


What Role Does Regulation Play in Responsible Innovation of Nanotechnology in Food and Agriculture? Insights and Framings from U.S. Stakeholders

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Abstract

Historically, market regulation has played an important role in shaping the trajectory of scientific and technological innovation in food and agriculture. However, regulators' traditional focus on safety and efficacy may be insufficient to address more complex ethical, legal, and social implications (ELSI) of novel products, such as the use of nanotechnology and nanomaterials in food and agriculture (nano-agrifoods). One solution might be to implement the principles of responsible innovation (RI) to challenge innovators and policymakers to better anticipate risks further upstream and be responsive to societal desires and concerns, although substantial barriers to implementation persist. This paper presents stakeholder views on the relationship between regulation and RI in nano-agrifoods based on a broader U.S. stakeholder engagement study conducted in the fall of 2020. We found that participants raised key issues that incorporated all 4 pillars of RI (anticipation, inclusion, reflexivity, responsiveness). We also found that participants' attitudes about the relationship between regulation and innovation informed their recommendations about the relationship between regulation and RI. These attitudes are represented in a spectrum of views, ranging from "regulation as barrier" to "regulation as driver" of innovation. We further identified implications for how each attitude might be used to operationalize RI in regulatory systems. Overall, these results suggest that just as regulation drove key innovations in the twentieth century, regulation may still have a role to play in helping to promote RI of nano-agrifoods in the twenty-first.

Keywords

responsible innovation, stakeholder engagement, nanotechnology, food & agriculture, regulation

Introduction

While the notion that regulation is a barrier to innovation continues to hold sway among public-choice economists and in the popular imagination (Rodgers, 2011; Stigler, 1971), social scientists and historians have shown that market regulation can be a driver of scientific and technological innovation (Balleisen & Moss, 2009; Taylor et al., 2005; Usselman, 2002; Vinsel, 2019). This dynamic may be especially evident in food and agriculture sectors, where regulatory interventions in the early twentieth century resolved market failures to reduce fraud, corruption, and inefficiencies in food and agricultural production (Cohen, 2019; Zeide, 2018). In the twentieth century, food and drug regulation proved essential to reduce informational asymmetries about ingredients and production processes through inspection, testing, and labeling (Balleisen, 2017; Frohlich, 2017; Young, 1990). Inspections and quarantines designed to control livestock diseases, such as trichinosis, contributed

to improvements in animal health as well as food safety (Olmstead & Rhode, 2015). Environmental regulations helped reduce some of the negative externalities of agricultural production by curtailing the use of agrochemicals, including pesticides and fertilizers that can cause adverse environmental impacts (Brickman et al., 1985).

However, food and agricultural regulators' traditional focus on safety and efficacy -- once essential for restoring

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market certainty and consumer confidence -- may pose a barrier to further innovation in these sectors. Furthermore, the field of *responsible innovation* (RI) goes beyond traditional innovation paradigms to “take care of the future through collective stewardship of science and innovation in the present,” based on four main “pillars” - anticipation, reflexivity, inclusion, and responsiveness, to use one commonly cited definition of RI (Stilgoe et al., 2013). RI explicitly challenges innovators and policymakers to go beyond regulatory approaches to shape innovation ecosystems, to better align research and innovation with societal needs and expectations. Ideally, the principles of RI should be incorporated into early stages of innovation, through the development of technology and formal regulatory systems, and during and after technological deployment. A parallel concept, responsible research and innovation (RRI), was also developed among European policymakers around the same time period (Sutcliffe, 2013; von Schomberg, 2013). RRI has since been formally incorporated into EU policy initiatives and funding streams and is defined by five “keys,” which are: public engagement, open science/open access, science education, ethics, and governance (Owen, 2019; Owen et al., 2021).

The use of nanotechnology and engineered nanomaterials in food and agriculture (termed nano-agrifoods) is an interesting case study to investigate the role of regulation in shaping RI. On one hand, nano-agrifoods have the potential to improve sustainability, safety, and availability of agrifood products in many cases, such as nano-pesticides and nano-fertilizers contributing to more sustainable agricultural production practices (Sampathkumar et al., 2020) and nanomaterials in foods to enhance nutritional content (Nile Shivraj et al., 2020). On the other hand, the vast diversity of these agrifood products, uncertainties in assessing the risks they may pose, and challenges to develop tools and protocols to detect and characterize these materials, all present challenges to effective regulation that are not readily addressed by existing frameworks (Allan et al., 2021; Grieger et al., 2016). For example, the risks and benefits of these nano-enabled products are still being evaluated for health, safety, and societal impacts, and public perceptions of these products are still forming (European Chemicals Agency (ECHA), 2020; Parisi et al., 2015). Although applications in agriculture may be perceived more favorably compared to nanomaterials used directly in food products, studies have repeatedly found that the public holds significant concerns about nano-agrifoods, is willing to pay a premium to avoid them, and recognizes that labels may be insufficient to give consumers the information they want and need to make informed decisions (Brown & Kuzma, 2013; Chuah et al., 2018; Porcari et al., 2019; Siegrist & Keller, 2011; Yue, Zhao, Cummings, et al., 2015; Yue, Zhao, & Kuzma, 2015).

Nano-agrifoods are currently regulated under a complex patchwork of laws, guidance, and informal codes of

conduct. In the U.S., nano-agrifoods are regulated under existing laws that govern food safety, chemical safety, and pesticide safety, all of which apply equally to non-nano products. U.S. agencies largely rely on guidance documents, which are less binding but often more flexible than rulemaking, to make specific policy judgments on oversight of nano-products (e.g. EPA, 2017, FDA, 2014). Even after much discussion and debate among policy scientists and academics, there remains a great deal of uncertainty regarding the circumstances under which nanotechnology products would be considered “new” or “novel” products for the purposes of triggering regulatory oversight and approval (Nawaz & Kandlikar, 2021). Meanwhile, European regulators have developed nano-specific regulations for food, drugs, and cosmetics containing engineered nanomaterials, including nano-labeling requirements for food and cosmetics (European Parliament and the Council, 2009, 2011). Some scholars argue that nano-agrifoods may be good candidates for a combination of public and private regulatory approaches, or “co-regulation.” These scholars tend to point to existing codes of conduct (The European Commission, 2009) as productive future models for expanded regulatory oversight, rather than a stopgap measure to bridge temporary regulatory gaps (Bowman, 2017; Bowman & Hodge, 2009; Hemphill, 2016; Marchant & Sylvester, 2006). In theory, some of these regulatory shortcomings for nano-agrifoods might be addressed through implementing principles of RI within early innovation stages. Crucially, RI encourages decision makers to move beyond technical assessments of risks and benefits to anticipate risks further upstream, include publics and stakeholders in assessing technologies further upstream, and be responsive to societal desires and concerns (Owen et al., 2012; Stilgoe et al., 2013).

Despite a rich academic literature on RI as well as strategic investment in these areas, many of the key principles of RI are not adequately institutionalized in regulation or in innovation ecosystems (Owen et al., 2021; Shelley-Egan et al., 2018). One scholar argues that the creation of distinct funding mechanisms for RI and RRI may have even created new silos and “served as an excuse not to incorporate RRI in the actual research” (Gerber, 2018). Further, recent work on U.S. stakeholder perceptions and concerns of nano-agrifoods revealed that stakeholders report regulatory issues as part of the key challenges they face in institutionalizing RI (Grieger et al., 2021). As reported in other papers by the same authors, stakeholders tended to frame regulation as both a potential barrier to and driver of RI (Cummings et al., 2021; Grieger et al., 2021; Kokotovich et al., 2021). Further, researchers and innovators of nano-agrifoods reported that “lack of regulatory guidance” and “lack of regulatory gatekeeping” were among the top challenges to ensuring RI in their own work (Cummings et al., 2021).

In this paper, we build off this body of literature and examine the extent to which regulation and governance has

a role to play in shaping not just innovation, but the *responsible* innovation (RI) in nano-agrifoods according to stakeholders in the U.S. In particular, this paper reports on U.S. stakeholder participant responses to several questions regarding regulation, including specific regulatory actions to ensure RI, the role of labeling and disclosure, and other barriers to RI that intersect with regulatory practices or systems. We then discuss the implications of these findings for the future of regulation and RI of nano-agrifoods, and provide some provisional recommendations for future work in this area.

Methods

This paper presents findings from a research study conducted as part of a larger U.S. Department of Agriculture (USDA), National Institute of Food and Agriculture (NIFA)-funded grant focused on societal implications and RI of nanotechnology in food and agriculture (Grant No. 2019-67023-29855; PI=Grieger, CoPI=Kuzma). As a part of this grant, we investigated stakeholder views regarding the role of regulation in ensuring the RI of nano-agrifoods. To conduct this study, we developed and conducted an online stakeholder engagement platform over a period of 3 weeks in the fall of 2020 with participants in the U.S. While we have previously reported on the process to develop the online stakeholder platform (Ruzante et al., 2022), as well as stakeholder perceptions of nano-agrifoods and RI more broadly (Grieger et al., 2021), this is the first paper from this study that has reported on stakeholder views of the role of regulation in terms of fostering RI for nano-agrifoods.

Stakeholder Engagement Platform

As described in Ruzante et al. (2022), we used CMNTY (<https://www.cmnty.com/>) to engage stakeholders virtually. This online platform offers a variety of modalities (e.g., surveys, discussion boards) to capture stakeholder perceptions. The landing page welcomed participants to the study and provided an overview of the activities that the study team asked participants to complete. It also linked to background information about the study and a participant consent form. To determine stakeholders' opinions on what role regulation should play in ensuring RI for nano-agrifoods, we evaluated participants' comments and participation on discussion boards, the "open forum" feature of CMNTY. Prior to the study, we tested the functionality and clarity of the platform and content with users internal to our institutions but not a part of the study team. Subsequently, we made revisions to the platform and content to address user concerns.

Participant Identification and Recruitment

Grieger et al. (2021) details the process used to identify stakeholders from diverse sectors in the U.S. including academia,

industry, government agencies, think-tanks, advocacy groups, and other non-governmental organizations (NGOs). In brief, potential participants were individuals serving in these stakeholder sectors that were interested or involved in the use of nanotechnology and/or nanomaterials in food and agriculture or emerging agrifood technologies more broadly. In total, we identified 442 potential participants. IRB approval was obtained from the study PI's institution (NC State IRB protocol 19207) prior to contacting them. All identified stakeholders were invited to participate in the study via email. To incentivize participation, a \$100 honorarium was offered to participants who completed all assigned activities on CMNTY. While 62 participants agreed to participate in the platform, only 55 participants completed all components of the study; and hence the final number of participants from this study was 55. Their respective sectors were academia (n = 19, 34.5%), government (n = 9; 16.4%), industry (n = 10, 18.2%), NGOs/think-tanks (n = 7, 12.7%), and NGOs/advocacy (n = 10, 18.2%). After signing a consent form, participants engaged on the platform by establishing a CMNTY account with a non-identifiable username.

Open Forums

We established a series of open forums on the platform. In the open forums, participants posted responses to a question or prompt and commented on posts made by other participants (Figure 1). In this study, each open forum contained a different prompt or question related to ensuring RI of nano-agrifoods. To gain insight into stakeholders' views of the role(s) of regulators and regulations in ensuring RI of nano-agrifoods, the following questions were posed to participants:

- (a) What should regulatory agencies that oversee food agricultural products that contain nanomaterials do to ensure responsible innovation occurs?
- (b) What types of barriers to responsible innovation using nanomaterials in food and agriculture can you envision? How can these barriers be overcome to ensure that responsible innovation occurs?
- (c) Should companies declare that they use nanomaterials in their food and agriculture products? Why/why not?

The results and discussion section focuses on findings from question (a), on regulatory actions to ensure RI, which are mapped onto the pillars of RI in Table 1. Responses from question (b) that directly related to regulation were used alongside responses to questions (a) and (c) to inform the contents of Table 2. Finally, question (c) was included in this paper because most participants' answers contained an implicit assumption that company declarations would involve a regulatory mandate or compulsory labeling

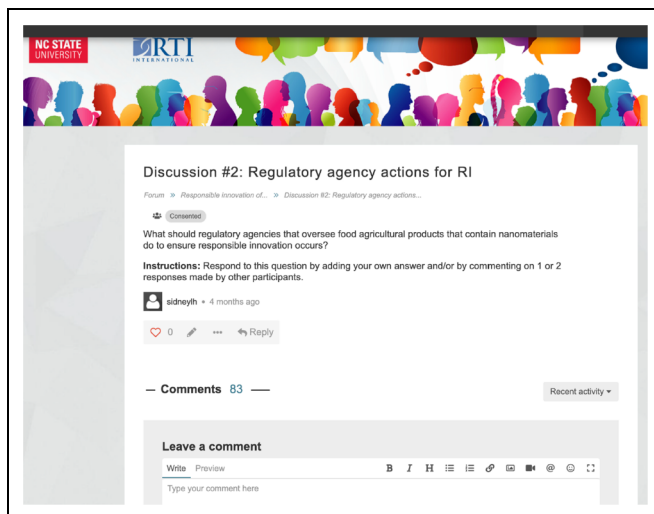


Figure 1. Screenshot of a stakeholder forum discussion board utilized in this study.

scheme. However, we note that labeling could take many other forms, such as a de facto private standard or a voluntary scheme.

To encourage discussion and debate, we instructed participants to respond to each forum question with a new post and to comment on 1–2 responses from other participants. In these responses, we asked participants to respectfully explain why they agreed or disagreed with the comment. Study participants were able to “like” or “upvote” comments by other participants, although this occurred infrequently in each forum. The instructions also encouraged participants to revisit the forums several times over the course of the study to review posts and comment.

Conduct Stakeholder Platform

As described previously (Grieger et al., 2021) the three-week study was initiated in late October and early November 2020. Team members monitored the platform daily to review participation and ensure there were no inappropriate comments. During this time period, team members also responded to technical questions and inquiries about the participation requirements through the chat feature of the platform. Outside of chat, the study team did not engage with the stakeholders in any capacity on the platform. After the three-week period, we closed the platform. All participants received an email thanking them for their participation and an honorarium if they completed all the study activities.

Analysis of Responses

Participant responses for all questions were collected and downloaded from the site at the conclusion of the study and

qualitatively coded using CAQDAS software (Dedoose) using inductive codes and subcoding. Each forum question was coded independently to account for variation in the wording of the themes of each question and different coding schemes that could result. A second analyst reviewed the codes for reliability and accuracy. Generally, the original codes were not changed or edited, but some codes were slightly reworded and, in a few cases, materially similar codes were combined to improve clarity of the final analysis.

In addition, we used several alternative analytical and discursive strategies, such as close reading and discursive content analysis, to identify themes and debates among respondents that are not as easily captured by frequency charts. For example, one feature of this platform allowed participants to reply to other comments and thereby create discussion “threads” within the set of responses to individual questions. We identified top-level comments (or “original posts”) that received the greatest number of comments in reply (up to 3 levels) and then considered each discussion “thread” as a unit of analysis. We also noted any comments that received 2 or more “likes,” regardless of the number of replies, for further examination. While this feature was infrequently used, it served as a helpful proxy for comments that might have a wider resonance than the number of replies alone might suggest. Then, using close reading methods and content analysis, we analyzed these selected comments and threads in more detail. Analysis of the conversation between participants in context allowed us to identify points of meaningful engagement, concurrence, or debate. Statements in this paper about stakeholders’ tone and intent (e.g. “stakeholders were unsure about X”) are interpretations gleaned from this approach in which the forum responses are examined as part of a larger dialogue.

Through this process of close reading of participant responses, we observed that debate among participants' views often hinged on contradictory definitions of what counted as RI and competing perspectives on the purpose and function of regulation. We also note that participant references to "regulation" in the platform were not exclusively referring to the rules set forth by public regulatory agencies, but referred to a broader range of voluntary and compulsory expectations and norms that govern a range of public and private forms of what scholars typically refer to as regulation and governance (Ayres & Braithwaite, 1992; Phillips Sawyer & Hovenkamp, 2019; Scott, 2002). In other words, participants frequently referred to more oversight and governance-based mechanisms and themes rather than strict regulatory actions and practices.

Thus, in an effort to better understand how participants' perspectives on regulation might map onto specific recommendations for regulatory actions to ensure RI, we developed a set of themes that capture a spectrum of attitudes regarding the relationship between regulation and innovation. These views ranged from "regulation as barrier" to "regulation as driver" of innovation. Given the size of the stakeholder group and the number of responses, making direct comparisons by stakeholder affiliation or by using stakeholder responses to questions that probed for cultural worldview (egalitarian, fatalistic, hierarchical, and individualistic) (Douglas, 1970; Douglas & Wildavsky, 1982; Kuzma & Cummings, 2021) were not scientifically sound. The approach used here offers a more flexible alternative, in that it might capture variations of perspectives within affiliation, and points of agreement across affiliations.

Finally, because this was an online forum in which all comments were typed by stakeholders (rather than transcribed from an audio recording, for example), some comments include spelling, grammatical, and typographical errors. To preserve stakeholders' own words in direct quotes as much as possible, any errors are indicated by the use of [sic] or the addition of omitted words in brackets.

Study Limitations

This study reports stakeholder views based on a sample of 55 participants in the U.S. across sectors of academia, government, industry, NGOs, think tanks, and advocacy. It is conceivable that stakeholders in other countries or regions, such as the EU, may provide different responses compared to those selected in the U.S. In addition, the sample size was not large enough to identify statistically significant differences between stakeholder groups. Such analyses could yield important insights across stakeholder groups and are worthwhile topics for future work. Our study also used an online engagement platform to provide more convenient access for participants and decreased costs compared to in-person meetings. We recognize that this approach may have limited the dialogue and conversations between

participants. We also recognize that we conducted the study during the fall of 2020, in the midst of the COVID-19 pandemic, which may have influenced participant access and availability. Finally, we did not provide formal definitions of RI or any background information about extant regulatory frameworks to our study participants. We were interested in understanding how stakeholders understood the concept of RI and what regulatory strategies they envisioned would best achieve their vision of RI. Even where our findings showed that participants lacked awareness or knowledge of the broader RI literature, we considered this to be a crucial finding that may be especially useful for regulators seeking to align regulatory frameworks with these principles.

Results and Discussion

Participant Views on Regulation and RI

Participants' views on how regulatory actions could promote or further the goals of RI largely fell within four main themes: i) strengthen nano-agrifood regulations (which typically referred to rulemaking or formal regulations), ii) improve nano-agrifood safety and safety testing, iii) best practices for stakeholder engagement, and iv) best practices for transparency and disclosure (Figure 2, Table 1). In terms of approaches to strengthen nano-agrifood regulations, the greatest number of excerpts related to establishing nano-specific rules and regulations, followed by pursuing RI through non-safety policy and/or funding, the need for regulations to keep pace with the science, determining what type of food systems we want, and addressing ethical and/or equity issues. Other themes included the need for regulation to not stifle innovation, differentiate between solving needs and societal problems, post-market monitoring and product inspection, as well as having social scientists in regulatory agencies, establishing incentives, address costs of regulations, and not base the framework on the coordinated network for biotechnology (Figure 2). In terms of approaches to strengthen safety and safety testing, the most cited stakeholder excerpt related to focusing on safety, followed by conducting more safety studies, and ensuring independent third-party testing. These were followed by determining what is an allowable risk and/or who can decide on an allowable risk, solicit own studies, and a focus on occupational safety (Figure 2). In terms of approaches to strengthen community and stakeholder engagement, participants suggested interacting with stakeholders early in innovation processes, involving the public and engaging stakeholders, engaging with companies to establish criteria for safety testing, and educating the public. Finally, in terms of strengthening transparency, participants suggested a range of processes to ensure transparency (through processes, safety studies, assessments), requiring disclosure, and change the use of confidential business information.

Table 1. Participant responses to the question “What should regulatory agencies that oversee food and agricultural products that contain nanomaterials do to ensure responsible innovation occurs?” mapped onto the pillars of RI (from Stilgoe et al. 2013). Note the emphasis on later stages of RI, and that some elements do not readily align with the 4 pillars.

Pillars of RI (from Stilgoe et al. 2013)	Techniques and approaches relevant to regulatory agencies (from Stilgoe et al. 2013)	Coded responses to the question “What can regulatory agencies do to ensure RI in nano-agrifoods?”	# of excerpts
Anticipation	Technology assessment	Decide what type of food system we want	5
	Horizon scanning	Determine what is allowable risk / who decides?	2
Reflexivity	Scenario planning	Set ethical criteria	2
	Multidisciplinary collaboration/training	Engage with companies to establish safety testing criteria	3
	Embedded social scientists and ethicists	Differentiate products by need/problem	3
	Ethical technology assessment	Solicit studies of own when needed	2
	Codes of conduct	Have social scientists on staff of agencies	1
Inclusion	Moratoriums		
	Citizens’ juries / panels	Interact with stakeholders early on	6
	Focus groups	Engage stakeholders	4
	Consensus conferences	Involve public	4
	Lay membership of expert bodies	Address issues of equity	3
Responsiveness	Open innovation	Federal agencies should work together to outline protocols	2
	Regulation	Educate public	1
	Standards	Establish nano-specific rules/regulations	14
	Open access / transparency	Ensure regulations keep pace with the science/issues	8
	Moratoriums	Transparency (of assessments, 2; safety studies, 2; process, 1)	6
	Stage-gates	Require disclosure of nanomaterials	4
		Clarify rules/policies/laws	7
		Change current use of Confidential Business Information	1
Other - Not necessarily part of RI		Pursue RI through non-safety policy/funding	8
		Ensure independent/third-party testing	6
		Conduct more safety studies (5), public funding for safety studies (1), consider short/long-term effects (1)	7
		Post-market monitoring (1) random product inspections (2)	3
		Occupational safety	2
		Establish incentives	1
		Do not use existing rules	1
Other - In opposition to the goals of RI		Focus on safety, not RI	9
		Use existing rules	4
		Should not be long / tedious / stifle innovation	3
		Do not involve public	1
		Address costs of regulations	1

At the same time, we also note the contrasting and even conflicting responses among participants within these themes. For example, while some participants advocated for a focus on safety, others said that safety should be specifically excluded from regulatory efforts to operationalize RI (Figure 2, Table 1). Some stakeholders advocated for more community engagement; others specifically suggested that less engagement would lead to superior outcomes (Figure 2, Table 1). We found that while some of these responses map

onto the four pillars of RI, not all of the responses do, and some responses are in direct opposition with key goals of RI (Table 1). We also found that participants focused their attention on strategies that promoted inclusion and responsiveness, with less mention of strategies related to anticipation or reflexivity (Table 1). These contradictory results raised new questions about how participants perceived not just RI, but also how they understood the overall relationship between regulation and innovation ecosystems.

Table 2. Stakeholder Attitudes of Regulation and Responsible Innovation of Nano-Agrifoods. These findings are derived from stakeholder responses to (a) What should regulatory agencies that oversee food and agricultural products that contain nanomaterials do to ensure responsible innovation occurs? and (b) What types of barriers to responsible innovation using nanomaterials in food and agriculture can you envision? How can these barriers be overcome to ensure that responsible innovation occurs?: Fifty-five participants provided comments through the online stakeholder engagement platform.

	Regulation as a barrier to innovation	Regulation as coordination	Regulation as "rules of the game"	Regulation as "guardrails"	Regulation as statement of values	Regulation as driver of innovation
<i>Stakeholder views of regulation</i>	<ul style="list-style-type: none"> Regulation tends to slow innovation Regulation trails science, regulators know less than private industry 	<ul style="list-style-type: none"> Regulations exist to coordinate markets Regulators benefit from the knowledge of private industry 	<ul style="list-style-type: none"> Regulations exist to order markets and reduce uncertainty Regulation is based on science; regulators are qualified experts Views regulatory costs as the "cost of doing business" 	<ul style="list-style-type: none"> Regulations exist to protect consumers and reduce risks in the marketplace Regulation is a necessary check on fraud / deception Regulation can protect individuals from excesses of capitalism 	<ul style="list-style-type: none"> Regulations reflect shared social values Regulations have the potential to remedy social and economic inequities 	<ul style="list-style-type: none"> Regulation can shape innovation Regulators are aware of the latest science and can use their power to push science forward
<i>Stakeholders' preferred regulatory framework</i>	<ul style="list-style-type: none"> Self-regulation / voluntary (codes of conduct, best practices, etc.) Preference for reduction or elimination of regulations 	<ul style="list-style-type: none"> Prefers incentives to act responsibly rather than penalties for bad behavior Believes that regulators can and should cooperate with the industry stakeholders 	<ul style="list-style-type: none"> Preference for clarity of expectations Preference for regulators to stick to their defined regulatory mission Ideal framework is independent, objective, and stable 	<ul style="list-style-type: none"> Believe that businesses need checks rather than incentives Ideal framework ensures that all products on the market are safe (if approval is granted, we can trust the product) 	<ul style="list-style-type: none"> Regulations should allow for individual evaluation of risk (e.g. consumer's right to know) Participation should be based on norms of deliberative democracy Regulations should adhere to an ethical framework 	<ul style="list-style-type: none"> Ideal regulatory framework is responsive and flexible enough to adapt to novel products
<i>Implications for RI in nano-agrifoods</i>	<ul style="list-style-type: none"> Likely to oppose efforts to embed RI in regulatory systems Likely to view RI principles as barrier to innovation 	<ul style="list-style-type: none"> Could accelerate RI implementation if other stakeholder groups are included Possibility of co-responsibility for RI Open to strategies that promote reflexivity 	<ul style="list-style-type: none"> Initially resistant to efforts to embed RI in existing systems, especially if RI modifies existing definitions of safety If RI mandated, likely to accept those rules 	<ul style="list-style-type: none"> Especially supportive of transparency/ openness (responsiveness) Potential for coalition with others on matters related to inclusion and responsiveness 	<ul style="list-style-type: none"> Ideal group to include in upstream engagement or conversations related to pillar of "anticipation" 	<ul style="list-style-type: none"> Another group whose input would be valuable in upstream engagement (anticipation)

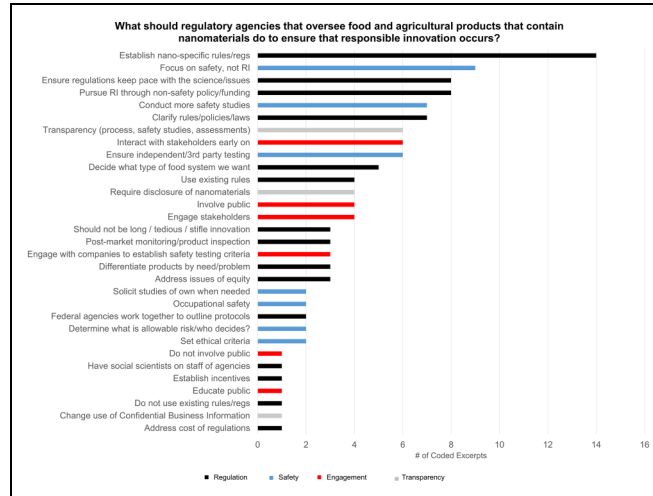


Figure 2. Participant responses to the question “what should regulatory agencies that oversee food and agricultural products that contain nanomaterials do to ensure responsible innovation occurs?” represented as a chart, with key themes indicated by color.

Participant Views of Regulation and Innovation, with Implications for RI

In light of the findings described above, we applied discursive analytical approaches to re-examine participant comments to assess how their responses might reflect more general attitudes about the relationship between regulation and innovation. The results of this analysis are shown in this section and in Table 2, in a provisional “spectrum” of attitudes on regulation. This table draws on extant literature that engages with broader debates on the relationship between regulation and innovation in addition to the substance of stakeholder comments as well as the literature on RI. Below, we explore each attitude in depth to show how participants’ views of regulation informed their recommendations for regulatory actions to ensure RI in nano-agrifoods.

Regulation as a barrier. The argument that regulation poses a barrier to innovation reflects a conventional wisdom in public-choice economic literature (Peltzman, 2005; Stigler, 1971). In the context of this study, comments such as “I don’t think the process should be very long and tedious” reflect this attitude that regulation slows down or stifles innovation processes. A few participants also described nano-agrifood regulation as “trailing the scientific knowledge.” This notion of regulators as lagging behind scientific knowledge is not as explicitly anti-regulatory as other arguments about “burden” or “lag,” but still offers a subtle critique that can be used to delegitimize public expertise by

framing it as inferior to experts in the private sector (Balogh, 1991). We would expect that this view with regard to “regulation as a barrier” would be generally less supportive of incorporating RI principles of inclusion and responsiveness into regulatory processes or other oversight mechanisms, as these practices of RI might stall regulatory processes even further (Kuzma & Roberts, 2018; Roberts et al., 2020).

Box 1. Regulation as a barrier. Exemplary Quotes from Stakeholders

- “The regulations are trailing the scientific knowledge.”
- “One major barrier to responsible innovation is intellectual property or proprietary information. Companies investing in new and innovative products may not want to talk about them with stakeholders because their competitors will know what they are doing.”

While participants described “regulation” as a barrier to RI elsewhere in the study (Figure 3a, below), closer analysis of discussion forum comments revealed that participants were more likely to argue that the absence of regulation or uncertainty about future regulation presented the greater barrier. Stakeholders also made the case for expanding or improving regulatory oversight, or modifying extant regulatory missions, such as in the following comment: “I think a major barrier is that regulators come at this from a ‘do no harm’ perspective rather than ‘do we really need this?’” In

short, participants were more likely to comment that regulatory agencies should create a “safe pathway to market” than to reduce all regulations and remove oversight of new products.

The relative absence of explicit anti-regulatory or deregulatory views has several logical explanations, some of which may be related to the composition of the stakeholder group itself. First, our sample size from industry-affiliated stakeholders was relatively low, and industry developers and researchers who participated in our larger study generally recognized the need for basic regulations to ensure safety and efficacy (Grieger et al., 2021; Kuzma & Cummings, 2021). A more intriguing possibility is that the lack of strong arguments for “regulation as barrier” might indicate the political possibilities within nano-agrifoods. That is to say, that while skepticism of formal regulation may always exist in some quarters, from these comments, one could expect minimal opposition to the creation of novel regulatory systems in nano-agrifoods that embedded principles of RI along various points of the innovation ecosystem. The biggest concern expressed by participants who held this view was related to the protection of intellectual property with respect to disclosure, which is described in more detail in a subsequent section (“Transparency and Disclosure”).

Box 2. Regulation as coordination. Exemplary Quotes from Stakeholders

- *“Regulatory agencies should include incentives for responsible innovation not just penalties for non-compliance.”*
- *“Innovation is driven by the scientists to solve practical problems that are not always well understood or clear to the public. The process should remain transparent, but not guided by public input (often a vocal minority).”*
- *“Again, what is allowable [sic] risks for nanomaterials and who decides this? ... Seems like a regulatory oversight responsibility but would benefit from industry and academic engagement in some instances perhaps where industry and academia research may move faster than regulatory entities.”*

Regulation as coordination. The second theme included in our set of attitudes about regulation (Table 2) is the notion of “regulation as coordination.” The idea that regulation should involve cooperation or coordination between public and private actors is also derived from literature on management-based regulation or “coregulation.” This viewpoint is especially important to capture for nano-agrifoods, as scholars have previously identified food regulation as an area in which co-regulation might be especially promising (Garcia Martinez et al., 2013; Merck, 2021; Verbruggen & Havinga, 2015).

Box 3. Regulation as “rules of the game.” Exemplary Quotes from Stakeholders

- *“Regulatory agencies should act appropriately while protecting public health, but without stifling innovation. They should, in line with their mission, provide a set of science-based information that explains the rules of the game and levels the field. ... Nobody likes to be surprised, particularly not in a later stage of the product development.”*
- *“The job of the FDA is to ensure that the food product is safe to eat by humans and animals (if it is a product for them). Their regulatory role is not to ensure responsible innovation, just safe products. However, they may have other roles, ... that might involve ensuring responsible innovation.”*
- *“[s]afety testing is just part of any responsible product development - an ethical company will understand this and will budget for it.”*

Consistent with that literature, comments that reflected the view of regulation as coordination were likely to emphasize incentives rather than penalties (Box 2). Comments that emphasized the need for stakeholder engagement with experts, rather than the general public, also reflect this attitude: “Innovation is driven by the scientists to solve practical problems that are not always well understood or clear to the public. The process should remain transparent, but not guided by public input (often a vocal minority).” Similar to commenters who view regulation as a barrier, comments that reflected this attitude tended to include assumptions that “industry and academia research may move faster than regulatory entities.” (Box 2) Unlike the comments above about regulation trailing science, this commenter argues that if the private sector has more advanced knowledge than regulators, then they are obligated to take a more active role in the regulatory process.

Regulation as coordination might evoke negative connotations of agency capture, corruption, or a revolving-door culture in which the line between regulator and regulated becomes irrevocably blurred. However, participant comments in this study suggest that this attitude could be marshaled in ways that would promote or even accelerate operationalization of RI. For example, one participant offered an especially promising view of what “coordination” might mean: “The regulator, as well as the product developer, is co-responsible for responsible innovation.” However, coordinating efforts between regulators and industry must also include explicit efforts to involve other stakeholder groups as well, to remain congruent with RI principles of inclusion, reflexivity, and responsiveness.

Regulation as rules of the game. Instead of explicitly characterizing regulation as “burdensome” or a hindrance to innovation, participants who expressed favorable views towards industry or R&D were far more likely to describe regulation

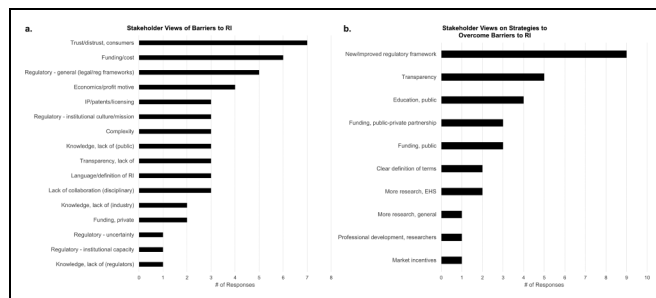


Figure 3. Themes in participant responses to the question “what types of barriers to responsible innovation using nanomaterials in food and agriculture can you envision? How can these barriers be overcome to ensure that responsible innovation occurs?” Figure 3a depicts stakeholder views on barriers to RI; Figure 3b depicts stakeholder views on strategies to overcome barriers. Note that regulation appears as both a barrier and a strategy to overcome barriers.

as what one participant called the “rules of the game” (Box 3). Comments that reflected an attitude of regulation as “rules of the game” expressed a preference for clarity, structure, and certainty in expectations. Commenters who approached regulation from this perspective tended to have a baseline understanding of the ways that regulations provide structure and order to markets, and expressed a clear preference for that structure to be aligned with their own interests. This attitude is best exemplified by commenters who are eager for regulators to develop rules and regulations to resolve “regulatory uncertainty,” especially if the regulations contained clear nano-specific provisions that were easy to follow. As one participant explained, “We need regulation in place to be able to bring nanomaterials into the ag and food market. Regulatory agencies need to have a plan on how to regulate this technology.” Here, regulations are framed as a crucial element of bringing new products to market, rather than a barrier to innovation or a guardrail against the risks of novel products.

Responses that reflected the key tenets of “rules of the game” tended to advocate against specific regulatory action (by this, they often implicitly mean “rulemaking” or the creation of specific laws and guidelines) to ensure RI unless it was already part of the regulatory agency’s mission. For example, one commenter stated “[The FDA’s] regulatory role is not to ensure responsible innovation, just safe products” (see Box 3). Similarly, another commenter noted that “As a starting point, the regulatory agencies should follow the regulatory guidelines put in place regarding [sic] placement of food products on the market.” These attitudes distinguish this theme from “regulation as guardrails” (described in Table 2 and below) in that commenters sought to make a very clear distinction between existing regulatory mandates to ensure “safety” and related efforts to promote RI.

Crucially, commenters who characterized regulation as “the rules of the game” described the current regulatory landscape as one in which the rules were unclear, inchoate, and inadequate. As one participant explained, “developers that might act more responsibly are not [on] a level playing field and can be undercut by rivals that don’t mind duping consumers, ignoring risks, etc.” A key hallmark of comments that reflected a view of regulation as “the rules of the game” is a focus on clarity and certainty over and above other aspects of RI, like anticipation, inclusion, or responsiveness. While this stakeholder group overall agreed that more safety studies were needed, “rules of the game” commenters valued increased safety primarily as a means of reducing uncertainty about whether products could obtain market approval. Similarly, “transparency” was also important to this group as a whole, but with respect to process and regulatory decision-making, rather than as a general ethical principle.

Overall, participants who expressed this set of attitudes seemed resistant to initial efforts to embed RI in regulatory systems, especially if RI is seen as changing rules that already exist, such as existing statutory definitions of safety or efficacy. In extreme cases, this group might align with stakeholders who view regulation as a “barrier” to oppose operationalization of RI in regulatory systems. However, if the principles of RI were framed as generalized expectations and “rules” intended for all researchers and developers to follow, this group would likely accept those changes and follow those rules.

Regulation as guardrails. Other commenters emphasized “safety,” but upon further analysis, their perspective differed notably from the attitudes described above as “rules of the game.” In contrast, these comments generally focused on the value of developing regulations to check the behavior of potentially unscrupulous, fraudulent, or deceptive actors - in other words, to create “guardrails” to check the power of private

interests (Table 2). This theme corresponds roughly to a constellation of attitudes held by consumer advocates, think tanks, and some academic researchers (exemplified by works such as Nader, 1965). Stakeholders with this attitude share a common assumption that private actors can be expected to behave irresponsibly without external incentives (Box 4).

Box 4. Regulation as guardrails. Exemplary Quotes from Stakeholders

- *“What often seems to be lacking in nanotechnology innovations is a thorough assessment of the risk to human health, as well as the environmental and ecological impact. . . . This is where government funding and regulation need to fill in the gap. Regulating bodies need [to] mandate a more complete understanding of the risks an innovation poses and more government funding should be directed to studying the impacts of nanomaterials already on the market.”*
- *“Without checks or incentives, private companies do not have enough incentive to ensure that new technologies or products are developed responsibly.”*

Importantly, commenters whose views reflected regulation as “rules of the game” and “guardrails” both emphasized safety, but to achieve different regulatory purposes. In the comment quoted above about the role of the FDA, eight second-level commenters and two third-level commenters replied with concurring statements. Yet it was clear that even where commenters “agreed,” they were making different arguments about the need for safety. For example, one of those commenters stated that “safety of products is the issue whether they are innovative or not.” “Rules of the game” commenters tended to emphasize safety as a strategy to narrow (or at least contain) the scope of regulatory action, while commenters who viewed regulation as “guardrails” were more likely to advocate for safety as a strategy to improve or expand regulatory oversight.

Participants in this study who expressed views of regulation as “guardrails” also occasionally equated “safety” with RI. As one stakeholder described it: “The only ‘responsible’ innovation would be to make foods safer.” This phrasing may reflect a more binary conception of safety that is not as well grounded in the tenets of risk science or RI (in which stakeholders contrast “safe” with “unsafe” rather than “less safe”). More extreme versions of this perspective may even make demands for “no-risk” regulation, which explicitly opposes the rationale for RI as a framework designed to go beyond safety as the primary consideration of responsibility in technological innovation. Nevertheless, the persistence of this view suggests that stakeholders continue to value safety. Without more information on what RI entails, these stakeholders may be concerned that implementation of RI might reflect a de-prioritization of safety, even if that is not the case.

The commonalities and overlaps between “regulation as guardrails” and other themes also offer a few promising opportunities to form coalitions among stakeholders who might not otherwise agree on how to implement RI in regulatory frameworks. “Guardrails” stakeholders are likely to be ideologically aligned with “statement of values” stakeholders, but are also more willing to engage in the practicalities of what kinds of regulatory actions will best achieve those ideals, to create a level playing field and set the “rules of the game.” This group might be especially likely to support informational regulation and other “sunshine” disclosure strategies to foster RI principles of transparency and openness (e.g. disclosure of materials in an open access database, public notice of recalls, etc.).

Regulation as a statement of values. Another theme we observed in the participant comments was that several participants made strong claims and assertions about regulation or RI, but rarely offered clear articulations of how those ideas could be operationalized. We describe this set of attitudes as “regulation as a statement of values;” while we are using participants’ language of “regulation,” here we are envisioning regulation in a broader sense, more akin to oversight or governance. These participants were likely to point to the need for “ethical criteria,” “honesty,” and “transparency,” but rarely provided explicit articulations of how those criteria related to the goals of RI. This was most evident among commenters who favored transparency and disclosure in principle, but openly expressed doubt that transparency or disclosure would work well in practice.

Box 5. Regulation as a statement of values. Exemplary Quotes from Stakeholders

- *“Use of nanotechnology should be stated on product labels so people have information to make decisions that correspond to their values and risk tolerance.”*
- *“My initial reaction is yes for no reason other than consumers right to know and to chose. [sic] However, there are already plenty of nanoscale materials and nanoemulsions added to food,.. Not sure requiring consumer disclosure is going to get us anywhere except consumer freak out.”*
- *“The main question is what type of food system we want, and what value priorities are driving that vision? Only after we’ve come to a working consensus on that question, as informed by participatory democracy platforms, will we have anything resembling a public agreement on nanotech.”*
- *“I would ask the question “ensuring” responsible innovation to who? Ensuring innovation satisfies scientific criteria of safety, ensuring an ability to address consumer concerns, or ensuring a reasonable benefit to society.”*

Participants whose comments reflected this attitude about regulation tended to question the underlying premise of the questions that were up for debate in the discussion forums. For example, several participants pushed back on the framing of the question about “ensuring” RI. As one commenter noted, “I would ask the question “ensuring” responsible innovation to who?” This comment (reproduced in full in Box 5) offers several valuable insights for understanding how participants viewed the connections between regulation and RI. First, this stakeholder explicitly correlates RI with “scientific criteria of safety,” addressing consumer concerns, and providing “reasonable benefit” to society. The latter two points about addressing consumer concerns and providing a benefit to society speak to larger concerns expressed across the platform about ensuring that innovations address a concrete “need” (Grieger et al., 2021). This comment was not the only one to question the limitations of current regulatory missions for agri-food regulators. When asked about barriers to RI, one stakeholder replied “I think a major barrier is that regulators come at this from a ‘do no harm’ perspective rather than ‘do we really need this?’” While this commenter is technically describing barriers, they are doing so in a way framed around institutional mission and shared values, rather than efficiency, burden, or lag. This perspective thus frames regulators themselves as the barrier to RI, and one that might be overcome through embedding RI principles in regulatory agencies.

Based on their comments and perspectives on regulation, participants who view regulation as a statement of values are the most inclined to view RI as broader than safety, and to see regulatory systems adopt RI principles. These views are perhaps most congruent with scholarly definitions of RI and the relationship between RI and regulation. Further, precisely because they are inclined to focus on the underlying ideals, philosophical questions, and values in innovation rather than the practical details of implementation, this attitude is especially well aligned with the goals of upstream engagement and the scholarly and policy vision for RI (e.g. Stilgoe et al. 2013). Stakeholders with this attitude might be especially well-suited to think about dimensions of RI that other groups seem to ignore, such as inclusion, reflexivity and responsiveness. By contrast, if this group is engaged later in the innovation process, they may question the entire premise of regulatory action as invalid.

Regulation as a driver of innovation. The final theme included in Table 2 is “regulation as driver of innovation.” This theme is included as it reflects the opposite of “regulation as barrier,” and thus covers the breadth of an ideological spectrum of views about regulation as reflected in the literature on regulatory governance (Balleisen & Moss, 2009; Eisner, 2000; Vinsel, 2019). However, there were very few clear examples of comments in which participants explicitly described regulation as a potential driver of RI. While a few participants alluded to the need for a more holistic

view on goals and objectives (Box 6) in general, those views overlapped substantially with value statements or questions about the extent to which regulation can or cannot achieve goals of equity, sustainability, or efficiency. This absence of comments might suggest that the participants in this study did not think that regulation alone was sufficient to drive further innovation in nano-agrifoods, which is consistent with broader principles of RI that emphasize the need to move away from regulatory interventions as the only means of shaping innovation systems.

Box 6. Regulation as a driver of innovation. Exemplary Quotes from Stakeholders

- *“It would be helpful if there was some clearly articulated policy about how nanotechnology and food and agriculture fit together and what we as a nation or the industry is trying to achieve. ... Policy and regulation also needs to be revisited from time to time as the state of knowledge advances: these issues cannot be addressed in “one and done” mode.”*

Stakeholder Views of Regulation and RI

Below, we focus in more depth on three key themes within the set of participant comments (Table 1). We selected these themes as they cut across more than one pillar of RI and generated valuable discussion and debate, especially among participants who expressed different attitudes about regulation and different perspectives about what is involved in RI. These themes are: (1) safety (including safety studies, testing, and risk assessment), (2) stakeholder engagement, and (3) transparency (including disclosure and labeling). While we observe that participant comments in aggregate incorporated all four pillars of RI (Table 1), within specific themes, there was considerable debate and disagreement that was often based on competing definitions or understandings (and occasional misunderstandings) of the principles of RI. By taking into consideration participants’ overall attitudes about regulation and innovation, as described in the above section and in Table 2, we can better contextualize the potential value of comments that might otherwise be dismissed as “not RI.”

Safety. As noted in the introduction, a key dimension of RI is an explicit call for practitioners to move beyond safety considerations and to shift engagement and study further “upstream” to anticipate, reflect, and respond to potential impacts. As shown in Table 1, participants did raise some points that related to these pillars of RI, such as anticipation (e.g. on allowable risk and decision making), reflexivity (e.g., the need to engage with companies to establish safety testing criteria, government bodies soliciting studies of their own when needed,) as well as responsiveness (e.g., calls for

transparency in safety studies). However, participants frequently defined RI in terms of its relationship to safety, which proved to be a matter of some discussion on the stakeholder engagement platform. While some participants advocated for regulators to require more safety studies, others argued for pursuing RI through non-safety measures. Crucially, some participants' views of safety actively opposed core principles of RI, exemplified by commenters that called for regulators to "focus on safety, not RI." The most "liked" comment in response to the question about regulatory actions (5 likes) diagnoses stakeholder attitudes about the current state of nano-environmental, health and safety (EHS) research accordingly (see Box 4 for full quote): "What often seems to be lacking in nanotechnology innovations is a thorough assessment of the risk to human health, as well as the environmental and ecological impact." Note that this commenter is most interested in regulatory oversight at a relatively late stage ("nanomaterials already on the market"). We also note that while expansion of risk assessment and safety studies alone cannot ensure RI, RI principles can be productively incorporated into these evaluative tools (Grieger et al., 2019; Kuzma, 2021).

Participants strongly disagreed on who should fund all of these safety studies and tests. Several participants suggested that funding decisions represented "a good example of how regulatory agencies could influence responsible innovation in a non-regulatory way." Another commenter noted "I think that regulatory agencies can incentivize responsible innovation through the decisions they make about grants and public funding for nanotechnology research." In these comments, funding and research is explicitly set apart from regulatory action, and public funding is defined as a crucial dimension of ensuring RI. Yet several participants disagreed with the need for public funding; as one participant explained: "[s]afety testing is just part of any responsible product development - an ethical company will understand this and will budget for it." Another participant noted, "Why should I pay for the development of a for-profit company's new products?" Across several forum questions, many stakeholders expressed a preference for company-funded safety studies with third-party verification. In their comments, participants tended to define "third-party" to mean "objective" and "without financial interests." Even as some participants advocated for company-funded studies and against public funding, most responses revealed an overall lack of trust in industry-funded research. At times, even the stakeholders themselves seemed unsure about how to square their distrust of companies with their desire not to overburden regulators with safety tests. As one participant inquired: "Who should do it? Who should pay for it?"

Typically, participants could agree that more EHS studies and safety tests were valuable and necessary, but their attitudes about regulation shaped commenters' precise reasons for their support of safety studies. Some participants argued for a fairly equal division of responsibility between

regulators and regulated: "I agree that the burden should be on the developer of a product to prove it's [sic] safety, not the government regulator. The purpose of the regulator is to set forth the safety tests that need to be done and then review the results to see if the product is safe." On the other hand, some participants argued that regulations may need to be strengthened in order for companies to behave responsibly:

"Many companies can't go above and beyond -- at least at first -- to be the great sustainable steward we all want them to be. So we need to lean on the regulator to set the bar, and maybe that bar needs to be raised if we think dangerous products are reaching the market."

These comments exemplify points of potential agreement between "rules of the game" attitudes and "guardrails" attitudes about regulation, particularly the point about setting clear expectations for safety tests and review, and the point about "lean[ing] on the regulator to set the bar."

Even when participants agreed on the need for something like enhanced EHS studies or third-party testing, their motivations for doing so were slightly different, depending on their attitude about regulation. Commenters who viewed regulation as "rules of the game" advocated for safety studies or clearly defined safety tests as a means of reducing uncertainty for researchers and businesses. These participants concurred with those who favored third-party verification, especially if it was likely to increase public trust in the results. By comparison, comments that reflected the attitude of regulation as "guardrails" were likely to oppose public funding but distrust company-funded research, and favor third-party verification.

It is easy to read these participants' emphasis on safety as a simple misunderstanding or mischaracterization of RI. However, the degree to which these participants used this discussion forum question about regulation as a space to debate the importance of safety – specifically the need for more robust EHS studies – *as an important dimension of RI* deserves to be taken seriously by RI scholars and practitioners. Regulatory agencies seeking to embed RI principles into their processes should take this as a cautionary note – in their efforts to operationalize RI principles, agencies should take care not compromise existing regulatory missions of safety and efficacy.

Stakeholder engagement. Another core principle of RI is the pillar of "inclusion," which calls for upstream engagement with stakeholders to co-develop solutions that respond to known societal needs and challenges. By comparison, this study group openly questioned the value of inclusion. Across several forum questions, participants expressed doubt or outright skepticism about the capacity of the general public to successfully engage on nano-agrifood issues. While some participants favored upstream engagement -- as noted in Figure 2 and Table 1, six excerpts included recommendations that regulators "interact with

stakeholders early on” -- participants generally preferred engagement only with experts, or engagement that was focused on increasing public awareness rather than inclusivity. As one stakeholder explained in their response:

“First we need regulation in place ... Second, there is the need for public awareness. Only by educating the consumers there will be an acceptance of the technology without the potential problems that for example we witnessed with GM products.”

This view corresponds with the “deficit model” of public knowledge commonly associated with the Public Understanding of Science model that has been largely discredited by scholars in STS and RI (Jasanoff, 2005; Kuzma & Roberts, 2018; Roberts et al., 2020). This perspective was in the minority of comments, as only six participants suggested “public education” or “increase public awareness” as strategies to overcome barriers to RI out of a total of 75 comments. (Figure 3b)

All of these views actively go against RI principles of inclusion; nevertheless, participant attitudes on this issue seemed to be consistent across the spectrum of attitudes about regulation, albeit for different reasons. While some participants appreciated the principle of public engagement, even those participants questioned its effectiveness in reality. In particular, these stakeholders expressed concerns about the role of misinformation and erosion of public trust in science. Participants’ views on public engagement were best summed up by this comment, in response to the question about what regulators should do: “The public should definitely be involved but it is extremely difficult to get informed input when people are not well informed.” In response to this comment, one participant offered the following clarification, that “any public involvement should be with regards to education of the technology rather than input on decisions of responsible innovation” (Box 2). This latter comment best reflects the nexus of attitudes of “regulation as coordination” or even regulation as a barrier to innovation. This perspective also reflects a

belief that private-sector practitioners are the real “experts” relative to public sector regulators or other stakeholders.

Perhaps as a consequence of this widespread skepticism of the general public’s ability to meaningfully engage, a few commenters explicitly defined stakeholder engagement in terms of a dialogue between experts, here defined as regulators and nano-agrifood researchers. As one stakeholder explained, “What I witnessed in the early days of nano was that simply having regulators around (e.g., from EPA, OSHA, etc.) and sharing their insights on regulation and responsible development greatly improved the discussions.” One participant described stakeholder engagement as “a permanent communication with stakeholders ... such communication will be beneficial to everyone.” This comment emphasizes the importance of stakeholder engagement as an ongoing dialogue that is mutually beneficial for regulators as well as researchers. While these study participants defined stakeholder engagement in ways that frequently went against RI principles, the consistency in responses across attitudes about regulation in general suggests that more work needs to be done not just to foster inclusive processes, but to ensure that those involved in those engagement processes have sufficient confidence that inclusion will truly lead to superior outcomes.

Transparency and disclosure. While these participants openly questioned the value of inclusion, they were a bit less skeptical about the need for transparency and openness, concepts which align with the principle of responsiveness (Table 1). When asked about potential regulatory actions to ensure RI, several commenters mentioned the need for transparency and others explicitly mentioned that disclosure of nanomaterials should be required (Figure 2, Table 1). When asked in a different question about whether companies should be required to disclose the presence of nanomaterials, a subset of these participants explicitly justified their position on disclosure in the language of consumer rights: 15 stakeholder responses used phrases like the “consumer’s right to know” or the “right to make informed decisions” (Figure 4b). Four

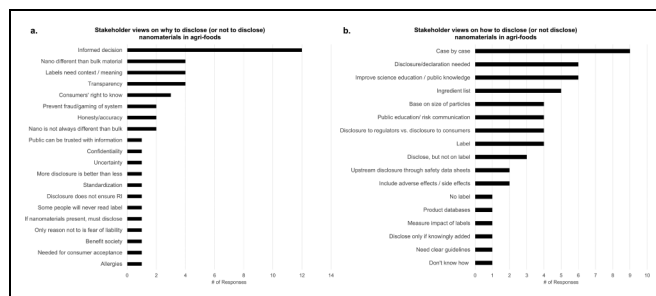


Figure 4. Coded responses to the question “should companies declare that they use nanomaterials in their food and agriculture products? Why/why not?”. Figure 4a depicts stakeholder views on why to disclose (or not to disclose) nanomaterials in agri-foods; Figure 4b depicts stakeholder views on how to disclose (or not to disclose) nanomaterials in agri-foods.

responses mentioned “transparency” as a key justification for disclosure (Figure 4b).

While the question about disclosure was worded so as to incorporate public or private forms of disclosure, it is noteworthy that most participants responded with an implicit assumption that labeling and disclosure involved some degree of regulatory intervention. Four respondents distinguished between disclosure to consumers and disclosure to regulators (Figure 3a). Participants who raised this distinction tended to prefer the latter: “Companies should be required to declare use of nanomaterials to regulatory agencies.” Most participants spoke about mandated disclosure as just one of several policy tools to ensure RI in nano-agrifoods. As one participant stated: “disclosure is necessary but not a sufficient condition to ensure responsible innovation.” For example, several participants also favored improvements to public education and knowledge, so that consumers could accurately interpret any disclosed information: “if we label something as “containing nanomaterials” to inform consumers, then we are equally responsible for informing consumers about what that label means.”

The following comment also offers an indicator of participants’ overall perspective on the issue of disclosure, as it received the greatest number of “likes” (seven) and second-level replies (six) of any other response to this question:

“This is a difficult question. It [disclosure] is dependent upon the nature of the nanomaterial and how different it is from regular food components. For example, nano-emulsions are probably already present in a large number of food systems ... Also, if structures are built from nanomaterial components, are they still nano?”

This question prompted a few concurring replies and some heated debate. One respondent wrote “I wholly disagree. Compounds have different properties and have different effects on the nanoscale and people have the right to know what risks they may/may not be exposing themselves to.” In reply to that comment, another stakeholder wrote:

“Sorry, but this is simply wrong. I have done a lot of work on this over 15 yrs. and some chemicals ... do not have significantly different properties [at the nanoscale]. Some obviously do ... But some do not.”

While initially this might appear like a straightforward debate on the scientific facts of nanotechnology, when viewed through the lens of regulatory attitudes (Table 2), it also represents a forum on the degree to which regulation (here generally envisioned more narrowly as rulemaking or formal regulation) serves as a statement of values or a reflection of unbiased, objective scientific authority.

In their responses, several participants explicitly acknowledged a tension between their own principles and the

practical challenges of regulating disclosure and labeling. These commenters tended to make two-part statements that initially spoke favorably of the “right to know” or the principles of disclosure or transparency, but then acknowledged the practical limitations or tangible problems with those ideals, such as this stakeholder comment: “they should disclose this information but I’m certain it will be confusing to people.” Another stakeholder noted “Not sure requiring consumer disclosure is going to get us anywhere except consumer freak out.” (Box 5) Three participants who favored disclosure in principle explicitly mentioned that labeling would not be a productive means of disclosure, as reflected in this comment: “I think that the companies need to say what they did but don’t put it on the labels.” Some of the comments suggested that this stakeholder group was acutely aware of the ways that labeling had become a flashpoint with genetically modified foods: “As we’ve seen with the GMO, natural, and organic products, labelling can get out of hand quickly.” From their comments, it appears that several participants correlated improved regulatory oversight and/or RI with greater transparency, either with respect to review, expectations, or disclosure. For example, one commenter noted that “Having a clearer and more rigorous review process that is transparent will help with responsible innovation in that practioners [sic] will see how to get their products reviewed and on the market in a timely way.”

A few participants also acknowledged the ways that intellectual property (IP) and patent laws presented barriers to RI more generally, including specific challenges related to disclosure. One participant observed that “it will be difficult to find a balance between protecting private IP and promoting public trust at the same time.” Another stakeholder criticized the use (or potential misuse) of trade secrets / confidential business information to protect companies’ interests and undermine transparency in safety studies:

“The companies persist in claiming Confidential Business Information to exclude their health and environmental studies. The companies should use patent law to protect their business interests, not CBI.”

These comments offer valuable insights on the tensions between RI ideals of inclusion and openness and a reminder that the kinds of challenges that prompted development of the RI principles still affect the development of emerging technologies almost twenty years later. Regulatory agencies may be especially well positioned to promote these ideals of openness and disclosure, but as these comments also suggest, it is crucial that the agencies in question possess adequate legitimacy and are considered a trusted source of information in the first place.

Moving Forward

Overall, these findings are important and relevant for regulators and scholars who wish to operationalize RI for nano-agrifoods for at least two reasons. First, the overlap in views across regulatory attitudes suggests the potential for an advocacy coalition (Sabatier, 1988) between groups who might not otherwise trust one another (e.g. consumer advocacy groups and industry trade groups), framed around shared values of safety, disclosure, and transparency. For example, Kuzma and Cummings (2021) found that coalitions of product developers versus consumer and environmental groups had very different core values which may impact their views on principles and practices of RI. These differences in core and policy values might be barriers to agreeing on practices to implement RI within technology innovation systems (Kuzma & Cummings 2021; Roberts et al. 2020; Kuzma & Roberts 2018). At the same time, the very need to examine not just the overall trends in stakeholder comments and views, but the context and connotation of words like “safety,” “transparency,” and even words like “regulation” suggests that precise language and clear communication will be crucial to avoid miscommunication and ensure a truly inclusive and responsive engagement process. For example, when a stakeholder makes a claim like “the only responsible innovation is to make food safer,” instead of dismissing this remark as misunderstanding RI, it may be valuable to reflect more on what that stakeholder means by “safety” and how it can be achieved through a combination of regulation and application of the principles of RI. As another participant noted,

“Can we create a regulatory environment that promotes a willingness on the part of everyone involved to take a step back from their own work to look together at the bigger picture - clearly, honestly and with deep integrity?”

In other words, to achieve sustainable and responsible innovation ecosystems, new, adaptive approaches may be just as important for regulators as they are for researchers and innovators.

Conclusions

This study evaluated U.S. stakeholder views of the role of regulation in ensuring RI of nano agrifoods, through the use of an online stakeholder engagement platform. Overall, stakeholders envisioned a role for regulation in fostering RI, especially in order to ensure safety, engage stakeholders, and encourage transparency. At the same time, we also found that there was considerable variation (and on occasion, disagreement) among study participants about what constituted RI and how to embed it in regulatory systems. Further, this study found that most themes raised by participants fell into the ideological center of the spectrum of attitudes

about regulation; that is, most comments reflected views of regulation that we describe as “rules of the game,” “guardrails,” or a “statement of values.” We also found that most, if not all, participants acknowledged that regulation (or governance more broadly) could play at least some role in furthering the goals of RI. This observation is intriguing for future research and innovation in nano-agrifoods, in that it may reflect the political possibilities within the nano-agrifood space; that is, almost no participants expressed outright opposition to regulatory action. While there was some support of nano-specific regulation or oversight measures, there also remains much discussion regarding the approach(es) that might be most effective in embedding RI in regulatory systems. Moving forward, we found that to achieve sustainable and responsible innovation ecosystems, new, adaptive approaches may be just as important for regulators as they are for researchers and innovators.

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