

Regulating Gene-Edited Crops

Advocates of second-generation genetically modified crops are making choices likely to trigger another round of public opposition.

Crop gene editing emerged just over a decade ago as a promising set of biotechnology techniques designed to more quickly and precisely introduce new or altered genes to change plant characteristics for better growth, product quality, processing, nutrition, or sustainability. Scientists in academia and the ag-biotech industry alike are promoting gene editing, through techniques such as CRISPR-Cas9, as the start of a second biotechnology revolution in agriculture.

Whereas human gene editing continues to garner public attention for its future promises and risks, agricultural applications are meanwhile rapidly emerging and slated to enter the market in the next few years. In the United States, numerous field tests are under way, and companies and academic developers are switching from first-generation transgenic biotechnology approaches to gene editing. Dozens of gene-edited varieties have been produced, with hundreds more in research and development, including vegetable and specialty crops such as non-browning mushrooms, low-nicotine tobacco, and fragrant moss for homes, as well as commodity crops such as herbicide-tolerant soybeans and corn. In the next year or two, Dupont-Pioneer's "waxy" corn with higher amylopectin content for industrial chemical production and Calyxt's high-oleic acid soybean for healthier oils, longer shelf life, and better frying are expected to be on the market.

In my ongoing professional interactions with plant biotechnologists, as well as through research my colleagues and I have conducted on their attitudes, I have found that these scientists earnestly want to avoid the problems of communication and politics that occurred with the first generation of genetically modified (GM) crops. These ongoing problems include a highly contested policy

environment, consumer rejection of many varieties of GM foods, tensions between organic and GM crop producers, protracted court challenges on the adequacy of GM regulations, and an increased number of food companies avoiding GM ingredients. For example, we found that US consumers were willing to pay a 20% premium to avoid GM ingredients; and from this and many other studies we know that the vast majority of consumers desire mandatory labeling of GM foods. The market for organic foods is growing, and in the past few years a greater percentage of US consumers have been actively seeking foods bearing non-GM labels. In the United States, sales of foods labeled as non-GM increased to \$21.2 billion in 2016 from \$12.9 billion in 2012, and 46% of US consumers report actively avoiding GM ingredients and foods. Such types of public rejection are ones that developers of gene-edited crops are seeking to avert.

Social science research shows that trust in institutions developing or managing genetically modified organisms (GMOs), a catchall term that includes GM crops, is a significant factor in how people perceive them in both the United States and the United Kingdom. Although scientists and developers cite the need to instill public confidence in the second generation of crop biotechnology, they are continuing to make mistakes that erode public trust and neglect ethical principles. These failings fall into four categories: 1) lack of integrity; 2) lack of transparency; 3) lack of oversight; and 4) lack of openness to concerns of citizens.

If gene-edited crops are to productively and responsibly contribute to global agriculture, food security, and environmental and social sustainability, then advocates for their development and diffusion need to correct the mistakes they made with first-generation GM crops. Instead, decision-makers in the US biotechnol-

ogy-development community, including government regulators, federal advisory committees, and plant biotechnologists in industry or academia, seem to be setting themselves up for a replay of the public mistrust and opposition that have surrounded GMOs since their introduction into the marketplace in the early 1990s.

Lack of integrity: Playing the name game

Plant developers in academia and industry, concerned about the public's negative reactions to first-generation GM crops, are hoping to create more positive public attitudes about gene-edited crop varieties by coming up with new names for gene editing meant to engender positive attitudes. These efforts are likely to have the opposite effect of what biotech advocates intend; the public is likely to view the nomenclature as dishonest and the communicators as lacking integrity.

Modern biotechnology had its origins in the 1970s with a suite of laboratory methods called recombinant DNA (rDNA) technology. The first generation of GM crops was produced in the mid-1980s using these methods and entered the market in the mid-1990s. With first-generation GM, before genes were delivered into plants, they had to be isolated and cut out of a donor organism, increased in copy number, pasted together with DNA elements that would make them work in the host, and then introduced into the host by a process called transformation.

In first-generation rDNA, changes to plant genomes were randomly introduced as the donor gene could land in the host at nearly any site in the genome. Donor genes could be derived from unrelated species (transgenes) or closely related species (cisgenes). Plant biotechnologists hoped the introduced donor genes would land in a place where they would express a desired trait and not be affected by endogenous and neighboring DNA regions that would deactivate the gene.

In contrast, with newer gene-editing methods, scientists can modify DNA sequences at precise locations in a plant's genome. These techniques rely on protein complexes—CRISPR-Cas 9 being the most recent and highly touted of them—that can recognize specific DNA sequences, or target sites, in the plant being engineered. These gene-editing protein complexes, termed site-directed nucleases (SDNs), cut the plant's DNA at the target site to produce double-stranded breaks. After the break is made, three options may be used for changing the host plant's DNA. The first option, called SDN-1, is to allow the cell to repair itself so that a small point mutation is made in the native gene that can potentially activate or deactivate it. A second approach, SDN-2, is to add an engineered DNA template along with the SDNs so the cell can use this template to copy insertions or deletions into the target site. The third method (SDN-3) is to provide a brand new gene template (either from a related or unrelated species, or a synthet-

ically designed gene) for copying into the targeted site.

For gene editing, older rDNA techniques are used to prepare, modify, and introduce either the SDNs alone (for SDN-1 point mutations) or the SDNs and the DNA templates (for SDN-2 and SDN-3). Thus, the gene-edited plant contains foreign DNA, which is the gene-editing machinery. But sometimes, developers of gene-edited crops will then remove the gene-editing machinery (e.g., CRISPR-Cas9 transgenes and a DNA template) through conventional genetic “backcrossing” to nonedited, wild-type parents followed by selection for plants that contain only the edits and no transgenes. With this approach, SDN-1 gene-edited crops will, at the DNA level, “look like” crops mutated by older methods such as ionizing radiation, or even by natural and spontaneous mutation. There will be no trace of foreign DNA, even though the crops were produced using rDNA technology during the preparation and introduction of the gene-editing machinery.

These differences in biotechnology methods, the resulting products, and the terminologies used to describe them are inevitably confusing—not only to the public, but even to those within the field of biotechnology. The complexity could be a significant barrier to informed decision-making about GM crops and GM foods.

Developers of gene-edited crops are taking advantage of the muddle around terminology to devise a moniker for gene-edited crops that will not trigger US or European Union (EU) regulations and will not provoke negative consumer reactions such as those that have emerged in reaction to first-generation GM foods. In recent meetings, publications, press, and scientific advisory reports, plant biotechnology developers have been suggesting names for gene editing such as “new plant breeding technologies,” “precision breeding,” “new mutagenesis,” and “accelerated breeding technology,” among others. These terms are neither comprehensible to the nonexpert nor transparent about the scientific methods used and products that result. Specifically, they hide the facts that 1) rDNA technology is used in laboratory settings to splice, paste, and deliver the genetic machinery for the construction of gene-edited crops; 2) not all kinds of gene edits will be simple mutations that could otherwise be achieved through conventional breeding; and 3) some gene-edited crops will contain foreign, transgenic, or synthetically designed DNA sequences.

Yet plant developers are claiming that gene-editing methods should not be grouped with first-generation “genetically modified” foods. For example, Zachary Lippman, a plant biotechnologist at Cold Spring Harbor Laboratory, a leading international center for research and education, explains that gene-edited crops are “not GMO ... you're left with what would be equivalent to a natural mutation.” Consumer and environmental nongovernmental organizations (NGOs) are already indicting plant biotechnologists for this evasion. Jim Thomas of the ETC group says that “it's

dangerous fiction,” and that scientists are now “constructing a definition of GMO so that gene editing falls outside of it.”

Decades of scholarship on public attitudes about risk show that honesty and accuracy in communicating about new technologies is the best way to engender public trust. Efforts to prevent a repetition of the public rejection of GM foods through rebranding the products and disguising the complexities of gene-editing technology will likely backfire, further diminishing public trust in the new products.

Lack of transparency: Keeping secrets

The first generation of GM plants and GM food products tiptoed into the US food supply. Over the first two decades of GM food on the market (1996-2016), developers and regulators were able to resist public calls to require mandatory, positive labels for GM foods (e.g., “contains genetically modified ingredients”). Instead, the federal government promoted voluntary, negative labeling of “non-GM” products. The growing number of consumers seeking to avoid GM foods pay a premium for organic foods (which by definition must not contain more than 1% accidental presence of GM ingredients) or non-GM labels. Companies seeking to avoid GM ingredients to meet these consumer demands bear the costs of certification as non-GM. Negative labeling not only puts the burden of cost on consumers and companies seeking to avoid GM products, but also undermines consumer autonomy. A fundamental bioethical principle affords citizens the autonomy to make informed, uncoerced decisions, a right that cannot be exercised without mandatory labeling.

Based on several polls and studies over the past decade, about 20% of US consumers are against GM foods and will reject them at any cost and regardless of possible benefit; most consumers (about 60%) will weigh the risks and benefits, and some of them (20%) don’t really care. But the vast majority (over 90%) wants them labeled. We’ve found in our focus groups with US consumers that very few want to be surprised about what is in their food 10 or 20 years down the road. Yet that is essentially what happened with GM food. Policy-makers and regulators are now responding to these concerns with new requirements for positive mandatory labeling, but the standards being developed fall short of the transparency necessary to enable consumers to make autonomous choices.

The first GM animal-based food, a growth-enhanced salmon, was approved by the Food and Drug Administration in 2015. This approval, along with the spread of a hodgepodge of state-level GM labeling laws, sparked a change to US federal policy for GM food labeling. In 2016, Congress passed and President Obama signed the National Bioengineered Food Disclosure Law (NBFDL), requiring food manufacturers to disclose the presence of GM foods and ingredients. The US Department of Agriculture (USDA) was assigned the job of designing regulations to implement

the mandatory labeling law by July 29, 2018. Although that deadline for final rule was not met, the Trump administration proposed a draft rule in May 2018 that is now under review.

The USDA made some important decisions in the draft rule. First, in another slick move in the name game, the agency suggested the use of the term “bioengineered” instead of GM. This move avoids association with the negative history of “GM foods,” a term, as I have discussed, that biotech developers are seeking to avoid. The USDA defines bioengineered food products as those “(a) that contain genetic material that has been modified through in vitro recombinant DNA techniques; *and* (b) for which the modification could not otherwise be obtained through conventional breeding or not found in nature.” This definition would likely exempt any gene-edited foods derived from SDN-1 methods (and potentially SDN-2 methods) from the disclosure requirement if the gene-editing machinery is removed from the final product via backcrossing. rDNA technology would be used in the process to produce these gene-edited crops, but some of the final modifications could theoretically be achieved by conventional mutagenesis (e.g., via ionizing radiation) or could arise spontaneously in nature. Therefore, foods and ingredients derived from many gene-edited plants would not have to be labeled under the law.

In another blow to transparency, the draft rule proposes that valid labels may include scannable QR codes or a logo with “be” (short for bioengineered) in the middle. These formats would not require any text indicating that the food product was indeed bioengineered. In addition, the rule proposed designs for the logos that look like either a smiley face or a sun, symbols clearly meant to evoke positive feelings about “be” foods.

Various parties submitted thousands of comments on this draft rule through the federal register in late spring 2018. Industry groups, academic biotech-crop developers, and trade organizations expressed a high level of support for either the QR codes or “be” symbols. They also praised the term “bioengineered” as an alternative to GM. In contrast, consumer and environmental advocacy groups and some food companies that already voluntarily label their GM-food products (e.g., Campbell Soup) argued that using the term “GM food” instead of “be” would be less deceptive and more familiar to consumers. Some NGOs also maintained that the logo options evoke too positive an image of GM foods. In reviewing the comments, many stakeholders outside biotech development (e.g., food companies, consumer groups, academics not making biotech crops) criticized the QR codes, contending that very few consumers will scan food products to find out whether they are bioengineered.

The cynicism in the current draft rule is stunning, as the proposed labeling formats give companies an opportunity to again conceal GM and gene-edited food ingredients, but this time while they claim to support mandatory labeling.

Regardless of whether gene-edited foods are as safe as conventionally bred foods from a human health standpoint (more on this point below), consumers will likely feel duped, public trust in biotech in food production will likely decline, and in the end, gene-editing industries are likely to suffer the consequences of their sleight of hand. The USDA's labeling proposal and plant-biotech developers' support of it do little to increase transparency or consumer autonomy over food choices.

Lack of oversight: Dodging regulation

Given consumer skepticism about the benefits of agricultural biotechnologies, effective government regulation provides one route for building confidence among the public. Yet in this domain, once again, those seeking to advance second-generation biotech foods are taking an approach counter to what consumers desire and what is likely to engender trust. Emerging technologies challenge regulatory systems. Often regulatory adaptation lags behind the rapid pace of technology development, creating uncertainty for industry as well as opportunities for products to enter the market in the absence of full understanding of potential risks. In the past decade, the ag-biotech industry has faced significant uncertainty about the regulation of gene-edited crops and how they might fit into existing statutory definitions for first-generation GM crops. In 2015, the Obama administration initiated an effort to update existing regulations to deal with new biotech products, including gene-edited crops, but this effort came to a halt under the Trump administration. Given the current administration's broad distaste for regulation, this change is no surprise, but it is a mistake, one that will likely haunt the plant biotech industry and gene-editing developers.

Since the mid-1980s the United States has overseen biotechnology under a federal system called the Coordinated Framework for the Regulation of Biotechnology (CFRB). The CFRB was based on the view that the final *products* of genetic engineering are the source of risk and thus the appropriate target of regulation, not the *processes* by which GM products are made. The focus on products was purported by the authors of the CFRB, as well as by the authors of several reports from the National Academies of Sciences, Engineering, and Medicine, to be a "science-based" approach to regulation, and many parties used this rationale to argue against the need for Congress to pass laws regulating emerging biotechnology processes. Existing laws, covering product categories such as pesticides, plant pests, toxic substances, and drugs, thus provided the frameworks deployed to regulate novel biotechnology products.

Guided by the CFRB, the USDA was given oversight of the first generation of GM crops under the Federal Plant Pest Act of 1957. In the 1980s, the USDA argued for regulation under the 1957 law because at that point, the vast majority of GM plants were made with DNA sequences from plant pests, such as the cauliflower mosaic virus and

Agrobacterium, a common microorganism that lives in soil and can infect plants. These sequences were used to chaperone foreign DNA into the host plant to create new functions such as pest resistance. In essence, the USDA used existing laws and regulatory authority to argue that since most GM products included genetic material from plant pests, those products should therefore be regulated as if they were plant pests. From 1987 to the mid-2000s, the USDA regulated all GM crops by first requiring field trial permits or notifications, and then after assessments for environmental and plant-pest risks, the agency would "deregulate" the GM crop so it could be marketed.

Pursuing a similar legal logic, the Environmental Protection Agency (EPA) in 2000 used its pesticide authorities under the Federal Insecticide, Fungicide, and Rodenticide Act to promulgate regulations for GM crops that were engineered to produce pesticidal molecules (e.g., insecticidal Bt proteins from *Bacillus thuringiensis*). In this case, the engineered molecules were reviewed by the EPA for toxicity and nontarget risks. The FDA, pursuing a somewhat different approach for food and feed derived from GM plants, implemented a voluntary consultation policy in 1992 that covered "plants developed by recombinant deoxyribonucleic acid (DNA) techniques," citing authority under the Federal Food, Drug, and Cosmetic Act. Under this policy, companies are invited to submit tests for allergenicity or toxicity to the FDA during consultation. But companies are not legally required to do so, and the FDA does not make a safety determination. Rather, the agency states that it has "no further questions," after which the producer may assume that the GM food product is "generally regarded as safe."

In 2010, a request to the USDA from the agricultural consulting firm Thenell & Associates under the Freedom of Information Act revealed that "letters of inquiry" to USDA staff from biotech developers were directly seeking regulatory approval for new gene-edited plant varieties that did not use plant pest DNA sequences. Without any advisory committee or public discussion, the USDA made several decisions to not regulate gene-edited crops, thus establishing de facto regulatory policy that exempted gene-edited crops not engineered with plant pest sequences from the agency's oversight. Since then, dozens of gene-edited crops have been grown in the field without undergoing formal government assessment, and soon they will be on the market.

In part triggered by these revelations, the Obama administration called for an interagency and outside-expert review of the CFRB, which took place from mid-2015 to December 2016. In January 2017, in the administration's last few days, the USDA published a new draft rule for biotech crops based on this review. The draft rule proposed that most gene-edited plants would fall under USDA regulation in a "screen first, regulate second" option that allowed the USDA to consider the potential for noxious

weed risks in an assessment process, and then decide if the full regulatory process of field trials followed by risk assessment needed to be invoked. GM crops, including most gene-edited ones, could now be regulated not only if they contained plant-pest DNA sequences, but also if there was a chance that they could become weeds or result in weeds.

This approach made a lot of scientific sense because weed potential, or “weediness,” is one of the few well-documented risks from the first generation of GM crops. Herbicide tolerant (Ht) genes are engineered into over 90% of US corn, soybean, and cotton crops. The overuse of the companion herbicides (such as Roundup) has led to an increase in herbicide resistance in native weed populations. In some cases, the engineered genes have been found in wild relatives or hybrids, and in other cases, the overuse of the herbicide has sped up the evolution of unrelated herbicide-tolerant weedy plants. Some of these, such as pigweed, are very difficult to remove and are wreaking havoc on farms.

The story of GM Ht bentgrass makes clear the potential risks and costs of exempting emerging, second-generation biotechnologies that are herbicide tolerant from regulatory oversight. Designed by the Scotts Miracle-Gro Company for use on golf courses, it had been grown in experimental fields trials for several years. Resistant to Roundup, the GM grass had previously escaped from field trials in Oregon and was clogging irrigation ditches, soaking up water, appearing in National Parks and on farms, and costing the company millions of dollars to remove. The company chose not to commercialize the GM variety, yet the USDA still cleared the grass for full-scale marketing and release in 2017, although the state of Oregon and consumer and environmental groups had fought the decision. The USDA stated that it had no choice but to allow the release of the grass because its regulatory authorities were limited to plant pests and did not include weed risks. Since then, other Ht grass varieties that are gene-edited have been submitted to the USDA, and the agency has not exerted authority for them.

In light of this story and other cross-contamination mishaps, the Obama administration’s last-minute proposal to include weed risks under the USDA’s biotech crop authorities made a lot of economic and environmental sense.

Even as Ht GM crop concerns and consumer rejection of GM foods were growing, President Trump’s USDA withdrew the proposed rule on November 6, 2017, saying that it would reconsider whether any regulatory changes were needed. Apparently responding to political pressure from Congress and biotech crop developers, the agriculture secretary issued a public memo in March 2018 that assured crop developers that the agency had no intention of regulating gene-edited crops. The USDA restored the regulatory loophole for the vast majority of gene-edited crops, and excluded potential weed risks from all GM crop regulation.

But this rollback makes little sense given the desires of

plant developers to engender public trust and acceptance of second-generation crop biotechnology. In our own studies on gene editing, my research group interviewed and surveyed a broad set of biotechnology experts from multiple sectors and disciplines, including ecologists, risk scientists, social scientists, and ethicists, as well as plant molecular biologists. Over 60% of them supported premarket, mandatory oversight. My work and that of other researchers has also found that consumers want to know that the government is making sure that GM crops meet standards of environmental health and safety. Trust in government to manage the technology is a key component of public acceptance. Even as the Trump administration seeks to pander to the short-term interests of biotech crop developers that want to avoid regulatory oversight, the lessons of first-generation biotech, combined with what we have learned about public and expert attitudes, suggest that such an approach is likely to further stoke public skepticism and distrust.

Lack of openness: Hiding behind science

Plant biotech developers have argued for decades that the risks posed by GM crops are not related to the process of their making, and the CFRB is predicated on this argument. The logic served GM crop developers well when they were opposing premarket regulation of the first generation of GM crops: they argued that the risks of GM products were no different from those associated with conventionally bred crops—since the final product, not process of engineering, matters—and thus GM products should not be regulated. With the advent of gene-edited crops, crop developers are now saying precisely the opposite. They make claims that the process of gene editing is more precise and thus safer than first-generation GM; therefore, gene-edited crops should not be regulated.

Biotech crop developers promote the view that regulation should be science-based. Crop developers opposed the January 2017 rule because it lacked a “scientific basis” and was based on “process not product.” Yet the proposed rule actually made sense scientifically and was more product-focused than current regulations. The old USDA approach of using plant-pest sequences as a regulatory hook is not based on any particular scientific foundation and has little to do with risk, whereas weediness was a demonstrated, scientific risk created by first-generation of GM crops. Crop developers’ support for withdrawal of the 2017 rule under the Trump administration suggests that crop developers promote scientific findings that advance their interests and downplay those that do not.

On a more fundamental level, no regulatory system can be completely science-based. For example, we might know the dose-response curve for the harm caused by a certain product, but that does not tell us where to draw the line for an acceptable safety limit for that product. Even more often, we do not know the dose-response curve very well, or at all.

This uncertainty leads to various interpretations of the data, interpretations that are inescapably shaped by the worldviews of those doing the interpreting. The science gives us a guide, but the determination of what should be regulated and what is safe is based on values, taking into consideration the benefits (and who defines them), controllability, familiarity, and other features of the system in which the product is embedded. The biotech industry's opposition to the January 2017 USDA rule makes clear what scholars of risk have been saying for decades: attitudes about risk and regulation reflect a wide variety of values, interests, and beliefs about how the world works. Biotech developers' rhetoric hides the subjective essence of risk assessment behind mantras such as "science-based" and "product-based."

Similar dynamics can be seen in plant biotech developers' warnings about the recent ruling by the European Court of Justice (ECJ) on the regulation of gene-edited crops. In July 2018, the ECJ determined that gene-edited crops fall under a 2001 EU directive for the regulation of GMOs. The EU's definition of GMO is an "organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." The court concluded that "the risks linked to the use of these new mutagenesis techniques might prove to be similar to those that result from the production and release of a GMO through transgenesis." The ECJ, recognizing that it has to draw the regulatory boundaries somewhere, stated that the EU directive does not apply to conventionally bred crops because they have "been used in a number of applications and have a long safety record," although it leaves open the possibility that individual member states could decide to regulate them in the future.

The ECJ ruling and rationale are consistent with reports from the National Academies, product-based arguments, and the scientific definitions accepted by the United States of what is genetically modified. Yet plant biotechnologists from academia and industry have claimed that the ruling is "completely incorrect by any scientific definition" and "backward looking and hostile to progress." But Andrew Sterling, a professor at the University of Sussex in the United Kingdom who studies the sociology and politics of risk, sees such black-and-white claims as essentially political: "It is this disrespect for other ways of understanding issues around GM—and such single-minded, partisan, all-or-nothing advocacy—that has helped provoke such polarized and counterproductive debates in this field." The United States and the European Union are taking different approaches to regulation not because the United States has a claim to "sound science," but rather because the balance of political and economic power in the GMO debate is different there than in Europe, leading to different values in drawing boundaries around what should be regulated. That drawing

of boundaries must be based, at least in part, on worldviews toward the role of government in protecting society versus unfettered technology deployment. Values used in determining regulatory policy should include not only those of biotech developers but also those from a diverse set of stakeholders and publics as determined by democratic processes.

Advocates of gene-edited crops—in academia, industry, and government—seem not to have learned the key lessons from the widespread and ongoing public debates over, and in places widespread rejection of, the first generation of GM foods. If coming advances in agricultural biotechnology are to achieve their potential, those advocating for gene-edited crops would better serve their own interests by adopting a much more transparent and restrained stance. They will need to avoid obfuscation (communicate with integrity), reject efforts to sneak new products into the food supply (increase transparency and respect consumer autonomy), accept the role of regulation in assuring social accountability (support reasonable premarket oversight), and resist the temptation to hide their values and interests behind scientific claims (respect democratic values). Otherwise, agricultural biotechnology's political future may end up looking very much like its past.

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Recommended reading

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