Bulletin of Science, Technology & Society
2014, Vol. 34(3-4) 108–120

DOI: 10.1177/0270467614565695
bst.sagepub.com
SAGE

Conflicting Futures: Environmental Regulation of Plant Targeted Genetic Modification

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Abstract

Novel targeted genetic modification (TagMo) techniques for plants have the potential to increase the speed and ease of genetic modification and fall outside existing regulatory authority. We conducted 31 interviews with expert-stakeholders to explore the differing visions they have for the future of plant TagMo environmental regulation. To guide our analysis we review the tenets of anticipatory governance in light of future studies literature on emerging technology, focusing on how to contribute to reflexivity by making explicit the assumptions within envisioned futures. Our findings reveal that the environmental regulation futures articulated by expert-stakeholders could be classified into three categories—optimistic, pragmatic, and critical—based on their differing underlying assumptions concerning what constitutes environmental risk and the adequacy of existing U.S. genetically modified plant regulations. By gathering these diverse perspectives on the future and studying how they differ, we hope to further the anticipatory governance-informed engagement with regulation and foster a more productive discussion of plant TagMo regulation.

Keywords

anticipatory governance, environmental risk, future studies, plant targeted genetic modification, regulation

1. Introduction

Plant targeted genetic modification (TagMo) is a term we use to describe a variety of emerging technologies that are poised to significantly change plant genetic engineering. Targeted genetic modification, also called "targeted genome editing" and "new biotechnology-based plant breeding techniques," refers to techniques that create more precise changes in DNA than the relatively random changes made in the first generation of plant genetic engineering (Box 1).[1] TagMo techniques will likely improve the efficiency of plant genetic engineering and increase the number of traits and plant species that can be engineered (Bogdanove & Voytas, 2011; Porteus, 2009). In addition, because TagMo techniques fall outside existing United States (U.S.) regulatory definitions for genetically engineered plants, it is uncertain how U.S. regulatory agencies will handle plant TagMo products. The U.S. Department of Agriculture (USDA) has already ruled that certain TagMo-derived plants will not be regulated as genetically modified organisms in the United States (Waltz, 2012). Many other regulatory agencies across the world are also grappling with how they will address plant TagMo products (Podevin, Devos, Davies, & Nielsen, 2012).

Box 1. Plant Targeted Genetic Modification and Its Relationship to First-Generation Plant Genetic Engineering.

First-generation techniques for plant genetic engineering randomly insert DNA sequences containing desired traits into plants using Agrobacterium or biolistics-based methods. The random nature of this insertion means that many insertions are needed to arrive at a plant that expresses the desired trait. As a result, much effort is required to determine when the inserted DNA leads to the successful expression of the desired trait within the transformed plants. The plants expressing the desired trait then need to be bred with conventional plant varieties to produce plants suited for commercial use. First-generation modification techniques are the dominant methods used to create the herbicide tolerant and insect resistant traits

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Box 1. (continued)

used in existing genetically modified crop varieties that in 2013 made up 90% of cotton, 93% of soybean and 90% of corn grown in the United States (U.S. Department of Agriculture [USDA], 2014).

We use the term plant TagMo (targeted genetic modification) to describe a set of genetic engineering techniques, such as those using zinc-finger nucleases, meganucleases, and transcription activator–like (TAL) effectors, that all rely on similar mechanisms for creating changes in a plant's genome. These techniques use molecules that read DNA sequences and that create double-strand breaks at precise places within DNA (Bogdanove & Voytas, 2011; Gao et al., 2010; Shukla et al., 2009; Townsend et al., 2009). The double-strand breaks within a plant's DNA activate the cell's own repair mechanisms that can then be used to alter the targeted gene within a plant's DNA. If a DNA fragment is provided that shares sequence similarity with the broken site in the DNA, the cell repair mechanism will use this fragment as a template for the repair. This can allow for the insertion of foreign DNA in a similar yet more precise and efficient way than the first generation of plant genetic engineering. More specific changes, down to a single nucleotide, can also be made with TagMo techniques. These changes can be used to create small insertions or deletions that can alter or delete gene function.

Plant TagMo is still in the early stages of development and basic understandings of what plant TagMo is, plant TagMo's potential future, and how it should be governed are being established and contested (Lusser, Parisi, Plan, & Rodriguez-Cerezo, 2012; Podevin et al., 2012). As part of a larger project examining plant TagMo oversight, we explored differing ways of understanding how plant TagMo should be addressed by environmental regulation. We gained insights on the possible futures of plant TagMo environmental regulation through in-depth individual interviews with 31 expert-stakeholders from academia, industry, government, and nongovernmental organizations (NGOs). In designing and conducting this work, we drew on governance approaches developed at the intersection of the fields of science and technology policy and science and technology studies (STS), including upstream public engagement (Wilsdon & Wills, 2004) and anticipatory governance (Barben, Fisher, Selin, & Guston, 2008). Much of the scholarship on anticipatory governance has focused on how to move societal engagement with technology beyond the regulatory realm by, for example, encouraging societal deliberation on emerging technology during the initial stages of technological development (Selin, 2011). We believe, however, that the principles of anticipatory governance can also inform efforts to improve environmental regulation itself.

In this paper, we begin by reviewing the tenets of anticipatory governance and exploring their implications for our analysis of plant TagMo's environmental regulation. We highlight the importance of the concept of reflexivity in anticipatory governance and draw on the STS subfield of future studies in exploring how to engage with futures in a way that contributes to reflexivity. Building on these ideas, we contribute to a reflexive engagement with the environmental regulation futures of plant TagMo, as articulated by expert-stakeholders, by exploring how they conflict. We outline how these futures are built on contrasting understandings of what constitutes environmental risk and of the adequacy of existing genetically modified (GM) plant regulation in the United States. We conclude by exploring the implications of our findings for the regulation of plant TagMo and for anticipatory governance.

2. Anticipatory Governance

Anticipatory governance is an approach to technology development and governance that builds on the principles of foresight, engagement, and integration. It seeks to insert reflection into technological development in an upstream manner so as to guide development toward desired societal outcomes and away from undesired ones (Barben et al., 2008). At their most basic, anticipatory governance's three founding principles can be summarized as follows:

- Foresight describes the process of developing plausible and evolving scenarios of possible futures that can be the subject of the public deliberation.
- Engagement encompasses the suite of activities that stimulates public deliberation.
- Integration brings the engagement and foresight activities into the domain of scientific practice in order to enhance reflexiveness (Sarewitz, 2011, p. 103).

Anticipatory governance builds on critiques and ideas developed within the field of STS, and has informed how science and technology policy scholars engage with emerging technologies such as biotechnology and nanotechnology (Karinen & Guston, 2010; Kuzma et al., 2008). To better understand anticipatory governance and the intervention it is making within science and technology policy, it is helpful to take a closer look at two of its foundational principles: foresight and engagement. Both ideas emerge from a lineage of scholarship and critique developed at the intersection of STS and science and technology policy.

2.1. Foresight

The critiques built on in the principle of foresight involve moving technology assessment from a reactionary position to a proactive one (Guston & Sarewitz, 2002). Within the classical paradigm of technology assessment, technology development is largely unquestioned and takes place outside of the realm of societal influence. Instead of substantively influencing a technology's development, technology assessment is used only to advise society on how best to react to the consequences of a technology. Some of the initial critiques of technology assessment emerged from scholars developing constructive technology assessment and real-time technology assessment (Guston & Sarewitz, 2002; Schot & Rip, 1997). They argued for incorporating technology assessment activities into research and development decision making processes to proactively improve technology. Instead of reacting to technologies already developed and on the market, they proposed generating knowledge concerning the potential societal impacts of potential technologies and pursuing mechanisms to incorporate that knowledge into existing research and development decision making. Schot and Rip (1997) locate constructive technology assessment within a trajectory of thought that has challenged the "two-track" regime of societal technology management that separates promotional activities from control and regulation. They see constructive technology assessment as: critiquing the "sequential approach of optimizing the technical before considering uptake, use, and effects" (Schot & Rip, 1997, p. 263); creating and maintaining a space for sociotechnological criticism; and challenging the conflation of social progress and technological progress.

Although the scholarship surrounding constructive technology assessment, real-time technology assessment and anticipatory governance share an interest in "foresight", they do not share a clear definition of its meaning. One concept essential to the meaning of foresight is "reflexivity." Barben et al. (2008) argue that anticipatory governance's foresight principle "aims to enrich futures-in-the-making by encouraging and developing reflexivity in the [decision-making] system." Genus (2006, p. 18) states that a central characteristic of constructive technology assessment is that "actors should be 'reflexive' about the processes of co-evolution of technology and society, of technology and its impacts" and that without such reflection stakeholders will be "reluctant to accept close scrutiny of their positions by others, or themselves to probe the assumptions which underlie their own viewpoint." Sarewitz (2011), writing about the experience with real-time technology assessment and nanotechnology, argues that

> reflexivity moves innovation towards more socially desirable outcomes and away from undesirable ones, as diverse decision makers reflect more deeply on the context of their decision. And this of course can happen either through a change in innovation paths, or through a change in the conceptions of desirability, or, more likely, through the interaction of both. (p. 103)

These articulations of anticipatory governance share the idea that revealing and scrutinizing previously uninterrogated assumptions concerning the future of technologies will improve technology related decision making. Engagement is integral to an anticipatory governance based approach for revealing and scrutinizing such assumptions.

2.2. Engagement

The principle of engagement builds on the vast scholarship developed on participation in science and technology policy (Hagendijk & Irwin, 2006; Jasanoff, 2003; Lengwiler, 2008). In anticipatory governance, engagement is an essential part of critiquing and reflecting on the development of technology. We see two distinct goals for engagement, or participation, within anticipatory governance, exemplified in the following quotation:

> The aim of such [anticipatory governance] exercises [is to] . . . [a] increase dialogue about and current understanding of the range of possible technological trajectories and respective alternative governance frameworks, and to [b] elaborate how these two future projections should develop interactively. (Karinen & Guston, 2010, p. 228).

The first goal (part (a) above) is to expand the number and type of potential futures taken into consideration. Underlying this goal is the belief that by broadening the discussion of possible futures, potential technology and governance options will be better understood and the best possible future will be articulated and thus potentially achieved. Involving stakeholders with a diverse set of values, worldviews, and epistemologies will help achieve this. Explicit conflict here is minimal in the sense that the goal is not to narrow or distinguish desired futures, but only to gather and better understand possible futures.

The second goal (part (b) above) is to determine what types of futures are desirable. Underlying this goal is the idea that in order to influence technological decision making in a positive way, there must be discussion and discrimination between the types of futures that are desired and those that are not. This goal is fraught with conflict-prone normative questions concerning the desired state of the world. If the first goal produces a variety of possible technological and governance futures, with some of them undoubtedly resembling the course of technological development initially critiqued by anticipatory governance, how does anticipatory governance ensure better societal outcomes? The anticipatory governance literature relies on the idea of reflection, including critique and the interrogation of assumptions, to ensure that a better decision is arrived upon. So there is a close relationship between foresight, participation, and reflexivity. Without foresight, there is no way to leave reactionary technology assessment. Without participation, there is no way to ensure that a sufficiently broad set of futures and concerns are available for consideration. Yet without reflexivity, there is no way to ensure that participation and foresight will lead to better technology-related decisions. And it is in thinking about reflection, critique, and the interrogation of assumptions in futures that we find it useful to turn to insights from future studies scholarship.

3. Future Studies for Emerging Technology

Building on the STS work examining the role of expectations and promises in technology development (Brown & Michael, 2003; e.g., Van Lente, 1993), the STS subfield of future studies has produced a wealth of recent work examining emerging technologies. Many insights have been made concerning how to understand and interrogate the potential futures of emerging technologies through the study of expectations (Borup, Brown, Konrad, & Van Lente, 2006), legitimacy and narrative (Lopez, 2008), hopes and affect (Anderson, 2007), utopian dreams and apocalyptic nightmares (McGrail, 2010), and futures more broadly (Selin, 2008; Tutton, 2011; Venkatesan, 2010). This is in addition to the literatures developed by other social science disciplines on related topics, including, for example, technological futures and computing (Kinsley, 2011) and potentiality in biomedicine (Taussig, Hoeyer, & Helmreich, 2013).

As Groves (2009) states, "that the future is uncertain is a precondition of both political and ethical action" (p. 1). If the future was given, there would be no need or ability to discuss and influence how the future should be. Our ability to influence the future invites, and perhaps obliges, us to consider what type of future we want to live in, with respect to technology or otherwise. A foundational assumption of future studies is that how we think about, discuss, and give meaning to the future influences how it materializes. In other words, how we envision what will happen to an emerging technology substantively influences what will become of this technology; such discussions legitimize, inspire, enroll actors, mobilize resources, dampen dissent or force silences concerning a technology (Anderson, 2007; Selin, 2008). In addition, futures not only influence how things will be, but also how things are in the present moment. Futures assign relationships among actors that mediate across scales, levels, times and communities (Borup et al., 2006). So when we talk of a possible "future" of a technology (or multiple possible "futures" of a technology) we are referring, broadly, to the understanding of how a technology could influence, and be influenced by, the social and natural world.

To elaborate on what constitutes futures, why they are consequential and how we should study them, we highlight two insights developed by the futures studies literature. First, futures do not emerge from nothing but are partially constituted through already existing discourses and narrative strategies (Lopez, 2008). Lopez states that, "approaching an emergent technology in this way allows us to understand how the not-yet-materialized (which all emergent technologies are) becomes not only thinkable but also invested with cultural authority and social legitimacy" (2008, p. 1269). Analyzing the narratives and meanings used to construct futures provides a way to see how futures build on and challenge particular understandings of the past and present. For example, for hype to exist around the future of a new technology, both the contingencies that may disrupt its development and the continuities tying the technology to past technologies need to be marginalized (Borup et al., 2006). In the context of environmental regulation, one can explore how a certain approach to regulation comes to be seen as appropriate for an emerging technology by studying what meanings are privileged and marginalized within a particular future.

Second, conflict is an essential part of futures. As Tutton (2011) argues, "every future is predicated on others to be avoided" (p. 412). Furthermore, Lopez (2008) emphasizes that it cannot be assumed that differing narratives concerning the future will easily converge in a complementary way. Venkatesan (2010) emphasizes the importance of considering the diversity within society and social existence when determining the desired form of emerging technologies. People are influenced by and desire technology differently and it is important to consider what values, meanings, and assumptions are privileged in particular futures. These values, meanings, and assumptions within futures will influence what forms the future will and will not take. By calling attention to these values, meanings, and assumptions and what is at stake in them, we can move from merely listing the potential paths a technology could take to interrogating and reflecting on them. For example, in making sense of nanotechnology and its role in the world, one can draw on a variety of meanings concerning the desired state of nature and how nanotechnology influences it (Wickson, Grieger, & Baun, 2010). Whether one draws on a narrative that sees nanotechnology as threatening or treating nature will influence how one considers nanotechnology, including how it should be governed. Furthermore, each narrative supports and is supported by a set of beliefs, assumptions and values. By examining and making explicit the implications of these beliefs, assumptions and values, it is possible to highlight the underlying issues and to pursue a more transparent deliberation about technology development (Wickson et al., 2010).

4. Reflecting on the Environmental Regulation Futures of Plant TagMo

Insights from the anticipatory governance and futures studies literatures informed our study of plant TagMo environmental regulation futures. First, the articulated futures of plant TagMo environmental regulation will influence current and forthcoming decision making, and it is therefore desirable to study these futures and their implications. Second, these regulatory futures will conflict in that each will privilege certain understandings and assumptions at the expense of others. Third, to study the breadth of possible futures (with their differing implications and assumptions) it is necessary to engage with people holding a diversity of views, beyond those views that are most prevalently held. In our case we did this by conducting interviews with a diversity of expert-stakeholders knowledgeable of plant TagMo and genetically modified plant environmental regulation. Finally, reflection on plant TagMo's environmental regulation futures can be fostered by exploring the understandings and assumptions they privilege and their implications.

Table 1. Summary of the Optimistic, Pragmatic, and Critical Environmental Regulation Futures of Plant TagMo (Targeted Genetic Modification).

Plant TagMo environmental regulation futures		Plant TagMo environmental risk	Existing environmental regulation
Optimistic	Govern as non–genetically modified (non-GM) plants	Plant TagMo products are more natural than first generation GM plants and are significantly less risky	Adequate; tiered approach needed to not overregulate
Pragmatic	Incrementally ease ⇕	Risks surrounding plant TagMo lessened due to increase insertion precision	Adequate but tiered approach needed to not over- or underregulate
	Keep status quo ⇕	Increased precision will not reduce risk	Adequate: No major issues have emerged
	Incrementally strengthen	New traits and species will pose new risks	Inadequate: Coordinated framework lacking
Critical	Reconfigure, increase rigor	New traits and species and increased ease of production will worsen risks from first generation and pose new risks	Paradigm inadequate: Not capturing harm and not independent

Our in-depth interviews with expert-stakeholders were guided by two overarching questions: How do expert- stakeholders provide meaning to the future of plant TagMo and its environmental regulation? How do the articulated futures of plant TagMo regulation conflict? Given that we wanted to examine the diversity of plant TagMo futures that exist, we selected expert-stakeholders from a diversity of backgrounds and disciplines to represent the breadth of possible understandings. Conducting individual in-depth interviews also facilitated uncovering this diversity as each interviewee could articulate his or her specific understanding of plant TagMo's future. We conducted thirty-one qualitative, semi-structured interviews with expert-stakeholders knowledgeable of the technical, environmental, social, and/or governance aspects of TagMo and first generation GM plants. Interviewees included TagMo scientists, genetically modified organism policy expert-stakeholders, social scientists, and natural scientists from the affiliations of academia, industry, government organizations, and NGOs.[2] These interviews took place between October 2010 and February 2011 and averaged about 1 hour each. To help interviewees understand how we defined plant TagMo, in advance of the interview we provided interviewees a document outlining the methods we considered TagMo (based on figure 1 from Kuzma & Kokotovich, 2011) and an article from the journal *Nature* discussing zinc-finger nucleases, one type of TagMo (Porteus, 2009). To elucidate interviewees' understandings of plant TagMo's future we discussed their definition of plant TagMo, key concerns and opportunities surrounding plant TagMo, the potential impact of plant TagMo, and their desires for plant TagMo regulation (see the appendix for interview questions). We transcribed and coded the interviews using Atlas.ti and guided our analysis with insights provided by our review of the fields of anticipatory governance and future studies, as described below.

First, we identified the overall differences in how interviewees thought plant TagMo products should be addressed by environmental regulation. From interviewee's responses we were able to identify five types of suggested changes to the existing environmental regulatory system in the United States to make it adequate for plant TagMo products (Table 1). We classified these five suggested changes into three categories: *pragmatic* that sought to address plant TagMo products with the existing environmental regulatory paradigm with possible minor changes; *optimistic* that sought for plant TagMo products to be regulated as conventionally bred plant products rather than as GM plants; and *critical* that sought to reconfigure and strengthen the existing regulatory paradigm to make it adequate for plant TagMo products. Drawing on the insights from the anticipatory governance and future studies literature, we further explored how these futures conflicted by examining how the assumptions and understandings they were built on differed. For example, we studied how interviewees drew on differing understandings of past and present events, and how they understood what constituted harm to the environment. We found two key underlying understandings that noticeably differed between the optimistic, pragmatic and critical categories: how the environmental risks associated with plant TagMo products differ from those associated with first-generation GM plants and the adequacy of current GM plant regulation in the United States (Table 1). We examined the differing assumptions across these underlying understandings and their implications for environmental governance. Finally, we identified the institutional affiliation and area of expertise of interviewees to better understand the contexts that influence particular futures.

5. The Conflicting Futures of Plant TagMoEnvironmental Regulation

5.1. Pragmatic Environmental Regulation Future

The vast majority of interviewees, representing a diversity of affiliations and areas of expertise, believed that to best address plant TagMo environmental regulation, existing GM plant environmental regulation should be kept the same, incrementally strengthened, or incrementally eased. We classified these futures as pragmatic because they generally viewed the existing regulatory paradigm as sound and argued for incremental changes to the existing GM plant regulation to best address plant TagMo products. Interviewees articulating pragmatic regulation futures held a diverse set of views concerning the environmental risks associated with plant TagMo products. One group of interviewees viewed plant TagMo as increasing genetic engineering precision but not decreasing the environmental risk of plant TagMo products compared to first generation GM plant products. They viewed plant TagMo as one of many techniques for plant improvement, all of which can cause adverse environmental effects. They diminished the role of genetic engineering technique for environmental risk and instead focused on the plant's resulting phenotype. As one natural scientist in academia said,

> Traditional crop improvement occasionally leads to weedier weeds, evolution of new invasives, and the endangerment of species at risk of extinction, and there's no reason to assume genetically engineered organisms would be any different. There's no reason to assume that species improved through targeted modification would be any different. I mean, they're the techniques but they are not the phenotypes. So these sort of risks depend on phenotypes and—yeah, the risks depend on the phenotype, not on the technique.

Other interviewees viewed plant TagMo as increasing genetic engineering precision and incrementally reducing the environmental risk from GM plants by lowering the likelihood of off-target effects during the genetic engineering process. As an academic trained in public policy explained,

> By reducing some of the uncertainty associated with traditional recombinant DNA engineering, I think [TagMo] helps to remove some of the concerns that have been raised about the potential risks of the technology by allowing us to be more comfortable with predictions about how the plant will in fact behave and perform in the environment.

Finally, others believed that plant TagMo would facilitate the creation of new traits and species and, as a result, would pose new risks. For example, one plant TagMo researcher in academia stated with regard to environmental risk,

> As we're able to modify plants more and more . . . essentially, we will be able to modify these plants more and more from their standard configurations. Especially with gene addition, we can completely rewire a number of these plants. So I guess the one concern I have is that if we're creating plants before we really know what the sort of products are . . . we really could rewire these to the point that they're not really the same plant anymore. Is it going to be toxic to insects that are still going to recognize it as a food, but it's no longer really a food for them?

Even within this pragmatic category, we see a variety of differing understandings concerning how plant TagMo will influence environmental risk. A tension emerged in the pragmatic futures with regard to environmental risk between plant TagMo's ability for increased insertion precision and its ability to produce new phenotypic traits. Some justified their view that plant TagMo would reduce environmental risk by arguing that plant TagMo's increased insertion precision would reduce the off-target effects of genetic engineering. With fewer unpredicted changes in plants as a result of their genetic engineering, the potential for significant environmental risk will be reduced. Others within this category argued that it is the resulting phenotypic traits, and potential new phenotypic traits, that are more of a concern for environmental risk than imprecise genetic engineering. They believed that plant TagMo should be scrutinized because of its potential to create new phenotypic traits that may negatively affect the environment.

Interviewees articulating pragmatic futures viewed the regulation of first generation plant genetic engineering as successful or as adequate and in need of only incremental adjustments. Those who viewed it as successful believed that there had been no major problems resulting from the existing regulation, as this academic in public policy said,

> I think if you look at the record to date, we clearly have in the United States, we've clearly witnessed the introduction of a widely adopted technology without any apparent health or environmental problem, so to that extent, you can argue that the regulatory system has been adequate and has worked well, because we've had the benefits of the technology, and we've avoided any potential risks.

Those who viewed existing GM plant regulation as adequate but in need of incremental change cited a variety of existing problems within the regulatory system. These changes sometimes were framed in terms of increasing or decreasing the stringency of the regulatory system and sometimes simply framed in terms of correcting existing problems. One frequent suggestion, for example, was to implement a tiered approach to regulatory oversight that would allow products similar to those already deemed safe to move through regulatory review with less scrutiny, allowing more attention to be placed on newer and potentially more risky products. Another set of suggestions involved addressing the regulatory gaps and other issues resulting from the U.S. Coordinated Framework for Regulation of Biotechnology that divided the responsibility for regulating biotechnology between the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture (Office of Science and Technology Policy, 1986).

5.2. Optimistic Environmental Regulation Future

A smaller subset of interviewees, consisting of researchers in the plant TagMo field and members of the plant TagMo-related industry, stated optimistic futures for plant TagMo and its environmental regulation. We identified these futures as optimistic because they foresaw plant TagMo leading to drastic improvements in plant genetic engineering including not being able to distinguish between plant TagMo products and those derived through conventional breeding. We see this view articulated in the following quote by a plant TagMo researcher:

> As long as you're able to keep the [TagMo agents] from actually integrating into the genome, there is no evidence as to how that particular mutation was made. So in that sense, when people get worked up about that type of genetic engineering, it's largely unfounded because you've just sped up what was essentially a natural process. If you can't distinguish between the natural product and the unnatural product, there really isn't any basis for concern between the two. Or at least any additional concern than what we've been accepting as standard practice for the last thousand years.

When describing the implications of plant TagMo for environmental risk, these interviewees describe the modifications from plant TagMo techniques as being more natural, and therefore less risky, than first generation techniques. These views emerge from seeing plant TagMo techniques not as a new form of first generation genetic modification, but as a new form of mutation breeding. Mutation breeding, also known as induced mutagenesis or classical mutagenesis, creates improved plant varieties by exposing plants to radiation or mutagenic chemicals and developing the resulting plants that contain random genetic mutations (Shu, Forster, & Nakagawa, 2012). Thousands of plants with these random mutations are grown to screen and select for those that may contain desired traits. The vast majority of these plants will contain undesirable changes, but a small number may, by chance, result in desirable traits. Naturally occurring random genetic mutations occasionally result in desired traits in plants, and selecting plants with beneficial natural mutations is the foundational way to pursue improved crop varieties. Mutation breeding, then, can be seen as a way to induce random genetic mutations in plants instead of waiting for natural mutations to occur. The first plant variety created by mutation breeding was released in 1936 and the use of mutation breeding took off worldwide in the 1960s, including in Europe, Japan, India, and China—areas that have been much more skeptical of GM plants than the United States. To date, over 3,000 varieties of plants across 190 plant species have been created through mutation breeding (Shu et al., 2012).

Although genetic mutations are artificially induced in plants using radiation and chemical mutagens, mutation breeding never received the regulatory scrutiny that genetically modified plants have. In the U.S. and many other countries, plants derived from mutation breeding are not differentiated from plants derived from conventional breeding. In the U.S., plants derived from conventional breeding, and as a result mutation breeding, fall outside of regulatory scrutiny. As McHughen and Smyth (2012) explain, "the US does not routinely regulate safety of new crop cultivars, relying instead on breeders and developers to exercise due diligence and prudence in their evaluations" (p. 37). McHughen and Smyth go on to argue that this system has worked remarkably well because so many mutation breeding derived varieties have been made "none of which have had the relevant DNA mutations fully characterized, and none of which have had to be removed from the market for safety reasons" (2012, p. 37). Others, however, have argued that this exclusion of all conventionally bred crops from regulatory oversight is questionable since the broad set of plant breeding techniques that are considered conventional can produce crops that have substantial negative environmental impacts (National Research Council, 2002, p. 86).

Since plant TagMo techniques can produce desired traits by creating changes in a plant's own DNA, without the insertion of foreign DNA, this optimistic group of interviewees argued that TagMo techniques should be seen as a better, more deliberate, more precise form of mutation breeding. With this understanding, plant TagMo is an improved version of mutation breeding, which itself is a process to speed up naturally occurring mutations. First-generation genetic modification is a more risky and less natural plant breeding technique because it relies on the insertion of DNA from other species to obtain desired traits. Within this line of thought, the long precedent of regulatory acceptance and environmental safety for plants resulting from mutation breeding provides a clear justification for treating TagMo-derived plants as conventional plants.

Interviewees in this category largely viewed the existing environmental regulation for first generation GM plants as being adequate. A few echoed the sentiment that a tiered approach to regulation should be implemented to prevent products from being overregulated. Interestingly, regulation of first generation GM plants was not as important to their understanding of the desired regulation for plant TagMo products, because they viewed plant TagMo products outside of the lineage of first generation GM plants. As one interviewee from the plant TagMo industry said,

> Anything that is similar to products that can be obtained by mutagenesis or tilling, should be considered as a non-regulated article. If the product is similar to what can be obtained by other methods which are non-regulated, I don't see why this product should be [regulated as a GM plant].

In other words, if regulatory agencies have trusted breeders to ensure that only safe products from mutation breeding are released, and if certain applications of plant TagMo are similar to versions of mutation breeding, shouldn't certain regulatory agencies treat products from plant TagMo in a similar way?

5.3. Critical Environmental Regulation Future

Interviewees stating a critical future of plant TagMo and its environmental regulation made up the smallest group of interviewees and were affiliated with either academia or a non-governmental organization. We classified these futures as critical because they were based on understanding plant TagMo as a continuation of first generation GM plants, which were seen as both inadequately regulated and causing significant adverse effects. They viewed the existing regulatory paradigm as not adequately independent and not adequately assessing the environmental consequences caused by GM plants. As one natural scientist in academia described,

> Well, there's not enough testing, there's definitely no independent testing, the testing that is done is really voluntary and done by the same people who stand to profit from the application of these things. The testing that is done is also inadequate, even if it was done properly and independently . . . there are molecular, ecological, social, economic consequences that are specific to the transgenic manipulation that are really excluded from the testing that happens and the regulations that are in place.

This future stems from the belief that the first generation GM plants provided few benefits while producing many negative environmental effects such as the development of herbicide tolerant weeds, adversely affecting nontarget species, and the impacts from the increased application of the herbicide glyphosate used with herbicide tolerant crops. Plant TagMo is seen as not addressing the negative impacts of first generation genetically modified plants and as likely leading to further risks and negative impacts through the creation of new plant traits.

The existing regulatory paradigm was deemed inadequate because of how regulatory agencies operate and what type of testing is completed. As an interviewee affiliated with an NGO explained,

> They [the USDA] are not properly assessing environmental impacts . . . And I know in my own interactions with them over the years that it's—my saying is pretty much that they haven't met a genetically engineered plant they wouldn't approve . . . the agency, the scientists, many that I've talked to, are proponents of genetic engineering. They think it's good, think it's good for U.S. agriculture, and their biases inform their analyses . . . I pay close attention to risk assessments, the environmental assessments that they do, and I still am amazed that they cannot see where their assurances are not supported by data.

One set of concerns expressed by these interviewees involved the influence of industry on U.S. regulatory decision making. As examples of this, interviewees cited the lack of independent analysis resulting from the acceptance of industry's safety data in regulatory review as well as the conflicting priorities that arise from the USDA's role as both regulator and promoter of U.S. agriculture. The interviewee above argues that the USDA and its employees have such convictions of the safety and benefits of first-generation GM plants that it biases the assumptions and interpretations of their analyses. Another set of concerns involved the types of studies completed for environmental safety testing. The lack of long-term and post–market safety studies were deemed part of a wider decision not to look for and therefore not to possibly find potential negative impacts from first-generation GM plants. An additional example given of this inadequacy was the failure to comprehensively examine how GM plants differ from other plants by, for example, conducting proteomic profiles to examine how a genetically modified plant's entire set of proteins may have changed through the modification process. Interviewees articulating these critical futures felt that the fundamental problems they saw would not be addressed by plant TagMo, and therefore they viewed plant TagMo and first generation GM plants as similar in all consequential ways.

6. Discussion

In line with the future studies literature (Borup et al., 2006; Lopez, 2008; Tutton, 2011), we found that conflict was central to the plant TagMo futures, as demonstrated by differences in the interviewees' desired forms of environmental regulation and in the related understandings and assumptions concerning risk and existing regulation. With regards to environmental regulation for plant TagMo products, futures varied from calling for incremental changes to existing regulations, to calling for significant strengthening of existing regulations, to calling for plant TagMo products not to be regulated as GM plants. We helped reflect on these futures by analyzing the understandings and assumptions that these perspectives were built on. For example, we examined how diverging understandings of what constitutes environmental risk (captured in how risks associated with plant TagMo would differ from those associated with first generation GM plants) and of the adequacy of existing GM plant regulations aligned with desires for plant TagMo environmental regulation (Table 1). These findings can help focus and refine discussions about the future of plant TagMo environmental regulation because they identify the consequential understandings and assumptions that plant TagMo regulatory futures are built on.

6.1. The Regulation of Plant TagMo

With the exception of the interviewees articulating optimistic futures—who were all plant TagMo researchers or in a plant TagMo–related industry—our interviewees largely believed that all TagMo-derived plants should face no less regulatory scrutiny than first-generation GM plants. Recent decisions by U.S. regulatory authorities, however, are not in line with this belief. The USDA gains its authority for regulating genetically engineered plants from the federal Plant Protection Act (PPA) of 2000, which states that a plant should be regulated as a genetically modified organism if recombinant DNA (rDNA) from a listed "plant pest" organism is used in the process of creating the modifications or inserted into a plant to achieve a desired trait, or if the USDA administrator has reason to believe the resulting genetically engineered plant is a plant pest. Most first-generation genetic engineering both uses such rDNA in the process of creating GM plants and inserts this rDNA to confer a particular trait (e.g., promoters with viral genes or constructs with bacterial genes). TagMo techniques, however, do not need to do so (Kuzma & Kokotovich, 2011; Podevin et al., 2012). Plant TagMo techniques can be used to insert rDNA from a differing species, but they can also be used to create genetic modifications that do not use rDNA and therefore fall outside the existing regulatory definitions within the United States. This may lead to the situation where certain TagMo derived plants will only be regulated by the USDA when the administrator decides the resulting GM plant poses a significant risk.

Since our interviews took place, documents released by the USDA through a Freedom of Information Act request demonstrate that, in at least two instances, the USDA has in fact excluded TagMo-derived plants from regulatory scrutiny because of a lack of reason to believe that they were created using plant pests (USDA, 2011; Waltz, 2012).[3] In the first instance, the company Cibus was told by the USDA in 2004 that their products created by the TagMo technique olionucleotides would not be considered GM plants. Cibus is currently using the technique to create herbicide-tolerant canola. In the second instance, DOW AgroScience created a corn product containing less phytate, an anti-nutritional component of feed grain, using the zinc-finger nuclease TagMo technique. This product was deemed to be non-GM by USDA in 2010. In both examples, products derived from plant TagMo techniques will be allowed onto the market as conventional varieties, without the regulatory review typically given to genetically engineered plants. USDA justified these decisions by saying that the techniques fell outside of their regulatory definitions. In the case of Cibus, USDA called the technique in question a "mutagenesis technique" to explain why it has no authority to regulate the products. Therefore it seems that the USDA is considering certain plant TagMo techniques to be equivalent to mutation breeding. Although we began this project seeking to help proactively begin and advance a conversation about how plant TagMo should be regulated, the regulatory decisions treating plant TagMo as a form of classical mutagenesis began, without transparency, as early as 2004. This lack of openness surrounding regulatory decision making demonstrates how anticipatory governance-based engagements with regulation are impeded by a lack of transparency and a lack of opportunities for stakeholder participation. Without transparency and an opportunity for participation, the assumptions and potential implications of these decisions cannot be exposed to scrutiny, eliminating the potential for an anticipatory governance-based approach.

Our examination of plant TagMo's environmental regulation futures also highlights some of the broader issues surrounding the regulation of crops in the United States. To begin, it emphasizes the tensions concerning how to differentiate GM and non-GM plants, and how to regulate the environmental risks of GM and non-GM plants. In the U.S. regulatory system, whether a product is classified as genetically modified or not has important consequences, as it will, in most cases, determine whether the product comes under expensive regulatory scrutiny. Yet in the era of plant TagMo techniques that can create novel traits without the use or insertion of rDNA, the existing Untied States regulatory definition of what constitutes a GM plant seems arbitrary. If plant products with novel traits of similar significant risk to those created from first generation genetic modification can also be created from mutation breeding or plant TagMo, how can the differing levels of regulatory scrutiny be justified? This point speaks to previously raised concerns about the regulation of conventional plants in the United States (National Research Council, 2002). The U.S. regulatory system provides extra attention to the environmental risk associated with the use of rDNA in the plant modification process, yet, as has been convincingly argued, significant environmental risks can emerge from phenotypic traits resulting from conventional or genetic modification–based breeding (National Research Council, 2002). Other regulatory systems, as a point of contrast, are structured to address some of these concerns—Canada's, for example, regulates plants based on whether they contain novel features, no matter the technique used to create them (Smyth & McHughen, 2012).

If plant TagMo products fall outside of existing regulatory definitions and the USDA administrator's judgment becomes the only way for a plant TagMo product to receive regulatory scrutiny, it is unclear how these judgments would be made or whether they would be made in a transparent and participatory way. The recent example in which regulatory decisions concerning plant TagMo products only became public in response to a Freedom of Information Act request is not encouraging in this regard. Finally, and building on the concerns articulated by those interviewees supporting the critical future, one may ask how consequential it is for TagMo derived plants to fall under regulatory scrutiny if the regulatory process is currently inadequate. A more important initial goal would be to address existing inadequacies within GM plant environmental regulation in the United States. We believe that the attention given to whether products from plant TagMo techniques should be regulated as GM should not draw attention away from highlighting and addressing the inadequacies of the existing GM plant environmental regulation (e.g. Jasanoff, 2005; Kuzma, Najmaie, & Larson, 2009; Snow et al., 2005).

6.2. Anticipatory Governance and Regulation

We conclude by discussing the potential for anticipatory governance and future studies based insights to inform the study of environmental regulation. Such an approach, as we demonstrated here, is based on the notion that how future regulations are discussed and argued for influences existing thought as well as present and future decision making. As a result, it is important to garner and scrutinize these "futures" and the understandings and assumptions that they are built on. To garner these futures involves reaching out (e.g., through public or stakeholder engagement exercises, focus groups, or interviews) to the diversity of people holding differing views about the regulation in question, not only those holding the most prevalent views. This will help ensure that the breadth of current thought is well represented. Scrutinizing the diversity of ways people imagine these futures can take multiple forms. Certain scrutinizing, or reflection, can be completed through scholarship that systematically analyzes the assumptions and understandings that underlie differing futures. This type of work can be informed by the future studies literature and can help comprehend what understandings and assumptions inform stances on regulation, where conflict exists concerning regulation, and where consequential assumptions reside that should be subject to further societal reflection. Further forms of reflection can be fostered by designing engagement exercises where stakeholders and the public can scrutinize the gathered futures and their implications.

Our findings were put to use during a follow-up stakeholder workshop on plant TagMo oversight that took place in June 2013 (Korslund, Victor, Brown, & Kuzma, 2013). Insights from this study helped identify specific questions and tensions that were then further examined and reflected on by expert-stakeholders at the workshop. By revealing some of the differing assumptions concerning risk and the adequacy of existing regulation found in the plant TagMo environmental regulation futures, this study introduced some foundational, perhaps previously unconsidered, tensions to the workshop participants that they were then able to grapple with. These included, for example, how plant TagMo's increased insertion precision may or may not be seen as decreasing environmental risk depending on how risk is conceived; how plant TagMo is similar to and different from classical mutagenesis, and whether this should influence decisions about regulation; and how unresolved questions about the inadequacies of current genetically modified plant regulation complicate considerations of how to regulate plant TagMo.

Through studying the potential futures of plant TagMo environmental regulation we sought to demonstrate the promise of anticipatory governance principles for engaging with regulation. This work contributes to efforts to expand the use of anticipatory governance and related principles beyond the laboratory (Stilgoe, Owen, & Macnaghten, 2013). As Wynne (2011) argues, "there are significant actors and conditions in the external context of laboratory science which shape those scientific practices themselves, and the innovations which come from them" (p. 793). As one of the factors shaping what form innovation takes, regulation will continue to be an important site influencing emerging technologies. And as regulatory systems change to address these novel products, anticipatory governance-based approaches, like the one outlined here, will be vital for ensuring the efficacy and integrity of regulatory decision making.

Appendix

Interview Guide for Plant TagMo Expert-Stakeholders

1. What has been your experience with genetically modified organisms? And specifically plant targeted genetic modification?
2. What do you believe are the major differences between targeted genetic modification and standard genetic modification techniques?
    - ○ Where is the line between the two?
    - ○ PROBE: technically and environmentally as well as socially, (politically, ethically, legally)?

3a. How do you believe the world would change if the targeted genetic modification of plants was technically successful and widely adopted?
  - ○ How would these impacts be distributed? Effects on industry, environment, farmers, society? [Could you elaborate a bit and discuss how these impacts would be distributed . . .]

3b. How do you feel the world changed with the adoption of genetically modified plants
  - ○ How have these impacts been distributed? Effects on industry, environment, farmers, society?

4a. What concerns do you have surrounding targeted genetic modification?
  - ○ PROBE: Technically, environmentally, and socially
  - ○ PROBE (when relevant to interviewee): Intellectual property rights picture

4b. How do they compare to the concerns you have surrounding genetically modified organisms (GMOs)?
  - ○ What possible risks you are concerned about?
  - ○ What should be done to address these concerns?
  - ○ Probe: How are these concerns similar/different?

5. What do you find most fascinating about the field of targeted genetic modification of plants? What do you find most fascinating about genetically modified organisms?
6. How would you describe the relationship between public (e.g., academia) and private (e.g., industry) in the TagMo (or GMO) field?
   - ○ What do you believe are some of the effects (both positive and negative) of the current relationship between public and private in the TagMo field?
   - ○ What form should the relationship between public and private take?
   - ○ Intellectual Property Rights issues
   - ○ (How does this compare to other areas you have studied?)

7. Are the current federal regulations for first generation GMOs adequate for products resulting from the targeted genetic modification of plants?
   - ○ Are they adequate for GMOs?
   - ○ In what ways should they be changed?
   - ○ Should participatory processes be further utilized within the oversight and development of targeted genetic modification (or GMOs)?
   - ○ What are your thoughts or concerns over international governance issues?
   - ○ What are your key concerns surrounding the regulation of plants resulting from targeted genetic modification?

8. In what ways may targeted genetic modification be less controversial than the first generation of genetically modified organisms? In what ways may targeted genetic modification be more controversial than the first generation of GMOs?
9. What additional opportunities do you see for TagMo (and/or GM plants)?
   - ○ What conditions are necessary to achieve them?

10. What additional concerns do you have surrounding GM plants?
    - ○ How can such concerns be addressed?
11. Do you have any other concerns, comments or issues that we haven't raised that you feel are important?
12. What is your affiliation (e.g., academia, NGO, government) and your area of expertise (e.g. ecological scientist, biotechnology scientist, social scientist, policy analyst).

Acknowledgments

The authors would like to thank Daniel Voytas, Kristen Nelson, and Karen-Sue Taussig for their helpful conversations and feedback. The authors would also like to thank the study participants for their valuable time and insights.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by National Science Foundation Grant No. 0923827.

Notes

1. We use the terms genetic engineering and genetic modification interchangeably in this article.
2. Affiliations of our interviewees (with frequency in parentheses) included the following: NGO (3), law (1), industry (3), government (5), academia–TagMo researcher (5), academia–other (14). Primary area of expertise included the following: biology (3), biosafety (2), ecology (2), economics (1), entomology (1), genetics (1), TagMo researcher (5), genome engineering (1), molecular biology (3), public policy (7), risk assessment (3), and social studies of science (2).
3. This decision by the U.S. Department of Agriculture was revealed after our interviews and was not discussed within our interviews.

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