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Governing Agricultural Biotechnologies in the United States, the United Kingdom, and Germany: A Trans-decadal Study of Regulatory Cultures

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Abstract

Comparative studies of agricultural biotechnology regulation have highlighted differences in the roles that science and politics play in decision-making. Drawing on documentary and interview evidence in the United States, the United Kingdom, and Germany, we consider how the "regulatory

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cultures" that guided national responses to earlier generations of agricultural biotechnology have developed, alongside the emergence of genome editing in food crops. We find that aspects of the "product-based" regulatory approach have largely been maintained in US biosafety frameworks and that the British and German approaches have at different stages combined "process-based" and "programmatic" elements that address the scientific and sociopolitical novelty of genome editing to varying degrees. We seek to explain these patterns of stability and change by exploring how changing opportunity structures in each jurisdiction have enabled or constrained public reasoning around emerging agricultural biotechnologies. By showing how opportunity structures and regulatory cultures interact over the long-term, we provide insights that help us to interpret current and evolving dynamics in the governance of genome editing and the longer-term development of agricultural biotechnology.

Keywords
genome editing, biotechnology, genetic modification, GMO, governance, policy, regulation

Introduction

Comparative studies of the governance of technology across countries have illuminated how the application of scientific evidence in decision-making has been shaped by institutional, political, and cultural differences (e.g., Vogel 1986; Jasanoff 1991). Within this broad literature, the transatlantic divergence in agricultural biotechnology regulation has attracted significant attention over the past three decades, including in the pages of this journal (e.g., Levidow et al. 1997; Joly and Marris 2003; Levidow, Murphy, and Carr 2007; Kuzma 2016; Frow 2020). In particular, distinctions have been made between the regulatory approaches taken in the United States, which was the first country to develop a framework to govern the first generation of agricultural biotechnology, and different nations within the European Union (EU), each of which developed their approaches within the EU's framework. These adopted approaches, as Chataway and Tait (1993) state, were of two kinds: "product-based" or the reactive regulation of genetically modified organisms (GMOs) on the basis of hazards from existing product categories, and "process-based" or the proactive regulation of GMOs as a new category with potential novel and unforeseen hazards. In a further contribution, Jasanoff (1995) identified three cultures of biotechnology

regulation, which she termed *product* (in the United States), *process* (in the United Kingdom), and *program* (in Germany). Jasanoff's "three cultures" thesis revealed how cultural and historical differences in each country's regulatory regime could help explain divergences in their respective approaches to genetically modified (GM) crops; divergences which led to controversy and a World Trade Organization (WTO) dispute.

The arrival of another generation of agricultural biotechnologies, notably those involving genome editing techniques such as CRISPR-Cas, again draws our attention to international and transatlantic differences. In this paper, we consider genome editing in food crops and interrogate the evolving regulatory approaches of the United States, the United Kingdom, and Germany. We ask how the regulatory cultures that emerged in response to the first generation of agricultural biotechnology have developed over the intervening three and a half decades and in response to the advent of genome editing? We build upon the work of Jasanoff (1995) and others to explore how legal and political developments have contributed to regulatory changes, and ask what conceptual tools can help us to explain change over this longer duration?

Our approach is both comparative and longitudinal, allowing an empirical investigation over broad temporal and geographical scales that is absent from other recent country studies (Helliwell, Hartley, and Pearce 2019) or multi-country (Meyer and Heimstädt 2019). Between 2001 and 2021, the authors were involved in several separate projects investigating the regulation and governance of GMOs in each of the three countries that are the focus of this paper. Each of these projects drew on documentary analysis, as well as interviews and group discussions (see "Reconsidering Regulatory Cultures"), but in utilizing these data, we limit our analysis to the period from 1986 to January 2021, when both the United Kingdom's Brexit transition period and the US Trump presidency concluded. By examining the long-term regulatory approaches to agricultural biotechnology across these three countries, we show how elements of the three cultures identified by Jasanoff continue to shape how the governance of genome editing and its products are being grappled with in the United States, United Kingdom, and Germany. We also discuss how key moments such as the new EU Directives in 2001 and 2015, the US move toward labeling of bioengineered food, the July 2018 ruling by the European Court of Justice (pertinent to genome editing), and the United Kingdom's departure from the EU have affected possibilities for policy change.

We explore the notion of "opportunity structures" as a means to understand these changes. In so doing, we reveal when and how regulatory cultures that might appear static (e.g., Jasanoff 1995) can actually evolve or change over time, with implications for subsequent generations of

technology. The social movements literature has traditionally pointed to political opportunity structures, alongside other factors, to explain the effectiveness of campaigns against the state (McAdam et al. 2001, 41). In the pages of this journal, the concept has been applied to understand how scientists and entrepreneurs have mobilized within the political opportunity structures provided by mainstream institutions (Woodhouse and Breyman 2005), and to explain how activists were able to create alternative sociotechnical infrastructures (Espinoza Vasquez 2021). In this paper, we focus on opportunities for different stakeholders—scientists, corporates, activists, and campaigning organizations—to participate in public debate and decision-making about agricultural biotechnologies. Such opportunities are "situational" rather than permanent (Tarrow 1998, 76-77), and thus the notion of opportunity structures offers a more dynamic viewpoint that allows scholars to appreciate how events such as political or legislative changes can influence shifts in regulatory cultures that shape stakeholder contributions to regulatory decision-making.

Within biotech regulation specifically, the notion of opportunity structures has more recently been applied to industrial as well as political structures. Calling for scholars of social movements to "decenter the state," Schurman (2004, 247-48) examined the importance of "industry opportunity structures," including behavior, culture, and actor networks in explaining the effectiveness of the "anti-biotechnology" movement in Europe. Macnaghten and Habets (2020, 355) describe the opportunity structure afforded to the same movement by the labeling of GMOs in the EU, creating unprecedented space for public debate and consumer pressure. For our purposes, we define opportunity structures as the changing social, legal, and political frameworks within which public reasoning about controversial technologies can take place.[1] Using this broad definition, we seek conceptual tools that take us beyond regulatory cultures and help to explain policy change and stability over the longer term. We explore how opportunity structures enable or constrain spaces for stakeholders to question and debate the physical, social, and political risks of agricultural biotechnologies and demonstrate how these processes have shaped the regulation of those biotechnologies over consecutive generations.

Comparing Regulatory Cultures of Agricultural Biotechnology Regulation

Why compare regulatory decision-making across jurisdictions? Comparative studies of the legal and institutional contexts in which regulatory

decisions are made offer a nuanced and persuasive explanation of divergence. As Jasanoff (2005b, 43) has written, "whether or not such understanding leads to greater convergence in public values or policy action, it should increase the intelligence and sophistication of the global debate on these issues." Longitudinal comparisons allow a deeper appreciation of the interplay of social and technical aspects of decision-making over time and enable further reflexivity.

Prior to the 1990s, emerging regulatory frameworks on both sides of the Atlantic largely followed an apparent consensus that there should be a case-by-case assessment of physical risks arising from recombinant DNA techniques (OECD 1986), with food safety assessment based on the principle of "substantial equivalence" (OECD 1993). Toward the end of the 1980s, significant divergences began to appear between jurisdictions. The key distinction contrasted the US approach, which focused on characteristics of the GMO product as a trigger for regulatory oversight, with the EU approach, which treated the process through which GMOs had been created as a trigger for regulatory oversight (Cantley 1995). This split became entrenched when the EU enacted legislation in 1990 to govern deliberate release and marketing of products derived from specific techniques of genetic modification (listed in Annex 1 of Directive 1990/220/EC).

This transatlantic divergence set the stage for subsequent studies of science and regulatory policy, analyzing the limits of "substantial equivalence" as a framing assumption for risk assessment (e.g., Levidow, Murphy, and Carr 2007) and compared how different procedures and institutions reinforced distinct risk framings in the United States and the European Union (e.g., Levidow 1999). According to Macnaghten and Habets (2020, citing Grove-White 2001, 469), the divergence provided an opportunity structure for controversy to arise, which "facilitated an operating space for NGOs (and later, the media and other actors) to translate 'diffuse or unfocused public concerns into terms compatible with what they understand to be the particular policy world in question.'"

Adopting a longer analytical time frame that included the period before EU-wide legislation, Jasanoff (1995) examined the development of different regulatory cultures in the United States, United Kingdom, and Germany. They showed that the US product–based approach interpreted the risks from biotechnology primarily as physical risks to health or the environment, while the UK process–based approach also focused on broader social risks, and the German program–based approach incorporated political risks alongside social concerns (Jasanoff 1995, 323). In later work, Jasanoff (2005a, 249) explored how these differences could be explained with

reference to different civic epistemologies—culturally specific, historically, and politically grounded ways in which citizens expect the state's expertise, knowledge, and reasoning to be produced, tested, and used in decision-making. Conceptualizing United States, British, and German civic epistemologies as contentious, communitarian, and consensus-seeking, respectively, Jasanoff (2005a, 259; 2005b, 44) identified how the regulatory decisions that flow from these different civic epistemologies "position the ontological novelties created by biotechnology either on the side of the familiar and manageable or on the side of the unknown and perhaps insupportably risky." By adopting an even longer time frame, our study is able to trace how these regulatory decisions have shaped the contingent dynamics of policy debate, stability, and change. As we discuss below, by framing GMOs as unknown and risky, the EU Directive 1990/220/EC created an opportunity structure that bounded the possibilities for public reasoning around later generations of agricultural biotechnology.

Comparative studies of liberal democracies point to clear differences in regulatory cultures that are interesting in their own right. Moreover, given the international economic and political influence of some of these countries, they have been shown to have broad implications. For example, several studies have pointed to the influence of US and EU discourse and direct lobbying on emerging national biosafety regimes in African countries (Paarlberg 2008; Aerni and Bernauer 2006; Schnurr 2019). Ely (2006) has applied Jasanoff's notion of a "program" culture to study Austrian biosafety policy, while the product/process distinction has been applied in studies of several other jurisdictions (Applegate 2001; Schnurr and Smyth 2016) and has been a subject of debate in international fora such as the EU and WTO (Kinchy et al. 2008). Therefore, we find that these three so-called regulatory cultures provide a useful framework to use as a starting point in comparative studies of agricultural biotechnology regulation. After introducing regulatory debates regarding new genome editing technologies applied to agriculture and food, we consider how these regulatory cultures have been influenced by changing opportunity structures to shape current policies in the United States, the United Kingdom, and Germany.

From Genetic Modification to Genome Editing

Conventional techniques of genetic modification pioneered in the early 1970s involve the manipulation of DNA to create chimeric molecules containing one or more genes that are inserted somewhere into a target organism's genome. The resulting GMOs are commonly labeled transgenic to

reflect this transfer of DNA. The technology has been used widely as a tool to produce industrial and medical products in simple organisms, to increase expression of specific traits in crop plants, and, in a few cases, to modify animals. In agriculture, the diversity of commercialized transgenic crops has fallen far short of the early predictions from biotechnologists that applications "are only limited by our imaginations, and at the moment, imagination is running unchecked" (Alper 1984, 13). In reality, just the two transgenic traits of herbicide tolerance and *Bacillus thuringiensis* (Bt)-based insect resistance account for 99 percent of acres planted to GM crops (NAS Committee on Genetically Engineered Crops 2016).

Genome editing manipulates a particular site in the target organism's DNA, and is the basis of a new generation of agricultural biotechnology products. Until 2012, two genome editing techniques appeared to be most promising. They involved the use of zinc finger nucleases (ZFNs) or transcription activator-like effector nucleases (TALENs), which are artificial enzymes that can be engineered to target specific DNA sequences for cutting and recombination. These tools have now been superseded by CRISPR-Cas-based tools, which have been widely heralded as a more nimble, versatile, and inexpensive tools for genome editing. CRISPR-Cas techniques have been taken up very rapidly by the scientific community, first in prokaryotes (Jinek et al. 2012), and later in eukaryotes (Cong et al. 2013) including crop plants (Shan et al. 2013). Further research extended the application of CRISPR-Cas techniques to important food crops such as maize, sorghum, wheat, barley, soybean, brassicas, potatoes, sweet oranges, and tomatoes, producing stable heritable changes in the transformed organisms' germ lines (e.g., Bortesi and Fischer 2015), with emerging approaches deploying CRISPR-Cas-based tools across wider taxa, including simultaneous edits at multiple locations in the genome and their application in directed evolution. As in the early days of GM crops, there have been enthusiastic, and sometimes breathless, media claims about how agriculture will be improved (e.g., Parrett 2015). Not surprisingly, the question of how the technology will be, and should be, regulated is urgent and hotly contested.

Contours in Regulatory Debates over Genome Editing

To date, regulation of genome editing in agriculture is following a more permissive path in the United States than in Europe, where controversy continues (Mampuys, this issue). A qualitative study of official reports and position statements from EU member states (Meyer and Heimstädt 2019)

showed subtle differences in themes such as innovation, risk, ethics, economy, legislation, food quality, epistemology, and intellectual property, pointing toward the challenges of coexistence between policy options across the union. The emergence of familiar, contrary positions reminds many observers of arguments that raged two decades ago, over how to regulate GMOs (Macnaghten and Habets 2020; Nawaz et al. 2020). Current tensions hinge on three issues, each with specific technical dimensions, which we do not discuss in detail here (see EFSA 2012; Sprink et al. 2016), and physical, social, and political risk implications.

The first major tension concerns the degree of precision within genome editing, which rests on its ability to manipulate site-specific genomic sequences. While proponents claim that this precision leads to safer products, some recent reports suggest that CRISPR-Cas9 technology is capable of creating unintended on- and off-target mutations in plants and other genera, which could induce deleterious effects and make breeding efforts more complicated and costly (e.g., Kosicki, Tomberg, and Bradley 2018; Hahn and Nekrasov 2019). Even if other scientists insist that such mutations are extremely rare and can be effectively mitigated, opponents remain unconvinced, labeling the CRISPR-Cas9 technique "unpredictable" and suggesting that risks created by genome editing are equivalent to those generated by gene transfer between organisms (e.g., ENSSER 2017).

Secondly, some scientists argue that genome-edited organisms should not be classified (or stigmatized) as GMOs if their genomes do not contain foreign DNA (Duensing et al. 2018). Critics respond that genome editing nevertheless often involves the introduction of foreign DNA, even if only transiently. Even when breeders later select plants that are free of transgenes, thereby sometimes avoiding regulatory oversight (Khatodia et al. 2016), some regulators still call for a case-by-case risk evaluation of genome edited organisms proposed for commercial release to identify unintended effects (Eckerstorfer et al. 2019).

The third tension, relating to detection, has implications for post-approval monitoring and trade. Whereas transgenic crops can easily be identified by exotic DNA signatures, some genome-edited organisms can be indistinguishable from organisms that might have mutated naturally or been altered using established mutation breeding technologies which are not regulated in the same way (Ledford 2015; Grohmann et al. 2019). This makes it difficult to monitor and enforce process-based regulation. Genome-edited crops could thus pose a new kind of challenge with respect to responsible use and safe stewardship (Macnaghten and Habets 2020). Detection challenges could also make it harder for breeders or seed

companies to claim or enforce proprietary rights over genome-edited products that contain no transgenes. While this could be a disadvantage to breeders and seed companies, it may mean that some applications of genome editing technology might be more readily accessible than GMOs to small firms and public breeders in emerging economies. Helliwell, Hartley, and Pearce (2019, 21) thus suggest that "genome editing may also disrupt some of the established NGO critiques surrounding power dynamics in the sector." The technology's social and political implications will depend in large part on how intellectual property is framed and enforced in each jurisdiction (Grohmann et al. 2019).

The resolution of these debates could have substantial implications for the commercial release of genome-edited plant varieties. Besides ensuring that genome edited organisms can be released into the environment and food chains safely, regulatory regimes will determine whether it may be practical, affordable, and profitable for various public and private stakeholders to develop and release genome edited varieties.

Reconsidering Regulatory Cultures

In revisiting the regulatory cultures outlined above, we deepen our consideration of the evidence underpinning Jasanoff's (1995) distinctions with regard to the regulation of GMOs and analyze subsequent changes in each jurisdiction that have shaped debates with regard to genome editing. Collectively, we were able to draw upon our previous and ongoing research to investigate the same three countries—the United States, United Kingdom, and Germany—allowing Jasanoff's (and others') earlier work to serve as a baseline, and for subsequent political and legal changes over the past three and a half decades to be investigated through the lens of opportunity structures. Extending our analytic perspective back to the 1980s reveals a more dynamic and nuanced interpretation of the three regulatory cultures, and highlights the utility of opportunity structures in understanding policy changes.

Documentary analysis across each of the jurisdictions firstly involved legal texts: this required assembling a dataset of laws (e.g., laws and statutory instruments for the United Kingdom, the Gentechnikgesetz (GenTG) and amendments as well as relevant EU Directives and Regulations for Germany, and relevant standards and rules from the Federal Register for the United States). We also drew on other official reports and policy documents produced by relevant ministries or departments, (as identified through interviews or documentary analysis) and texts from political

speeches. In interpreting expert decision-making processes at national levels and in the EU, we drew upon reports, press releases, statements, and minutes of meetings from advisory committees (e.g., UK Advisory Committee on Releases to the Environment, EU European Food Safety Authority). To clarify details of policy discussions and decisions, we conducted 57 semi-structured interviews with administrators, regulatory experts and advisors, nongovernmental organization (NGO) and corporate representatives and other stakeholders across the three jurisdictions.[2] We complemented this documentary and interview data with an online forum conducted under the project *Genome Editing and Agricultural Policy, Practice, and Public Perceptions* (http://geap3.com).[3] These data have been brought together and synthesized for the first time in this article.

Product-based Regulation in the United States

The United States was, according to Cantley (1995), where "the debate about the regulation of biotechnology was first played out in depth and breadth." The 1986 Coordinated Framework for Regulation of Biotechnology centered the responsibility for environmental regulation of GMOs in the hands of existing agencies, especially the US Department of Agriculture (USDA), which held statutory mandates to regulate crop pests under the *Plant Pest Act* (PPA); the Environmental Protection Agency (EPA), which oversaw agricultural chemicals under the *Federal Insecticide, Fungicide and Rodenticide Act* (FIFRA); and the Food and Drug Administration (FDA), which invited voluntary premarket review of products under the *Federal Food, Drug and Cosmetic Act* (FFDCA). This limited regulatory action to scientific issues that were well-understood based on experience with plant pests (e.g., cauliflower mosaic virus) or with previous technologies (e.g., insecticides in the case of Bt crops). Regulatory agencies' powers and procedures were tightly defined by legislation and their decisions had to be defensible against legal challenges brought by nongovernmental actors, including the biotechnology industry and public interest groups (Jasanoff 2005a; Ely 2006). The challenges created by this approach have been evident for many years, as illustrated in an interview with an EPA scientist (December 9, 2004):

> in many respects we're trying to fit a square peg into a round hole. You see all our laws are written for conventional chemical pesticides, and nobody has written laws specific for PIPs [plant-incorporated protectants], so we're trying to fit it into the regulations for chemicals and they don't fit in some places.

The FDA's oversight was based on an expectation or "de facto requirement" (Parrott 2018) that firms would voluntarily demonstrate products' safety before placing them on the market. Despite its challenges, the predictability provided by this product-based framework served to accelerate the rapid commercialization of GMOs within the United States.

This US regulatory system has continued to evolve, while retaining its principal focus on the same characteristics of transgenic products covered under earlier laws. However, two deviations are worth discussing. Firstly, in 1998, the EPA moved to protect the biopesticide Bt in transgenic crops as a "public good," by mandating farmers to adopt practices that would prevent or delay resistance among target pests. These changes arose as a result of intense advocacy by groups such as the Union of Concerned Scientists and the Environmental Defense Fund (Mellon and Rissler 1996) and a lawsuit brought by 73 plaintiffs, led by Greenpeace, the Washington-based Center for Food Safety, and the International Federation of Organic Agricultural Movements (Wadman 1999). In line with the US contentious civic epistemology, this forced insect resistance management onto the agenda of the FIFRA Scientific Advisory Panel. Thus, by engaging with the broad product-based approach and its focus on health and environmental risks, civil society mobilization created an opportunity structure that allowed critical experts to force policy to address previously neglected risks associated with specific GM products (Bt crops) in a way that was not applied in other (microbial) Bt formulations.

A more recent and significant deviation from a product approach has been the shift toward labeling of GMOs in food. Following voluntary initiatives and hard-fought campaigns (Bain and Dandachi 2014; Bain and Selfa 2017) and a state-level labeling law in Vermont (Velardi and Selfa 2020), the federal *Biotechnology Labelling Solutions Act* was passed in 2016, with USDA's National Bioengineered Food Disclosure Standard in 2018 specifying mandatory compliance from 2022. In some ways, this represents a programmatic response to political risks, for the first time enshrining a process-based element within US law with "bioengineered foods" being defined in process terms as those which "contain detectable genetic material *that has been modified through certain lab techniques* and cannot be created through conventional breeding or found in nature" (USDA-AMS 2021, emphasis added). However, as emphasized by a Congressional Research Service report (see Croft 2020), this process-based distinction "does not affect how foods derived from biotechnology are regulated for safety and approval for human consumption" or cultivation; the implementation of the standard involves the USDA Agricultural

Marketing Service (USDA-AMS) rather than the Animal and Plant Health Inspection Service (APHIS), which is the part of the department responsible for GMO risk regulation under PPA. Through this separation, bioengineered foods are subject to labeling requirements but remain isolated from the kind of process-based biosafety regulatory trigger seen in the EU.

The Vermont GM labeling law demonstrates how public reasoning can be both enabled and constrained by opportunity structures. After years of campaigns, in July 2016 the state passed a law mandating clear labeling of foods containing GM crop ingredients. Supporters emphasized the importance of local agricultural identity, democracy, and socioeconomic community welfare (Velardi and Selfa 2020). Civil society action forced open an opportunity structure allowing for broad debates that included programmatic concerns. In contrast, the federal law was brought in just two weeks after Vermont's state-level legislation. Focusing on "right-to-know" issues and designed to avoid the emergence of a patchwork of state-level laws, the Act was passed, according to the state's Democratic Party Senator Patrick Leahy, "with no committee process, no debate or amendment process" (Lugo 2016). In contrast to the broad process or program-related debates seen earlier in Europe, the rapid federal move toward labeling imposed a restrictive opportunity structure through which commercial interests sought to quell social mobilization across the country and constrain the possibility of a national moment of more profound public reasoning. Meanwhile, the USDA's 2018 standard was expected to be challenged in the courts (Parrot 2018), reflecting a contentious US civic epistemology in which litigation represents a common response to regulatory uncertainties. Numerous ambiguities leave the standard open to legal challenge, among them the extent to which genome-edited foods require labeling given that the USDA-AMS has said it will respond on a "case-by-case basis" (Croft 2020, 6).

US researchers have argued that "framing the debate around 'product versus process' is neither logical nor scientific" and, in the face of biotechnological advances, "is stalling productive dialogue on the development of appropriate oversight" (Kuzma 2016, 165-66). While this may be true, the US approach to the biosafety regulation of genome-edited organisms has continued to rely on existing legislation and primarily product-oriented arguments around the absence of physical risks under FIFRA or PPA. Based on an Obama administration memorandum, a new National Strategy for Modernizing the Regulatory System for Biotechnology Products was published in September 2016 and the Coordinated Framework itself was updated in January 2017 to clarify agency responsibilities. Their effect is

that the government's commitment to administrative decision-making has been reaffirmed while virtually eliminating regulatory oversight for most existing genome-edited crops. For example, the USDA stated that CRISPR-edited varieties of waxy maize (corn) and nonbrowning mushrooms may be commercialized without oversight—a decision in line with its previous rulings relating to plants transformed using ZFN and TALEN techniques (Waltz 2016). Since 2015, some US farmers have been cultivating Cibus's genome edited "Falco" variety of *Brassica napus*, which is also unregulated under PPA.

The product-based approach met Trump's "America First" agenda in the President's Executive Order 13874 of June 11, 2019. The order emphasized a product-based approach by specifying that the Federal Government's policy was to "avoid arbitrary or unjustifiable distinctions across like products developed through different technologies" (Section 3). It mandated the review and streamlining of regulations for "low-risk products" (Section 4) and "genome-edited-specialty-crop-plant products designed to have significant health, agricultural, or environmental benefits" (Section 6), and the development of a strategy "to increase international acceptance of products of agricultural biotechnology" in support of US agricultural exports. Following a process of soliciting public comments to help define the alternatives, impacts, and issues for APHIS to consider (Federal Register 2018), USDA-APHIS implemented these mandates by publishing the "Sustainable, Ecological, Consistent, Uniform, Responsible, Efficient" (SECURE) rule (USDA-APHIS 2020a) which specifies the instances where products are not subject to regulation on the basis of product characteristics (USDA-APHIS 2020b).

Thus, through a sequence of largely administrative decisions, the US regulatory system has curtailed new opportunity structures that would enable agencies to explore wider environmental and health uncertainties associated with genome-edited crops and continued to downplay potential social and political risks. Controversies over labeling have been addressed separately through legislative changes that continue to be subject to challenge.

Beyond Process-based Regulation in the United Kingdom

Until the 1990s, the United Kingdom's GMO regulation approach mirrored that of the United States in its permissiveness toward both field trials and food imports. The UK *Environmental Protection Act 1990* translated the original EU "Deliberate Release" Directive 1990/220, which required risk

assessment on the basis of product characteristics outlined in Annex 2. But foods containing unlabeled GM ingredients appeared in UK supermarkets in 1996 at an awkward moment—the British government having recently admitted that, contrary to its previous claims, new variant Creutzfeld-Jakob disease could be caused by eating beef products infected with Bovine Spongiform Encephalopathy (BSE). Trust in both government institutions and scientific expertise evaporated (Van Zwanenberg and Millstone 2003, 28), contributing to a significant public backlash against GMOs in the late 1990s. In response to similar political risks emerging across Europe, the EU temporarily ceased approvals of GMOs and introduced requirements for labeling. This process-based approach, embodied within Directive 1990/220/EC, provided an opportunity structure that allowed public reasoning about programmatic social and political risks associated with transgenic technology to hold up GMO approvals. In response, the new EU Directive 2001/18/EC further opened up public and parliamentary debate to include social and political issues, highlighting process-related uncertainties and updating the principles of environment risk assessment (Annex 2) to include "interactions with other organisms, transfer of genetic material, or changes in use or management" which might elicit "indirect" effects. Regulations (EC) No 1829/2003 and 1830/2003 later amended this Directive, introducing rules for traceability and labeling of GMOs in response to consumer pressure from across the EU.

In response to similar pressures, including direct action against GM crop trial sites, the UK government experimented with broader forms of democratic input; a narrow and technocratic style of safety assessment was widened to a more programmatic approach. This incorporated social and ethical concerns through the "GM Nation?" public dialogue on GM crops convened in 2001 (Poortinga and Pidgeon 2004; Dryzek et al. 2009, 275), and significant debate in parliament throughout the early 2000s. The Advisory Committee on Releases to the Environment became more open to public scrutiny, independent from industry, and biased toward ecological expertise (Ely 2006, 118-19). Farm-scale evaluations and a GM Science Review provided additional scientific inputs to government decision-making. Another government-appointed body, the Agricultural and Environmental Biotechnology Commission (AEBC 2001-2005), broached programmatic questions about the forces shaping the agricultural biotechnology research agenda (AEBC 2005). Even though its advice was not statutory, the Commission played a key role in determining the consumer choice and liability implications of the government's decisions over GM herbicide-tolerant crops in 2004 (see AEBC 2003). It also advocated for

a more strategic or programmatic approach to "agriculture as a whole" (Grant 2005).

On June 23, 2016, the UK public voted through a popular referendum to leave the EU, with "Brexit" taking place on January 31, 2020. The United Kingdom's departure from the EU raised many questions about the direction that the country would take in the coming years and thereby provided a new opportunity structure for public reasoning about the regulation of genome editing. Clues about the deregulatory approach favored by the ruling Conservative Party were provided by Prime Minister Johnson's (2019) call to "liberate the United Kingdom's extraordinary bioscience sector from anti-genetic modification rules" and "develop the blight-resistant crops that will feed the world" in his first speech as prime minister. Brexit created numerous opportunity structures for both social movements and industry interests. The strong Conservative majority in the House of Commons has meant that the Johnson government has used these opportunities to forward the Brexit objective of regulatory independence from previous EU laws at least performatively.

This is particularly significant in the context of a European Court of Justice (ECJ) decision in July 2018. In Case C-528/16 the ECJ ruled that, while the "products obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record" were exempt from regulation under Directive 2001/18, this did not extend to products of mutagenesis in general (e.g., directed mutagenesis through genome editing), which should otherwise be regarded as GMOs. As a result of this decision, a new opportunity structure for public reasoning around genome editing did not emerge in the EU, though some UK politicians expressed their disapproval. In a letter in October 2018, the Secretary of State for Environment, Food and Rural Affairs, George Eustice, described the regulation of genome edited crops as "an early candidate for us to depart from the approach the EU is taking" (Byrne 2020, para. 7).

In 2018, but prior to the ECJ decision, UK authorities gave approval for field trials of genome-edited plants of the *Brassica* family. At the time, the Advisory Committee on Releases to the Environment advised that "*Camelina sativa* plants produced by CRISPR-Cas9 genome editing could have been produced through traditional breeding techniques" (ACRE 2018) and judged that the risks to human health and the environment associated with the release were "extremely low," leading the Department of Environment, Food and Rural Affairs (Defra) to permit the trials. Later, in a June 2020 statement to the UK Environmental Audit Committee, Eustice

commented that "some of these [genome editing] techniques are really just an extension of conventional plant breeding. I am not saying there would not be any kind of regulation, but I think it is a moot point as to whether it is appropriate to have the same regulation as you would for transgenesis" (EAC 2020, Q44). At the time, Eustice also stated that the government did not propose to change current regulations on GMOs.

More broadly, debates in the United Kingdom about GMOs and genome-edited crops lay within a once-in-a-lifetime reconfiguration of domestic agri-food-environment policy, with the 2020 *Agriculture Act* and 2021 *Environment Act* possibly paving the way for a systemic restructure. The process to produce England's first National Food Strategy was launched in 2019, with ambitious plans for a "National Food Conversation" signaling a desire for broader public consultation and engagement (NFS 2020). The country found itself in the midst of a period of thinking strategically about both biotechnology and, as the AEBC proposed, "agriculture as a whole." This is signaled in parliamentary debates of these changes, which began to offer opportunities for wider process-based considerations. In 2020, the UK National Farmers' Union called for policy changes to allow British farmers access to genome editing technology after Brexit—a call supported by the All-Party Parliamentary Group on Science and Technology in Agriculture. An amendment to modify definitions in the *Environmental Protection Act 1990* regarding "products of breeding techniques where nucleic acid changes could have occurred naturally or through traditional breeding methods" (Lord Cameron of Dillington 2020) was tabled in the House of Lords then withdrawn in July 2020 after mobilization by campaigning organizations. Lord Gardiner then announced that the government would soon launch a public consultation on the issue, indicating a process-based distinction from the regulatory trajectory of GMOs.

This consultation was eventually launched by Defra on January 7, 2021, just one week after the United Kingdom's Brexit transition period came to an end (Defra 2021). The consultation implicitly maintained the EU's earlier definition of GMOs but also sought to define genome editing (which it referred to as "gene editing" or GE) as "a range of technologies that can achieve genetic changes of the type that are selected for in traditional breeding, such as insertions, deletions and, occasionally, translocations of genetic material." In Part 1 of the consultation, it put forward the proposal that "organisms produced by GE or by other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods." As such, while the consultation was ambiguous as to whether GE as a process was distinct from GM, it was proposing to remove

the same process-based regulatory trigger for some products. If the United Kingdom had still been constrained by the ECJ's 2018 ruling, this proposal would have been problematic, but the opportunity structure provided by Brexit was strategically deployed by Defra to frame GE within the same category as conventionally bred crops, for biosafety purposes, and as distinct from transgenic GM products regulated under the EU's process-based framework. The consultation also asked whether there were any "non-safety issues to consider," pointing to social and political risks that go beyond the traditional product-based approach described by Jasanoff (1995). Defra (2021) stated that it might "seek to amend the statutory definition of a GMO" depending on Part 1 results, potentially leading to "legislative change in the next 1-2 years."

Part 2 of the consultation dealt with "questions on broad reform of legislation governing organisms produced using genetic technologies," responses to which would inform "the start of a separate engagement process" that would then inform further policy development and stakeholder engagement (Defra 2021). It remained to be seen whether these would resemble programmatic approaches of the sort seen in the early 2000s. Other UK studies of social and ethical debates regarding genome editing have stressed the important role of NGOs in bringing such issues into political discussions, while also suggesting they need to be addressed formally, arguing that politicization should be welcomed by public institutions and research bodies "if they are committed to wider public dialogue and involvement" (Helliwell, Hartley, and Pearce 2019, 789). Part 2 of Defra's consultation sought to lay the foundation for a more thorough overhaul of the wider agricultural biotechnology sector. The promised enactment of new primary legislation provided an opportunity structure in which scientific uncertainties and broader programmatic concerns could be discussed within and beyond parliament.

Program-based Regulation in Germany

In the early days, the key discussion about biotechnology regulation in Germany was whether existing regulatory frameworks were sufficient or whether a "new political order" was needed (Jasanoff 1995, 322). After an initial focus on physical risks, the German regulatory system rapidly identified political risks such as strong resistance and intense conflicts—like those experienced in the 1970s and 1980s regarding nuclear energy—to be graver than either physical or social risks, adopting a deliberative political response exemplified by the parliamentary Enquête-Kommission

(Commission of Enquiry) "Chances and Risks of Genetic Engineering" (Deutscher Bundestag 1987). At the end of the 1980s, a court in Hessen ruled that the use of biotechnology in industrial production processes required specific legislation. By attending to technical, social, and political risks in the parliamentary search for consensus, Germany took into account the "programmatic relationship between technology and society" (Jasanoff 1995, 324). The Gentechnikgesetz (GenTG, Genetic Engineering Law) came into force in 1990 and sought to balance the principles of precaution and innovation by combining the protection of nature and humans with the possibilities for the advancement of biotechnology (§1 GenTG).

Both GenTG and decisions around the deliberate release of specific products have since been amended several times. The law was amended to implement parts of the European Directive 2001/18 on deliberate release in 2005. The establishment of the Standortregister (location register) for trials and cultivation in 2005 (Bundesamt für Verbraucherschutz und Lebensmittelsich [BVL] n.d.) and the Fourth Amendment of the GenTG in 2008, adding the Gentechnik-Pflanzenerzeugungsverordnung or "Regulation on Good Practice in the Production of Genetically Modified Plants" (GenTPflEV 2008, see below) is especially relevant to Germany's programmatic focus on political risks.

The 2005 changes paved the way for the cultivation of MON810 insect-resistant maize, providing civil society with a renewed focus for debate and protest. While the Standortregister led to intense conflicts in villages and rural areas, as it clearly identified areas where GMOs were cultivated, it also enabled transparency about the extent of GMO cultivation. The 2008 GenTG amendment included regulations associated with "ohne Gentechnik" (GMO-free) labeling. Furthermore, with GenTPflEV it established the possibility of agreements between neighbors to waive legally required separation distances between GM and conventional or organic crops. This led to an individualization of the conflicts on the one hand, and a reinforcement of deliberation between neighbors on the other. As in the United Kingdom, sites became a visible and iconic focus around which public attention and debate emerged, with regulatory decisions about specific products providing the opportunity structure for more programmatic issues to surface.

Following cultivation from 2005 to 2008, MON810 was banned in spring 2009 (BVL 2009) with the BVL justifying its decision with scientific evidence concerning risks for nontarget organisms (2001/18/EC and § 20 GenTG). These arguments became the subject of subsequent scientific

debate across Europe. Some public sector scientists argued that the BVL's justification was incomplete and confused (Ricroch, Bergé, and Kuntz 2010), while others pointed to the need to follow up on laboratory studies showing negative effects on nontarget species (Bøhn et al. 2012), both claiming that data had been selectively cited and interpreted. Regardless, these arguments illustrate the country's attention to physical risks, which were then the only basis upon which GMOs could be banned under the EU Directives. Technical risks were further examined, for instance by the GeneRisk research project that was funded in the 2000s by the Federal Ministry of Education and Research (BMBF; Breckling et al. 2012) and the Federal Agency for Nature Conservation (BfN; BfN n.d.). Other studies have also illustrated that political considerations, such as the likelihood of protests at cultivation sites, also played a role in the decision to ban MON810 (Friedrich 2020). For instance, a few weeks before the ban, in February 2009, the Green Party had proposed a general ban on all GMO cultivation in the country (Deutscher Bundestag 2009). In this initiative, programmatic arguments played a crucial role and the growing resistance to the cultivation of MON810 maize was listed as a prominent reason for the ban (Deutscher Bundestag 2009, 1). The initiative, however, did not find a majority.

After April 2009, commercial cultivation of GMOs continued with the GM potato Amflora marketed in Germany between 2010 and 2011. Like MON810, this led to activist mobilization against both commercial cultivation and field trials, including the destruction of crops. But a significant difference between MON810 and Amflora was that there was almost no demand from farmers for Amflora and therefore it had very limited cultivation (BVL n.d.). Although policy continued to permit cultivation, marketing of Amflora was halted by BASF in 2012. This time, programmatic considerations around consumer rejection and citizen concerns around coexistence played a significant role for the firm involved rather than for the government. A headline from the *Süddeutsche Zeitung* (2012, translation by authors) read: "No chance for genetic engineering in Europe. BASF gives up and relocates this sector to the United States. People on the continent simply don't want the GM potato Amflora."

EU Directive 2015/412 was later passed, allowing member states to restrict the cultivation of GMOs on the basis of wider considerations, such as "environmental or agricultural policy objectives, or other compelling grounds such as town and country planning, land use, socioeconomic impacts, coexistence and public policy." The Directive represents a legal opportunity structure that emerged as a result of political pressure from

member states within the EU's process-based framework, which treated these wider programmatic considerations as a legitimate basis for policy decisions. Alongside several others, Germany restricted GMO cultivation in 2015 (European Commission n.d.), but to date the EU Directive 2015/412 has not been translated into national laws such as the GenTG. There were several draft versions and a broad debate. Beyond regulations translating the Directive's opt-out process, a key question was whether to include not only the precautionary principle but also an "innovation principle" in light of emerging gene editing techniques (Deutscher Bundestag 2016). In the end, the coalition of conservative and social democratic parties could not find a consensus and the revision of the GenTG was declared "failed" in May 2017, a few months before elections (SPD Bundestagsfraktion 2017).

Bearing in mind the political risks, Germany's programmatic approach has enabled participation of civil society at several points since the original Enquête-Kommission, the roundtable initiated by the BMBF in the 2000 that seemed to reflect its "consensus-seeking" civic epistemology and the deliberative quality of its democracy. However, critics have argued that the commitment to public participation has been mostly symbolic, in that the German approach has sought an "acceptance of irresolvable differences" rather than a resolution of conflicting positions (Böschen 2010, 116, authors' translation). With respect to the aforementioned roundtable, all environmental NGOs eventually withdrew from the process (Friedrich et al. 2019, 170), further calling into question the consensus-seeking civic epistemology.

The emergence of genome editing has led to another round of discussion about a possible change to the GenTG. During the period covered by this paper, genome edited organisms have been treated as GMOs in Germany, as prescribed by the ECJ, and none had undergone field trials. However, in 2020 the German government saw genome editing as a promising innovation. Julia Klöckner, CDU Minister for Food and Agriculture, told the Bundestag, "there are new breeding techniques that save us time and I plead for us to be open here" (Deutsche Bundesregierung 2020, translation by authors). In the debate after her speech, politicians who were critical of the minister's point of view referred mainly to product-related arguments associated with scientific risks. Rainer Spiering, an MP from the social democrats (SPD) asked for instance: "Can we take responsibility for those?" (Deutscher Bundestag 2020, 24213, translation by authors). Ministry of Education and Research policy statements in the same year supported the view that the whole range of biotechnologies should be used in agriculture, while continuing to seek consensus on a balance between innovation and precaution (BMBF 2020).

The arrival of genome editing technology has been met with other calls for openness. In the summer of 2020, a group of 22 members of the Greens, a party that played a formative role in the early GMO debates based on strong opposition to GM technology, produced a paper calling for genetic engineering regulations to be updated, arguing that the existing situation promoted monopolies and that new genetic technologies could potentially contribute to more sustainable agriculture (Christmann et al. 2020). On the one hand, this can be seen as part of the Greens' move away from more radical positions, but on the other it also addresses political challenges or risks. During a party conference in November 2020, the party adopted a new basic program (Bündnis 90/Die Grünen 2020). Whether to approve or reject new biotech techniques was a key subject of controversy, with many members still clearly opposed to all kinds of agricultural biotechnology. Eventually, the majority of the party members voted to keep the principles of GM-free agriculture and precaution in the basic program, as well as strict regulation of new techniques, while also enabling research in that field. This was a departure for the party. Even if short-lived and based on a minority view, the discussion within the Greens illustrates how political risks still played a role in German debates and political differences persisted even within the same party. Differences in opinion have also been evident for various government agencies: the BfN "welcomed" the 2018 ECJ decision, whereas the Federal Office for Consumer Protection and Food Safety did not (Meyer and Heimstädt 2019).

Among the public, recent government research has suggested high levels of skepticism—not only toward traditional GMOs but also to newer techniques (BMU/BfN 2020, 58-63). Environmental NGOs have also mobilized by calling for strict regulation of genome editing, trying to shut down an opportunity structure for new, more permissive policies. The political opportunity structure provided by the EU Directives and confirmed by the ECJ decision has led to a resurrection of many earlier debates. In line with Germany's programmatic regulatory culture, the government has responded with several consultation processes regarding genome editing, which have included forums involving scientists and civil society organized by the Federal Ministry of Food and Agriculture, and a consumer conference on genome editing organized by the Federal Institute for Risk Assessment. This illustrates a continued commitment to the public engagement characteristic of the programmatic regulatory culture on the part of the government. However, in the absence of a new opportunity structure, this did not evolve into a new round of public reasoning at the national level. Constrained by the ECJ decision, the settlement on a no-GMO consensus remains.

Nonetheless, ensuing developments in the EU may change this. The strong commitments of Chancellor Merkel and her Christian Democratic party (CDU) to the European project, and the need for EU states to move forward together, led Germany and 13 other member states to call for a "unified approach to gene editing in plants" in 2019 (Fortuna 2019). This would need to be informed by EU and national parliamentary debates, offering a new opportunity structure in which programmatic concerns such as the potential contributions of GE to sustainable agriculture could be debated.

Discussion: Comparing Regulatory Cultures and Governance

Jasanoff (2005a, 260) argues that "the attributes of civic epistemology have to be performed and reperformed to maintain their hold as living, breathing instruments. It follows that radical breaks and disjunctures can always occur in theory, but shocks of exceptional severity may be needed to precipitate them." Our analysis identifies no such shocks; however, our consideration of the politics surrounding the governance of GMOs and genome editing in the United States, the United Kingdom, and Germany demonstrates how regulatory cultures in each case have developed and changed. Despite the years that have passed since Jasanoff's analysis was published, it is still possible to identify substantial continuities in the regulatory cultures of these three countries. At the same time, new opportunity structures have enabled the adoption or rejection of elements from other regulatory cultures, providing a more dynamic picture that helps to explain policy change in some cases, and stability or even entrenchment in others. While civic epistemologies define the "how" of public reasoning, opportunity structures can be understood as defining "when" it has taken place.

In the United States, adherence to the Coordinated Framework and reluctance to introduce new laws to regulate the techniques and products of genome editing has helped to cement a form of "lock-in," whereby regulatory agencies have largely been prevented from examining or considering anything but a narrow and circumscribed set of risks associated with specific product characteristics as prescribed by Congress. Critics and skeptics of biotechnological techniques in food and agriculture have articulated alternative process- and program-oriented principles for governing GMOs and genome editing in the United States, yet the product-based approach to biosafety regulation has remained largely unchanged for 30 years (notwithstanding policy shifts around Bt insect resistance

management). The question of labeling, on the other hand, has emerged within a different regulatory sphere outside these constraints, in which programmatic concerns were initially forced onto the legislative agenda at the level of individual states. When the debate was transferred to the federal level, the National Bioengineered Food Disclosure Standard thus had no direct impact on biosafety regulation. It is possible, given the EU experience following labeling regulations, that new opportunity structures for public debate may be opened up by the continuing conflicts over the Standard's implementation. Overall, the combination of the country's contentious civic epistemology and the regulatory framework's stability over six presidential administrations from Reagan to Trump, strongly supported by US-based transnational agribusinesses, have led to an outcome in which genome-edited crops with certain product characteristics are almost completely unregulated in the United States (see Kuzma, this issue).

Soon after the turn of the 21st century, public resistance prompted the UK government to broaden the process-based frameworks that characterized the country's governance of the first generation of agricultural biotechnologies, namely GMOs. The "GM Nation?" debate marked a shift toward more programmatic attention to political risks, and led the country toward a more cautious stance on GMOs in the United Kingdom than some politicians and many scientists and farmers wanted. Brexit created a new opportunity structure in which the national policy frameworks relating to biotechnologies could be revisited. By early 2021, the UK government had recognized certain applications of genome editing as distinct from GMOs on the basis of their equivalence to conventionally bred products. However, this apparent shift toward a product-based approach was combined with a consultation on the new generation of agricultural biotechnologies that included a question about their wider societal implications and entanglements. Until the British government gave notice of the country's intention to leave the EU, the space for a consultation of this kind had been limited by the parameters of European law and politics. Brexit, its proponents argued, offered a space in which a fresh approach could be designed in the context of a once-in-a-generation rebooting of national strategies and laws relating to agriculture, food, environment, trade, and consumer rights. The government's recognition of genome editing and its products as distinct from existing GMOs, and inclusion of "nonsafety" concerns in its 2021 consultation, were early signs of a more programmatic engagement with the new technology that considered its political dimensions, public concerns and societal implications—though the extent to which these will be addressed remains unclear. The promised primary legislation created an opportunity

structure for the United Kingdom's communitarian civic epistemology to deliver a framework incorporating novel combinations of product, process, and program elements.

In Germany, an early interaction between opportunity structures and regulatory cultures was the amendment of the GenTG in 2005. This enabled the commercial cultivation of MON810 maize, precipitating intense conflicts at cultivation sites as well as at federal state and national levels. Paradoxically, this amendment was not only the target of protest but it also gave both GMO proponents and the environmental movement opportunities to articulate their positions in a moment of public reasoning (Friedrich 2020, 5), culminating with the ban of MON810 maize in 2009. Although officially the ban occurred through the safeguard clause, due to technical risks associated with the product, political considerations played a significant role. There have not been further amendments of the GenTG because there was no consensus about how to implement EU Directive 2015/412 nationally.

Since the emergence of genome editing, Germany has maintained a programmatic approach in line with its deliberative tradition and consensus-seeking civic epistemology. Recently, attention to political risks was demonstrated by members of the Greens (Christmann et al. 2020), emphasizing corporate monopoly control and opportunities for more sustainable agriculture. Even if most Greens remained critical of biotechnologies, the minority contribution can be seen as an appeal to renewed public reasoning. However, as long as genome editing was regulated in the same way as GMOs, there was no opportunity structure to enable a differentiated debate with regard to this new generation of agricultural biotechnology.

Conclusion

We have reconsidered earlier distinctions between product, process, and program approaches in light of three and a half decades of policy change and the arrival of new techniques of genome editing. Our analysis of biotechnology regulation in the United States, the United Kingdom, and Germany over that period leads us to suggest they do not have fixed regulatory cultures but rather three somewhat dynamic trajectories, each exhibiting varying degrees and elements of product, process, and program approaches at different times. These shifts have been possible without evident changes in the countries' underlying civic epistemologies. We have further examined how the developments in each case have been precipitated by changing social, legal, and political opportunity structures. These have interacted with each other in different ways, whether this be social

mobilization creating opportunity structures for subsequent legal changes (e.g., the US labeling case), new legal frameworks precipitating opportunities for government-led consultation (e.g., the UK post-Brexit), or legal decisions precluding deep and broad societal debate (e.g., the ECJ ruling's effects in Germany). Mobilizing concepts from STS and social movement theory in the long-term comparative analysis of how societies cope with consecutive generations of agricultural biotechnology illustrates the interplay between regulatory cultures and opportunity structures. As well as highlighting a degree of lock-in to the product-based approach in the United States, we have also shown lock-in to process- and program-based approaches in Germany and the United Kingdom.

What are the broader implications of these insights for scholars of technology policy and regulation? For future studies, these results imply that greater attention should be afforded to changing opportunity structures, seen as the moments when countries' civic epistemologies can be, in Jasanoff's words, "performed and reperformed." They define the moments when public reasoning can be strategically deployed, not just by NGOs as social movement studies have emphasized, but also by other actors in government and industry and citizens more generally. Bringing together these concepts from STS and social movement theory contributes to our understanding of continuity and change in national regulations and suggests particularly promising avenues for long-term analyses.

Our comparative study began with the initial divergences of the 1980s and illustrated how these developed across the three nations in question. Such an approach could be applied to trace the evolution of regulatory policies in other liberal democracies in which risk regulation plays an important role. It could also be applied to build upon analyses that have described how countries such as Norway (Binimelis and Myhr 2016), South Africa, and Kenya (Beumer 2019) have brought socio-economic considerations into policy decisions in a more explicit way than either the United States, the United Kingdom, or Germany. What role opportunity structures have played in the emergence of these and other national frameworks needs to be considered in the context of different historical and political backgrounds. China's political system poses particular questions with regard to the conventional application of social movement theory concepts; however, opportunity structures may prove useful in explaining policy shifts that other studies have attributed to the changing influence of activists and social media (Ely 2015) or international debates (Cao 2018).

Our analysis has focused at national levels, however also illustrated the importance of transnational opportunity structures. These influences are

evident within the World Trade Organization, whose Dispute Settlement Panel ruled on the GM crops dispute on the basis of sanitary and phytosanitary science (Bonneuil and Levidow 2012), and where the United States has joined with other countries to advocate for gene editing regulations that were "science- and risk-based, transparent, predictable, timely, and consistent with relevant international trade obligations" (WTO 2018, section 2.3). The strategic linking of neoliberal and scientistic discourses within the multilateral trade regime, seen by Kinchy et al. (2008) as an attempt to depoliticize agricultural biotechnology, shuts down opportunity structures that could enable programmatic concerns to inform national decisions. We suggest further studies are necessary to analyze interactions between countries, and the international influence of national-level opportunity structures, just as our study illustrates the influence of EU-level decisions. Opportunity structures could also inform analyses in other domains in which different national styles or regulatory cultures have been identified, for example nanotechnology (Justo-Hanani and Dayan 2016), civil nuclear energy (Johnstone and Stirling 2020), or pharmaceuticals (Abraham and Davis 2020). We suggest that insights from longitudinal studies such as this will enable a more informed and reflexive approach to the regulation of genome editing and other emerging technologies, by helping us to consider the potential impact of contemporary decisions upon future generations of agricultural biotechnology.

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Notes

1. We recognize that other types of opportunity structures may exist; however, we focus in this paper on: social changes relating to broad public opinion and mobilization; legal changes associated with codified laws, rules, regulations, and guidelines; and political changes involving changes in administration or ministerial responsibility. These interact with each other in ways that we explore in each case.
2. Interviews were conducted across the three jurisdictions between 2002 and 2021: 14 in the United States, 7 in the United Kingdom, 34 in Germany, and 2 at the European Union level.
3. While we do not quote from the forum, our analysis is informed by 190 contributions from a total of 24 (primarily Europe-based) experts, regulators, private sector, and nongovernmental organization representatives who exchanged perspectives between October 1 and 24, 2020.

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