

# The Decision Phases Framework for Public Engagement: Engaging Stakeholders about Gene Editing in the Wild

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## Introduction

Hardly a week passes without the release of a new report detailing a new dimension of the intractable problem of global species loss. Despite decades of conservation efforts, the losses continue largely unabated and therefore may call for new and transformational tools, including a range of environmental biotechnologies. Two key examples include transgenic forest trees to protect against invasive pests and pathogens (NASEM 2019) and gene drive to manage invasive species (Faber et al. 2021; Godwin et al. 2019; Kinnear 2018). We argue that the use of environmental biotechnologies also calls for transformational governance tools, particularly for technologies designed to be released in shared and unmanaged environments. One such tool, stakeholder engagement, can transform decision-making spaces both in terms of timing and participation. We introduce a **Decision Phases Framework** to provide much-needed architecture to attend to both *when* diverse stakeholders should be engaged and *who* might be engaged.

Currently, most of the scholarship engaging with the governance around the use of environmental biotechnologies is situated within the science and technology studies literature, particularly the sub-fields of responsible research and innovation, public understanding of science, and public engagement of science and technology. Most broadly, this emerging technology governance scholarship calls for engagement to be early and upstream (Barben et al. 2008; Karinen and Guston 2010; Guston 2014; Macnaghten et al. 2014; Stilgoe, Owen, and Macnaghten 2013). While important, the upstream approach does not fully account for the range of governance decisions surrounding environmental biotechnologies, including management and monitoring considerations for the environmental release of genetically engineered (GE) organisms designed to introgress into and even persist in wild populations. In this essay, we argue that pairing the STS literature on engagement with the concept of “adaptive management” from the natural resources’ literature (Stringer et al. 2006) effectively attends to both the upstream and the downstream dimensions of decision making about gene editing in the wild.

As engagement scholars and practitioners in this space, we propose a **Decision Phases Framework** for shaping engagement throughout the potential lifespan of a GE organism designed to persist in the environment. The Decision Phases Framework -- which structures discussions around 1) research and development, 2) regulatory review, and 3) deployment and management -- responds to calls for early and upstream engagement, but also paves the way for meaningful and deliberative engagement to follow the technology downstream through its life in shared environments. The framework attends to upstream engagement -- to interrogate assumptions about the use of technologies and to shape the innovation process in real time -- and downstream engagement -- to build in responsiveness, social learning, and adaptive management to collectively shape environmental biotechnologies as they persist in shared and unmanaged environments.

Drawing on two case studies, the genetically engineered American chestnut tree (GEAC) and the Genetic Biocontrol of Invasive Rodents (GBIRd) partnership, this paper demonstrates the utility of the Decision Phases Framework as both a design strategy and an analytical tool. Specifically, we argue that the Decision Phases Framework provides opportunity to identify the myriad decisions to be made about an environmental biotechnology, how public engagement can influence those decisions, and which stakeholders need to be engaged to inform these decisions. We begin by discussing two perennial questions in public engagement of science and technology: when and whom to engage. Next we provide brief orientations to our two case studies (GEAC and GBIRd). These cases then serve as illustrations as we describe the three phases of the Decision Phases Framework: 1) Research and Development; 2) Regulatory Review; and 3) Deployment and Management. For each phase, we detail the kinds of relevant decisions to be made and how to integrate public engagement into making such choices. We conclude with a discussion of the strengths and limitations of the Decision Phases Framework as a means to design and analyze public engagement for emerging biotechnologies.

### **When do we engage?**

First, we must clarify what we mean by engagement. With respect to an operational definition of engagement, we follow the National Academies of Sciences, Engineering, and Medicine in defining engagement as “Seeking and facilitating the sharing and exchange of knowledge, perspectives, and preferences between or among groups who often have differences in expertise, power, and values” (NASEM 2016, p. 131). These kinds of exchanges can and should take place throughout the life cycle of an innovation.

Temporality -- *when* engagement activities occur in the development of new technologies -- has been an important component of recent technology governance paradigms seeking to foster engagement in decision making. Key examples include “upstream” stakeholder engagement (earlier than when a technology is ready for deployment) (Wilsdon and Wills 2004) and “anticipatory governance” (Barben et al. 2008; Karinen and Guston 2010; Guston 2014). These paradigms share a common desire to move engagement upstream in order to maximize its ability to influence the design of technology before it becomes finalized and fixed. Moving upstream is also seen as a way to allow engagement to extend beyond a discussion of a technology’s risks, as essential as that may be, to the more influential and often uninterrogated values and assumptions that guide the innovation process itself.

Wilsdon and Willis (2004), for example, see upstream engagement as a way to address the limitations that occur when engagement takes place late in the technology development process. They argue that engagement needs to take place earlier to move beyond debating the risks of a technology and to foster discussions on the more influential and often uninterrogated “values, visions and vested interests that motivate scientific endeavour” (p. 18).

Anticipatory governance builds upon both “constructive technology assessment” (Schot and Rip 1997) and “real-time technology assessment” (Guston and Sarewitz 2002) to move the consideration of a technology’s societal impacts into the research and development process, to broaden the impacts considered, and to involve more diverse participants in that process. Anticipatory governance arose in the context of emerging technologies and is organized around the focal points of foresight, engagement, and integration (Guston 2014). In emphasizing foresight, it calls attention to the consideration of a technology’s potential futures in deliberation and decision making (Barben et al. 2008). Yet it simultaneously acknowledges the need to call

into question the assumptions, visions, and imaginaries that construct potential futures. The future, then, becomes the focus of engagement practices:

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

In this way, engagement is essential to foresight, and foresight is essential to engagement, and both help develop reflexivity within the future of innovation and technology (Barben et al. 2008).

Relatedly, “responsible innovation,” with its four key dimensions of anticipation, reflexivity, inclusion, and responsiveness (Stilgoe, Owen, and Macnaghten 2013), traces similar roots to critiques of technology assessment and the desire to change society’s relationship with technology (Macnaghten et al. 2014; Owen and Pansera 2019). Responsible innovation seeks to bring engagement upstream as it “asks for inclusive deliberation concerning the direction of travel for science and innovation - from the outset - opening up opportunities for these to be directed towards socially desirable ends” (Owen, Macnaghten, and Stilgoe 2012, 754). Stilgoe et al. also trace the move upstream, seeing responsible innovation as a “location for making sense of the move from the governance of risk to the governance of innovation itself” (Stilgoe, Owen, and Macnaghten 2013, 1570). The foundational ideas of these areas of scholarship highlight the need for engagement to move earlier in the research and development process so as to avoid a narrow, reactionary paradigm of engagement.

Other engagement scholars have highlighted complex issues that emerge when attending to temporality. Participants engaging with emerging technologies can often feel overwhelmed by not only the pace of technological change but also by how different parts of the technical development process follow different speeds and different rhythms (Felt, 2015, p. 14). Important here is a time-sensitive analysis that can “render visible and thus debatable the multiple temporal regimes governing any innovation and their relationship to society” (p. 16). Krzywoszynska et al. (2018) point to the limitations of the open future model of upstream engagement, one that constructs the future as an abstract open space. They argue that while the open future model may allow creativity, it “ruptures the relationship of ownership, responsibility, and care: as the open future belongs to everyone, it essentially belongs to no one” (p. 20). They point to the potential for engagement with local, situated publics to establish a different relationship to the future that respects the emergent potential of futures.

Key to our analysis, explicit tensions remain concerning the question of when engagement for emerging technologies should take place (Delgado, Lein Kjølborg, and Wickson 2011). First, there is contestation over exactly what upstream means and how far upstream it makes sense to go in any particular context. Second, the further upstream one travels, the less likely that the technology or issue in question has become a “matter of concern” (Latour 2004). This will impact the interest that individuals may have for participating in engagement while also providing the organizers of engagement power to provide initial meaning to these technologies. Third, there is a tension between the linear, unidirectional image of technology development implied by the “upstream” concept and the broader ideas within the STS community that emphasize the non-linear, iterative, and context dependent nature of technology development in complex socio-technical systems (Pinch & Bijker 1986).

Although perhaps not unique to environmental biotechnologies, innovation also continues “downstream.” While STS engagement scholarship attends thoroughly to early and upstream

engagement practices, environmental releases of gene edited or genetically engineered organisms pushes us to consider how engagement might follow the technology downstream if or when these organisms enter and persist in shared environments. Here we draw lessons from the scholarship and practice of “adaptive management” that occupies a central role in environmental and natural resource governance. Bringing adaptive management concepts into conversation with STS engagement scholarship and practice builds a more integrated approach to the Decision Phases Framework throughout the life cycle of a project.

Adaptive management is a structured decision-making process within environmental and natural resource governance that is driven by continuous learning to move towards improved environmental outcomes (Failing, Gregory & Higgins, 2013). Adaptive management also builds in critical social and institutional learning, cultivated through the development and maintenance of learning communities, crucial for understanding how emerging environmental biotechnologies live and interact with complex socio-ecological systems. Adaptive management practices have been put forth to guide emerging technologies with respect to environmental issues such as climate change responses (Tompkins & Adger 2004), ecosystem restoration monitoring (Failing, Gregory & Higgins, 2013), and even geoengineering (Galaz, 2012). From these cases, we can draw inspiration for structuring engagement practices for addressing uncertainty, collective and institutional learning, and responsive decision-making .

In short, the Decision Phases Framework combines upstream engagement and downstream adaptive management to offer a more comprehensive view of how public engagement can influence the design, governance, and management of emerging environmental biotechnologies.

## Who do we engage?

Engagement scholars and practitioners continually call for broader inclusion in the governance of emerging technologies more broadly, and in the governance of environmental biotechnologies more specifically (serial sites). Yet, such calls can be vague and difficult to operationalize without clear definitions or goals, particularly with how inclusion intersects with diversity goals. Given some of the histories, politics, existing networks and power dynamics at play when selecting engagement participants, we devote explicit attention to these questions.

We articulate three pillars for broadening engagement as we consider who should be engaged and how using the Decision Phases Framework creates space for wider inclusion. We call for broader diversity and inclusion of *expertise*, *identity*, and *perspective*. Components and example attributes for each category can be found in Table 1. Broadening expertise would include a wide range of academic disciplines and sectors, as well as local and traditional knowledge bases as expertise. Attending to identity would look specifically at the diversity of lived experiences in engagement; in our cases we focus largely on Indigenous participation as one example. And finally, wider normative perspectives such as beliefs about nature, technology, economy, and regulation are also important to consider in engagement for emerging environmental biotechnologies. For example, if all participants in an engagement process on emerging biotechnology governance held the same view that nature should be controlled by humans and market mechanisms are the best way to make governance decisions, then the resulting deliberations would be limited, in that certain ideas would not likely be called into question. This is an important insight for productively engaging with existing thought and practice. If, for example, there are no perspectives present that challenge the established norms

and views concerning technology, nature, the economy, and regulation, then the status-quo is unlikely to be questioned. Alternatively, if there are no participants with perspectives that align with status-quo views, then the resulting deliberations may become totally disconnected from current thought and decision making, which must be grappled with. Ultimately, a breadth of perspectives, identities, and expertise is needed to ensure the status quo is at once represented and productively called into question.

[[Insert Table 1]]

The categories outlined in the table above are useful heuristic devices, but realities are much more complex. Engagement scholars and practitioners should also consider the ways in which intersectionality might inform diversity and inclusion in these activities. For example, academic sciences and leadership positions are still dominated by white men (Woolston 2020). Therefore prioritizing specific forms of expertise or seniority may prohibit meaningful representation from women, Indigenous peoples, and people of color. Alternatively, prioritizing lived experience forms of diversity -- such as race, Indigeneity, and gender -- may also expand types of knowledge, expertise, and perspective represented.

The Decision Phases Framework draws upon this complexity when considering the key question of who to engage in the design, governance, and management of environmental biotechnologies. While there is no a priori formula to follow for any particular project, we argue that attention to diversity of expertise, identity, and perspective - and their intersections - will strengthen the substance and power of public engagement.

## **Case Studies**

For this paper, we draw upon two potential applications of emerging environmental biotechnologies to illustrate the utility of the Decision Phases Framework: the genetically engineered American chestnut tree and the gene drive mouse for invasive species management on oceanic islands. We have selected these case studies because we have organized and researched some of the public engagement associated with them.

### **Genetically Engineered American Chestnut Tree**

In the early 20th century, an invasive pathogen began infecting American chestnut trees, and within a few short decades, the blight had killed upwards of four billion trees. Decades of traditional breeding research managed to confer some level of blight resistance in the subsequent decades, but without producing a tree ready for environmental release. In the 1990s, researchers began the process of developing a transgenic, blight tolerant American chestnut tree, which after showing promising success in field trials is currently under regulatory review in the United States. If deregulated, GE chestnut trees may become the first genetically engineered organisms to be deployed into unmanaged forests. For some, this project offers hope for a restoration effort, generations in the making (Powell 2016). For others, the risks and uncertainties further threaten already stressed forest ecosystems, expand the reach of unwanted GMOs, and raise questions about transboundary movements of an environmental biotechnology that will not respect national borders or sovereign boundaries (Rosen 2019).

As engagement scholars and practitioners who focus on environmental biotechnologies, we secured funding from the National Science Foundation (SBE#1632670) to study the socio-cultural and political issues that surround this test case. To that end, we organized and facilitated a stakeholder workshop framed around public engagement at three key decision phases in innovation: research and development, regulatory review, and deployment and management. As we worked to develop a stakeholder network, we also collaborated with members of the Haudenosaunee Environmental Task Force to explore how Indigenous communities have been considered in the development and potential deployment of the GE American chestnut (Barnhill-Dilling, Rivers & Delborne 2020; Barnhill-Dilling & Delborne 2019).

### **Genetic Biocontrol of Invasive Rodents (GBIRd)**

Invasive rodents pose significant threats to island ecosystems and to charismatic and endemic populations of bird species in particular (Leitschuh et al. 2018). Current tools for managing these invasive rodents are broad spectrum toxicants that have limited utility and a number of negative non-target effects (Campbell et al., 2019). The Genetic Biocontrol of Invasive Rodents (GBIRd), an international consortium of scientists and partners including the NGO Island Conservation, coordinates research to explore the feasibility of producing gene drive mice to suppress and ultimately eradicate invasive house mice on islands - taking into account ecological, genetic, cultural, ethical, and policy expertise (Godwin et al. 2019).

Co-author Author3 has led GBIRd's engagement team since its organization in 2016. Author1 joined the engagement team in 2018, at the time funded by the DARPA Safe Genes program. Author2 was not take part of this project team associated this case study. Author3, along with other colleagues, conducted a landscape analysis through stakeholder interviews and organized a stakeholder engagement workshop in 2019, attending to current and future decisions in the GBIRd program and considering how public engagement could inform such choices going forward.

### **The Decision Phases Framework**

We offer the Decision Phases Framework to organize attention to three phases of a technology's "life." The framework thus explicitly emphasizes temporality while also highlighting the stakeholders most relevant at each phase. We identify three phases within an innovation timeline: **(1) research and development, (2) regulatory review, and (3) deployment and management.** While these phases may overlap at the boundaries, they serve as a reminder of the diversity of activities associated with technological innovation. Within each of the phases, we identify two primary questions that guide our analysis: *(1) what decisions need to be made that can be informed by engagement?* and *(2) how do we approach engagement to influence those decisions?* For the second question, we explore how three strategies improve engagement and thus innovation governance at each phase. For the second question, we believe that such an approach to engagement should: (a) broaden the types of expertise considered in research and development of a technology, (b) foster greater diversity and inclusion in early governance processes, and (c) widen the breadth of normative perspectives in order to have the most meaningful impact on the relevant decisions

### **Research and Development**

The research and development decision phase encompasses all activity from problem identification and framing to experimentation to development of prototypes. While the genre of the scientific article often encourages the telling of a “just so” story that progresses rather neatly from an idea to a proposed technology (Gross et al. 2002), the reality is much more messy (Kleinman, 2003; Latour & Woolgar, 1986). In other words, this phase is not linear, in the sense of reflecting a neat progression from idea to artifact, but iterative with multiple designs, periods of rapid progress, setbacks and failures, and steady work to navigate research protocols, analyze data, and adjust course where necessary.

### **What decisions?**

Research and development decisions often begin with identifying the problem, puzzle, or challenge in question. Therefore one of the most important decisions is: *what precisely is the problem?* In the context of gene editing in the wild, the groups with whom we have worked have identified the problems in various ways: individual species loss (e.g., chestnut trees, albatross birds), reduction in biodiversity (e.g., in Appalachian forests or on oceanic islands), ecosystem degradation (e.g., of complex forests or island ecosystems), and undesirable impacts of existing technologies for intervention (e.g., planting non-native trees, using rodenticides with off-target effects). Deciding which problem drives the project influences not just outward-facing communication, but also choices about prioritizing some solutions over others, with whom to collaborate, and what design elements are negotiable or not.

As researchers begin to see and scope a problem, they also begin to *choose among potential tools and solutions*. In the case of gene editing in the wild, a century or more of conventional conservation efforts have not stymied global species loss, so researchers began exploring transformational tools such as genetic engineering or synthetic gene drives. For example, after nearly a century of trying to mitigate the effects of chestnut blight, members of the New York State chapter of the American Chestnut Foundation approached scientists at SUNY-ESF about the potential utility of then-new genetic engineering tools (Kelly 2020). The controversy of this choice reverberates to this day (Thompson 2019). Similarly, Island Conservation, an NGO that has carried out invasive species eradication on island for decades using conventional methods (e.g., rodenticides, traps), saw the need to develop new tools to deploy on larger islands and those with humans and livestock that would otherwise complicate eradication strategies. Motivated by their own experience of methodological limitations, Island Conservation played a pivotal role in the formation of GBIRD to explore gene drive mice as a potential tool and solution (Campbell et al. 2019).

Once the problem and proposed solution become relatively fixed, researchers begin to develop a research and development agenda, where they will make important decisions that will shape how the project unfolds. Some of these decisions include choosing *which funders they will seek in support of basic and applied research* and deciding upon *strategies and methods for research, such as* developing prototypes, and selecting laboratory or field experiments for proof of concept. In the case of the GE chestnut, researchers had to decide which genes to insert into the American chestnut genome (Newhouse et al. 2014), find funding sources for both basic research and product development, and figure out how to apply tissue culture and clone the transgenic lines of the American chestnut (Andrade & Merkle 2005). GBIRD scientists had to make choices about which rodent species to work on first (i.e., rats or mice, both of which are problematic invasive species on oceanic islands), which molecular strategies to pursue (CRISPR gene editing or harnessing a pre-existing “natural” gene drive in house mice), which population suppression strategies to pursue (male or female bias), and how to design large cages for pre-

release trials that would best mimic the complexity of an actual island environment, yet provide sufficient security to prevent accidental escape (Farooque et al. 2019).

## **Role of Engagement**

Each of the above sets of decisions typically take place within the technical research and development teams, but we argue that these are inherently values-laden decisions that would often benefit from engagement. The examples we provide below illustrate how this might work. In addition, we offer three strategies to broaden engagement in order to maximize impact: broadening expertise, broadening diversity and inclusion, and broadening normative perspectives. These approaches do not provide a simple methodological recipe for engagement about environmental biotechnologies, but rather inform the priorities and strategies of those who design and convene engagement activities.

In addition, upstream engagement, even early in the research and development phase, can foster relationship development between research teams and stakeholders that benefit the project during subsequent phases. Through relationship building and perspective seeking, engagement throughout the research and development phase can inform socially responsive research, even as laboratory experiments are still unfolding.

### ***Broaden Expertise***

While the technical team is critical to the research and development phase, we argue for the importance of engagement activities that expand what kinds of expertise inform research and development processes. Below we discuss the value of local, lay, or traditional knowledge, as well as insights from interdisciplinary natural science and the social sciences.

Local, lay, or traditional knowledge can offer insights into local social and ecological conditions that may have direct influence on a project's success. In the case of the GE chestnut, local ecologies matter a great deal for the success of restoration. Because the membership of TACF has been scouring the woods for generations looking for and mapping relic wild type chestnuts (TACF 2018), they may know more about local conditions than expert ecologists less familiar with those environments. Knowledge of these relic trees and their locations could help researchers develop sufficient genetic diversity in the GE chestnut trees that will eventually be produced (Westbrook, Holliday & Newhouse 2020).

Even broadening the kinds of natural science expertise beyond the primary development team widens the kinds of issues researched. In the case of the chestnut, engaging with colleagues pointed the GE chestnut scientists to develop research protocol for impacts on wood frogs (Goldspiel et al. 2019). And in the case of GBIRD, animal welfare experts raised concerns about behavioral impacts on sex ratio changes in island mouse populations (Farooque et al. 2019, p10), a question that could be tested in caged experiments. If such tests show that the drastic changes in sex ratios -- expected with a genetic strategy that produces no female offspring -- elicit violent behavior in males, then developers may reconsider which gene drive strategies to pursue (e.g., a mouse population suppression strategy that shreds the Y chromosome, producing only female offspring; see Prowse et al., 2019).

Social scientists bring insight about social, cultural, and political dimensions in the research and development phase that can shape the innovation process in subsequent phases. For example, even though gene drive research is still only in the laboratory phase, large-scale public survey research in New Zealand demonstrates that the moderate level of support for using gene drive to manage invasive mammals varies widely across segments of the population (MacDonald



et al 2020). In other words, social science data can highlight that there is broad agreement about the problem -- the threat of a particular invasive species, for example -- but broad disagreement about which management tools should be used. MacDonald et al. (2020) argue that knowing about these differences can inform engagement that is more attuned to perspective and worldview. We further argue that knowing these distinct perspectives could prompt research and development teams to focus on a more comprehensive toolkit rather than treating environmental biotechnology solutions as proverbial “silver bullets.”

### ***Broaden Diversity and Inclusion***

Engagement during the research and development phase that emphasizes greater diversity of representation and inclusion strengthens the potential for impact on decisions. Below we explore the benefits of broadening participation from groups traditionally underrepresented in environmental decisions and the importance of attending to geographic diversity in environmental biotechnology governance.

In terms of including groups often marginalized in environmental decision making, engaging with Indigenous communities can help researchers understand a number of culturally and politically important issues. If engagement occurs during the problem identification dimensions of research and development, Indigenous representatives can inform problem identification. For example, working with Indigenous communities to identify a cultural keystone species (Kimmerer 2011) may help researchers identify which species to protect or which species to avoid (Barnhill-Dilling and Delborne, 2019). Early inclusion of Indigenous representatives can also highlight what ethical concerns are more important than others, such as how protecting sovereignty—being able to make decisions about Tribal land using Tribal governance structures—may be more important to some Indigenous groups than whether or not a restored species is genetically engineered (Barnhill-Dilling, Rivers, and Delborne, 2020).

Geographic diversity is also an important dimension of engagement in research and development. Not only will wild releases of genetically engineered or gene edited organisms extend beyond national borders, but different geographic contexts highlight different priorities. Some members of TACF chapters in southern states worry that because the molecular research and field trials started with the NY chapter, that their priority concern—phytophthora, or root rot, which is ubiquitous in the southern end of the range—did not receive sufficient attention (Delborne et al. 2018). This dilemma highlights the importance of engagement around problem identification.

### ***Broaden Normative Perspectives***

In our two case studies, American chestnut and island biodiversity losses were the points of focus for conservation non-profits for a number of decades; the membership and support base of conservation organizations brought these priorities to the fore. In other words, groups of stakeholders actually approached technology developers with a problem already in hand, and in a sense, the stakeholders engaged the scientists. Particularly in the case of the GE chestnut, in which the research team engaged mostly with interested and enthusiastic stakeholders for nearly three decades, other, less supportive perspectives remained distant and unengaged. What are the consequences of failing to engage with oppositional stakeholders, even during the research and development phase? Stakeholders who hold stridently opposed positions, for example, may be difficult to engage within a constructive dialogue, but their perspective should still be known and considered as scientists research and develop potential applications of

environmental biotechnologies. Such explicit attention to broadening normative perspectives can reveal assumptions, blindspots, and even potentially build trust among stakeholders that may never reach consensus but still cooperate in the governance of emerging biotechnologies.

Critical perspectives can broaden conversations about controversial technologies - challenging not just the scientific “facts” about a technology (e.g., its ecological safety) but the boundaries of the governance discourse. Regarding the GE chestnut, for example, the Global Justice Ecology Project is concerned about the uncertainty of the science surrounding genetic engineering and worries that GE organisms may further stress already-stressed ecosystems, but they also raise systems-level questions about whether the GE chestnut addresses key challenges facing forest ecosystems and the downstream impacts of an approved GE chestnut tree on the future of forest biotechnology applied to other species, including those that might further enable and expand corporate tree plantations, which they find problematic for a mix of social and ecological reasons (Smolker & Petermann 2020). Likewise, the ETC Group has published numerous reports challenging the wisdom of pursuing any kind of gene drive research, explicitly criticizing the GBIRd initiative. For example, a report entitled “Reckless Driving: Gene Drives and the End of Nature” states: “Such a powerful tool may be too tempting to military funding agencies and hi-tech agribusiness who see advantages to exploring this Pandora’s box. This raises the basic question: who will this technology benefit and who decides how it will be used?” (Civil Society Working Group on Gene Drives, 2016, p. 5; also see ETC, 2018, 2019, 2020). Again, such questions go beyond narrow concerns about ecological safety to raise systems-level concerns about how technologies have political impacts beyond their most immediate applications (Winner, 1980).

In other words, we recommend engaging a broad range of normative perspectives, not so that scientists and developers can persuade polarized voices to change their minds, but in order to expand the discourse that might impact decisions during the research and development phase. We are not naive enough to think that such engagement will erase or settle such controversies, but we believe that actors with very different positions and interests can still learn from one another and potentially build enough trust and respect to disagree in ways that are more constructive than destructive.

## **Regulatory Review**

Regulatory review consists of the steps of designing and conducting safety studies, designing and conducting risk assessments, and going through the regulatory review process itself. Below we describe some of the key decisions within regulatory review that can be informed by engagement and explore what approach to engagement is needed to inform these decisions..

## **What decisions?**

The Coordinated Framework for the Regulation of Biotechnology traditionally governs biotechnology in the United States, where it draws on existing statutory jurisdictions of the US Department of Agriculture (USDA), US Environmental Protection Agency (USEPA), and Federal Drug Administration (FDA). Questions that drive these agencies in their regulatory review are centered around risk. With novel applications such as the GE chestnut tree, what under first generation agricultural biotechnologies were considered a risk -- the spread of a genetically engineered organism -- will become the goal, as proponents hope that chestnut trees

will introgress into wild populations. Such novelty prompts questions about how to define harm and evaluate risk under the current regulatory framework.

Decisions made in designing and conducting scientific studies and risk assessments determine what information will ultimately inform regulatory decisions and societal discussion about a particular biotechnology. For example, a key step of the risk assessment process is the hazard identification or problem formulation phase where the scope, scale, and other pertinent details of the risk assessment are determined (Nelson and Banker 2007; Hayes et al. 2018). In the context of risk assessments, then, decisions must be made concerning a host of questions, including: *What are the most important potential adverse effects and risk pathways to study in a risk assessment for the technology? What studies are needed to answer these questions and inform the risk assessment? What standards of evidence should apply?* Environmental releases of genetically engineered organisms present novel challenges to regulators. Returning a functionally extinct species like the chestnut to the eastern forests may have unexpected impacts in forest composition. Key decisions need to be made concerning what studies should be conducted on such genetically engineered organisms. For example, the developers of GEAC have made public their safety studies concerning potential adverse effects on tadpoles, mycorrhizal fungi, bumble bees, mayfly, caddisfly, and gypsy moths (<https://www.esf.edu/chestnut/poster.htm>), but others have suggested a larger set of potential adverse effects should be studied (GeneWatch 2020).

More broadly, because environmentally released genetically engineered organisms will not respect traditional political boundaries, decisions also need to be made concerning: *how will regulatory decisions fit into broader governance systems?* How will the regulatory review process in the United States, for example, fit into other national regulations and/or the global governance of gene editing in the wild? As an example, if the potential range of the American Chestnut is such that the GE chestnut released in the US may eventually spread into Canada, how will US regulatory decisions relate to those made in Canada? Alternatively, the islands where GBIRD may one day deploy the gene drive mice may well be subject to any number of distinct layers of governments and treaty agreements. Regulatory review decisions will need to navigate how all of these governance and jurisdictional layers fit together.

## **Role of Engagement**

Currently in the United States, engagement's role in the regulatory review process is generally limited to a public comment period, which for the GE chestnut took place in 2020. In the case of the GE chestnut, TACF developed materials to guide supporters' statements in the federal register, hoping that the federal register would reflect their messaging using the kind of scientific language that would 'count' in the public comments' evaluations: that a greater portion of the engaged public supported the project than opposed it and that this was a positive use of genetic engineering. Kuzma argues that the current public comment system is narrow in scope and attends almost exclusively to a limited range of technical issues, an exclusion that masks the values-laden nature of framing and evaluating risk (Kuzma 2018). Scholars working on engagement in risk assessment discipline argue that engagement is an essential tool for relevantly and rigorously deciding upon the key value judgments within risk assessment (Hartley and Kokotovich 2018; Hayes et al. 2018; Kokotovich et al. 2020). Building upon this work, we argue that engagement should expand beyond existing public comment periods to inform the breadth of important decisions within risk assessment and regulatory decision-

making. Again, we look at how engagement could broaden expertise, diversity and inclusion, and perspectives in the regulatory review phase.

### ***Broaden expertise***

Engagement can help broaden the kinds of expertise that informs regulatory review. Making substantive improvements to decision making is a key justification for engagement (Dietz and Stern 2008), and this holds true for engagement in risk assessment and regulatory decision making as well. Broadening expertise, by including a breadth of academic disciplines, indigenous knowledges, and/or local knowledges, can help ensure that risk assessments and regulatory decision making are not missing any important information. In the GBIRd case, for example, such a breadth of expertise will be essential for determining the following risk assessment-relevant information: 1) whether there are locally occurring closely related species to any gene drive organisms that could lead to the spread of the gene drive trait through hybridization, 2) whether there are particularly important (e.g., keystone) species at any potential release site that could be impacted by changes in ecosystem dynamics, and 3) what the key pathways for escape from an island could be - especially given the socio-economic context of an island. Well designed engagement can ensure that a broad set of expertise is informing these and other key risk assessment and regulatory decisions.

### ***Broaden diversity & inclusion***

Engagement can also broaden diversity and inclusion within risk assessment and regulatory decisions making - an important consideration given how one's lived experience and worldview impacts their definition of desirable technology or what constitutes harm from a technology (NASEM 2016). Engagement with local communities and Indigenous peoples impacted by a potential gene edited product can inform key risk assessment and regulatory decisions and help ensure that they are in alignment with local values and worldviews. In other words, engagement can help ensure that technologies or particular understandings of harm are not imposed on communities. Relatedly, the United Nations has, in the context of gene drive technology, emphasized the importance of Free, Prior, and Informed Consent (FPIC) of local and indigenous communities before the deployment of such technology (Wit 2019). While FPIC is relevant for informing ultimate decisions about whether and how to use a gene editing technology, it also points to the importance of involving indigenous and local communities in engagement for risk assessment. For example in the GBIRd case, there may be culturally important species in a potential use location that need to be rigorously analyzed in any risk assessment for its findings to be relevant and trusted. Engagement that broadens diversity and inclusion can also reveal key historical contexts that impact risk assessment and regulatory decision making. For example, Oceanic islands are being explored as possible sites for gene-drive field trials, but the essay "Empowering Indigenous Knowledge in Deliberations on Gene Editing in the Wild" in this special report points out that the Indigenous peoples of these islands have long been subject to experimentation in ways that influence the current decision-making context and that make them uniquely impacted by potential regulatory decisions.

### ***Broaden perspectives***

Engagement can also broaden the perspectives involved in risk assessment and regulatory decision making - bringing in different worldviews surrounding nature, technology, regulation,

and the economy. Bringing in a diversity of perspectives makes it more likely that risk assessment and regulatory decision making will be productively interrogated than, for example, if only people who are happy with existing regulations are involved. Kokotovich and Kuzma (2014) found that stakeholder views concerning how gene editing should be regulated were impacted by whether they thought first generation genetic engineering was adequately regulated or not. As a result, rigorous deliberations about future risk assessment and regulations will be more likely if a diversity of views concerning existing regulations are involved. A diversity of perspectives also makes it more possible to critically examine the need for technology as part of regulatory decisions. For example, while some argue that the introduction of genetically engineered organisms are threats to the very species and ecosystems they are designed to protect or restore (Smolker & Petermann 2019), others argue that we have a moral imperative to use all of the tools available to us to reverse the tide of species loss (Brister et al. 2021). While current regulatory processes do not integrate these questions, engagement with broad perspectives offers one way to provide a space to hear and consider these issues as part of broader governance processes.

### **Deployment and Management**

This phase occurs after the regulatory review process is complete and the technology has been de-regulated or approved for release. We identify *deployment* as activities that push the technology beyond experimental environments and into practical use. *Management* calls attention to efforts to care for technologies and their users and environments. An important dimension of management includes monitoring, the activities that produce information about the technology's impacts to inform ongoing management decisions and detect problems or unintended effects that emerge after deployment. We suggest paths forward for these emerging technologies and decisions.

### **What decisions?**

Decisions about deployment begin with *where and how should the organisms be deployed and who will deploy these organisms?* By extension, decisions will be made about where they should not be deployed. If the potential landscape is vast, like the chestnut's historic range, which geographic locations should be prioritized? How quickly or how slowly should these species be deployed? Are there areas -- like mining reclamation sites -- that may seem less risky for initially planting? GBIRD's deployment decisions will come about after a long series of deliberations about island selection criteria that attend to ecological and socio-political dimensions to consider (Farooque et al. 2019).

Within the management of a technology, project organizers must consider what monitoring data will be collected and what management decisions will be made in the face of emergent data. For example, *what ecological entities will be monitored and how will they be studied?* What decisions will be made if certain outcomes are seen in the monitoring data? For example, what if the primary targets are being met -- island rodent populations decrease such that a protected population or ecosystem has started meaningful recovery -- but the gene drive mouse has been detected on a neighboring island? What actions will be taken? How does this response depend on the attributes of the particular gene drive (e.g., self-limiting or self-sustaining)? If this happens after multiple rounds of gene drive animals have been released and relative 'safety' has been demonstrated, will the presence on a neighboring island be less alarming than originally identified to be, especially in light of conservation targets being met? The complexities around

biological control management issues warrant careful consideration on their own, and paired with novel genetic tools such as gene drives, *which indicators and thresholds may be considered signs of success or signs to pause?* How far into the future will monitoring take place? And with such uncertain time horizons what institutions will bear responsibility for funding the monitoring systems and accountability for any potential adverse effects?

### **Role of Engagement**

In this section we draw on concepts from adaptive management to bridge upstream and downstream engagement to develop engagement strategies that broaden expertise, diversity and inclusion, and normative perspectives for environmental biotechnologies to make responsive and just deployment and management decisions.

#### ***Broaden expertise***

To inform the breadth of decisions that will be made in the deployment and management phase, organizers should structure engagement in order to expand the nature of expertise informing the decisions made at this phase. Drawing on local environmental expertise, citizen scientists, volunteers, and other local knowledge holders can participate in decisions about where an organism should or should not be deployed, as well as management plans.

Framing the deployment and management landscape as a complex social-ecological system is an important dimension of broadening expertise in engagement (Colvin et al. 2016). Using this perspective engagement specialists could engage diverse stakeholder experts in participatory exercises (e.g. participatory mapping; see Ramirez-Gomez et al. 2013) that shape where the organisms are deployed and where they are not. In the case of the GE chestnut engagement specialists could enroll participation from the wide range of stakeholders that may well be directly planting GE chestnuts. For example, if the GE chestnut achieves nonregulated status, members of the American Chestnut Foundation and contributors to SUNY-ESF's 10,000 Chestnut Campaign may receive transgenic chestnuts to plant on their private property. Managers of land trusts and other privately owned parks may also choose to plant transgenic chestnut trees on their property. Other potential stakeholders interested in deployment may be less obvious. For example, early research suggested that mine reclamation sites might be an interesting location for chestnut restoration because of the relative lack of blight in the soil (McCarthy et al. 2008). Additionally, the Eastern Band of Cherokee Indians have expressed interest in planting chestnut trees on their reserved land in Western North Carolina, in the heart of the chestnut's historic range (Losiah 2020). Engaging such a diverse range of stakeholders that could be directly responsible for planting the GE chestnut trees -- and taking their knowledge as expertise -- could fundamentally shape the restoration landscape for the American chestnut.

Engagement specialists can also facilitate strategies to broaden expertise in the development of management strategies. For example, engaging a variety of stakeholders familiar with the local environments -- including but not limited to citizen scientists and other volunteers, public land managers, Tribal natural resource officers -- can make management systems more responsive and adaptive to local contexts. Engagement activities can also be designed around structured decision-making where management decisions are phased and monitoring data shapes each subsequent phase. Engagement specialists could structure the processes so that citizen scientists and other volunteers, public land managers, Tribal natural resource officers, project scientists, and other relevant stakeholders could share power and each set of expertise considered

meaningfully in these decision-making processes (Berkes et al. 2006). Specific issues that could be addressed through these engagement practices include deliberating and deciding upon targets for species restoration, indicators for success and for harm, and thresholds for other forms of intervention.

### ***Broaden diversity & inclusion***

Developing engagement strategies in the deployment and management phase should consider the landscape scale to allow for diverse sets of experiences to co-exist elevating concerns of communities and groups that are often marginalized. In addition to considering the patchwork of private and public land ownership in restoration ranges, we must also recall the sovereign Tribal lands that may exist within the historic or restoration ranges of the organism. These patchworks are complex and nuance should be considered across geographic space; some public lands may be managed differently than others; some private landowners may want to deploy while others do not; indeed, some Indigenous groups in the chestnut range are broadly opposed to the chestnut project (Francis, 2015; Rosen, 2019), while others -- like the Eastern Band of Cherokee Indians -- are supportive and hope to plant a chestnut on their reserved land (Losiah 2020). Engagement strategies that broaden diversity and inclusion create space for diverse lived experiences on the landscape.

Engagement that attends to diversity and inclusion can also unearth unique examples of management and monitoring. For example, when asked about the GE American chestnut tree and the potential utility of its restoration, one Onondaga elder talked about tests they would conduct to see if the GE chestnut would play a role in traditional medicine like the wild type chestnut has in the past. The elder said they have their own tests, one of which would be to see if the chestnut responded to its (old) name (Barnhill-Dilling & Delborne 2019). While so many management and monitoring plans consider benchmarks and thresholds, this test would examine the relationship with the GE chestnut. What if inclusive management and monitoring strategies could make space for Indigenous priorities on their terms? What if Onondaga elders' understanding of their relationship with the GE chestnut was part of a measure of success in restoration metrics? Engagement strategies that attend to diversity and inclusion facilitate opportunities to expand what issues are managed and monitored in ways that may center unique cultural relationships.

### ***Broaden Normative Perspective***

Engagement that attends specifically to broad normative perspectives fosters careful and adaptive deployment and management decisions. Engaging stakeholders who are more cautious about the uncertainty or the ethical implications of releasing gene edited organisms into the wild may shape a more tempered deployment plan, one that exercises greater caution and greater attention to phased releases after careful monitoring. Similarly, engaging with stakeholders that have diverse ethical perspectives may have management concerns that, say, chestnut enthusiasts might not have and issues might be raised, and then monitored for, could make for a more adaptive management system overall. Choosing engagement strategies that integrate a broad range of normative perspectives supports goals of adaptive and responsive deployment and management decisions.

Building on the concepts of broadening expertise and diverse representation, stakeholder engagement can also create opportunities to integrate wider normative perspectives in the process by which indicators and thresholds are decided upon for management. Much like the

role of engagement in risk assessment described above, engagement at this phase could also inform what in fact is considered to be an adverse effect that requires interventions. The importance of these processes being open to broader engagement cannot be overstated. In order for a restoration effort to be collaborative, adaptive, and socially responsive, particularly in the context of gene edited organisms in the wild, the process by which benchmarks, benefits, and burdens must be open to a range of socio-cultural perspectives. This will be particularly important for GBIRD's restoration hopes, as the likely sites will be remote and hard for broader publics to access. If broad collaboration and engagement go into developing management plans, stakeholders with different ethical views on the project may more readily develop trust in a process for which they cannot see direct evidence.

[[Insert Table 2]]

## Conclusion

As we explore innovative ways to reduce species loss, such as the environmental biotechnology examples described here, we must also take this opportunity to explore innovative decision-making systems that govern shared environments. Here we hope that broader stakeholder engagement in its many forms is central to the governance of environmental biotechnologies. Building on that normative commitment, we suggest that more specific architecture around stakeholder engagement is needed. We put forth a Decision Phases Framework that links upstream engagement and downstream adaptive management to guide such governance efforts. While the decision phases concept may be modified to suit a range of issues, in the context of emerging biotechnologies we propose that research and development, regulatory review, and deployment and management are appropriate and useful categories for framing stakeholder engagement. This framework allows scholars and practitioners of stakeholder engagement to consider the nuances of each phase (see Table 2) and how each phase may draw on overlapping stakeholder networks. In part, distinguishing phases may help attend more specifically to diversity and inclusion in deliberative decision-making spaces.

While we indeed argue that the Decision Phases Framework responds to calls for broader and more inclusive engagement, we must acknowledge that an important gap remains: developing clearer mechanisms for engagement outcomes to feed directly into formal decision making. While engagement outcomes from research and development, as well as deployment and management, can inform decisions that scientists and non-profit organizations are making about restoration, that connection is less clear in regulatory contexts. In other words, implementing the Decision Phases Framework would require substantial institutional changes for which this paper does not offer a full roadmap to implementation.

Despite that limitation, the utility of the Decisions Phases Framework remains for framing specific engagement strategies. Drawing on examples from both the genetically



engineered American chestnut tree and the GBIRD projects, we demonstrate the utility of the framework in highlighting that researchers make distinct decisions at each phase and how engagement that includes three important dimensions -- (1) what expertise is considered, (2) diversity and inclusion of stakeholders, and (3) normative perspectives included -- facilitates more just and adaptive decisions at each phase. Together, these engagement strategies facilitate decision making structures that reflect the socio-cultural and ecological complexity of the environments where gene edited organisms may one day be released.

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## TABLES

<b>Table 1: Dimensions of Diversity for Engagement of Environmental Biotechnologies</b>		
Diversity dimension	Components	Example attributes
Expertise	Academic discipline	<ul style="list-style-type: none"> <li>• Natural and physical science - Biology, Chemistry, Ecology, Entomology, Molecular biology, Statistics,</li> <li>• Social science - Anthropology, Economics, Geography, Political science, Public policy, Risk analysis, Science and technology studies, Sociology,</li> <li>• Humanities - Art, Communication, English, History, Philosophy</li> </ul>
	Indigenous knowledge	<ul style="list-style-type: none"> <li>• Traditional Ecological Knowledge</li> <li>• Cultural practices</li> </ul>
	Local knowledge	<ul style="list-style-type: none"> <li>• Ecology, culture, politics</li> </ul>
	Sector	<ul style="list-style-type: none"> <li>• Government, university, industry, non-governmental organizations</li> </ul>
Identity	Lived experience	<ul style="list-style-type: none"> <li>• Ability, Age, Class, Ethnicity, Gender, Geographic origin, Indigeneity, Race, Religion, Sexual orientation</li> </ul>
Perspective	Technology	<ul style="list-style-type: none"> <li>• Level of confidence in technical solutions to solve problems</li> <li>• Ethical stance on biotechnology</li> </ul>
	Nature	<ul style="list-style-type: none"> <li>• Relationship to nature (e.g., master over, steward of, partner with, participant in [see Flint et al. 2013])</li> </ul>
	Economy	<ul style="list-style-type: none"> <li>• Trust in market mechanisms to make good decisions relating to nature and technology</li> <li>• Levels of concern or enthusiasm about historical patterns of commercial biotechnology</li> </ul>
	Regulation	

		<ul style="list-style-type: none"> <li>• Confidence in technology developers to produce safe technological products on their own</li> <li>• Level of support for existing paradigms for regulating risk</li> </ul>
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**Table 2: Decision Phases and Example Guiding Questions**

<i>Decision Phase</i>	<i>Example Guiding Questions for Engagement</i>
Research and Development	<ul style="list-style-type: none"> <li>• What precisely is the problem?</li> <li>• What are potential tools and solutions available to address the problem?</li> <li>• Which funders will researchers seek?</li> <li>• What strategies and methods will be used in research?</li> </ul>
Regulatory Review	<ul style="list-style-type: none"> <li>• What are the most important potential adverse effects and risk pathways to study in a risk assessment for the technology?</li> <li>• What studies are needed to answer these questions and inform the risk assessment?</li> <li>• What standards of evidence should apply?</li> <li>• How will regulatory decisions fit into broader governance systems?</li> </ul>
deployment and management	<ul style="list-style-type: none"> <li>• Where and how should the organisms be deployed?</li> <li>• Who will deploy these organisms</li> <li>• What ecological entities will be monitored and how will they be studied?</li> <li>• Which indicators and thresholds may be considered signs of success or signs to pause?</li> </ul>