



Emerging sociotechnical imaginaries for gene edited crops for foods in the United States: implications for governance

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Abstract

Gene editing techniques, such as CRISPR, are being heralded as powerful new tools for delivering agricultural products and foods with a variety of beneficial traits quickly, easily, and cheaply. Proponents are concerned, however, about whether the public will accept the new technology and that excessive regulatory oversight could limit the technology's potential. In this paper, we draw on the sociotechnical imaginaries literature to examine how proponents are imagining the potential benefits and risks of gene editing technologies within agriculture. We derive our data from a content analysis of public comments submitted to the Food and Drug Administration's (FDA) 2017 docket titled "Genome Editing in New Plant Varieties Used for Food." Our sample frame consists of 26 comments representing 30 agriculture and biotech companies, organizations, and trade associations. Our findings reveal three key sociotechnical imaginaries, including that gene editing technologies in agriculture: (1) are *not* GMO but instead equivalent to traditional plant breeding; (2) have the potential to usher in a new Green Revolution; and (3) could facilitate the democratization of agricultural biotechnologies. We argue that forming and projecting these collective interpretations of the potential of gene editing technologies for crops and foods plays an important role in efforts by proponents to influence regulatory oversight, modes of governance, and build public acceptance. This research contributes to calls by science and technology studies scholars to investigate emergent concerns and imaginaries for novel technoscientific advances to help inform upstream models of public engagement and governance decisions.

Keywords Biotechnology · Food and agriculture · Governance · Consumer acceptance

Abbreviations

ASTA	American Seed Trade Association	EPA	Environmental Protection Agency
BIO	Biotechnology Innovation Organization	EU	European Union
CSSA	Crop Science Society of America	FDA	Food and Drug Administration
CFRB	Coordinated Framework for the Regulation of Biotechnology	GMO/s	Genetically modified organism/s
CODEX	Codex Alimentarius, International Food Standards	KWS	This is the name of the company KWS SAAT SE
CRISPR	Clustered regularly interspaced short palindromic repeats	RNA	Ribonucleic acid
DNA	Deoxyribonucleic acid	STS	Science and technology studies
		UN FAO	United Nations Food and Agriculture Organization
		US	United States
		USDA	United States Department of Agriculture
		USDA-APHIS	USDA's Animal and Plant Health Inspection Service
		USDA-ARS	USDA's Agricultural Research Service
		TALENs	Transcription activator-like effector nucleases
		WHO	World Health Organization

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Introduction

Gene editing is being heralded by its scientist and business proponents as a powerful new tool with “endless possibilities” (Gupta 2017, p. 1) for delivering agricultural products and foods with benefits for producers, consumers and the environment (Doudna and Sternberg 2017). Unlike genetically modified organisms (GMOs), gene editing does not require the insertion of foreign DNA to produce a desired trait. Instead, scientists using gene editing techniques, such as CRISPR–Cas9 (clustered regularly interspaced short palindromic repeats),¹ and other gene editing techniques, including TALENs, meganucleases, and zinc finger nucleases, are able to delete, substitute, and insert strands of the organism’s own DNA to produce desired traits² (NAS 2016). The gene editing process has been compared to using a word processing program to write a sentence and then remove, rearrange, or substitute words (Gullickson 2017). The relative simplicity of CRISPR and its purported ability to create new traits “rapidly in a precise and predictable manner” has led to an explosion in crop and food research and development (Bortesi and Fischer 2015, p. 41). The technology can be used to develop crops and livestock with particular traits, including resistance to pests, diseases, herbicides, drought and flooding, as well as with improved yields and nutritional composition (Epp 2017).

Realizing the technology’s potential will depend on how it will be regulated (Giddings 2018). As a “disruptive technology”, gene editing for crops and foods are challenging existing regulatory paradigms for biotechnology (Wolt and Wolf 2018; NAS 2017b). The speed with which this powerful technology is being developed has led to some concern about whether regulatory institutions are fully prepared to govern its use (Fernandez 2018). On the other hand, proponents have cautioned that government regulations may “stifle its promise”, “bottleneck [the] innovation” (Brasher and Davies 2018, npn), and burden it “with unnecessary regulatory hurdles” (Marchant and Stevens 2015, p. 237). Within this context, Rodolphe Barrangou, editor of *The CRISPR Journal*, argues that “[n]ow is the time to opine on questions that need to be addressed in regard to how CRISPR-based

technologies should be implemented and regulated” (Mary Ann Liebert, Inc. 2018, npn).

Proponents are also concerned about whether the public will accept gene editing in food and agriculture at a time of growing public skepticism and debate over GMOs (Bain and Dandachi 2014; Wolt and Wolf 2018; NAS 2017a, b). In 2015, for example, only 37% of the public believed GMO foods were safe compared with 88% of scientists (Pew Research Center 2015; Wolt and Wolf 2018). Since 2012, the anti-GMO movement in the US has gained momentum in its demand for GMO food labels (Bain and Dandachi 2014) and, as a result, in 2018 the USDA established the National Bioengineered Food Disclosure Standard that requires foods containing GMO ingredients to be labeled (Food Business News 2018).

Advanced gene editing methods, such as CRISPR, raise novel social, ethical, environmental and legal issues (Wolt and Wolf 2018; NAS 2017a, b) that critics are starting to highlight. In their critiques of gene editing, groups such as the Center for Food Safety (2018) and Friends of the Earth (Cotter and Perls 2018), are drawing from many of the same discourses used previously by the anti-GMO movement (Schurman and Munro 2010; Bain and Dandachi 2014). Coining gene editing, “GMOs 2.0”, critics are frustrated that many of the same claims about the benefits of GMOs, such as promises to “reduce pesticides, provide nutritious foods, and help feed the world”—that they argue fell short—are being made again to justify gene editing (Roseboro 2017, npn). Their primary concern, however, is that changes as a result of gene editing are not fully predictable. According to Friends of the Earth (Cotter and Perls 2018, p. 4), “Precise edits do not necessarily result in precise outcomes.” Unintended changes to DNA and the potential for off target effects could produce negative human and environmental health effects (Roseboro 2017; Charles 2016). Given these risks, these groups argue that crops created using gene editing technologies should require government review and approval (Charles 2016; Niiler 2018; Cotter and Perls 2018). Without a formal regulatory review it is “difficult to know exactly what’s been done to the crop” since company data is private (Charles 2016, npn). In addition, these groups argue that to ensure transparency and consumer choice, the USDA’s National Bioengineered Food Disclosure Standard should include foods that are the result of gene editing, which the standard currently does not (Center for Food Safety 2018; Niiler 2018; Cotter and Perls 2018).

The agriculture, biotech and food industry is eager to avoid a repeat of the costly public controversy over GMOs (Bain and Dandachi 2014; Schurman and Munro 2010; Bunge and Dockser Marcus 2018). Many within the industry believe their handling of the controversy was an “unqualified public-relations disaster” (Dewey 2017, npn). From industry’s perspective, if “done right”, gene editing technologies,

¹ Cas9 is the most common guiding enzyme currently used with CRISPR. Other enzymes can also be used, such as Cpf1.

² CRISPR uses an antiviral defense mechanism paired with single-guided RNAs, while TALENs, meganucleases, and zinc finger nucleases identify their DNA targets through protein/DNA interactions (CAST 2018; Germini et al. 2018). CRISPR has the potential to create a variety of novel changes more efficiently, accurately and cheaply as compared to alternative methods because of its use of relatively simple, programmable single-guided RNAs. This has made CRISPR highly versatile for use in a plethora of new projects and products at the basic and applied research levels (Germini et al. 2018).

Table 1 Classification of organizations in FDA docket sample frame

Type of Entity	Name
Farm and Agricultural Commodity Organizations	American Farm Bureau Federation
	American Soybean Association
	American Sugarbeet Growers Association
	Iowa Corn Growers Association
	Minnesota Soybean Research and Promotion Council
	National Corn Growers Association
	National Cotton Council of America
	National Council of Farmer Cooperatives
	Oklahoma Farm Bureau
	Information Technology & Innovation Foundation (ITIF)
Technology Advocacy	Benson Hill Biosystems
	Betaseed Incorporated
	DuPont Pioneer
	J.R. Simplot
	KWS SAAT SE
Agribusiness, Biotech, Seed Companies	Monsanto
	Donald Danforth Plant Science Center
	Maize Genetics Executive Committee
	AACC International (Cereals and Grains Association)
	Crop Science Society of America
Biotech Research Centers	Society for In-Vitro Biology
	American Seed Trade Association (ASTA)
Science Societies/Organizations	Biotechnology Innovation Organization (BIO)
	CropLife America
Industry Trade Associations	Grocery Manufacturers Association (GMA)
	Corn Refiners Association, National Grain and Feed Association,
	National Oilseed Processors Association, North American Export
	Grain Association, and North American Millers' Association

such as CRISPR, will be accepted by the public (Menayang 2017).

In this paper, we identify the key sociotechnical imaginaries being constructed by proponents of gene editing technologies within agriculture. That is, how gene editing is being imagined by proponents and “the implicit assumptions, values and visions” that they assert (Macnaghten et al. 2005, p. 279). Sociotechnical imaginaries play an important role by projecting an image of what futures should emerge (Macnaghten et al. 2005; Jasanoff and Kim 2009). Proponents seek to frame science and technological trajectories as being in the public interest, that is, what is desirable and good for the public. These are often counterposed against risks and hazards of not realizing these futures (Burnham et al. 2017; Eaton et al. 2014; Jasanoff and Kim 2009; Levidow and Papaioannou 2013; Macnaghten et al. 2005).

Sociotechnical imaginaries can be identified and examined through multiple data, including texts, to explore how actors link sociotechnical imaginaries and technological pathways in certain ways, and why some linkages are more

persuasive than others. These imaginaries can be analyzed to understand how they are linked to governance approaches (Burnham et al. 2017; Eaton et al. 2014; Jasanoff and Kim 2009; Levidow and Papaioannou 2013; Macnaghten et al. 2005; Macnaghten 2016). We derive our data from a content analysis of public comments submitted to the Food and Drug Administration’s (FDA) 2017 docket titled “Genome Editing in New Plant Varieties Used for Food.” This provides a sample frame consisting of comments from organizational proponents of gene editing, including agriculture commodity groups, agribusiness, biotech and seed companies, biotech research centers, industry trade associations, science organizations, and technology advocacy groups (see Table 1).

Our findings identified three key imaginaries in the testimony that we argue proponents use to promote gene editing within agriculture and food, attempts to build public acceptance, and influence the regulation and governance for this novel technology. These imaginaries include that gene editing: (1) is not GMO, but instead equivalent to traditional plant breeding; (2) will usher in a new Green Revolution

and; (3) facilitates a democratization of biotechnology for agriculture and food. We use the imaginaries concept to provide analytical insight into gene editing proponents' collectively imagined visions of the role this technology ought to play in the US economy, scientific research communities, agrifood industry, and global affairs.

Our research is intended to contribute to calls by science and technology studies (STS) scholars for social scientists to investigate emergent concerns, informational climates, and sociotechnical imaginaries related to novel technoscientific advances, such as gene editing. Such findings can help inform upstream models of public engagement and governance decisions before the technology becomes hardwired and manifest in governance infrastructures, including laws, policies, international agreements, or labels (Macnaghten et al. 2005; Macnaghten and Chilvers 2014). STS scholars have found that in some cases proponents succeed in establishing positive imaginaries of a technology before others have formulated an opinion, thus building further expectations and momentum in and about the technoscience and its use (Brown et al. 2000; Borup et al. 2006; Yamaguchi 2019). Within this context, making explicit sociotechnical imaginaries, and their role in efforts to build public acceptance and shape governance, is critical to meeting calls for more inclusive public deliberation and diverse input into the governance of gene editing (Jasanoff and Hurlburt 2008; Kuzma 2016; Kofler et al. 2018; Shukla-Jones et al. 2018; NAS 2016; Montoliu et al. 2018).

The paper is organized as follows. In the next section, we present an overview of the regulatory framework for biotechnology in the US. We then present the theoretical framework that guides our analysis. The next section explains our data and content analysis methods. We then present our results, which focus on the three key sociotechnical imaginaries used by proponents. In the final section, we draw on the sociotechnical imaginaries framework to discuss our results and explain how each imaginary is persuasive in terms of framing the benefits and risks of gene editing in a way that proponents hope can build public acceptance and shape regulatory regimes for this novel technology. Finally, we conclude that as counter-imaginaries emerge to contest these dominant imaginaries, we hope that our findings can contribute to efforts for more informed and inclusive public engagement and governance around gene editing technologies.

Regulatory framework

In 1986, the Coordinated Framework for the Regulation of Biotechnology (CFRB) was enacted to regulate foods, crops, and animal feed produced using biotechnology. Within the framework, regulatory authority is divided among three agencies: FDA, US Department of Agriculture's Animal and

Plant Health Inspection Service (USDA-APHIS), and Environmental Protection Agency (EPA) (USDA n.d.). Jurisdiction of a product depends upon its traits, and more than one agency may be required to evaluate a product.

USDA-APHIS functions as the dominant authority on plant health. GMOs are fully regulated by the agency because an agrobacterium, a plant pest, is used to introduce foreign DNA into a product. Products are considered on a case-by-case basis to determine if a potential risk is present and if USDA-APHIS regulatory review is necessary (Wolt et al. 2016). Should a known or suspected plant pest or noxious weed be created, USDA-APHIS will regulate the product, including its release into the environment, and its import, handling, and interstate movement (USDA n.d.).

In March 2018, USDA's Secretary of Agriculture Sonny Perdue released a statement regarding the agency's oversight of plants produced through gene editing. It states that gene edited products will not be regulated if they could have been created using traditional breeding techniques or mutagenesis, or if they "are not plant pests or developed using plant pests" (USDA 2018). Prior to Secretary Perdue's statement, the USDA had already exempted DuPont Pioneer's waxy corn and The Pennsylvania State University's non-browning mushroom, stating that these gene edited products were outside of its authority because they did not contain plant pests (Waltz 2018; Brodwin 2016).

The role of the EPA is to protect environment and human health and safety through use of a registration process guiding the sale, dispersal, and use of pesticides (USDA n.d.). The EPA focuses on the pesticidal traits that may be present in a plant. For instance, the EPA regulates GMO insect resistant plants, such as Bt corn. The EPA does not regulate gene edited plants unless they possess a plant-incorporated protectant trait rendering the organism itself a pesticide (Custers 2017).

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 (Wolt et al. 2016; Smyth and McHughen 2008). However, due to public pressure, the FDA adopted a process based approach by recommending that developers using GMOs participate in a premarket voluntary consultation with FDA to ensure safety and address any regulatory concerns prior to the product entering the market (USDA n.d.; Marchant and Stevens 2015; Wolt et al. 2016, p. 513). To date, every GMO food product has gone through this voluntary consultation (Marchant and Stevens 2015).

The FDA's approach reflects a central debate over whether the regulation of biotechnology should be product or process based (Marchant and Stevens 2015). A product based regulatory stance assesses the potential risk of the final product, as opposed to a process based assessment that focuses

on the technique used to create products. The assumption behind a process based approach for GMOs is that food, crops, or feed made using GMOs are riskier than products made using other methods (Marchant and Stevens 2015). The CFRB is “ostensibly product based” (Wolt et al. 2016, p. 513) because it views the risks posed by GMO products as equivalent to those of non-GMO products (Kuzma and Kokotovich 2011). In practice, however, regulators often use a process based approach to determine how crops and foods should be regulated and approved (Wolt et al. 2016; Kuzma and Kokotovich 2011).

In 2016, the FDA indicated it would update and clarify its policies related to the regulations of gene edited products (FDA 2017). The FDA recognized the ease with which plant developers could create new plant varieties using gene editing techniques (FDA 2017). The FDA posted the “Genome Editing in New Plant Varieties Used for Foods” comment docket in order to inform possible oversight and regulation of gene edited foods and to update existing guidance documents (FDA 2017). In May 2018, the FDA assembled a Biotechnology Working Group composed of individuals from FDA with the goal of creating an Action Plan outlining the FDA’s intended process of ensuring a “flexible regulatory framework for evaluating the safety of products that also supports plant and animal biotechnology innovation” (Gottlieb and Abram 2018, npn).

To date, only a few countries outside of the US and European Union (EU) have adopted processes for regulating gene edited foods, most of whom favor a final product based approach. Canada regulates gene edited crops similarly to any crops determined to contain novel traits, which then undergo a risk assessment and market approval procedure (Custers 2017). Argentina employs a case-by-case approach in deciding whether a gene edited crop will go through a GMO risk assessment and market approval process. To date Argentina has exempted crops from this process if they only contain small deletions (Custers 2017). In March 2019, Japan decided that gene edited foods would not be regulated if they did not contain foreign genes in the final product (Normile 2019).

In the EU, the regulatory debate around gene editing has been contentious. Court cases in France and Germany have resulted from non-governmental organizations fighting attempts to place gene edited crops outside of the jurisdiction of EU and national GMO regulations (Custers 2017). The EU’s regulatory system was established in 1990 and defines two categories of plant breeding techniques for regulatory purposes: (1) traditional breeding and mutagenesis, and (2) GMO. The EU’s definition of a GMO is based upon the process of creating the organism, not the final product (Pollock and Hails 2014). In July 2018, the EU Court of Justice ruled that gene editing in plants will be regulated as GMOs, even if the gene edited plant does not include

foreign genes (Stokstad 2018). This is similar to New Zealand’s 2014 decision to use process based determinants and regulate gene edited foods as GMOs (Fritzsche et al. 2018).

Sociotechnical imaginaries

Sociotechnical imaginaries are described as “collectively imagined forms of social life and social order reflected in the design and fulfillment of nation-specific scientific and/or technological projects” (Jasanoff and Kim 2009, p. 120). Imaginaries are often counter-posed against the risks or hazards of not pursuing or realizing these futures (Jasanoff and Kim 2009). STS scholars examine the role of political culture and practices in stabilizing particular imaginaries, as well as other resources that must be mobilized to represent technological trajectories as being in the public interest (Jasanoff and Kim 2009; Bronson 2015; Welsh and Wynne 2013). Jasanoff and Kim (2009) applied the sociotechnical imaginaries concept to a comparative examination of the development and regulation of nuclear power in the US and South Korea.

Other scholars have applied the imaginaries concept to examine the promotion of alternative energies, such as bioenergy, for a desirable renewable energy future (Eaton et al. 2014; Burnham et al. 2017; Levidow and Papaioannou 2013). Building on Jasanoff and Kim’s (2009) work on the imaginaries of the role of nuclear power in the US and South Korea, Levidow and Papaioannou (2013) focus on the promotion of bioenergy futures in the United Kingdom. They identify several state imaginaries at work in promoting innovation and renewable energy as being in the public interest, namely that domestic bioenergy production brings public benefits of economic localization, oil substitution, and agri-diversification. They explore how actors link sociotechnical imaginaries and technological pathways in certain ways, and why some linkages are more persuasive to the public than others.

Eaton et al. (2014) observe how local actors in rural northern Michigan responded to and re-imagined the national bioenergy vision as one that focused on local environmental, economic, and energy benefits of bioenergy and fit the local economic and political context of these communities. Burnham et al. (2017) describe the politics of competing bioenergy imaginaries in the Northeastern US, comparing those who promote a community-based, small-scale bioenergy future versus those who argue for a regional, scalable renewable energy future. They illustrate the politics of contested imaginaries in terms of “whose imaginary ‘wins’—that is, becomes manifest in technology infrastructure, policy, and standards” (Burnham et al. 2017, p. 67).

In our case study below, we explore how sociotechnical imaginaries of gene editing crops for foods—as not GMO

Table 2 Coding scheme

Code	Definition
Science	Reference to the scientific method/technique of gene editing to make a recommendation or assessment about potential impacts of a technology
Scientific	Reference to previous scientific research to make a recommendation or assessment about potential impacts of a technology
Scientism	Reference to science to dismiss social, economic, environmental concerns, etc., as irrelevant, unscientific or illegitimate
Regulations	Reference to type and adequacy of government regulations/regulators required for gene edited foods
Food Safety	Reference to food safety risks associated with consuming gene edited foods
Social	Reference to the social impacts, risks, or benefits of gene edited foods
Economic	Reference to the economic impacts, risks, or benefits of gene edited food
Environment	Reference to the environmental benefits, risks, or other considerations related to the environment

but equivalent to traditional plant breeding; as facilitating a new Green Revolution; and as fostering technological democratization—are being promoted by industry proponents in testimonies to the FDA. These sociotechnical imaginaries promise global food security in an environmentally sustainable manner using technologies that are akin to, but more precise than, traditional plant breeding, and provide greater potential for innovation coming from more decentralized and smaller scale, innovative, biotechnology companies. Thus, the interested actors in our study—proponents of gene edited agriculture and food—promote collective interpretations of a future that they want to see materialize. These imaginaries attempt to influence and shape technological innovations, public funding, public acceptance of the technology and its applications, perceptions of risks and benefits, and the possible regulatory actions that may emerge.

In the sections below, we examine discourses used by actors in the FDA docket to illustrate sociotechnical imaginaries deployed to promote gene edited foods. These discourses can potentially construct the perceived risks, benefits, and necessary actions to be taken in regard to the development and acceptance of gene editing in crops. Such visions are not always explicit, but can be embedded within norms, metaphors, and cultural meanings used by actors to express their perspectives on policy (Jasanoff and Kim 2009).

Data and methods

Content analysis was used to identify, categorize, and describe the key sociotechnical imaginaries used by proponents of gene editing in agriculture and food within the FDA’s call for public comments. On January 19, 2017 the FDA opened docket “FDA-2016-N-4389”, or “Genome Editing in New Plant Varieties Used for Food,” and invited the public to respond to a set of questions pertaining to regulatory requirements and safety assessments of gene edited agriculture and food. The stated purpose of the call for

comments was “to inform [FDA’s] thinking on risk considerations going forward” (FDA 2017, npn).

Our sample frame included 26 comments submitted on behalf of 30 organizations that were proponents of gene editing, including agribusiness and biotech companies, agricultural commodity groups, scientific societies, and industry trade organizations (see Table 1). Comments were also submitted by two environmental and consumer-oriented advocacy groups critical of gene editing, one of which was signed by over 23,000 organizational members. These two groups argued that the FDA should comply with the internationally recognized WHO/UN FAO CODEX definition of biotechnology, which includes gene editing. We excluded these two comments, as well as individual comments submitted by the public, from our sample frame because our objective was to assess how organizational actors who are proponents of gene editing were seeking to influence governance and public acceptance.

Following Bruce (2016), we developed an initial set of codes that were based on previous studies that had utilized discourse analysis to examine the regulation of biotechnology. Our initial list of codes included science, scientific, scientism, regulations, food safety, social impacts, economic impacts and environmental impacts. In Table 2 we describe the definitions that we used for each of these codes. The 26 comments submitted to the FDA docket were uploaded into NVivo, a qualitative software program for coding. Two of the authors then independently coded each comment using the list of codes. To ensure consistency and credibility of the coding and the study’s findings, cross-checking took place after the authors each coded an initial sample of the same five documents. The authors then compared and reconciled differences in coding through discussions delineating criteria for inclusion and exclusion. Each author then finished coding the entire sample frame, and a final cross-check took place to ensure inter-coder consistency.

The next step was to identify the key themes related to sociotechnical imaginaries. The three authors of this paper carefully read the coded data and identified three key

imaginaries that proponents were using to influence how the FDA should understand gene editing in terms of its risks and benefits, and how it should be regulated. We now turn to describe each of these imaginaries in detail.

Results

Three socio-technical imaginaries of gene edited crops for foods.

Gene editing is not GMO

A key imaginary used by proponents to emphasize the benefits of gene editing was that the technology is *not* GMO. Instead, they argued that the scientific process is equivalent to traditional plant breeding methods that produce products that are “nature identical.” This imaginary is critical in a context where one of the major questions facing regulators is whether gene edited products should be considered analogous to traditionally bred products, which would ensure they are not regulated as GMOs, or whether they are unique biotechnology products that should be regulated under the current biotechnology regulatory framework (Wolt and Wolf 2018). In their comments, proponents emphasized that gene editing produces changes that theoretically *could* occur in nature with the terms “natural” and “naturally” used 45 and 16 times, respectively, within the 26 comments. For example, KWS, a biotech, plant breeding and research company, argued that gene edits could occur through natural mutations or traditional plant breeding methods, such as crossbreeding or mutagenesis, that could be used to change the genome. They argued:

Plants produced by SDN1, SDN2, and certain SDN3³ approaches are nature identical and could have been produced by means of traditional breeding methods or through natural mutations.

Proponents sought to distinguish gene editing from GMOs, a process that could not occur naturally because a foreign gene could not enter a plant’s DNA on its own. It must be hosted by agrobacterium. In terms of public acceptance, this imaginary is important because one of the primary ethical and religious concerns among the public is that GMOs are ‘unnatural’ because GMO crops contain genes from more than one species (Bruce 2016; Du 2012). In contrast, CRISPR–Cas9, for example, enables scientists

to edit the DNA of any living species using a process that was adapted from one that bacteria use to protect themselves from viruses (United States National Library of Medicine 2019). Proponents emphasized that—distinct from GMOs—gene edited products are indistinguishable from those produced using traditional plant breeding techniques in terms of their “molecular composition and trait characteristics” (KWS). Innovations using the “next generation of breeding products”—that is, gene editing—will be “targeted at replicating natural variations of alleles within a species” where successful products will “be indistinguishable from other natural variants” (National Corn Growers Association).

Proponents emphasized that gene editing is “substantially equivalent” to traditional plant breeding, but superior because it is significantly more precise and efficient. Companies and trade associations involved in plant breeding and biotechnology research, development and promotion argued that changes to a species’ genome using CRISPR–Cas9 in the laboratory are “remarkably precis[e]” (Biotechnology Innovation Organization (BIO), a biotech trade association), “targeted” (American Seed Trade Association (ASTA)) and incomparably faster than what could occur in nature. DuPont Pioneer, a biotech plant breeding and research company, explained:

[Gene editing] allows scientists to more precisely and efficiently improve a plant that could be obtained using traditional breeding methods or found in nature.

Imagining gene editing as *not* GMO but instead akin to natural plant breeding—only more precise and efficient—was central to proponents’ framing of the minimal or low food safety risks of gene edited foods. In these imaginaries, proponents drew on both product and process based arguments about risk. Proponents sought to minimize concerns regarding potential food safety risks by comparing the *process* of gene editing with ‘low risk’ traditional plant breeding as distinct from GMOs. KWS argued that gene editing approaches do not “contain any foreign genes or genes that were modified outside of the plant” and therefore the risks associated with them are “significantly reduced compared to the method of non-targeted genetic mutations using in vitro recombinant DNA technologies.” AACC International, an association for advancing cereal grain science, asserted that gene editing is “not expected to introduce novel risks” and KWS concurred that the food safety risks are “no different than the risks obtained through conventional breeding.” Similarly, the Sugarbeet Growers Association stated that:

There is no reason to believe that a particular genetic change (e.g., insertions, deletions or substitutions) that relies on the existing inherent diversity in a plant’s gene pool would be more or less likely to present new or novel food safety risks.

³ These are different site directed nucleus editing methods. SDN1 and SDN2 create simple, subtle changes to DNA. However, SDN3 introduces large sequences of DNA and can include the insertion of foreign DNA (CAST 2018).

Proponents, such as ASTA and BIO, buttressed these arguments by pointing out that few sectors have the strong food safety record that plant breeding does. Benson Hill Biosystems, a biotech, plant breeding and research company, agreed:

[T]he plant breeding process using mutation and crossing methods have produced hundreds of varieties without safety concerns.... There is no reason to believe that reproducing those same types of genetic changes using gene editing would carry additional risks.

At the same time, proponents emphasized that it should be the characteristics of the final *product*, not the process through which the product was created, that the FDA should use as the basis for assessing any food safety risks. For example, the Sugarbeet Growers Association argued:

[T]he final characteristics of the new plant variety are the best indicator of whether a new plant variety will present a food safety risk. Scientists have argued that the gene or target should be evaluated for potential food safety risk and if deemed safe, the breeding methods used to impart the change are inconsequential.

Similarly, J.R. Simplot Company, a large agribusiness company, argued that the FDA had:

appropriately recognized that the regulatory status of a food should be determined by the objective characteristics of the food and its intended use, rather than the method by which the food was developed.

Most proponents were opposed to the FDA developing a policy that would require mandatory premarket notification for gene edited foods.⁴ Instead, most proponents supported the status quo of a voluntary premarket consultation with FDA because it offered developers “the opportunity to clarify any questions or concerns regarding food and feed safety risks of the new product” (Betaseed). Nevertheless, Benson Hill Biosystems, Inc highlighted the contradiction of arguing that gene editing was akin to plant breeding and then

supporting voluntary premarket consultation. They argued that since “crop varieties produced through traditional breeding techniques are not involved in FDA’s voluntary consultation process, neither should crop varieties generated from these genome edited applications.”

In this imaginary, proponents drew on—sometimes contradictory—product and process-based frames to support their arguments. Proponents sought to frame gene editing as not GMO but instead akin to traditional plant breeding, only more precise. This is desirable because the public is more likely to accept a process that is perceived as natural rather than transgenic. Proponents also drew on process and product based claims to argue that gene edited products are desirable because they have the same ‘low risk’ associated with traditionally bred products. Since products of traditional plant breeding are currently not regulated, and the food safety risks are equivalent, the FDA should not regulate gene edited products as GMOs.

Gene editing can deliver a new Green Revolution

A second key imaginary used by proponents is that gene editing technology has the potential to deliver a *new* Green Revolution. Lasting from 1966 until the mid-1980s, the first Green Revolution was aimed at improving agricultural productivity and enhancing food security in developing nations (Pingali 2012). The Green Revolution was a response, in part, to post-World War II fears of a Malthusian “population bomb” and famine (Ehrlich 1968; Pingali 2012). Scientific efforts built upon agricultural advances already achieved in developed nations, such as improved varieties of rice, wheat, and maize (Pingali 2012). These efforts resulted in increased yields, poverty reduction, and lower food prices and were credited with staving off famines in places such as India (Pingali 2012; Glenna and Tobin 2019; Macnaghten et al. 2005).

Nevertheless, the socio-economic effects of Green Revolution technologies were uneven. Most of the targeted developing countries were in Asia while sub-Saharan Africa was largely excluded (Pingali 2012). The Green Revolution also produced negative social impacts. For instance, technology transfer to developing countries was a critical component of agricultural improvement efforts, including hybrid seed varieties, chemical inputs, and irrigation (Pingali 2012). However, many smallholder farmers could not afford these inputs, nor access to credit and market infrastructures, leading to “depeasantization” as smallholders migrated in search of employment opportunities, transferring poverty from rural to urban areas rather than reducing it (Glenna and Tobin 2019).

According to proponents, investment in a *new* Green Revolution is imperative because the current world population is expected to reach 9.7 billion by 2050 (FAO 2017),

⁴ One submission supported an entirely unique governance approach, arguing that the FDA should “require premarket notification ... regardless of the technique used” (Corn Refiners Association et al.). This submission was submitted on behalf of five food and feed associations: Corn Refiners, National Grain and Feed, National Oilseed Processing, North American Export Grain, and North American Millers. From their perspective, “the level of FDA’s safety risk-assessment and regulation of gene-editing techniques should be proportional to the degree of risk, if any, posed by the characteristics of the end-product rather than based on upon the technology used to create it” (Corn Refiners Association et al.). However, the Associations argued that mandatory premarket notification was critical to ensuring consumer confidence, transparency, marketability and trade of human and animal food products in the US and globally.

up from 7.5 billion in 2018. At the same time, yields for some varieties of wheat, maize, and rice are stagnant or in decline in many regions, including China, India, Europe, and Africa (Ray et al. 2012). To feed this growing global population, gene editing technology is essential to increase crop yields and levels of food production (American Soybean Association). ASTA argued that without gene editing the food security situation would worsen globally, especially in developing countries:

[seed] innovation is crucial for ... global food security, particularly at a time when the global population continues to grow rapidly and many developing nations can ill-afford food shortages.

Commodity organizations argued that the daunting task of ensuring food security for the world's population was one that US farmers were best positioned to meet because they are the most productive and efficient producers in the world. For example, the National Corn Growers Association argued:

With [biotechnology, US] growers have consistently produced record crops while utilizing inputs more efficiently. This increased productivity has helped sustain the viability of U.S. farms, supported domestic and rural economies and contributed to a world food supply.

Nevertheless, proponents cautioned that US farmers are being asked to produce more while at the same time threatened by growing problems with pests, diseases, drought, and climate change (DuPont Pioneer). These factors are threatening agricultural resiliency and US farmers' ability "to secure global food production in sufficient quantities and at affordable prices" (KWS). To ensure the safety and security of the global food supply within this complex environment, gene editing is necessary to increase yields while also incorporating traits to resist pests, diseases, and the effects of drought and climate change. The Minnesota Soybean Research and Promotion Council forcefully made this point:

[T]he only way soybean growers can rapidly adjust to the ever-changing landscape of crop production, environmental sustainability, climate change and human nutrition is through genome editing.

Similarly, the National Corn Growers Association explained:

Farmers place a high value on the access to tools that allow them to continually improve the sustainability of their operations while supplying a safe, secure supply of food. ...growers are looking forward to the next generation of breeding innovations to further this trend.

The first Green Revolution was widely criticized for its detrimental environmental consequences. The adoption of crop monocultures of high-yielding, high-input varieties and their associated chemical fertilizers and pesticides, irrigation, and machinery produced long term harms to the environment and natural resources (Cullather 2010; Shiva 2016; Shaw 2018). This included degradation and erosion of soils, as well as pesticide and sediment run-off from farms that contaminated aquatic environments (Cullather 2010; Shiva 2016; Shaw 2018). In their comments, proponents argued that gene editing could produce a new Green Revolution where increased agricultural productivity to feed a growing world population could be accomplished but without compromising the natural environment. Within a context of natural resource constraints, proponents argued that gene editing technologies were necessary to allow farmers to increase yields while using resources, such as land, water, and chemical inputs, as efficiently as possible. The American Soybean Association explained:

Improving seed varieties through genome editing techniques means we can do more with less — growing more soybeans on less land with fewer inputs, including water, fertilizer, and pesticides.

Proponents suggested that a potential threat to US farmers' ability to feed the world while protecting the nation's natural resources was "burdensome" regulations on gene editing technologies. Some of the most frequently used terms throughout the comments were "burden", "burdensome" and "overburden" (19 times) to refer to the regulatory process for agricultural biotechnology. The American Soybean Association explained that a regulatory framework that is "not overly burdensome" would allow "individuals, small businesses and universities [to] meet global food demand while also creating jobs and market opportunities across the country." Proponents argued that the FDA must ensure regulatory conditions do not 'stifle' the innovation pipeline of gene editing technology nor farmers' ability to access it. For example, the American Farm Bureau Federation argued:

It is imperative that FDA ... sets policies that do not stifle innovation while creating an environment where America's farmers and ranchers have the ability to meet the challenges of the future in the most sustainable way possible.

In this imaginary, proponents asserted that if regulatory oversight is not overly burdensome, plant breeders and companies would be able to quickly and affordably develop new gene edited products for US farmers. In turn, these farmers will deliver a new Green Revolution that will help feed the world in an environmentally sustainable manner.

Gene editing can democratize agricultural biotechnologies

A third key imaginary used by proponents was that gene editing technology was desirable because of its potential to democratize the development of agricultural biotechnologies. Some proponents argued that a major shortcoming of GMO technologies was that they were controlled by a small number of very large, for-profit biotechnology companies and that the benefits of GMO biotechnology largely accrued to these companies and large-scale farmers. In contrast, gene editing provides an opportunity to develop a new model of innovation for agricultural biotechnologies. Due to its relative low cost and simplicity of use, a broader array of actors—from start-ups, to small- and medium-sized companies, to public scientists—could participate. This would result in greater, and more widely distributed, social and economic benefits. The biotech crop research and development company, Benson Hill Biosystems, for example, argued that control of biotechnology by a few companies was problematic and, alluding to the recent trend of mergers and acquisitions among multinational biotech, seed, and chemical companies, could worsen:

Developing better crops has traditionally been dominated by a few companies with the largest R&D budgets, and the industry continues through an unprecedented level of consolidation further limiting what crops and traits receive innovation.

Within this context, Benson Hill Biosystems argued that it was urgent that a new research and development (R&D) model be developed to unleash the power of gene editing to deliver widespread societal benefits:

There is an urgent need to redefine the model of innovation in the food and agricultural industries.... [to empower] a diverse community of innovators to leverage the global genomic potential of plants to help meet the needs of consumers while taking care of our planet and its natural resources.

Proponents argued that “burdensome” and “unnecessary” government regulations had played a critical role in concentrating control of biotechnology among a small handful of companies. For example, the Crop Science Society of America (CSSA), a scientific society comprised of members working in the field of crop sciences, argued that “current regulations stifle innovation and prevent all but the largest of companies from investing in genome editing applications.” Much of this burden was attributed to the cost of meeting regulatory requirements for introducing new GMO plant varieties. CSSA claimed that these costs amounted to \$35 million between 2008 and 2012. Similarly, the American Sugarbeet Growers Association

argued that costly government regulations limited participation to only the largest companies:

Part of the reason for many large firms dominating today’s landscape in offering genetically engineered crops, is the excessive cost associated with the burdensome and unnecessary regulations tied to one method of breeding.

In contrast, gene editing offers the potential for smaller companies and public scientists to fill a niche left by large companies, developing products with traits that are beneficial to farmers, food companies, and consumers, but are not profitable. CSSA argued that “with less burdensome regulations, smaller companies could attract investment capital, creating job opportunities and addressing niche issues or crops unsuited to larger agribusiness enterprises”. The Society for In Vitro Biology, a professional society focused on biological research and development, argued that gene editing technology had the potential to improve less profitable crops, such as fruits and vegetables:

Vegetables and fruits that could benefit from the application of the technology will be particularly affected, as they are not grown in sufficient quantity to justify the costs, which have been associated with the overregulation of GE crops.

According to proponents, gene editing has the capacity to deliver widespread social, economic, and environmental public goods. To accomplish this, participation by a wide range of actors, including both public and private researchers, is necessary to drive innovation in product development that can deliver these public goods. For example, the Maize Genetic Executive Committee for MaizeGDB, a USDA-ARS funded project to develop an online maize genetics/genome database, argued that democratizing the technology will be critical to meeting the challenge of feeding the growing global population:

Precision genome engineering technologies promise to democratize crop improvement. This will enable individual researchers in academia or in small businesses to solve arguably society’s most pressing issue: ensuring adequate nutrition and calories to a growing global population, and as a consequence improving the health and wellbeing of the next generation.

Without the “prohibitive expense” (CSSA) of meeting government regulations, which restricts participation in biotechnology development, economic benefits would be delivered to broader segments of society. The American Farm Bureau Federation argued that this would provide significant economic benefits through the creation of new jobs and markets:

Small companies and universities have already begun to utilize genome editing tools... these projects can ultimately lead to new products, jobs and market opportunities along the entire food value chain.

However, the Maize Genetic Executive Committee warned that if the US does not act now to take advantage of these opportunities, it will lose the chance to be the global leader in using this technology: “if the United States does not lead the way, other countries certainly will.”

Democratizing the technology is also important because it could potentially enhance public trust and acceptance in the technology. CSSA argued that “democratizing the technology ... would also enable not-for-profit groups to take advantage of the latest scientific advances, further boosting public trust.” The implication is that public trust would be enhanced if crop development efforts were broadened beyond large multinational corporations that had largely focused on developing products for profit rather than the public good.

In using this imaginary, proponents claimed that the democratization of gene editing is critical to enhancing public trust and delivering widespread societal benefits, including those necessary to advance a new Green Revolution. However, proponents warned that the democratization of gene editing depends significantly on how the FDA and other government agencies decide to regulate the technology.

In summary, the FDA docket provides a rich data set that reveals how proponents are framing the discussion of gene editing around these three key imaginaries. Gene editing proponents from agriculture commodity groups, seed and biotechnology companies, trade associations, and science organizations pull elements from three distinct, yet complementary sociotechnical imaginaries. These three imaginaries work together to argue for why the development and widespread adoption of this new technology, which will strengthen the US position as a global leader in technological innovation, food security, and environmental sustainability, depends on avoiding regulatory burdens.

Discussion and conclusions

Sociotechnical imaginaries are important because they can shape and legitimize regulatory regimes for novel technologies, as they, “like narratives and discourses, guide interpretation and frame the boundaries of the thinkable” (Smith and Tidwell 2016, p. 330). These regulatory regimes will be critical to guiding the trajectory of research and innovation for these technologies, as well as their social acceptance. Governance regimes also inform who gets to participate, who invests, how the technologies are applied, and who benefits from the use of the technologies.

In our content analysis of proponent stakeholder comments submitted to the FDA’s 2017 docket, we identified three key imaginaries. These interconnected imaginaries aimed to influence how the FDA should regulate gene edited foods and to articulate the risks of not doing so. The first imaginary—that gene editing is equivalent to traditional plant breeding, although more efficient and precise—is persuasive because it counters widespread social and political concerns associated with GMOs as “unnatural” “Frankenfoods” (Bruce 2016). It asserts that gene editing should not be regulated in the same way that GMOs are because changes made using gene editing could theoretically occur through natural mutations or traditional plant breeding. This reasoning is important because it is assumed that the food safety risks and potential for off-target effects from conventionally bred crops are low.

The second imaginary is that gene editing will usher in a new Green Revolution, allowing more food to be produced in an environmentally sustainable manner. This imaginary is persuasive because it responds to a widespread perception present in public discourse that the growing global population poses a significant social and environmental threat (CAST 2018). This threat can be overcome by increasing the productivity and efficiencies of US agriculture. The greatest risk is that burdensome regulations will hinder the ability of American farmers to use this technology to contribute to increased global food security and enhance the resiliency of our natural resource systems.

The third imaginary is that gene editing can democratize the development, application and adoption of biotechnology. Due to the relatively inexpensive nature and ease of use of this technology, researchers from public universities and small start-ups, in addition to large biotech companies, will be able to access this technology. This in turn will unleash innovation and help drive the development of products and traits with widespread societal benefits because some researchers will not be constrained by the need to generate large profits. This imaginary is persuasive because it responds to widespread criticisms that GMO technologies were concentrated in the hands of the largest companies, especially Monsanto, which narrowed the kinds of products and traits to only those that are most profitable (Pechlaner 2012). The narrowing of participants to only large biotechnology companies was also due to high regulatory costs related to previous approvals of new GMO crops. The risk then is that burdensome regulations will hinder this democratization, again preventing smaller players from participating with significant implications for who benefits.

Through these sociotechnical imaginaries, proponents are attempting to pre-emptively counter the transfer of activist critiques of the earlier GMO industry to gene editing (Schurman and Munro 2010). These critiques included corporate concentration by a small number of powerful agricultural

biotechnology companies; development of GMO traits that were beneficial for large farmers and biotechnology companies but not necessarily for consumers; that GMOs are not natural; and that transgenic agriculture brings potential food safety risks. Anti-GMO activists have also highlighted issues related to consumers' right to know and consumers' right to choose as fundamental to GMO labeling campaigns (Bain and Dandachi 2014; Bain and Selfa 2017). In addition to attempting to disassociate gene editing from critiques of earlier GMO agriculture, proponents suggest that gene editing is beneficial for the US economy, and indispensable for future global food security under environmental constraints.

The objective of this analysis has not been to make any claims regarding the accuracy of each imaginary, but rather to highlight that sociotechnical imaginaries "are materially powerful" because they attempt to "shape practices, relationships, and commitments (which are often rendered irreversible), and as such, they demand reflective, accountable attention and debate" (Macnaghten et al. 2005, p. 279). Their power emanates from the strength of their alignment with national "discourses, metaphors and cultural meanings" (Jasanoff and Kim 2009, p. 123) that include the importance of scientific and technological innovation, democratic access to opportunities for innovation, and US leadership in global agricultural production for food security, which can shape policy and regulatory preferences.

As Macnaghten (2008, p. 109) has argued with reference to other emergent technologies, while societal and scientific imaginaries project future imagined worlds and frequently inform and shape new scientific fields, they often tend to be "insulated from wider recognition, accountability and negotiation." The insulation from wider public debate can result both from narrow issue framing so that only certain topics are allowable in these fora, or by rendering political discussions inaccessible to a larger public via "scientization", that is, framing the issues in technical and scientific jargon (Kinchy 2012; Sarewitz 2004). For example, in her study of the public hearings related to approval of genetically engineered salmon, Bruce (2016, p. 2) showed how the FDA narrowed the hearings to focus only on the issue of labeling because the FDA had pre-determined that genetically engineered salmon are "generally regarded as safe" and as such, did not merit public debate over its efficacy nor require special regulatory oversight. Kinchy (2012) described how scientization of debates about biotechnology in Mexico and Canada were strategic political projects pursued by actors who benefitted from defining matters of social significance in this narrowly technical way.

In the case of emergent biotechnologies, the challenges for publics to counter dominant cultural metaphors and narrow scientific considerations are often significant (Kinchy 2012; Bruce 2016). STS scholars have shown that to contest dominant, or offer counter, sociotechnical imaginaries,

it is necessary to recognize the cultural processes involved in construction of these imaginaries. For example, Bronson (2015) highlights the important role that patriotic ideology and legitimization processes played in transforming the adoption of genetically engineered seeds in Canada from a private industry benefit into a project that was embraced by Canadians as a societal public 'good.' Our analysis of three sociotechnical imaginaries of gene editing demonstrates how industry actors frame the benefits of gene editing to appeal to defining cultural metaphors in the US, namely the importance of democratic access, technological innovation and dominance in ensuring global food security.

In writing about how publics can also be perceived as "threats" to technological innovations, Hess (2015), interrogates the social and political dynamics that determine *who* can speak to what is "best for society" in terms of how technological innovations benefit the public good. Mobilized publics can potentially pose counter-imaginaries of state, industry and sociotechnical futures (Hess 2015; Welsh and Wynne 2013). The opponent testimonies in the FDA docket counter the dominant sociotechnical imaginaries articulated by proponents by asking for mandatory regulations for genetically engineered plants and animals (including those created through gene editing and gene drives), mandatory labeling of food developed through any genetic engineering process, and corporate liability for harms to non-GMO farmers. They contest the idea that gene editing is *not* GMO by referencing UN FAO CODEX standards which define gene editing as GMO. Drawing from many of the same discourses used by the anti-GMO movement previously (Schurman and Munro 2010; Bain and Dandachi 2014) these counter-imaginaries propose a sociotechnical future that needs to be inclusive of a broader public, including non-GMO farmers and consumers who want to choose whether or not to consume GMOs. Additional international efforts to initiate a dialogue on broader social and ethical implications of gene editing technologies have begun and may hold promise for more informed governance and decision-making in the future (Kofler et al. 2018; Jasanoff and Hurlburt 2008). We hope that our research findings can help inform these discussions.

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