Regulating Gene Editing in the Wild: Building Regulatory Capacity to Incorporate Deliberative Democracy

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There have been a growing number of calls for policy makers to engage more broadly and consistently with the public about the development, use, and governance of technologies that can edit the genomes of nonhuman organisms.[1],[2] Rapid advances in the development of genome editing technologies have given scientists the ability to genetically alter the species of insects and other organisms in the shared environment. There is the potential to mitigate and possibly prevent the transmission of viral, bacterial, and fungal pathogens to crops, flora and fauna—as well as to humans—by genetically altering the genomes of the organisms that transmit those pathogens. Yet genetically altering wild populations of organisms will change inter-species dynamics and reshape ecosystems, and it is difficult to know in advance what risks those changes pose to the environment and human health and how to assess the potential magnitude of those risks.[3]

Some of the calls for public engagement regarding genetically engineered organisms endorse the use of deliberative democratic activities with public constituencies to inform the development and outcomes of relevant public policies.[4] Unlike town hall meetings, elections, or public comment periods during regulatory rulemaking, deliberative forms of public engagement involve a process whereby participants are informed about the issues at stake and then given the opportunity to "collectively decide their shared values and acceptable trade-offs in public interests through a process of fair, inclusive and respectful reasoning with each other."[5] There is growing evidence that, by engaging in deliberative activities about complex and controversial policy issues, participants (1) have greater understanding and more tolerance for opposing views, (2) develop a public-spirited way of thinking about social problems (as opposed to a more self-interested view), (3) are better at clarifying and refining their positions on issues, and (4) come to appreciate the consequences of implemented policies and the reasons for past policy failures.[6,7] There is also the potential that the general public will view the decisions of policy makers as more democratically legitimate when their decisions are informed from the input obtained from an open and inclusive deliberative process—even when there is still public disagreement about specific policy decisions.[8,9]

Given the scientific, ethical, and societal issues at stake with regard to releasing genetically engineered organisms into the shared environment, a strong case can be made that some form of deliberative public approach to inform policy making is warranted.[10,11] Yet little attention has been given to whether relevant policy makers have the capacity to sponsor or conduct deliberative activities with various public constituencies. This is especially true for federal regulatory agencies, where decisions are made within a complex web of regulatory, legislative, and judicial requirements. Moreover, multiple federal agencies play a role in the regulation and governance of genetically engineered organisms, which adds another layer of complexity to the issue of supporting or conducting public deliberative activities to inform regulatory decision-making. And it's unclear whether decision-makers will follow the recommendations from public deliberative activities if those recommendations reflect opposition

to a rule or policy, especially when private industry has invested financial and other resources to develop a regulated product.

Our goal in this paper is to shift the discussion about why public deliberation may be warranted in the context of genetically engineered organisms to a discussion about the role of relevant federal agencies in sponsoring or conducting public deliberative activities to inform regulatory decision-making. Our intent is to outline the issues that will need to be sorted out regarding the capacity of relevant agencies to undertake public deliberative activities. For purposes of our discussion, we are agnostic about which type of public deliberative approach regulatory agencies might use, though we note that public deliberation is a process that involves more than general public engagement activities that regulatory agencies currently undertake, such as public comment periods proscribed by the Administrative Procedure Act (APA), public meetings, and other forms public interaction. Although the APA encourages an exchange of views about proposed regulations and requires agencies to offer reasons for their response (or lack thereof), the public comment process does not lend itself to the sort of qualitative exchange that deliberative theorists have in mind. By institutional capacity, we mean that an agency (1) is not prohibited by regulation, statute, or judicial ruling from employing deliberative activities at any stage of its decision-making process and (2) has the resources in terms of funding and staff to support or conduct such activities.

We start by briefly describing two public deliberative activities regarding specific issues unrelated to genetically engineered organisms about which two federal agencies—the U.S. National Aeronautics and Space Administration (NASA) and the Agency for Healthcare Research and Quality (AHRQ)—wanted input from the public. Drawing from these brief case studies, we identify several practical issues that will need to be addressed if relevant federal agencies are to undertake public deliberative activities to inform decision-making about the release of genetically engineered organisms into the shared environment. We conclude by noting that, while agencies may have institutional capacity to undertake public deliberative activities, political forces may prevent them from doing so, and consider possible strategies for negotiating these political realities.

The NASA and AHRQ Deliberative Activities

NASA sponsored a set of deliberative forums to obtain public input about upstream engineering decisions related to the agency's Asteroid Initiative Project started by President Obama. Components of the asteroid project included developing approaches to detect asteroids, defend Earth from asteroid impacts, redirect the orbits of asteroids, and explore the planet Mars. The specific type of deliberative activity used at the forums was participatory technology assessment (pTA), "a deliberation method for assessing the societal benefit of research and empowering the public to consider decisions that some might otherwise think a lay public would be incapable of doing."[12] The carefully designed deliberative forums, which involved a total of 183 participants, were held in 2014 in Phoenix, Arizona, and Boston, Massachusetts. Participant demographics were generally comparable to the populations in those cities. The deliberative sessions explored the "value of different cultural perspectives, rationales, conceptualizations, and perceptions of risk" that participants used in assessing socio-technical issues" about the components of the Asteroid Project described above.[13]

In 2012, ARHQ sponsored a "Deliberative Methods Demonstration," which consisted of "a randomized controlled trial to compare the effectiveness of public deliberation and to compare alternative approaches."[14] Seventy-six groups were convened in four cities: Chicago, Illinois; Sacramento, California; Silver Spring, Maryland; and Durham, North Carolina. These sites were chosen to enable recruitment of a diverse sample of participants on the basis of racial, ethnic, and sociodemographic characteristics. Participants were assigned to either a control group or to one of four deliberative methods: Brief Citizens' Deliberation, Community Deliberation, Online Deliberative Polling®, and Citizen's Panel.[15] All of the participants were asked to deliberate on a specific question regarding the use of research evidence in health care decision-making: "Should individual patients and/or their doctors be able to make any health decisions no matter what the evidence of medical effectiveness shows, or should society ever specify some boundaries for these decisions?"[16] The public deliberative activities that NASA and AHRQ sponsored reveal several important issues that have yet to be carefully addressed by those calling for public deliberation regarding the release of genetically engineered organisms into the shared environment.

Who conducts the deliberative activities? Both NASA and AHRQ contracted with experts in public deliberation to develop and conduct the deliberative forums. NASA contracted with the network known as Expert and Citizen Assessment of Science and Technology (ECAST), "a network of universities, science museums, and non-profits invested in bringing the voice of the lay public into technical decision-making processes."[17] Tomblin reports that NASA program managers worked closely with ECAST organizers "to develop appropriate themes and content for the forums" and points out that this was "a challenging task" because the project was "the first deliberative public engagement on this scale undertaken in partnership with NASA (p. 5 of internet version, not journal version). AHRQ partnered with the American Institutes Research (AIR) to conduct deliberative demonstration project. AIR is a non-profit research organization founded in 1946 that has expertise in conducting behavioral and social science research and evaluation studies.

Deliberation at which stage of agency decision-making? NASA's deliberative activity was initiated to inform upstream engineering decisions, i.e., decisions about whether to carry out proposed projects and how. The deliberative project that AHRQ sponsored was not designed to obtain public input about a specific project. Two primary aims motivated AHRQ's project: (1) to obtain public input on questions regarding appropriate and acceptable ways to use research evidence, and (2) to evaluate whether deliberation with the public "is an effective and useful way to obtain informed public input" for health care research in the U.S. and to identify a "feasible set of choices among deliberative methods.

The cost of public deliberation. There is scant information in the literature on public deliberation—including reports from advisory organizations calling for deliberation—about what it costs to conduct different types of deliberative activities. The number of participants, the length and number of deliberative sessions, and the number of sessions that will be held at one or multiple sites are factors that will have an impact on the total cost of conducting public deliberative activities. No cost information was provided in the report about the NASA deliberative forums. The authors describing the AHRQ demonstration project reported only what

they referred to as implementation costs, i.e., costs that were directly associated with holding the deliberative sessions. They did not provide specific information about additional costs.[18] The total cost to implement the four deliberative methods was $39,800, with the Citizen's Panel alone costing $23,500, which was more than the other three methods combined. Of note, while the cost for the Online Deliberative Polling® session was $4,900, one estimate for conducting a face-to-face deliberative polling session lists the cost as roughly $300,000.[19]

Source(s) of funding. Whether agencies have funds in their budgets to sponsor public deliberative activities is obviously an important factor when considering the feasibility of undertaking this type of public engagement activity and the frequency with which it ought to occur. The report about the NASA project says that support came from the agency and from the Office of Knowledge and Enterprise Development at Arizona State University. ECAST is hosted by the university. AHRQ funded its deliberative demonstration project with initial funding from the federal American Recovery and Reinvestment Act, which was enacted in 2009. No other funding information is provided in AHRQ's project report.

Public Deliberation, the FDA, and the EPA: Points to Consider
(alternative: Considering Public Deliberation at the FDA and the EPA)

In 2011, the British biotechnology company Oxitec submitted the first request to a federal agency for permission to release a genetically modified mosquito in the United States. The company submitted a new animal drug application (NAD) to the FDA for permission to conduct field trials in Key Haven, Florida, to test the safety and efficacy of its genetically engineered *Aedes aegypti* mosquito species. Key Haven is an unincorporated community located on the island Racoon Key and considered a suburb of the island city of Key West. Both Key Haven and Key West are in Monroe County, and Key West is the county seat. The *Aedes aegypti* mosquito species is the primary vector of several viral diseases that affect humans: Zika, dengue, yellow fever, and chikungunya. The genetically engineered male OX513A mosquito was designed to decrease the size of the *Aedes aegypti* population.[20] Oxitech requested the NAD pursuant to a 2009 FDA *Guidance* in which the agency asserted regulatory authority over genetically engineered animals and insects.[21]

In March 2016—five years after Oxitec submitted its request to the FDA to conduct the investigational field trials—the agency released a preliminary finding that the field trials would not have no significant impact on the quality of the human environment in the United States and opened a 30-day public comment period to give any interested parties the opportunity to respond to its preliminary decision. Five months later, in August 2016, the FDA issued a final decision, in which it determined that the investigation field trial of the OX513A mosquito "would not individually or cumulatively have a significant effect of the quality of the human environment," and that based on this finding, the agency would not prepare an environmental impact statement.[22] Then, in October 2017, the FDA issued a final guidance clarifying that requests to conduct investigational field trials of genetically engineered mosquitoes should be reviewed by the EPA, pursuant to its authority to regulate new pesticides.[23] Oxitec subsequently withdrew its application to the FDA for field trials of the OX513A mosquito, and in May 2019, the company submitted a request to the EPA for an experimental use permit to conduct field trials with its

"second generation" genetically engineered male *Aedes aegypti* mosquito, OX5034, in Harris County, Texas (the Houston metropolitan area) and Monroe County, Florida. On September 11, 2019, the EPA opened a 30-day public comment period regarding Oxitec's application. On May 1, 2020 the EPA announced its approval of an experimental use permit for Oxitech to conduct field trials with the OX5034 mosquito in Monroe County, Florida, and in Harris County, Texas, pending approval by state and local authorities.[24] By a vote of 4-1 on August 18, 2020 the Florida Keys Mosquito Control District (FKMCD) approved the plan.[25] In February 2021, the *Miami Herald* reported that field trials were expected to begin in April.[26] An opposition group named The Coalition Against GMO Mosquitoes launched a web site in February with the goal of generating local and national opposition to the field trials.[27] The trials planned for Harris County are on hold. In a news report in February 2021, an official at the Harris County Public Health (HCPH) said that both the HCPH and Oxitec decided in 2020 not to move forward with field trials.[28]

We leave it to others to address the issue about whether the FDA, the EPA—or both agencies—should have regulatory authority over investigational field trials of genetically modified mosquitoes and about the adequacy of each agency's approach to risk assessment for genetically engineered organism.[29] Here, we consider issues about the FDA and EPA conducting public deliberative activities to inform decision-making about releasing genetically engineered organisms into the shared environment in light of the points discussed above regarding the deliberative activities that NASA and AHRQ undertook.

As to funding public deliberative activities, both the FDA and EPA conduct various types of public engagement activities. To our knowledge, aside from the essay titled "Deficits of Public Deliberation in U.S. Oversight for Gene-Edited Organisms" in this special report, no systematic analysis has been undertaken about how the FDA and EPA define and conduct public engagement in the context of policies related to genetically engineered organisms, whether those activities include deliberative activities, or about the amount and source of funding they receive to undertake public engagement activities. While some of the funding to the FDA and EPA for public engagement activities may be earmarked for specific types of general engagement activities, both agencies likely have some discretionary authority to decide what type of engagement activities to undertake. Even if current funding levels for public engagement are not sufficient to fully integrate deliberative activities into the rulemaking process, at minimum there may be sufficient funding to conduct a pilot deliberative project. And in future budget requests to Congress, both agencies could request funds specifically earmarked for conducting public deliberative activities. It is also possible that other federal agencies, such as the National Science Foundation and the National Institutes of Health, could provide funding through their competitive grants process to deliberative democracy experts to conduct public deliberative activities, whose outcomes would then be provided to the relevant agency.

It is important to note, however, that while the FDA and the EPA may have the institutional capacity to undertake public deliberative activities to inform decision-making about genetically engineered organisms, political forces may prevent them from doing so. Not only are both agencies enmeshed in the ongoing and fluctuating dynamics of partisan politics, but both have been accused of being overly influenced and even controlled by the industries they

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regulate.[30,31] And many scholars of regulatory rulemaking have demonstrated that, even when both agencies receive input from the public about proposed policy decisions, they often fail to adequately address the concerns raised by public constituencies, especially nontechnical concerns about risks that reflect complex values about humans, animals, and the environment.[32]

We conclude by suggesting ways to negotiate the political realities that may be a barrier to agencies expanding their public engagement activities to include public deliberative approaches. First, some of those who call for public deliberation on matters related to policies about genetically engineered organisms may be in a position to fund public deliberative activities, even if not in partnership with the FDA or EPA. They should do so, and the outcomes of those deliberative forums could be widely publicized and even submitted directly to the FDA and EPA. Second, scholars who have called for public deliberation could also lobby policy makers to support public deliberative activities. For example, they could submit policy briefs supporting public deliberation to relevant congressional oversight committees and to key agency officials. Implementing these suggestions would be a first step toward moving beyond making calls for public deliberation in the policy process and finding practical ways to carry out deliberative activities with or without the support of relevant federal agencies.

Notes

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