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RESEARCH ARTICLE

Implementing responsible research and innovation: a case study of U.S. biotechnology oversight

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Abstract
This article explores two research questions through a case study of U.S. biotechnology oversight: why visions of Responsible Research and Innovation (RRI) are difficult to implement in governance systems for emerging technologies, and how to get policies and programs to overcome barriers to RRI implementation on the national policy agenda. Recent research on barriers to RRI is first reviewed to categorize the types of barriers. Key barriers center around meso- and macro-level institutional and societal forces that disincentivize RRI in innovation systems, as well as micro-level attitudinal and capacity barriers. These barriers point to policy changes that are likely needed to implement RRI in governance systems, in particular incentives for RRI from national funding organizations. However, getting RRI on the policy agenda for biotechnology may be difficult given macro-level socioeconomic and political forces. Therefore, the article uses insights from policy process theory to identify possible ways to get RRI on the national policy agenda. It identifies several ways to promote RRI in national policy-making, such as shifting the policy image of RRI, changing policy venues to encourage RRI, expanding the scope of RRI as a policy issue, and catalyzing focusing events to raise national awareness about RRI.

Keywords Responsible Research and Innovation · Policy Process Theory · Genetically Modified Organisms · Gene Editing · Biotechnology · Governance

1 Introduction

Responsible Research and Innovation (RRI) is a framework that has been proposed to better align societal desires, hopes, and concerns with the research, technology development, and innovation. RRI moves discussions about responsible governance beyond simply regulatory approval and compliance to incorporating a broader range

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of perspectives on what it means to innovate responsibly and align societal expectations with research and development. One of the most cited papers on RRI proposes four main principles: reflexivity, anticipation, inclusion, and responsivity (Stilgoe et al., 2013). Reflexivity involves individual and researchers and stakeholders considering their underlying goals and motivations, their knowledge limits and assumptions, and alternative ways to consider research or development (R&D) problems. Anticipation considers the potential downstream consequences of R&D far upstream of any product entering the regulatory system or society, and even in the early stages of research. Inclusion engages publics, stakeholders, and outside experts in anticipation and reflection, making sure the hopes and concerns of diverse, interested and affected parties" for technology development are understood. Inclusion takes participation in technological development, risk analysis, and societal impacts beyond just subject-matter experts. Finally, responsivity necessitates that R&D incorporates the results of reflexivity, anticipation, inclusion, and responsivity into research and technological design and requires that there is a willingness in technology developers to change direction and incorporate public concerns into their innovation processes. The RRI framework proposed by Stilgoe et al. (2013) takes RRI beyond traditional research ethics and diversifying STEM fields, although it encompasses these elements as well. Other articulations of RRI call out additional elements of sustainability, care, openness, and transparency (Blok et al., 2015, Burget et al., 2017, Owen et al., 2019, Fraaije et al., 2020), although these are embedded in the 4 principles of Stilgoe et al. (2013) through the practices of reflexivity, anticipation, inclusion, and responsivity.

While RRI has been integrated into European Union (EU) national funding programs (Wittrock et al. 2020), it has not gained traction in the United States. RRI scholarship emerged from societal implications work on nanotechnology and other emerging technologies (e.g. Fisher & Rip, 2013; Guston et al., 2014; Wiek et al., 2016). There are considerable barriers to implementing it into biotechnology innovation systems. The history of U.S. biotechnology innovation, particularly associated with genetically modified organisms (GMOs) in agriculture and the environment, has been marked by contentious policy and legal debates, controversies over safety issues, consumer rejection of GM foods, almost exclusive reliance on natural science experts and industry in decision-making, and focus on direct toxicological risk with few spaces to consider broader risks or socioeconomic concerns (Jasanoff, 2005; Thompson et al., 2007; Kuzma & Besley, 2008; Kuzma et al., 2009; Kuzma, 2014; Kuzma, 2021). However, with the emergence of gene editing (e.g. through CRISPR), innovators have expressed desire to do a better job of engaging the public to avoid the backlash that the 1st generation of GMOs presented (Kuzma et al., 2016). For example, industry-funded non-profit groups have come up with responsible stewardship frameworks for gene editing technology developers to self-certify (CFI, 2022), and other collaborative governance models for gene-edited plants and foods have been proposed (Gordon et al., 2021; Jordan et al., 2017; Kuzma & Grieger, 2020). These governance proposals reflect the elements of RRI discussed above, but they have yet to be implemented in the practice of biotechnology oversight or innovation systems.

The motivation of this paper is to address the growing calls and importance for innovators to move forward together with the public as they develop gene editing, gene drives, and synthetic biology. RRI will be especially important for such products that enter open food, agricultural, or environmental systems which generally evoke heightened public concern. RRI proposes a well-articulated set of practices and principles for the co-design and co-production of technology with and for society. This motivates questions about how to formalize RRI institutionally so that the practices are trusted and seen as legitimate. The public is skeptical about governance systems for emerging technologies, and trust in governance processes is a key factor that influences public attitudes towards emerging biotechnologies (e.g. Siegrist, 2012; Brown et al., 2015; Yue et al., 2015). RRI practices are more likely to engender public trust if they are convened in independent venues, outside of groups that have a conflict of interest (COI) such as the biotechnology industry or its collaborators. Therefore, such programs should not rely on private funding (e.g. CFI, 2022), but rather be publicly funded.

In light of the above, this paper focuses on two questions: first, what are the major barriers to implementing RRI in U.S. biotechnology innovation systems, and second, in light of these barriers, how can policy entrepreneurs get RRI on the national policy-setting agenda. To address these questions, the article innovates by bringing together recent scholarship on barriers to implementing RRI in innovation systems with insights from policy process theory (particularly those that center focusing on events as catalysts for policy change). After a review of attitudes towards and barriers to implementing RRI in biotechnology innovation systems, policy process theory is used to explore how changes to biotechnology oversight systems have occurred over time (retrospective) to suggest ways for bringing more attention to RRI in the national policy-setting agenda in the future (prospective) so that funding incentives and programs can be put in place to overcome these barriers.

2 Barriers to RRI in biotechnology oversight

Using biotechnology oversight in the United States as a case study, this paper explores the barriers to and potential solutions for adopting RRI. Recent studies have investigated the attitudes of U.S. biotechnology stakeholders towards RRI, and in particular, RRI as framed according to the four principles from Stilgoe et al. (2013). This paper draws on an analysis of barriers to RRI from a content analysis of national reports on RRI (Wittrock et al., 2021 and from empirical research on the views of U.S. biotechnology stakeholders investigated by qualitative and quantitative analysis from surveys and focus groups (Kuzma & Roberts, 2018; Roberts et al., 2020; Kuzma & Cummings, 2021).

Kuzma & Roberts (2018) described three levels of barriers towards implementing RRI in biotechnology innovation systems: fundamental values and philosophical positions that individual actors hold (micro-level); organizational structures and institutions within innovation systems (meso-level); and larger political, economic, cultural, social contexts within which multiple actors and institutions operate (macro-level). For example, at the micro level, individual attitudes affect innovators

willingness to consider RRI as a worthwhile endeavor. At the meso level, organizations have incentive structures or lack capacities that may preclude innovators from doing RRI work, even if the individual desire to do so exists. And finally, at the macro level, socioeconomic or political contexts may not be conducive to implementing RRI in U.S. biotechnology innovation, and they influence the possibilities at institutional (meso) and individual (micro) levels (Fig. 1).

Wittrock et al. (2021) have also explored barriers to RRI and developed a different typology by which to think about barriers and drivers of RRI. Their work was broader than biotechnology innovation systems or the U.S., drawing from several countries and technologies, and they focus on organizational barriers uncovered in several national reports on RRI. They identify three types of organizational barriers: cultural, structural, and interchange-related. There are overlaps between their framing and the three categories proposed by Kuzma & Roberts (2018). Cultural barriers are associated with values, norms, and identities. They permeate the three levels from Kuzma & Roberts (2018) as national culture (macro-level) affects organizational culture (meso-level) which in turn can influence personal attitudes and behaviors towards RRI (micro-level). Structural barriers include the incentives, policies, programs, and resources available to implement RRI, and are more formalized than cultural barriers. They can occur at the meso and macro levels and may reside in international or national (macro-level) organizations, or within individual institutions or their interactions with others (meso-level). Interchange barriers from Wittrock et al. (2021) involve interactions between organizations and wider communities in open innovation systems. Interchange barriers can also permeate all three levels (micro-, meso-, and macro-) from Kuzma & Roberts (2018) as individuals, organizations, and wider communities participate in exchanges with those outside of their organization, nationally, or internationally.

This article organizes the barriers to RRI according to the micro-, meso-, and macro-level typology put forth by Kuzma & Roberts (2018) to more clearly assess where policies or programs should be targeted to overcome those barriers. However,

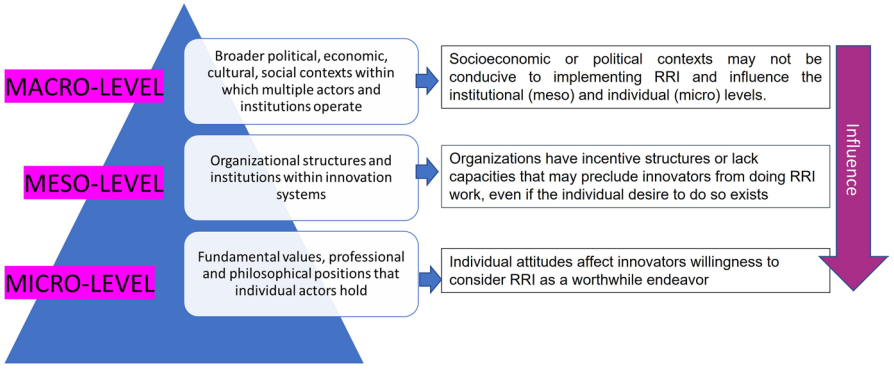

Fig. 1 Typology of Barriers to RRI. Three levels of barriers were uncovered through focus groups and surveys as described in Kuzma & Roberts (2018), Kuzma and Cummings (2021); and Roberts et al. (2020). The arrow indicates that barriers at the macro-level influence the creation of barriers at the meso- and micro-levels

insights from the typology developed by Wittrock et al. (2021) are also used to better understand the specific kinds of barriers at each level. The following sections introduce the key barriers to implementing RRI in biotechnology innovation at the micro-, meso-, and macro-levels of systems found in these and other prior works. Table 1 summarizes the barriers discussed below at each level and according to the categories from Wittrock et al. (2021).

2.1 Micro-level barriers to RRI

Recent articles specific to U.S. biotechnology innovation examine stakeholder attitudes towards RRI drawing from qualitative (focus group interviews) and quantitative (survey) data (Kuzma & Roberts, 2018; Roberts et al., 2020; Kuzma & Cummings, 2021). These point to micro-level barriers towards implementing RRI in biotechnology innovation, which are reviewed below.

2.1.1 Delays to innovation

Individual researchers worry about implementing RRI because it could potentially delay their work and innovation timelines (Roberts et al., 2020; Kuzma & Roberts, 2018). They view RRI processes and practices, such as those outlined in Stilgoe et al. (2013), as onerous and unnecessary, especially if they are mostly involved in upstream R&D for biotechnology or more basic research (as opposed to downstream endeavors closer to product-development stages). Consistent with these qualitative results, survey work points to disagreement among innovators with RRI practices,

Table 1 Summary of Barriers to RRI

	Cultural	Structural	Interchange
Micro	Deficit thinking Cynicism (re: public inclusion)	"Not our responsibility" Lack confidence-capacity Worries about delays to their work & losing competitiveness	Fear of public fear "biotech-phobia-phobia"
Meso	"Academic capitalism" Tech Innovation seen as good Any delays seen as threat	Lack of resources—time, money Lack of incentives & rewards Lack of policy and guidance	Organizational need to satisfy funding agencies and investors (avoid any delays) Pace of innovation and need to keep up to compete
Macro	Socio-political context of tech innovation = social good Private/profit interests and values Techno-optimistic culture	No federal incentives for RRI Narrow regulatory governance system for biotechnology Decision making closed Power concentrated Protection of CBI/IP	Pressures from funding agencies and investors to advance work quickly Competition from other organizations for funding streams promotes pressure to advance Private–public revolving door

The two dimensions of Table 1 relate to the three levels described by Kuzma & Roberts (2018) (micro, meso, marco) and the three types of barriers described in Wittrock et al. (2021)

especially inclusion and responsivity. These attitudes and perceived barriers to RRI were prevalent in both academic and industrial biotechnology sectors, although there was slightly more agreement among academic sectors with the principles and practices of RRI in quantitative surveys (Kuzma & Roberts, 2018; Kuzma & Cummings, 2021; Roberts et al., 2020). Both academic and industry researchers (referred to collectively as "biotechnology innovators" throughout the paper) view inclusion and responsivity as particularly time-consuming and threatening to their work. They are afraid that considering and responding to public concerns will delay or even require stopping the work. Biotechnology innovators have an aversion to RRI practices that relinquish control over the R&D to external actors, as anticipation and reflexivity were more positively viewed than practices that open-up decision-making in innovation systems like inclusion and responsivity (Roberts et al., 2020).

Meso-level and macro-level factors were tied to these micro-level attitudinal barriers, as innovators pointed to the constraints that funding streams put on their work (more on this below in the "Meso-Level" section).

2.1.2 Deficit-thinking and cynicism

Biotechnology innovators, both academe- and industry-affiliated, expressed concern about the RRI practice of inclusion, expressing "cynicism" that diverse publics or "non-expert" stakeholders would be able to engage in informed conversations about the trajectory of biotechnology R&D (Roberts et al., 2020). This attitude relates to the "deficit model" of science communication (Suldovsky, 2016) which has been rejected by social science and Science and Technology Studies (STS) scholars but still persists in thinking among biotechnologists. Deficit thinking suggests that non-expert publics generally do not understand science well enough to have a voice in shaping its course, and therefore, their viewpoints are not valid. Other groups have also found this to be a barrier for implementing RRI for GM crops in India. Here, anti-GM groups are seen as ignorant, and therefore, they should not be included in decision-making (Carro-Ripalda & Macnaghten, 2015, p 25). Related to this attitude, innovators are afraid that a lack of public knowledge, coupled with inclusive practices and transparency, could provoke fears of biotechnology among publics and non-expert stakeholders that engage in RRI processes. Marris (2015) terms this fear among innovators in the context of synthetic biology "synbio-phobia phobia". Therefore, the public is constructed in the minds of innovators as a threat to biotechnology, and implementing RRI is risky, as it gives them greater agency and voice.

2.1.3 Lack of capacity

The third set of micro-level barriers centers around the confidence and capacity of innovators to engage in RRI. Even if there is a desire to do so, U.S. biotech innovators express a lack of knowledge of how to do so, and a lack of standards, resources, and partnerships to guide them (Kuzma & Roberts, 2018; Gutzmann, 2018; Cummings et al., 2021).

2.2 Meso-level barriers to RRI

The micro-level barriers discussed above can be supported by institutional structures at the meso-level. Wittrock et al. (2020) use document analysis of national reports to identify potential barriers and drivers of RRI at the organizational or meso-level. Building on their work and studies specific to U.S. biotechnology innovation (Roberts et al., 2020; Kuzma & Roberts, 2020; Kuzma & Cummings, 2021), three key meso-level barriers are discussed below.

2.2.1 Structural barriers

Wittrock et al. (2020) list key structural barriers to the adoption of RRI in organizations as a lack of resources (money, time, people, training, expertise); a lack of incentives; and a lack of strategies, policies, frameworks, systems, and formal structures. Related to the last category, Cummings et al. (2021) also found that researchers cited the lack of policies as a barrier to RRI for nanotechnology innovation systems. Researchers put their careers at risk when they focus on RRI efforts, as they take time away from technical projects, grant-seeking, and papers by which they are judged (Kuzma & Roberts, 2018; Gutzmann, 2018). Pansera et al. (2020) emphasize the need for institutions (at the meso-level) to provide training, flexibility, and resources for willing researchers to engage in RRI practices.

2.2.2 Cultural barriers

Cultural barriers at the meso-level relate to the norms, values, and predominant ethos of organizations in which innovators reside. For example, in the context of U.S. biotechnology, innovators referred to the values of universities as most aligned with the economic interests of companies, the state, and individuals, termed "academic capitalism" in the literature (Slaughter & Rhoades, 2010). This culture was viewed as a barrier to RRI. More broadly, innovators saw any process that might slow innovation down as culturally undesirable at the meso-level, given the drive to compete for and obtain resources, professional stature, or economic profits (Kuzma & Roberts, 2020; Roberts et al., 2020). Wittrock et al. (2021) found similar cultural barriers, pointing out that the drive towards innovation operates in tension with RRI. Values of academic freedom and autonomy also persisted across countries (Wittrock et al., 2020), as well as among U.S. biotechnology innovators (Kuzma & Roberts, 2018; Roberts et al., 2020). While it has traditionally been assumed that scientists should have complete scientific freedom in their pursuits and this viewpoint permeates the scientific community, Douglas (2003) challenges this notion by arguing that scientists as human moral agents must instead accept their responsibilities to carefully reflect on the consequences of their work.

Pressures to satisfy funding agencies, investors, and succeed in a fast-paced field that values technological development as a societal good above all else

permeate U.S. organizations engaging in biotechnology. These issues relate to macro-level national culture (discussed in the next section), and permeate institutions at the meso-level. In turn, meso-level pressures impact individual innovators' feelings about and capacities for RRI at the micro-level.

2.3 Macro-level barriers to RRI

Macro-level barriers to RRI stem from the dynamics between organizations and institutions at the national level and what they encourage or discourage. They also include the values, norms, and cultures of the broader societies within which innovation systems operate. These two categories are discussed below.

2.3.1 Inter-institutional barriers

Inter-institutional barriers reside in the relationships between organizations from different sectors (e.g. government and academe) or interactions between organizations and wider communities. Wittrock et al. (2021) term these under the umbrella of "interchange barriers" for RRI. Several relate to the role of funding or regulatory agencies, which in turn are influenced by national policies and expectations. Biotechnology innovators mention the expectations of funders as one of the most important barriers to implementing RRI (Roberts et al., 2020; Kuzma & Roberts, 2018). For example, researchers most often do not have the ability to change their R&D plans without risking significant delays and thus future funding. Their relationship with funding agencies lowers their ability (and desire) to implement RRI practices, especially inclusion and responsivity (Roberts et al., 2020), which can jeopardize the progress of their research.

Established relationships among industry, academe, and government within innovation systems impact the ability to execute RRI practices. For example, the U.S. biotechnology regulatory system has no expectations for public or private innovators making biotech products to implement RRI approaches, as they fall outside the narrow legal mandates of federal regulatory agencies that focus narrowly on specific health and environmental risks (Kuzma, 2021). Furthermore, private and commercial interests infiltrate into academe and come into tension with RRI, as public researchers look to profit from intellectual property protection of their work and universities encourage it. Confidential business information is also protected in U.S. government oversight systems, and therefore public transparency and inclusion are not incentivized (Kuzma, 2021). The biotechnology regulatory system in the U.S. is almost entirely closed to all but agency reviewers and the innovators submitting the biotech product for regulatory review (Kuzma, 2021).

2.3.2 Socio-political context

The broader socio-political context of nations and regions (macro-level) impacts whether RRI is practiced at the institutional (meso-level). In the U.S., technology development is seen as a force of economic development and thus a public good to

be protected. By implementing RRI, that promise is put at risk. The U.S. is a more permissive and optimistic culture with regard to biotechnology innovation than other nations (e.g. the EU has more restrictive GMO policies). Furthermore, political power resides in the hands of industry groups and companies which have greater access to decision makers through lobbying or other efforts. Congress often puts pressure on regulatory agencies to relax their standards in the interest of advancing national competitiveness and technology development (Kuzma, 2014). The drive in favor of biotechnology development is great, and RRI, with its potential to be more deliberative and inclusive, is seen as a threat to U.S. interests. This context filters down to the institutional and individual level and is manifested in the barriers discussed in the meso- and micro-level sections.

3 Policy incentives for RRI

The above analysis suggests that policies and programs are needed for institutionalizing RRI at the meso and macro-levels so that they provide the support and incentives to individuals at the micro level in order for them to engage in RRI practices. Several barriers stem from the expectations of funding agencies and entities. With regard to public or governmental agencies, Wittrock et al. (2021) capture this problem as an opportunity by stating that "national funding organizations have the potential to significantly alter the current landscape in the science system. In short, money talks, and our findings indicate that the values and logics promoted by the way funders organize their grants and calls for proposals, trickle down into research performing organizations beyond the people and organizational units directly affected" (p. 60). They suggest that research funding organizations "provide drivers to mitigate these barriers, and significantly change the way research is evaluated." (Wittrock 2021, p. 44).

Funding agencies could provide greater resources for teams that integrate RRI into their proposals, beyond those that would cover the RRI direct expenses, and could also compensate for any time delays. They could expedite proposal review times for teams that incorporate RRI or provide block grants for institutions that have ways to structurally integrate RRI into multiple projects. Universities or public-sector research-performing organizations could be evaluated and certified by funding entities for good RRI practices, giving them competitive and resource advantages over organizations that do not institutionalize RRI.

Incentives and programs that formalize RRI in research-performing organizations could help to change the cultural and structural context at both the meso and macro-level, although several barriers will still exist. First, different stakeholders hold various biases and worldviews at the micro level, that may not be tied to funding climates. Kuzma and Cummings (2021) found that stakeholders holding egalitarian worldviews had more positive views towards RRI, whereas those with hierarchical or individualistic world views had more negative views. Although government funding policies may be effective for changing cultural and organizational contexts, RRI could still face resistance due to individual, micro-level biases, especially related to autonomy (aligned with individualism) and expert-control over decision making

(aligned with hierarchical thinking). Industry-affiliated innovators also tend to hold more negative attitudes towards RRI (Kuzma & Cummings, 2021; Roberts et al., 2020), and government funding policies are not likely to have as much influence on resources or incentives in the private sector.

Despite the micro-level barriers, there is considerable promise for federal-level policies and programs, especially those instituted by funders, to make RRI a priority for R&D in U.S. biotechnology innovation systems, at least among those innovators dependent on federal funds. These national policy incentives might not be sufficient; however, they seem necessary. In order to spark organizational changes, national-level funding policies can serve to address the barriers that current incentives and cultural contexts present.

However, funding agencies will still face macro-level socio-political barriers to making RRI a priority in the United States. These include the drive towards a biobased economy that has been pushed on the U.S. policy agenda for the past few decades, an anti-regulatory climate to prevent stifling innovation, the desire for national dominance in the biotech sector, and the view that technology development is a social and economic good in and of itself. Therefore, funding agencies are not likely to act on their own to implement RRI widely. They will need greater resources from Congress and the blessing of high-level decision-makers.

In light of the above, this article now turns to the difficult question of how to get RRI on the national U.S. policy-making agenda. It presumes that instituting RRI will be important for responsible technology development as more and more products of genetic engineering, gene editing, and synthetic biology enter ecosystems, food and agriculture, industry, physical infrastructures (e.g. synthetic biomaterials in living buildings which is a current program funded by the National Science Foundation), healthcare, and consumer products. With the exponential growth of technology, any public mishap or safety issue could cause significant public backlash towards biotechnology. Furthermore, if consumers are not given voice and choice in the course of technology development, even small potential risks will be seen as unacceptable (Slovic, 1987). RRI practices can help to bolster the process of technology development, making it less likely to be a public failure. However, significant challenges to getting RRI on the policy-making agenda exist.

4 Policy process theory insights for instituting RRI

Wittrock et al. (2021) (p. vi) find that "National policies, regulatory frameworks, laws and monitoring systems appear to be the most effective drivers" of RRI. But what is the potential for getting these on the national policy agenda for biotechnology innovation in the U.S.? Policy process theory can provide some insights into what catalyzes policy change over time and how to get issues on the national policy-setting agenda (Birkland, 2015). In this section, policy process theories that center "focusing events" and coalition dynamics to catalyze policy change are discussed. These theories were chosen because their central

elements, specifically focusing elements and coalition dynamics, have been found to play a role in the policy changes to U.S. biotechnology oversight over time (Kuzma, 2020, 2022). For each theory, the insights that it provides for catalyzing policies for RRI in U.S. biotech innovation systems are discussed.

4.1 MSA—entrepreneurs and focusing events

The Multiple Streams Approach (MSA), considers how policies are enacted by government agencies under conditions of ambiguity and complexity (Kingdon, 1995; Zahariadis, 2014). In MSA, three streams—policy *problems*, policy *ideas*, and *politics*—are coupled together by policy entrepreneurs at important moments in time, termed "policy windows", which then present opportunities for getting the policy issue on the national agenda. The unit of analysis for MSA can be either the entire policy subsystem (in this case, U.S. biotechnology governance or funding) or a specific decision or problem (in this case, getting RRI on the U.S. biotech governance agenda to ensure future public legitimacy, equity and safety). MSA emphasizes the dynamic and complicated nature of politics, recognizing that a limiting factor is getting the attention of policymakers, who are under significant time constraints.

In MSA's first stream, policy *problems* are ones that policymakers and citizens want to see addressed by the government or other authorities. Getting the need for RRI in biotechnology innovation to be viewed as a *problem* that requires policy attention could be quite difficult. The current national context is one in which most politicians and groups in power (biotech companies and innovators) see biotechnology innovation as a public good, and many innovators view RRI as an impediment to biotechnology progress, as discussed above (Kuzma & Roberts, 2018; Roberts et al., 2020). The second stream of MSA, the *politics* stream, influences whether RRI is seen as a problem or not. The politics stream captures the political context of a situation, such as the national discourse, priorities, and mood. In the case of biotechnology innovation, the current political and economic climate, which views innovation as a social good, may serve as a macro-level barrier to getting RRI on the national policy-setting agenda as RRI may stall innovation from occurring (Fig. 1).

However, MSA also identifies ways to raise attention to policy problems and potentially overcome these political forces. One is through the efforts of *policy entrepreneurs*, who are adept at forming coalitions, brokering power, and framing issues so they become policy problems worth attention (Zahariadis, 2014). In the case of U.S. biotechnology innovation, some groups are emerging as policy entrepreneurs in the RRI space and putting forth policy *ideas* (the third stream of MSA). One example is the Coalition for the Responsible Stewardship of Gene Editing in Agriculture. It is developing a voluntary, self-governance program for ensuring responsible stewardship (CFI, 2022). However, because it is advocating for self-certification, not open processes or government policies, and it is largely funded and dominated by industry, its efforts are not fully congruent with the visions of RRI as discussed in Stilgoe et al. (2013) and may not be trusted by the public in light of the inherent conflicts of interest.

Groups with the ability to broker power and gain the attention of policymakers, such as powerful industry organizations or groups, are not likely to advocate for government RRI policies for biotechnology given their concerns about RRI practices slowing innovation (Roberts et al., 2020). History shows that biotechnology innovators advocate for voluntary standards and self-governance (Kuzma, 2014, 2020). Although these efforts are important, they are likely to fall short of the RRI practices of inclusion and responsivity (Cummings & Kuzma, 2021; Roberts et al., 2020). More neutral and independent groups, without conflicts of interest and who see the need for RRI practices, are needed to serve as policy entrepreneurs. However, the question remains as to whether they would be able to broker power and gain the attention of policymakers to the same extent as industry-led coalitions. Strategies for increasing the independent coalition's leverage in the context of other policy process theories are discussed below.

The second way that problems can garner attention in MSA is through influences on policymakers due to changes in national mood, indicators, or focusing events. In particular, focusing events have played an important role in changes to U.S. biotechnology regulatory policy over time (Kuzma, 2020). These have included national media attention to mishaps and contamination events with the first generation of GM crops (e.g. Starlink contamination in food; pharma GM crops comingling with food), legal suits brought to federal courts by consumer and environmental NGOs over the adequacy of environmental assessments for GM crops (e.g. over Ice Minus and GM alfalfa and sugar beet), and Congressional hearings prompted by media and legal attention (e.g. 2011 just prior to the GM alfalfa release decision by USDA) (Kuzma, 2020). Focusing on events having to do with safety mishaps and subsequent legal challenges were successful in bringing forth regulatory policies to the national agenda. However, although regulatory agencies have legal authorities for safety, they do not for RRI implementation. Therefore, legal challenges are not viable focusing events for getting RRI on the national policy agenda. Safety mishaps as focusing events might bring national attention through the media to the need for RRI (especially goals of anticipation). However, an adverse event from the release or consumption of a GMO would be undesirable to the industry and put the public or ecosystems at risk. Raising attention to potential safety concerns in the media prior to them occurring seems preferable.

In summary, MSA provides insights about the need for independent policy entrepreneurs to help catalyze RRI by joining the ideas, politics, and problem streams and for focusing events, such as safety issues conveyed in the media, to open up policy windows. Other theories provide deeper insights into different types of focusing events that could help to open policy windows and catalyze change as discussed below.

4.2 PET—policy images and venues as focusing events

Punctuated Equilibrium Theory (PET) builds on MSA and also centers focusing on events as catalysts for policy change (Baumgartner et al., 2014). However, it goes further than MSA to propose that policy subsystems (like U.S. biotechnology

oversight) are not always chaotic and complex, but have relative periods of stability and incrementalism accompanied by periods of more dramatic policy change (Baumgartner et al., 2014). PET draws from systems theory in which negative feedback loops keep things stable and in balance, and positive feedback loops create inflections and more exponential changes in policy. According to PET, stability stems from political systems favoring the status quo or groups that are currently in power, and this makes policy change difficult. However focusing on events can act as destabilizing forces to overcome powerful interests, get issues on the political agenda, and lead to sudden and dramatic changes.

PET expands focusing events beyond what MSA does to include not only occurrences in time but also changes in ways of understanding or framing a policy issue–i.e. shifts in the "policy image" (Baumgartner et al., 2014). In the context of getting RRI on the national policy agenda, policy entrepreneurs could change the policy image of RRI away from being a technology-development obstacle (Kuzma & Cummings, 2021; Roberts et al., 2020; Wittrock et al., 2021) and instead towards RRI as a technology-enabler. Policy image shifts are a way to attract new participants to a cause to increase the chance that policymakers will see the issue as important (Baumgartner et al., 2014). In this way, policy image shifts also overlap with the idea of expanding coalitions to catalyze policy change (as discussed below).

In a policy image shift, RRI could be reframed as an important way to help make biotechnology more successful in the long run, especially in light of the contentious history associated with the first generation of GM foods. Contamination mishaps and potential ecological safety issues sparked focusing events in the media and courts, which in some cases, prompted stricter regulations (Kuzma, 2020, 2022). The 1st generation of GM crops also sparked trade disputes with the EU, rejection by the U.S. organic industry, and an increase in consumers seeking organic foods (Kuzma, 2018). Reframing or shifting the policy image of RRI towards improving consumer confidence and trust in biotechnology innovation could help to bring influential technology developers or users on board with RRI. RRI practices of inclusion and responsivity to public concerns could help to increase public legitimacy of biotechnology governance. The RRI practice of anticipation can improve how risks are anticipated so that mishaps do not occur in the marketplace and cause more damaging focusing events involving safety to occur. In addition, through practices of reflexivity, RRI can cultivate self-reflection among innovators to reduce their techno-optimistic biases so that they become more trustworthy. Public trust in those who manage technology is an important factor in public acceptance of GM (e.g. Siegrist et al., 2012; Yue et al., 2015), and there is considerable skepticism among the publics in technology developer communities (e.g. Brown et al., 2015). By opening up innovation processes to RRI practices, some of this mistrust may be mitigated.

However, it should be noted that RRI principles and practices do not guarantee public trust, acceptance, or biotechnology success. RRI practices should be open and inclusive enough to allow for public rejection of biotechnologies when warranted (responsivity ala Stilgoe et al., 2013). However, to get RRI on the national policymaking agenda, a policy image shift towards RRI as a "technology enabler" seems necessary for RRI to garner the attention of the more powerful biotechnology

industry, Congress, and technology development advocates. RRI needs on the whole to be seen as a force working in favor of technology development rather than against it.

There seems some hope for this policy image shift, as biotechnology and GMO developers have expressed desires to engage the public more to help improve trust and acceptance (Kuzma, 2018; Kuzma et al., 2016), and policy entrepreneurs could change the policy image of RRI as a way to do so. A recent publication, coauthored by a prominent CRISPR developer, provides an example of reframing RRI as a positive for the technology development community (Kuiken et al., 2021), stating that without active public engagement with RRI, the promises of CRISPR "are sure to be broken" (p. 30).

PET also expands focusing events to include the pursuit of new venues for considering an issue—i.e. shifts in the "policy venue". By bringing the issue to a new policy arena, away from old ones arenas where powerful interests dominate, groups with lesser power are more likely to garner the attention of policymakers. In the case of the 1st generation of GM crops, consumer and environmental NGOs used the media and federal courts as more neutral policy-making venues to argue for reform in regulatory policies for GMOs (Kuzma, 2014, 2020, 2022). Groups with less power often "venue shop" to find a place more sympathetic to their cause (Baumgartner et al., 2014). Given that the most significant barriers to RRI seem best addressed through changes to federal funding policies, which are not governed by federal regulatory statutes that can be challenged in court, the federal judicial branch does not seem a viable, neutral policy venue for RRI. However, raising attention to the need for RRI in the media might be. Other neutral policy-making venues like government meetings or workshops should be sought to bring attention to RRI.

In summary, PET points to the need to shift the policy image of RRI—away from preventing innovation towards promoting it. PET also suggests the need for independent policy venues to get RRI on the policy agenda beyond the federal courts.

4.3 ACF--expanding coalitions and the scope of policy issues

The Advocacy Coalition Framework (ACF) is another policy process theory that can provide insights for getting RRI on the policy agenda for biotechnology innovation. ACF also centers focusing events as catalysts for change. However, in contrast to PET and MSA, ACF pays more attention to competing coalitions within a policy subsystem and their beliefs. Coalitions across sectors and organizations tend to form around shared beliefs. ACF proposes that the beliefs of the predominant coalition have the greatest influence on policies that are enacted, and that shared deep core beliefs lead to tighter and longer-lasting coalitions (Jenkins-Smith et al., 2014).

With the ACF, at least two coalitions compete in a policy subsystem and employ strategies to influence policymaking and decisions. The ACF identifies relatively stable parameters, such as the macro-level constitutional structure of a political system, and dynamic external events that are congruent with "focusing events" of PET and MSA. Under ACF, strategies for getting RRI on the policy agenda through

focusing events are similar to those discussed above for PET and MSA. The discussion below, therefore, focuses on ACF elements related to coalitions and beliefs.

A recent study found that U.S. biotechnology stakeholder groups hold different deep core beliefs according to ACF theory and that core beliefs correlate with attitudes towards RRI (Kuzma & Cummings, 2021). Biotechnology industry-affiliated sectors tend to disagree more with RRI and hold less egalitarian world views compared to other sectors. Coalitions that are more in favor of RRI and hold more egalitarian world views tend reside in consumer and environmental NGOs (Kuzma & Cummings, 2021; Roberts et al., 2020). Along with NGOs, academics and government representatives hold more moderate views about RRI and are more egalitarian in comparison to biotechnology industry affiliates and collaborators. To get the attention of policymakers and position RRI on the agenda, a coalition of NGOs that are more moderately positioned (i.e. not extremely anti-GMO) could work together with those holding positive beliefs about RRI across government and academe. The shared egalitarian and RRI beliefs could hold this expanded coalition together according to ACF. Expanding this coalition and working together on RRI issues could help to match the power of the industry-affiliated coalition and perhaps increase the chances of getting the attention of policymakers.

Across the history of 1st generation GMOs, expanded coalitions have formed to gain more power. For example, in the late 2000s, organic farmers and food companies worked with NGOs to bring forth federal court cases challenging the adequacy of environmental impact statements for GM crops, which prompted changes to regulatory policy (Kuzma, 2020, 2022). However, coalitions in favor of RRI and its implementation would not have the courts as venues, as discussed above. Instead, they might need to take their tactics to public media and other venues to expand their coalition and recruit those with shared positive RRI beliefs. Recently, a coalition of moderately positioned NGOs put forth a vision of responsible governance of gene editing in agriculture and the environment in the high-profile publication *Nature* (Gordon et al., 2021), illustrating a move towards raising attention to RRI in a neutral policy venue and recruiting others with shared beliefs to their vision.

Another important hypothesis under ACF is that powerful coalition groups will tend to confine policy issues narrowly to maintain control of the policy agenda and subsystem, whereas those with less power will attempt to expand the issues to recruit additional members to their coalition and increase their power (Jenkins-Smith et al., 2014; Schattschneider, 1960). Here the ACF overlaps with PET and the strategy of shifting the policy image of an issue to catalyze a focusing event. To gain more power and leverage, the expanded NGO-government-academe coalition discussed above could also recruit certain industry groups if the policy image of RRI were to shift (according to PET) or the issues were to be expanded (according to ACF). For example, making RRI about "consumer choice and voice" might recruit food companies to an expanded coalition and grow its power. Food companies more directly face the demands of consumers than biotechnology companies, and food and consumer product companies have been responsive to consumer pressures for non-GM and "natural" products. They also will be on the frontlines if a product safety issue or lack of consumer confidence should arise. These companies hold more political power and could help lobby Congress to increase federal funding to incorporate

RRI. The CFI efforts on responsible stewardship for gene-edited foods (CFI, 2022), which consists of several members from food companies, is an indicator that interest in this sector exists for partnerships with NGOs, government, and academics.

In summary, the ACF analysis points to the importance for proponents of RRI to expand their coalition to increase power and leverage and increase the scope of the policy issue to recruit other powerful sectors or actors, such as the food industry, to their coalition.

5 Limitations

Although the analysis points to strategies for raising the profile of RRI on the policy-setting agenda, it does not claim that these strategies will ultimately be successful. In fact, there are significant barriers to policy setting for RRI given the macro-level, socio-political forces and inter-institutional arrangements. Yet the literature points to national policies as the most effective way to change the landscape of innovation towards RRI generally (Wittrock et al., 2021) and within U.S. biotechnology innovation systems (Kuzma & Roberts, 2018; Roberts et al., 2020).

Regardless, the analysis is limited in its focus on national policy-making as the best possibility for RRI implementation and does not weigh the potential pros and cons of each strategy and its potential success. Significant bottom-up efforts for instituting RRI will also be required. Educating students, young researchers, and other innovators about RRI and building enthusiasm on the ground will be needed. However, in the absence of national funding structures for RRI, bottom-up efforts will eventually face roadblocks. Without sufficient financial incentives and professional rewards, RRI is likely to still face resistance due to individual, micro-level biases, especially related to autonomy (aligned with individualism) and expert-control over decision making (aligned with hierarchical thinking). Thus, the paper focuses on national policy-making and the contribution of policy process theory for insights to get RRI on the policy agenda.

The analysis is also constrained by the number of policy process theories and the hypotheses from those theories that are considered. It was beyond the scope of the article to give a full treatment of all policy process theories and their elements. The limited scope was designed to keep the analysis at a reasonable length. Also, the three theories chosen center focusing events and coalitions at their core, and these played significant roles in bringing regulatory changes to the national policy agenda during the history of U.S. biotechnology oversight (Kuzma, 2020, 2022). Thus, the choice of MSA, PET, and ACF seems justified.

Finally, although the analysis focuses on U.S. biotechnology innovation systems, it draws from work on barriers to RRI across several national contexts (Wittrock et al., 2021). It is likely that the conclusions for greater national support and incentives for RRI programs are applicable to countries outside of the U.S.

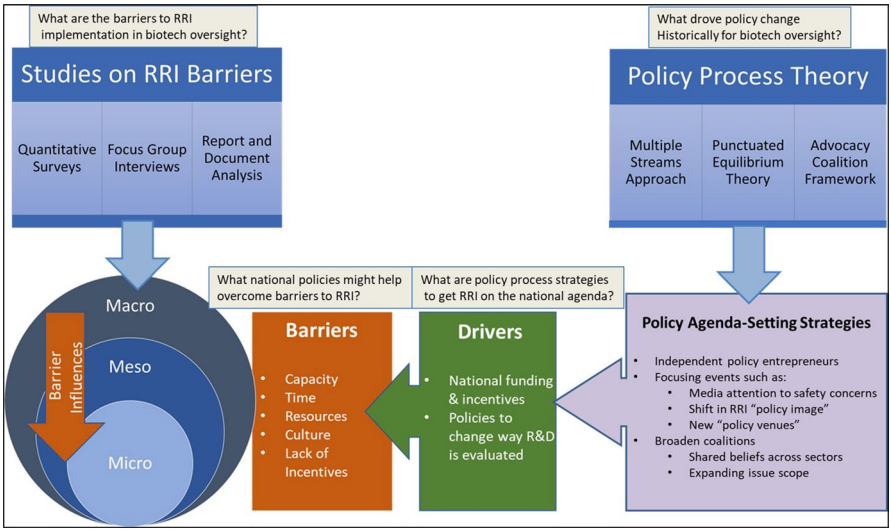

Fig. 2 Model for Analyzing the Potential for Policy Change Towards RRI Implementation

6 Summary and Conclusions

Figure 2 summarizes the approach taken to assess the challenges and opportunities for implementing RRI in biotechnology innovation systems. Starting on the left of Fig. 2, barriers to RRI were framed and discussed according to three levels: the individual, institutional, and societal (i.e. micro, meso, and macro, respectively). It is clear from the literature that macro-level forces, such as inter-institutional policies and socio-political contexts, filter down to the meso-level of organizations and institutions, affecting the climate for and creating structural and cultural barriers to RRI. These barriers then stand in the way of individuals who worry about delays to their work and the impact that it will have on future funding and their careers (Fig. 1, orange box on "Barriers", and orange arrow on "Barrier influences").

At least for organizations and individuals depending on public-sector funding, the most potent and widespread potential for implementing RRI is likely to come from national funding policies and programs. These can shift the climate towards RRI by providing incentive structures. The most important incentives will be financial to compensate for the professional risks and loss of potential revenue streams (Fig. 2, green box). Innovators worry about the delays in their work due to RRI (especially due to inclusion and responsivity practices of RRI), and they lack capacities and resources for RRI. Researchers, technology developers, and institutions implementing RRI should be well compensated for any delays and building RRI capacities. Given ample resources and funding incentives, reward structures and professional accolades for implementing RRI within organizations are likely to follow, as "money talks" (Wittrock et al., 2021). RRI funding policies and programs have the potential to reshape public and even private organizations (e.g. as they also can depend on public funding, as well as basic innovations and talent coming out of the public

sector). Much like intellectual-property policies and tighter university-industry relationships have reshaped the landscape of U.S. innovation systems in the last 5 decades, national funding policies in favor of RRI have similar abilities to change cultures and reward structures.

However, such bold funding allocations towards RRI will need to be authorized by U.S. federal decision makers and ultimately Congress. Significant barriers stand in the way of getting RRI on the U.S. policymaking agenda. These include the macro-level socio-political landscape, which currently views RRI as a barrier to technology development. As such, the most powerful coalitions for biotechnology consist of technology developers who hold skeptical attitudes towards RRI (Kuzma & Cummings, 2021; Roberts et al., 2020). Here, policy process theory can provide insights into strategies for potentially overcoming these barriers and bringing RRI to the attention of policy makers (Fig. 2, upper-right blue box). Therefore, this paper innovates by bringing policy process theory together with scholarship on barriers to RRI and the history of U.S. biotechnology governance.

Three policy process theories center focusing on events as ways to catalyze policy change—MSA, PET, and ACF. Using these theories and U.S. biotechnology history, several strategies for raising RRI issues on the policy agenda were identified in the analysis above (summarized in Fig. 2, yellow box). These include (1) cultivating independent policy entrepreneurs (arising from MSA), (2) bringing media attention to concerns about biotechnology (MSA and PET), (3) changing the policy image of RRI into a positive force for technology development (PET), () exploring more neutral policy venues to pursue RRI issues and policy change (PET), (5) joining forces across sectors to form larger coalitions of RRI advocates (ACF), and (6) expanding the scope of RRI issues and the policy image to recruit private-sector stakeholders to RRI coalitions (ACF).

In summary, there is considerable promise for federal-level policies and programs to catalyze RRI implementation. Funders especially have the potential to make RRI a priority for R&D in U.S. biotechnology innovation systems. Although these policy incentives might not be sufficient, they seem necessary to spark organizational changes and address the barriers that current institutional and cultural contexts present. Getting such funding policies on the national agenda will take the concerted efforts of trusted and independent policy entrepreneurs working together in expanded coalitions across sectors to change the image of RRI towards a positive force for technology development, while at the same time finding more neutral policy venues for RRI advocacy.

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Conflict of Interest The author has not declared any conflicts of interest.

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