

## RESEARCH ARTICLE

# Governing gene editing in agriculture and food in the United States: Tensions, contestations, and realignments

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Biotechnologies in agriculture and food are increasingly governed by both state and nonstate actors. In this article, we explore emerging tensions and contestations in the United States over how gene-editing technologies in agriculture and food should be governed and by whom. This article is framed theoretically by the literatures examining the politics of state and nonstate governance of the agrifood and biotechnology sectors. We draw on semistructured interviews with 45 key actors in the United States, including representatives of regulatory agencies, commodity groups, consumer and environmental nongovernmental organizations (NGOs), biotechnology and food industry, and scientists. In contrast to assumptions that commodity group and industry actors would share a preference for limited or self-regulation, we find growing contestations, with some calling for novel forms of regulatory oversight. Our findings reveal new tensions, fractures, and realignments between and among government, industry, and NGOs actors over gene-editing governance. These tensions and realignments reflect and respond to demands for broader engagement of publics and greater transparency in the governance of biotechnologies in agriculture and food. We argue that these emerging tensions and realignments between and among state and nonstate actors reflect efforts by these actors to incorporate lessons from the genetically modified organism labeling fight as they seek to (re)shape the governance of gene editing in a manner that reflects their interests.

**Keywords:** Governance of gene editing, Social and political dimensions of biotechnology, United States, GMO labeling, Agriculture

## 1. Introduction

Gene-editing techniques are major biotechnology advancements that promise significant benefits within the agricultural sector (Shukla-Jones et al., 2018; Council for Agricultural Science and Technology, 2018). Unlike transgenic genetically modified organisms (GMOs), gene editing does not necessarily require the insertion of foreign DNA to produce many desired traits. The application of gene-editing technologies has exploded in the last several years, especially with the advent of the CRISPR/Cas9 nuclease system, due to its relative simplicity, accuracy, and lower cost (National Academies of Science, Engineering, and Medicine [NASEM], 2016a; Shukla-Jones et al., 2018). These technologies allow scientists to produce novel traits for food and agricultural products, such as increased nutritional content, delayed spoilage, and improved resilience to drought or disease.

The future of gene editing in agriculture and food (GEAF) will depend on interactions among complex social, scientific, environmental, economic, and political factors, including how it is governed within and across nations and whether publics accept it (Friedrichs et al., 2019; Helliwell et al., 2019; Nawaz et al., 2020). GEAF is situated within the contentious history of GMOs and related struggles over state and nonstate GMO governance and labeling. GEAF is also currently challenging existing regulatory paradigms for biotechnology in the United States, which historically have been “product based” such that regulation is required based on whether the final product includes foreign DNA, which is not necessarily the case in gene-edited products (NASEM, 2017; Wolt and Wolf, 2018; Wolf, n.d.). Currently, there is no national nor international consensus on how to regulate GEAF. GEAF also poses significant public acceptance challenges due to its association with GMOs, scientific complexity, social and ethical concerns, and whether gene-edited foods should be labeled (Helliwell et al., 2019; Macnaghten and Habets, 2020).

In this article, we examine the United States as a case study illustrating emerging tensions and contestations over how gene-editing technologies in agriculture and

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food should be governed and by whom. Our findings reveal new tensions, fractures, and realignments within and between state and nonstate actors. Rather than expressing consensus about regulation of GEAF, our interviews indicated growing contestations within and between agricultural commodity group and industry actors, with some calling for greater and novel forms of regulatory oversight. We also see tensions among advocacy organizations, with some strongly opposing the application of gene editing in agriculture, calling it “GMO 2.0,” and arguing for more agroecological alternatives, while other nongovernmental organizations (NGOs) are more amenable about using gene editing to address increasing environmental challenges facing agriculture. These tensions and realignments reflect and respond to demands for broader engagement of publics and for greater transparency in the governance of biotechnologies in agriculture and food. We argue that these emerging tensions and realignments between and among state and nonstate actors reflect efforts by these actors to incorporate lessons from the GMO labeling fight as they seek to (re)shape the governance of gene editing in a manner that reflects their interests.

The next section describes the relevant background on state and nonstate governance of biotechnology in agriculture and food in the United States that provides important context for our research. In Section 3, we present the literatures examining the politics of state and nonstate governance of the biotechnology and agrifood sectors, which theoretically frame the article. In Section 4, we describe the research methods used, which include semi-structured interviews with key actors in the United States, such as representatives of regulatory agencies, commodity groups, consumer and environmental NGOs, biotechnology and food industry, and scientists. We present our findings in Section 5, followed by discussions and conclusions.

## 2. Background: State and nonstate governance of GEAF in the United States

As an emergent suite of agricultural biotechnologies, GEAF enters the contested regulatory and social terrain established throughout the history of GMOs. Since the emergence of agricultural biotechnologies in the 1980s, the U.S. government has actively promoted biotechnology for economic, innovation, and trade purposes, creating a relatively industry-friendly risk assessment process (Levidow et al., 2007). In 1986, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) was enacted in the United States to regulate foods, crops, and animal feed produced using biotechnology. Within the framework, regulatory authority is divided among 3 agencies: the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA; Wolt and Wolf, 2018).

The Coordinated Framework was patched together from 3 existing regulatory agencies, and regulation has been generally oriented toward fostering growth in the biotechnology industry. In the Coordinated Framework,

the need for regulations was not determined based on the *process*, or the technique used for genetic modification, but by the end *product*, and on a product-by-product basis, and rested on the assumption that products produced through biotechnology were “substantially equivalent” in terms of risks relative to products made through traditional breeding (Levidow et al., 2007). The USDA and FDA, more pro-industry agencies, were granted more prominent roles in the Coordinated Framework, while the EPA, with a more precautionary approach to regulating biotechnology in agriculture, was given a more limited role (Schurman and Munro, 2010). The respective roles and approaches of the 3 agencies within the Coordinated Framework have remained largely consistent in their initial regulation of GEAF.

In March 2018, the USDA stated that it did not intend to regulate gene-edited plants if the end product is indistinguishable from products produced through traditional plant breeding and as long as they are not plant pests or developed using plant pests (USDA, 2018). In May 2020, the USDA released the final rule for its biotechnology regulations, 7CFR part 340, called SECURE (Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient) rule for plants developed using biotechnology (USDA-APHIS, 2020). While under the Coordinated Framework, regulation of biotechnology in plants was triggered because an agrobacterium was used to introduce foreign DNA into a product, the updated SECURE rule states that plants produced through genetic engineering will only be regulated if they pose a risk (Hoffman, 2021). SECURE will exempt most gene-edited plants from regulation and will allow developers to decide whether their products qualify for these exemptions (Davies and Brasher, 2020; Montenegro, 2020b; Stokstad, 2020). The decision to exempt most plants from regulatory review brought rebuke from GEAF critics, from many mainstream environmental NGOs as well as from some scientists involved in gene-editing research, all expressing concern that allowing companies to self-regulate would heighten distrust in gene editing among consumers (Kuzma, 2019; Montenegro, 2020b; Gordon et al., 2021).

The FDA oversees the regulation of human food and animal feed by evaluating purity, potency, safety, and labeling. GMOs and gene-edited plants are considered equivalent to, and as safe as, their traditionally bred or mutagenesis-produced counterparts by the FDA (Smyth and McHughen, 2008; Wolt et al., 2016). The FDA has a voluntary plant biotechnology consultation process, in which developers submit a summary of their safety and regulatory assessment to the agency, after which the FDA provides feedback and works with developers to resolve safety issues. The FDA then sends the developer a letter stating they have no further safety concerns but that developers are obligated to ensure safety of the food in the marketplace. In February 2019, the FDA (2021) completed its first consultation on a genome-edited plant variety, a soybean variety modified to have increased levels of a fatty acid called oleic acid. In this case, because the oil is derived from a gene-edited crop and has a compositional difference that “make it materially different from its

traditional counterparts,” the FDA will require that the soybean oil be labeled “high oleic soybean oil,” but without any reference to the gene-editing process involved.

The role of the EPA is to protect the environment and human health and safety through the use of a registration process guiding the sale, dispersal, and use of pesticides (Wolt and Wolf, 2018). In 2020, the EPA also stated its intent to modify its oversight of plant-incorporated pesticides (PIPs) in order to exempt products made with newer biotechnologies, such as gene editing, if they are deemed to be similar enough to PIPs created through conventional breeding and are unlikely to present unreasonable risks to humans or the environment (EPA, 2020). Like the SECURE rule, the EPA’s proposed revisions to its regulations stated that if a developer believes a PIP should be exempt, the developer submits a statement to EPA certifying its PIP is exempt and retains the records supporting that determination. Consumer food safety advocacy organizations are calling for the EPA to reassess what regulatory procedures and safeguards are needed to ensure that only PIPs meeting the scientific criteria for low risk are exempted and that EPA publish a list of all exempt PIPs (Jaffe, 2021).

Following the preliminary regulatory decisions about GEAF by the FDA and the USDA, both agencies opened up public comment processes. Twenty-six comments were submitted to the FDA docket on behalf of 30 organizations supportive of regulating gene-edited plants as equivalent to conventionally bred plants, while 2 environmental and consumer-oriented advocacy organizations submitted comments, one of which was signed by over 23,000 members, stating that the FDA should follow the World Health Organization/United Nations Food and Agricultural Organization Codex Alimentarius definition of biotechnology that includes regulating gene editing as GMO (Bain et al., 2020). Over 6,000 public comments were received by USDA-APHIS on the draft SECURE rule, and the vast majority expressed general opposition to the rule. These critical comments did not appear to alter the regulatory outcomes related to GEAF for either agency (Bain et al., 2020; Montenegro, 2020b).

The contestations surrounding regulation of agricultural biotechnology in the United States are also reflected in struggles over nonstate governance and labeling of GMOs and GEAF. Although the USDA Organic label, approved in 2002, excludes GMOs, the label does not explicitly state it is non-GMO, and many consumers are not aware of the exclusion. In response to environmental and consumer advocacy group pressure, federal GMO labeling legislation was introduced in Congress 6 times between 1999 and 2011 but never had sufficient support to pass (Pechlaner, 2020; Velardi and Selfa, 2021). Between 2002 and 2014, citizen-led ballot initiatives for GMO labeling were advanced in several states. However, biotech, agribusiness, conventional food, and retail corporate interests aligned against GMO labeling. Led by the Grocery Manufacturers’ Association (GMA), food companies, such as Nestle and Kraft, together with seed, chemical, and biotech companies, spent tens of millions of dollars in a well-orchestrated campaign to defeat GMO labeling ballot initiatives in several states (Bain and

Dandachi, 2014). Labeling ballot measures during this period failed by relatively narrow margins until the state of Vermont successfully passed a GMO labeling bill in 2014 (Velardi and Selfa, 2021).

After years of federal government intransigence to pass a GMO labeling bill, and over a decade of campaigns by consumers to advance state-level GMO labeling ballot initiatives, industry quickly responded to the passage of the Vermont labeling bill to express concerns about the patchwork of state labeling requirements. The federal government then was compelled to respond to the Vermont labeling bill. In 2016, Congress quickly passed legislation for a federal GMO label, the National Bioengineered Food Disclosure Standard (NBFDS), which directed USDA to establish a national mandatory standard for disclosing foods that are or may be bioengineered, defined as “those that contain detectable genetic material that has been modified through certain lab techniques and cannot be created through conventional breeding or found in nature” (Agricultural Marketing Service—United States Department of Agriculture, 2021).

The NBFDS was to be fully implemented by USDA by 2020, with an extension for small food manufacturers until January 2021 and a mandatory compliance date of January 2022. The final ruling allows for a variety of options for disclosure and labeling of genetically modified (GM) ingredients, including text, symbol, electronic or digital link, and/or text message. Critics of the USDA’s decision to use the term “bioengineered” instead of more commonly used terms of GM or genetically engineered (GE), and the allowance of electronic or digital links, claimed the agency was catering to biotechnology industry interests to obscure transparency in labeling (Dumas, 2018). Importantly, “bioengineered” only includes foods that have been created by transgenic genetic modification and therefore do not require current gene-edited foods to be labeled. The fact that the final labeling law excludes requiring the labeling of gene-edited foods reflects the power and interest of antilabeling advocates to make the labeling law as narrow and as weak as possible.

The success of the anti-GMO campaign in raising consumer awareness around food labeling, and the state’s unwillingness to respond, provided an opportunity for nonstate actors to help fill the void. One of the most prominent nonstate actors involved in GMO labeling is the Non-GMO project and its label, Non-GMO Project Verified, that emerged in the U.S. market in 2010 (Roff, 2008; Bain and Selfa, 2017). The Non-GMO Project (2020) has grown tremendously over the last 10 years, and by 2021, over 3,000 brands and 50,000 products are certified by the Non-GMO Project, worth over \$26B in sales. In a statement on their website, the Non-GMO project declared that the USDA decision not to regulate or label GEAF as GMO “signals a clear strategic shift further away from transparency in the food system,” but that consumers can continue to trust their label to purchase Non-GMO foods.

Other important nonstate actors also responded to USDA’s delayed and unclear implementation of the GMO labeling standard, in recognition of the desires of a majority of consumers for labeling. In 2017, the large food

manufacturing company, Campbell's, left the GMA over the GMO labeling issue, followed by other large food manufacturing and trading companies such as Nestle, Mars, Cargill, Tyson, Kraft Heinz, and Hershey's. Although these mainstream food companies had previously been strong antilabeling advocates, many broke from the GMA over its antilabeling position and began to voluntarily label GMOs in food. Subsequently, in 2018, Danone, Mars, Nestle, and Unilever together founded the Sustainable Food Policy Alliance to advocate for more consumer transparency around food and more environmentally friendly and sustainable agricultural systems.

In 2019, the GMA rebranded itself as the Consumer Brands Association (CBA), reaffirming their position that state-level food labeling is confusing to consumers and difficult for manufacturers. CBA continues to support "smart, national regulatory solutions to benefit all consumers" and has been instrumental in the creation of the Smart label, which provides a digital link, or QR code, so that consumers can learn about ingredients, nutrition, allergens, and company sustainability commitment (CBA, 2020). Many GMO labeling advocates argue the use of the digital links on the Smart label or on the NBFDS is intentionally less transparent than a clear food label on a product or package.

The history and contestations over government regulation, and over nonstate GMO labeling and governance, of biotechnology in agriculture in the United States, provide important context for understanding how key actors position their interests in relation to GEAF governance. GEAF proponents are attempting to avoid association of GEAF with GMOs by strategically framing gene editing as equivalent to traditional plant breeding but more precise (Bain et al., 2020). GEAF critics assert that GEAF and GMOs are equivalent in terms of the application of biotechnology in agriculture and should be regulated as such and that both GMO and GEAF act to entrench corporate, industrial agricultural systems. Both proponents and critics reference the importance of governance of GEAF but differ on how these can be achieved and draw on differing discourses to justify their preferred governance mode. Following the USDA decision to not include gene-edited foods in the NBFDS, some actors, including both supporters *and* critics of GEAF, are calling for voluntary labeling as a way to enhance transparency for consumers. Other key actors see labels as not only unnecessary but as actually misinforming consumers while stigmatizing products by highlighting the use of gene editing.

### 3. Theoretical framework: Politics of agrifood and biotechnology governance

Social science researchers have asserted that new governance forms for GEAF will be necessary since existing regulatory instruments are inadequate to accommodate the complexity of gene editing and its novel risks (Chakradhar, 2015; Jasanoff et al., 2015; Kuzma, 2016; Kofler et al., 2018; Jasanoff and Hurlbut, 2018; Macnaghten and Habets, 2020; Montenegro, 2020a). Hybrid governance models, such as multistakeholder initiatives for agricultural commodities like soy (e.g., Roundtable on

Responsible Soy), have developed as a means for nonstate actors to govern global value chains so that production meets certain social, environmental, or economic standards. Scholars, such as Jordan et al. (2017) and Kofler et al. (2018), argue for the creation of similar networks to govern GEAF. However, scholars have also cautioned that these hybrid governance models can mask inequalities in actor participation behind a veil of "inclusiveness" of diverse actors in roundtables (Ponte and Chenys, 2013; Selfa et al., 2014; Kohne, 2014).

Within the agrifood literature, governance includes both state (e.g., legally enforceable regulations and government standards such as USDA Organic) and nonstate institutions (e.g., private food labels and certifications, commodity roundtables). Agrifood scholars have examined how a diverse set of actors have emerged to govern complex issues within national and global agrifood systems (Hatanaka et al., 2005; NASEM, 2016b). Nonstate actors, such as food companies and NGOs, have engaged in developing "technologies of trust" to govern GMOs, including food labels and certification (Fuchs et al., 2011; Bain and Danachi, 2014; Bartley et al., 2015; Devaney, 2016; Bain and Selfa, 2017; Withers, 2018).

Several scholars assert that state and nonstate authority interact in ways that make it difficult to disentangle the two but that private authority may apply more to areas that were never regulated by the state (Cashore et al., 2004; Ponte et al., 2011). Fuchs and Clapp (2009) note that the creation of permissive state regulations, as well as the absence of state regulations, facilitate the exercise of corporate power in agrifood governance. Falkner (2009) argues that the trend toward private global governance of biotechnology in agriculture does not indicate that private (business) power is superseding public power and authority. Instead, he suggests that private authority is "both linked to and embedded in the wider political framework which is provided by states" and regulations and that we need to look more carefully at these relationships between state and nonstate actors (Falkner, 2009, p. 231). Other scholars point to the importance of understanding the intersection of public and private standards, as an "elaborate layering of rules" in governing global supply chains and the politics surrounding them (Bartley, 2011, p. 541). Bartley (2007) argues that government regulation often emerges from political contestations between NGOs, market actors, and state actors, as was demonstrated in the eventual passage of GMO labeling federal legislation after years of struggle and pressure by nonstate actors.

Falkner (2009) looks at the tensions and conflicts *within* the agribiotechnology industry. He argues that these conflicts undermined what had been assumed would be the unbridled expansion of the industry and created political space for other actors to shape the future of agribiotechnology. He shows how the diversity of industry interests, the persistence of conflicts between firms at different points of the production chain, and between industry leaders and laggards, create opportunity structures for other actors, such as environmental movements or food retailers, to mobilize new alliances for governance within the agribiotechnology sector. The diversity of

industry interests, and conflicts of interests within the agribiotech industry, increasingly characterize the current GEAF landscape, as our interviews illustrate.

Political economy scholars have also investigated the political role that corporations and industry groups play in governing food and agricultural biotechnology through the use of instrumental and discursive power (Clapp and Fuchs, 2009). Clapp and Fuchs (2009) show how corporations use instrumental power, such as lobbying, to create norms, rules, and institutions, such as private standards, for governance of food and agriculture. Agribiotech actors also attempt to shape policies and regulations by using discursive power to frame issues. Clapp and Fuchs (2009) argue that agribiotech actors identify intractable social and environmental problems that they contend can only be solved with biotechnology. Agribiotech actors have used scientization discourses, that is, scientific arguments used to frame issues as technical, and therefore limit the discussions of biotechnology in agriculture to scientific and technical issues and risks rather than broader social and political concerns (Kinchy, 2012).

Scholars have also shown how activists use discursive power to mobilize against the agribiotech industry and argue for appropriate governance tools. Schurman (2004) argues that the antibiotech movement used industry opportunity structures, specifically the concentration in the food retailing industry in Europe that made food retailers and manufacturers so vulnerable to anti-GMO consumer movement campaigns, together with powerful discourses, such as calling GM foods “Frankenfoods,” to stop the sale of GM food in Europe. Schurman and Munro (2010) explain how antibiotech activists mobilized an alternative worldview and counter-discourses to transform the application of biotechnology in agriculture from a vaunted technological innovation into a social problem. Activists effectively mobilized opposition to biotechnology in food by tying it to consumers’ democratic right to know what is in their food and concerns about the technology’s unknown health and environmental risks (Falkner, 2009; Schurman and Munro, 2010). These discourses resonated with consumers, leading to moratoria on growing GMO crops and mandatory GMO labeling in Europe in the late 1990s, and also shaped the GMO labeling campaign in the United States.

These literatures—examining the relationships between state and nonstate actors related to agribiotech governance, the opportunities created through the tensions and conflicts within and between key agribiotech and food industry actors, and the important role of discursive power—frame the analysis of the tensions emerging over how GEAF should be governed in the United States and by whom. Key areas of contestation that emerged among our interviewees were whether GEAF should be considered to be equivalent to GMO or not and, relatedly, the need for regulation and/or nonstate governance, such as the use of voluntary labeling, for gene-edited foods. Our interviews show emerging tensions within and between agribiotech and food industry actors, which provide openings for other actors to play governance roles. Discursive power is used by proponents and critics to position their interests

in relation to their preferred GEAF governance mode. We explore these tensions in our findings below.

#### 4. Research methods

This research was conducted as part of a USDA—National Institute of Food and Agriculture-funded grant for a study titled “Identifying gaps in public trust and governance recommendations for gene-edited foods.” Data are derived from in-depth, semistructured interviews with 45 key informants. We employed purposive sampling to identify relevant stakeholders and individuals with diverse expertise on issues related to GEAF, including public policy, governance, safety and risk assessments, agriculture and food product development, scientific knowledge, global trade, and social and ethical concerns. Informants were identified with the aim of selecting a heterogeneous sample to capture the breadth of views and knowledge. Additional informants were located through web searches for organizations and news stories referencing gene editing in food and agriculture. Others appeared in public reports for work groups and meetings on the topic of gene editing or GMOs. Once interviews began, additional informants were obtained through snowball sampling (Blaikie, 2010).

We achieved heterogeneity in our sample. The interviewees represented key organizations including agricultural commodity groups, biotechnology, science and technology, industry trade associations, food and supermarket industry, university researchers, and government regulatory agencies. In addition, we interviewed advocacy organizations whose primary foci included science and society relations, environmental protection, biotechnology and food security, consumer food safety, alternative agriculture, and community development. In total, the data set included interviews from 36 different organizations, with some interviews consisting of more than one informant from the same organization.

Interviews were conducted between June 2018 and May 2019, shortly after the USDA’s initial decision in March 2018 that it did not intend to regulate gene-edited plants and as final details and time line for implementation of the federal GMO label were being released. This context is significant for interpreting our interview data. When we started the interviews, the European Court of Justice decision on regulating gene editing in agriculture was being widely anticipated by both proponents and opponents of GEAF, and most of the organizational representatives interviewed had not developed an official statement or position on GEAF yet. The timing and context of the interviews shape the still unresolved positions of many interviewees about GEAF, their contested views about appropriate governance, and the emergence of new fractures and alliances between and among actor groups.

Both in-person and telephone interviews took place, each spanning roughly 1 h. Interview guides and probing questions were adapted to the expertise of the informant and unique elements of the entity they represented. Broadly, interviews were designed to collect data on the informants’ understandings of gene editing in food and agriculture related to risks, benefits, governance methods, efforts to foster trust among publics, as well as lessons

learned from the GMO debates. Audio recordings were transcribed verbatim and uploaded into NVivo software. After developing an initial set of codes related to risks, benefits, governance, and efforts to foster trust among publics, 2 researchers coded the transcriptions, iteratively checking to achieve intercoder reliability. We reviewed the final code reports by hand, analyzing the text for the emergence of several key themes, such as modes of public and private governance of gene-edited agriculture and foods, strategies for building trust among publics, and possible positive and negative social implications resulting from GEAF.

## 5. Findings

Our interviews reveal tensions, contestations, splits, and realignments between industry actors, government regulators, NGOs, and advocacy organizations around the emergence of governance of GEAF. Below, we explore thematically the positions and claims of actor groups in greater depth, teasing apart tensions and new alliances within and between groups. The tension and contestations between actor groups that we discuss below are between GEAF proponents and critics over defining GEAF, between the food industry and agribiotech industry and within the agribiotech industry over GEAF labeling, and between newer start-ups and older, established agribiotech industry actors over the need for GEAF regulations.

### 5.1. Tensions between proponents and critics: Defining GEAF

A fundamental contested issue between proponents and critics that emerged in our interviews is whether GEAF should be considered GMO, and consequently how it should be regulated. Proponents claimed that GEAF is not GMO but is equivalent to conventional plant breeding, but faster and more precise. Because conventional plant breeding is considered safe and is not regulated, proponents reasoned that GEAF does not need to be regulated either. Many proponents repeated this claim in interviews, as one explained: “It’s just a different form of plant breeding, as far as I’m concerned” (Int. 207).

In contrast to GEAF proponents, many critics interviewed stressed that GEAF is GMO and should be regulated as GMO by regulatory agencies. As stated by an interviewee from an environmental NGO:

*But we need to be clear that gene editing is genetic engineering, and it needs to be regulated as such and have oversight. All products of genetic engineering at a minimum should be strictly regulated using a precautionary approach to protect humans and the environment. All products of the techniques of genetic engineering need to be independently assessed for safety and other impacts prior to entering the market. And they all need to be labeled and traceable. . . . And we need to have oversight and regulations, so we don’t have the current situation, which is companies that are self-*

*proclaiming their products as safe. And that’s the fox guarding the hen house. (Int. 204)*

Other environment, food, and consumer advocacy organization actors stated that GEAF should be labeled as GMO, consistent with the precautionary regulatory approach. Many of these advocacy group representatives stressed they would strongly prefer that government regulatory agencies had more oversight in relation to GEAF and acted as consumer safety watchdogs. However, they acknowledged that rather than acting as a neutral party, most government regulatory agencies favor and promote agribiotech interests. As one environmental NGO interviewee stated: “They’ve rigged the playing field there too, so I don’t think the government is neutral at this point as a spokesperson” (Int. 210). An interviewee from another environmental NGO criticized the USDA decision and highlighted the importance of disclosure for consumers:

*It is disingenuous for USDA to have made the decision that they have made, that gene editing is essentially equivalent to selective breeding. . . . I believe they just don’t know how to handle it, and they don’t want to, and the industry is pushing them not to, and it’s a path of least resistance. I and my organization believe that people should have the ability to make informed choices. Would labeling be my highest priority? No. Actually, appropriate regulation (emphasis added) would be my higher priority. (Int. 201)*

How GEAF should be defined, and thus governed, is a fundamental contested issue raised by both proponents and critics. Proponents attempt to disassociate GEAF from GMO, and downplay the negative connotations of GMO, by claiming gene editing is equivalent to plant breeding. In contrast, advocacy organizations attempt to link GMO and GEAF and the connections between the use of both biotechnologies in agriculture in order to justify more rigorous regulatory oversight and labeling of gene-edited foods.

### 5.2. Tensions between and within the food and agribiotechnology industry: Labeling

Tensions within the agribiotech industry also characterized discussions of GEAF governance. As articulated by Falkner (2009), the diversity of agribiotechnology industry interests and the tensions and conflicts within industry can create opportunity structures for other actors, such as advocacy movements or food retailers, to mobilize and forge new alliances for governance within the agribiotech sector. An interesting cleavage has widened between the corporate food and biotechnology sectors that began during the GMO labeling fight, when many food companies split from the biotech industry to support GMO labeling. This split was described in an interview with a food advocacy organization representative:

*A big split has opened between the food industry and the biotech industry. And the biotech industry has for decades opposed [the GMO label] but . . .*

*now that there is a law to label, they want it as weak as possible. They want it to exclude as much as possible. However, the food industry, which has traditionally gone along with that . . . in the past year there's been a big split. They've been represented mostly by GMA, a trade group. And GMA has opposed labeling, but a year or so ago, they started having defections. Like Campbell's. Campbell's said "We're going to label regardless." Nestle walked out of GMA because of this whole GMO issue. (Int. 220)*

The rift between the food and biotech industries has led to some new nonstate actors emerging to play a governance role related to biotechnology in food. Many consumer and advocacy organizations believe that the agribiotech industry and government regulatory agencies are aligned in their preference for limited regulation and are therefore pushing for nonstate governance, specifically labeling. As retailers are subject to increasing pressure by consumers, they articulate that they will make their own governance decisions regarding biotechnology. Reflecting on the absence of trusted state regulatory agencies, a food retailer suggested that retailers' decisions about governing gene-edited foods will likely respond to consumer demands. As he states:

*In the absence of governance, or absence of trusted institutions, or the absence of progress on legislative and regulatory fronts, more and more people are turning to companies to drive change. We have a lot of pressure to not carry certain products. We have a lot of pressure from animal welfare organizations to stop doing business with certain companies, stop selling products produced with certain practices, to not carry GMOs. . . . We as a company have a lot of external pressures on a number of fronts, and if we don't have a strong, trusted regulatory authority, or brand, then it invites this regulation from the retail food service community. (Int. 203)*

A key governance tension in many interviews centered on whether GEAF food products should be labeled, and if so, how labeling should be organized. U.S. consumers were relatively ambivalent about GMO labels on food products until labeling initiatives and social movements started gaining traction around 2010 (Velardi & Selfa, 2021). The NBFDS mandates that bioengineered food sold on the U.S. market will require a label, but the standard's narrow definition of "bioengineered" does not include most gene-edited plants currently in development. Our interviewees explored this tension while articulating and justifying desirable governance structures for labeling, including possible implications for both the food industry and consumers.

Several agribusiness and biotechnology representatives expressed clear opposition to *any* form of GEAF regulation or labeling. To them, neither voluntary labeling—such as through a nonstate third-party certifier similar to the non-GMO verified label or private company—nor mandatory

government labeling—such as the NBFDS symbol—is appropriate. An established agriculture industry trade association representative argued:

*I just want to get back to this idea of consumer confidence. . . . I don't think there's any evidence that having regulation inspires consumer confidence. . . . If anything, we have an experiment over the last 30 years that shows it doesn't inspire consumer confidence because we now have a Disclosure Bill. And consumer confidence hasn't gone up around GMOs, certainly. (Int. 215)*

Many agribusiness and biotechnology industry interviewees opposed labeling, arguing labeling is unnecessary, misleading, and actually detrimental to industry. They also countered the "consumers' right to know" justification for labeling by stating that labels do not actually contribute to consumer confidence. An agriculture industry association representative referenced his organization's position on GMO labeling to explain their opposition to GEAF labeling: "We're strongly against labeling for GMOs because we thought it was stigmatizing, and it drew a difference where there was no difference. . . . Would we support it [a label for gene-edited foods]? My guess is 'no'" (Int. 212).

However, other biotech industry interviewees recognized that GEAF food labels would be needed to address consumer demands for disclosure and transparency. Unlike many of the established agribiotech representatives, food retailers, manufacturers, and traders we spoke with believe labels contribute toward removing stigmas about GE products in general. They linked labeling with consumers' demand for transparency and choice about whether to consume gene-edited foods. While many stated they would strongly prefer that government regulatory agencies exercised more oversight, they acknowledged government regulators have opted not to. Because many of these interviewees assumed that government regulatory agencies would likely not require gene-edited foods to be labeled, they believe there is a role for private and voluntary labeling. A spokesperson for a large food company stated that he wished gene-edited foods would be included in the NBFDS. However, even if the final government regulation does not require labeling of GEAF, his company would advocate for labeling and would voluntarily label their own products:

*I can tell you that . . . things that are gene-edited, that will end up in our food supply chain, we most likely will label those. Under the bioengineered law, however that comes out, it is our position that those would also be considered things that need to be labeled. . . . I think it's important that the USDA and FDA . . . and EPA play an important role, maybe not in approving the technologies, but maybe a strong oversight responsibility. (Int. 224)*

Despite diverging attitudes about whether GEAF labeling should be included in the NBFDS, other food industry representatives stated they would also voluntarily label

GEAF as a means of giving consumers information and countering potential consumer concerns. A large conventional food trader explained that the fight over GMO labeling had led her company to assume that there would be consumer apprehension about gene-edited foods. In response, her company had decided that they would voluntarily label gene-edited foods, whether or not it is required by government:

*The reality is that GMOs somewhere along the line got a bad brand, right? There's a lot of work that needs to be done to recover from that, but the answer for these new products is not to go down that same path of "we're not going to tell consumers." . . . My company's position today . . . in respect to disclosure of use of genetically engineering is that you should do it, but not because the government is telling you to do it. (Int. 202)*

A retailer association representative echoed that regardless of whether labeling of GEAF would be mandated, it is preferable to disclose information in order to increase transparency for consumers. He explained that his organization wants to be sure that companies are able to provide that information through a label if they choose to. He said:

*From a practical point of view this is difficult because the law is clear that if the product doesn't include DNA then there is no need to disclose it on a label. We have the view that if the consumer wants to know if it comes from a bioengineered product then there is no need to hide that. There is tremendous value in [providing transparency] . . . this is the superhighway to trust and removes the stigma around the product. We think there should be a mechanism for companies to do this even if the law doesn't require it. We should be able to reveal this information. (Int. 239)*

Advocacy organizations, food companies, and retailers stress the importance of disclosure through labeling of gene-edited foods for consumers. Because they believe regulatory agencies are not adequately providing oversight through regulation, or requiring disclosure through labeling, they recognize the need for nonstate actors to govern and that labeling is the clearest way to provide consumers with the information needed to make choices. While some stated that they do not think the scientific evidence nor consumer safety concerns necessarily merit labeling gene-edited foods, they assert that information disclosure is essential for instilling consumer trust in their product, and therefore, they will voluntarily provide labels to consumers.

### **5.3. Tensions between agribiotech actors: Regulations**

The implementation of the USDA's SECURE Rule in 2020 presented the first large-scale changes to GMO risk

assessment policy since the Coordinated Framework was enacted in 1986. When our interviews took place in 2018, agribiotech industry interviewees deployed discourses of scientization and democratization in their efforts to shape emergent GEAF regulation and governance. While a majority of government officials and traditional biotech and agriculture industry actors articulated the need for minimal government regulations or industry self-regulation, other newer start-up biotech actors argued for the importance of some regulation.

Interviewees from large established agribiotech companies that desired minimal GEAF regulations often invoked discourses of scientization, as they had done previously in attempts to discredit and undermine demands for transparent public or private governance of GMOs (Kinchy, 2012). Most interviewees from traditional farm and commodity groups, agricultural industry associations, and agribusiness and biotech companies agreed with the USDA regulatory decision not to regulate GEAF as GMO because they claim that gene editing is the equivalent of conventional plant breeding, although faster and more precise, and conventional plant breeding is not regulated. Some agribiotech industry actors opposed any government regulations and argued instead for industry self-regulation. These interviewees often relied on scientization to downplay the need for regulation. Some contended that because GEAF is equivalent to conventional plant breeding, industry self-regulation is rational, especially because they have a strong history of safety and have proven to be competent and trustworthy. One agricultural commodity group association representative added that past experience shows how competent and trustworthy the agribiotech industry is:

*It doesn't necessarily have to be a federal agency coming in and regulating it; our industry has a lot of safety measures in place and checks and balances. And you know, we've had so much success in doing this over the years. (Int. 215)*

Key established agribiotech actors also referenced the importance of ensuring democratic access to gene-editing technologies, and the negative economic and innovation impacts, that would potentially result if GEAF were subject to excessive regulations. In interviews, many traditional agribiotech industry actors argued that the "over-regulation" of GEAF, as they claimed happened with GMOs, would hamper innovation and industry growth. Established biotech companies and conventional agricultural commodity group organizations drew on democratization discourses about GEAF (Bain et al., 2020; Montenegro, 2020a) to express concern that burdensome and costly regulatory approval processes would particularly hamper the ability of public sector plant breeders and smaller biotech start-ups to enter the gene-editing market. Some suggested this would lead to further concentration of larger firms and hinder development of improved staple food crops, both key criticisms of GMOs that pro-biotech industry actors are keen to avoid. A representative of a large, long-standing biotechnology firm

argued that reduced regulations are essential to “level the playing field” and open up opportunities for smaller companies to participate more fully in GEAF:

*If you think about innovation and what it really means to change societies, you have to level the playing field. In order to level the playing field for gene editing, I think those restrictions and barriers have to be reduced. (Int. 235)*

Other arguments for minimal GEAF regulatory oversight presented the GMO regulatory structure as an expensive barrier to agricultural innovations needed to help the Global South. An interviewee from an advocacy organization that works with developing country farmers stated that the regulatory approval process for GEAF will determine whether public sector scientists can participate in gene editing and make improvements to important food crops for developing countries. She lamented that the worst thing that could happen is that African countries take a precautionary approach to regulate GEAF like Europe has done because it would inevitably lead to greater food insecurity (Int. 230).

While many agribiotech industry interviewees advocated for minimal GEAF regulations, some qualified this by stressing the importance of having some regulations for fostering public trust in gene-edited foods. They conceded that minimal and sensible science-based regulations were needed. Several agribiotech industry actors argued that from a scientific perspective, there is no need for stringent regulation of gene-edited plants because they are equivalent to conventionally bred plants, but sensible, “science-based” regulation fosters consumer trust. A representative for an agricultural commodity group stated:

*The grudging acceptance or admittance of the industry is that while the science may tell us this, [that there is no difference between gene editing and conventional breeding] there needs to be some sort of a sane regulatory umbrella over the top of this that can help with public trust and confidence in the food system. (Int. 225)*

Several of the start-up biotech company interviewees also expressed awareness that promoting limited or self-regulation will not enhance consumer trust of gene editing in food but will likely “doom” the technology. As stated by a biotech start-up representative:

*The public is going to want and expect that there is some regulatory framework in place, so it is not a very good talking point to say these technologies are unregulated. And so anybody from the industry could push for no regulation. It's pretty much dooming this technology to failure. Now there's a really big difference between no regulation and a regulatory system that's consistent with the risk, and can be articulated in a way that the public understands. (Int. 213)*

Interviewees from biotech start-ups realized that using discourses to make purportedly rational scientific or technical arguments, while discounting other concerns by publics, would not advance their interests, or the interests of the industry as a whole, to expand the use of gene-editing technology. Instead, these actors suggest a framework is needed that incorporates risk concerns and a governance framework that is responsive to public concerns.

## 6. Discussion

Contestations, tensions, and realignments between key actor groups characterize the landscape around GEAF governance in the United States, as the first gene-edited products are entering the market and the federal label for GMOs will be fully implemented in late 2021. A fundamental tension between many proponents and critics of GEAF is whether GEAF is equivalent to GMO, and whether, and by whom, it should be governed. Increasingly, new tensions are emerging among and between key actors who previously were aligned in their positions toward the use of biotechnology in agriculture and food and its governance.

The tensions within and between agribiotechnology sector actors have opened spaces for other actors to enter and address consumer concerns that are beyond narrow scientific risk assessments. The contestations between the biotechnology and food sectors over the issue of labeling GMOs created a cleavage that appears to be widening in relation to gene editing and has led to new actors, such as retailers, preemptively responding to consumer concerns and playing a governance role for gene-edited foods. In addition, notable differences between more traditional, established biotech companies and newer start-ups in their approach to governing gene editing are emerging. Increasingly newer agribiotech start-ups and other non-state actors are less focused on using scientization discourses and are downplaying the importance of “debating the science.” Instead, they are more open to acknowledging potential consumer concerns and are therefore focused on enhancing publics' trust in the technology by drawing on discourses and governance tools that acknowledge the importance of transparency in regards to gene editing.

Political economy scholars of agribiotechnology have argued that private authority is not supplanting governmental regulatory authority but is linked to and embedded in the wider political framework that is provided by states and have directed other researchers to look carefully at these relationships (Clapp and Fuchs, 2009; Falkner, 2009). In our case study, we show how regulatory decisions taken by government agencies, as well as the decisions not taken, have facilitated and supported conventional agribiotech industry interests. The history of GMOs in agriculture illustrates how government regulatory agencies fostered agribiotech industry growth and only approved a mandatory GMO label after years of consumer campaigns for labeling in order to supersede the successful implementation of a state-level non-GMO label in Vermont. As Bartley (2007) articulates, government regulation of GMOs in food finally did emerge as an outcome

of political contestations between NGOs, consumers, market actors, and state actors.

The current regulatory decisions around gene editing taken by the USDA, FDA, and EPA illustrate how agribiotech industry interests and desires are privileged. The USDA has decided to consider gene editing to be the equivalent of conventional plant breeding and thus not to require extensive regulatory review or disclosure. The SECURE rule will exempt most gene-edited plants that could have been produced from conventional breeding from regulation and will allow developers to decide whether their products qualify for these exemptions. In addition, the USDA's decision to label GMOs as "bioengineered" and exclude gene-edited foods from labeling requirements under the new labeling law also reveals clear support for traditional biotech industry wishes to not require labeling because it "stigmatizes" products. The admission by a representative of a prominent anti-GMO labeling organization that his organization was the "driving force behind the labeling bill" reveals the power of the agribiotech industry in facilitating labeling regulations that are weak, not transparent, and friendly to biotech industry interests.

Established agribiotechnology industry actors use discursive power in efforts to frame the gene-editing debate and regulatory processes. These industry actors deploy scientization discourses to argue that scientific evidence supports limited and/or self-regulation by industry because gene editing is equivalent to traditional plant breeding, but better and more precise. They also use democratization discourses to claim that limited regulatory approval processes will allow for smaller companies and public sector plant breeders to participate in gene editing, which they claim makes the technology more accessible and democratic than GMO technology, which was dominated by large corporations. These democratization discourses are being used to counter concerns raised by advocacy organizations about corporate control of agriculture and food systems and the lack of benefits for smaller and developing country farmers. GEAF proponents suggest that having a greater number of players will lead to greater innovation for the U.S. agriculture sector and will ultimately benefit consumers in both advanced and developing countries. Montenegro (2020a) usefully teases apart the meaning of "democratizing CRISPR" to show how this discourse most often connotes inexpensive technology and freedom from regulation rather than greater access to knowledge or technology or the right to seed or food sovereignty by less powerful actors.

Established agribiotechnology industry actors leverage scientization discourses in an effort to discredit other non-scientific- and/or non-risk-based concerns raised by critics. Along with their reference to scientific evidence, the claim of neutrality is used to suggest that if regulation were needed, that governmental regulatory agencies would be the most appropriate institutions. However, as demonstrated in recent decisions, government regulatory agencies have responded in ways favorable to industry by requiring limited or industry self-regulation rather than as neutral arbiters.

Advocacy groups also employ discourses to contest both the framing of GEAF as not equivalent to GMO and the regulatory decisions made by USDA about gene editing. Many environmental organizations refer to gene editing as GMO 2.0 as a discursive strategy to ensure that GEAF is connected to GMOs and to capitalize on the negative connotations that GMOs have for many consumers. By clearly making linkages to GMOs and the hard-fought campaign for GM labeling, they are also highlighting that consumers also have a right to know about the application of gene editing in food. By tying GEAF to GMOs, advocacy organizations make the claim that actually nothing has changed in terms of the social, environmental, and economic implications of gene editing, contrary to democratization discourses used by agribiotech industry actors around gene editing.

## 7. Conclusions

The protracted contestations over GMO governance and labeling have been significant in shaping the governance discussion about gene editing. Emerging tensions and realignments between and among state and nonstate actors reflect efforts by these actors to incorporate the lessons from the GMO labeling fight as they seek to (re)shape the governance of gene editing in a manner that reflects their interests. Acknowledging that government has thus far taken a pro-large-scale, traditional agribiotech industry approach to GEAF regulation, actors from advocacy groups, agribiotech start-ups, and food and retail industries articulate the need for nonstate actors to respond to consumer concerns by providing greater transparency and disclosure in regards to gene-edited food and agriculture, including through food labeling.

Although the USDA, EPA, and FDA regulatory decisions to date have exempted most types of gene-edited plants from extensive review and excluded gene-edited foods from labeling requirements under the NBFDS, previous lessons from the protracted fight over GMO labeling in the United States may be instructive here. Pressure for GEAF labeling by consumers, food and retail industry, and advocacy organizations in the United States, and the divergent regulatory decisions between the United States and European Union (EU) over whether to regulate and label gene editing as GMO, may eventually force the USDA to reverse course and require labeling of gene-edited foods in the United States.

However, the history of the agribiotechnology industry development should give us pause about being overly optimistic about the ability of advocacy groups, the food and retail industry, and gene editing start-ups to change the agribiotech sector to be more democratic and responsive to consumer demands. While currently there appear to be greater opportunities for smaller companies and start-ups to participate in gene editing research and product development compared to GMO development, past history suggests that the economic, discursive, and political power exerted by larger agribiotech companies is unlikely to be seriously disrupted. If smaller start-up biotech companies do develop highly profitable gene-edited products, it seems highly likely that these companies will

be absorbed by larger, established agribiotech corporations, thus further entrenching these interests in governance of agribiotechnology (Howard, 2016; Clapp and Ruder, 2020).

### Data accessibility statement

The interview protocol has been submitted as supplementary material, SM1. Interview transcripts cannot be provided for reasons of confidentiality.

### Supplemental files

The supplemental files for this article can be found as follows:

Interview guide: Gene-edited foods, governance, and trust. Docx

### Acknowledgments

We thank all the interviewees who contributed to making this research possible. We would also like to thank the reviewers who provided extensive feedback to improve the article.

### Funding

This work was supported by the USDA National Institute of Food and Agriculture (NIFA), Agricultural and Food Research Initiative (AFRI) Foundational Program, Agriculture Economics and Rural Communities, Social Implication of Food and Agriculture Technologies program, Grant Number 2018-67023-27679.

### Competing interests

The authors declare that they have no competing interests.

### Author contributions

Contributed to conception and design: TS.

Contributed to acquisition of data: TS, CB, SL.

Contributed to analysis and interpretation of data: TS, CB, SL.

Drafted and/or revised the article: TS, SL.

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**How to cite this article:** Selfa, T, Lindberg, S, Bain, C. 2021. Governing gene editing in agriculture and food in the United States: Tensions, contestations, and realignments. *Elementa: Science of Anthropocene* 9(1). DOI: <https://doi.org/10.1525/elementa.2020.00153>

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**Knowledge Domain:** Sustainability Transitions

**Part of an Elementa Special Feature:** Gene Editing the Food System

**Published:** October 4, 2021    **Accepted:** September 4, 2021    **Submitted:** October 6, 2020

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