech crop developers would be able to obtain a CLEAR-GOV certification by contributing information about biotech crops and their market uses through open-access data repositories. Although this cannot guarantee public trust, a certification process could at least signify that the biotech crop producer is striving to become more transparent and trustworthy according to community-derived standards. As consumers increasingly include stewardship practices of products in purchasing behavior (*11*), a certification for biotech developers could help provide a win for consumers, industry, and regulatory officials in terms of having a better understanding of biotech crops on the market. Other certification programs have been successful, including those in forestry and farming of select commodities (*10, 12*). A verification scheme for gene-edited crops is currently being considered by a nonprofit coalition under the Center for Food Integrity (CFI) (*13*). Our approach differs from CFI's in that successful certification under CLEAR-GOV would be granted to developers who submit certain data and information to a publicly accessible repository. Minimum requirements of information in compliant formats would be required for CLEAR-GOV certification.

REPOSITORY OF HOST-TRAIT-PURPOSE-ENVIRONMENT-USE

Certification would depend on the sharing of data and information in the open-access repository whether or not the biotech crop is exempt from regulatory review or has cleared USDA regulations. Minimum categories of public information, in both common and scientific terms, would include the species and variety of plant, type of trait modified, the purpose of the trait modification (or improved quality), and the general areas where the crop is grown (without compromising farmer or field security).

Once a crop is sold on the market, CLEAR-GOV staff should work with the

biotech crop developer to compile a list of general food or other market uses for the biotech crop wherever possible. The list of uses would be linked to the plant host-trait-purpose-environment list and be available online. However, the identification of uses will be difficult for biotech crops that end up in larger commodity markets or food-ingredient streams. Certification in these cases will need to be made on a case-by-case basis to ensure that the desire for transparency is balanced with the limits of biotech crop developers' own knowledge of the use of their GM crop in the marketplace. The repository should also provide mechanisms for protecting privacy, confidentiality, and proprietary information and include options to balance the tensions between data provision and data protection.

Many biotech food ingredients and some gene-edited, whole-plant foods will not require labeling at the point of sale to consumers under the National Bioengineered Food Disclosure Standard (*14*). Thus, CLEAR-GOV would fill a critical gap for consumer access to information about the presence of a biotech crop on the market for multiple reasons. Regulatory databases will not be enough to ensure transparency for four reasons. First, if the biotech crop is not regulated by USDA SECURE (e.g., falls into the self-exempt category or the USDA's categorical exemptions), there will not be a publicly available record of that biotech crop being used in the United States. Second, CLEAR-GOV ensures that a minimal amount of information (e.g., plant host, trait, purpose, and potential uses) is available. This information could otherwise be claimed as CBI in regulatory documents. Third, CLEAR-GOV is designed to make it easier for consumers and stakeholders to find all biotech crop information in one place. Given the multiple and complex regulatory pathways under SECURE and through other agencies in the Coordinated Framework, many people may not know where to look for regulatory clearance information. Finally, CLEAR-GOV will translate plant-host, trait, purpose, and possible uses into nontechnical terms that are understandable to the public, whereas regulatory submissions often do not. As new types of biotech crops evolve for new purposes, the repository will need to be adaptive, flexible, and continuously improved and updated.

COMMUNITY-LED COALITION

We propose that CLEAR-GOV be operationalized through a coalition formed under the aegis of a new nonprofit organization (NPO) without a prior history in biotech crops, so it is not viewed as biased from the start. NPO staff must have expertise to support open-access data repository infrastructure and oversee data quality. The coalition should be cofunded by government (nonregulatory) agencies, public-sector donors, and private-sector funds if they are distanced from biotech crop producers. For example, studies on monarch butterfly impacts from GM crops were commissioned by a multisector coalition (*15*).

Coalition leadership should consist of nonconflicted, expert staff in the social and natural sciences, law, agriculture and business, data sciences, and ethics. A stakeholder advisory board with people from industry, government, environmental and consumer NGOs, trade organizations, and academe would provide input to devise the certification process. A public advisory group composed of consumers, indigenous and marginalized groups, and community groups would also help develop the certification. Members of the public will be one category of end users for the CLEAR-GOV data repository and therefore, they have important perspectives on the provision of meaningful and understandable information.

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Both advisory groups would be tasked with helping staff to detail the certification scheme, the type of information deposited, and the presentation of data on the public interface; reviewing and providing input for decisions to certify individual biotech crops and their developers; and periodically revisiting the repository design and making iterative improvements. Both coalition advisory groups and CLEAR-GOV staff would meet periodically together to gather input from biotech crop developers on the design and operations of the repository. Multisector coalitions have been employed in other cases to promote the sustainable production of commodities, and historical lessons should be derived from these experiences as the design and redesign of CLEAR-GOV take place (*10*, *12*).

Lessons can be drawn from other fields in which multistakeholder coalitions operate parallel or complementary to a regulatory agency. For instance, the Center for Science in the Public Interest has worked alongside federal regulatory agencies (including the U.S. Food and Drug Administration) and has housed independent databases on food safety. The U.S. National Nanotechnology Initiative has developed international Communities of Research between U.S. and EU researchers in the field of nanomaterial environmental, health, and safety topics and frequently exchanges information and dialogue regarding nanosafety, including collaborations on the development of databases and exchanges with industry partners.

EXPANSION TO OTHER AREAS

If CLEAR-GOV is successful in the above "phase 1" of the repository and certification, the coalition could consider expanding to promote the sharing of studies aimed at assessing the safety of biotech crops. CLEAR-GOV may even expand to fill a gap for convening and funding more holistic assessments of the risks and benefits of biotech crops from sustainability and socioeconomic perspectives.

We realize that it may be challenging for biotech developers to embrace the concept of providing transparent, open data regarding new GM crops through such a data repository. However, the benefits of doing so may help overcome concerns about transparency and trust that have lingered since the intense debates of the first generation of GM foods. Coalitions for responsible governance such as CLEAR-GOV could fill a critical governance gap as roles for federal agencies diminish and a plethora of new biotech products enter the market. ■

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ACKNOWLEDGMENTS

We thank F. Gould and reviewers for feedback.

10.1126/science.abd1512

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Science **370** (6519), 916-918.
DOI: 10.1126/science.abd1512