Commentary: Is It Possible to Determine the Extent to Which Informational Asymmetries and Prejudice Bias Responses?

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Introduction

"Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms," by Jennifer Kuzma, Pouya Najmaie, and Joel Larson explores U.S. regulatory oversight in the context of genetically engineered (GE) organisms in an effort to glean insight into strategies for regulating nanotechnology. The case of GE oversight in the United States is a useful case to explore because it is one that can be characterized by both successes and failures. For example, recent evidence suggests that the Environmental Protection Agency's (EPA) efforts to promote the sustainability of insect-resistant crops like Bt corn and cotton appear to be working,[1] while its approval of Starlink Bt corn only for animal feed resulted in the unintended release into human food supply. GE oversight is also a challenging case because there are many dimensions to oversight (e.g., human, environmental, and ethical concerns) that involve multiple federal agencies (e.g., EPA, U.S. Department of Agriculture [USDA], and the Food and Drug Administration [FDA]) operating under a coordinated framework and guided by a variety of legislation (e.g., Toxic Substances Control Act [TSCA]; Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]; Federal Food Drug and Cosmetic Act (FFDCA); and the Federal Plant Pest Act [FPPA]).

The authors use a three-pronged policy analysis approach to gain insight into how different attributes of GE oversight have affected regulatory outcomes and to formulate policy recommendations for nanotechnology oversight. This three-pronged approach included a quantitative expert survey, semi-structured expert interviews, and historical literature analysis. The quantitative and qualitative information generated from these three sources of information is evaluated holistically in order to generate hypotheses about the relationship between the attributes of the regulatory system and its outcomes, for comparison to other examples of regulatory oversight in the United States (e.g., for human drugs and medical devices, chemicals in the workplace, and gene therapy), and to inform recommendations for nanotechnology oversight.

The authors' analysis suggests that GE oversight in the United States has had its weaknesses and strengths. Important weaknesses include a lack of transparency, public input, informed consent, post-market monitor-

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ing, and financial resources. Prominent conflicts of interest, a closed approach to protecting intellectual property, voluntary data requirements, and insufficient oversight of environmental safety are also cited as weakness. Key strengths include the clarity of the subject matter and proactive nature of the regulation. The primary hypotheses generated from this analysis for comparison to other cases include whether greater public input, informed consent, and capacity improve health and safety outcomes; whether greater incentives for compliance improve environmental outcomes; and whether mandatory data requirements improve public confidence.

The authors offer a variety of recommendations for nanotechnology oversight based on their analysis. The complexity and uncertainty of the regulatory system should be managed to reduce obstacles for small product developers with limited financial resources. Regulatory authority should be consolidated to avoid gaps and eliminate redundancy, and there should be sufficient resources for regulators to fulfill their obligations. To foster public confidence, data requirements should be mandatory, and oversight should be transparent, informed by public input, provide for informed consent, and include pre- and post-market testing. To foster public acceptance, product development with broader consumer benefits should be encouraged.

Overall, the authors provide an insightful and comprehensive overview of GE regulation in the United States. Their methodology pulls together a rich set of information that represents expert knowledge from a broad range of disciplines, affiliations, perspectives, and motives. Their analysis is thorough, objective, and supportive of their conclusions. The authors also carefully critique their methodology and results, so its strengths and weaknesses are transparent.

The purpose of this commentary is twofold. First, I would like to provide some thoughts on how additional information from the experts who participated in the survey and interviews might provide additional insights into GE regulatory oversight. This is information that could still be elicited from the participating experts and used for further analysis with the existing data. Second, I would like to provide suggestions for how future studies might successfully build on the authors' methodology to further our understanding of GE regulatory oversight and other complex regulatory systems.

Benefits of Additional Information

The quantitative and qualitative data analyzed by the authors were derived primarily from a survey of experts and expert interviews. The experts who participated had varied backgrounds. There was representation from a variety of affiliations including academia, private industry, government organizations, non-government organizations, and think tanks. There was representation from a variety of disciplines including the physical sciences, social sciences, public policy, and law. Each expert had unique experiences with GE regulatory oversight. A key advantage to using experts from such a broad range of affiliations, disciplines, and experiences is that it allows the authors to craft a portrait of GE regulation as a whole. A potential disadvantage is that this portrait is an abstraction with distortions that can confound interpretation.

The authors discuss the potential for distortions in the context of motivational bias. Motivational bias occurs when experts do not report their true beliefs either consciously or subconsciously. The authors attribute these motivational biases to differences in experience with the regulatory system and differences in personal or professional interests.

The authors find that expert responses were often correlated with factors such as affiliation. For example, they find that all respondents from non-government organizations rated the distribution of health impacts as very inequitable (0-10), while all respondents from private industry rated them as rather equitable (71-100). They hypothesize that such varied responses could be attributable to motivational bias, assuming that this motivational bias is correlated with affiliation. Given the adversarial relation that exists between private industry and some non-government organizations regarding GE oversight, such an assumption is not too objectionable. However, an equally interesting finding is that half of the respondents from government rated the distribution of health impacts as very inequitable (1-10), while the other half rated them as very equitable (91-100). If motivational bias is again the explanation for such diverse responses, there must be other dimensions that are not so strongly correlated with affiliation. Alternatively, there might be other salient factors working to distort expert responses.

Another potentially useful way to think about these distortions came to mind after reflecting on the authors' discussion of motivational bias, design and administration of the expert survey and interviews, and results. These distortions can be thought of in terms of what I will call information and prejudice — information in terms of objective facts and theories, and prejudice in terms of subjective preferences, and personal or professional interests. An expert's assessment of the attributes and outcomes of a regulatory system can be thought of as reflecting the information and prejudices gained through the study of the regulatory system and personal experiences with it.

In this context, two experts may disagree about regulatory attributes or outcomes because each has incomplete information regarding the regulatory system as a whole, which is what the experts were asked to evaluate. One expert's information could be drawn from experiences studying and working with the EPA on the non-target effects of Bt corn, while another's information could be drawn from experiences studying and working with the EPA on the allergenicity of the insecticidal proteins in Bt corn. If these experts use a type of representative heuristic to evaluate the system as a whole based on personal experience with just part of it, their responses can be distorted by their incomplete information.[2]

Alternatively, two experts might disagree because of differing prejudices. One expert's prejudice could be drawn from a personal belief that GE is no different than conventional hybridization, while the other's prejudice might be drawn from a personal belief that GE is unethical because it combines the genetic material from different species. In this case, the first expert might rate the distribution of health benefits as relatively more equitable, while the second might rate them as relatively less equitable, even if both experts worked for the USDA's Animal and Plant Health Inspection Service on the deregulation of Bt corn and had the same set of information upon which to form their opinions.

There are other ways to think about how the authors' methodology may distort the portrait they paint of GE regulatory oversight. I believe that informational asymmetries are important, because most experts have experience with only a few facets of this complex regulatory framework. I also believe that prejudice is important, due to personal experience working on the regulation of Bt corn with experts from a variety of affiliations and disciplines. It is not surprising that prejudices differ between experts from some non-governmental organizations and private industry, but I hypothesize that there are also important differences in prejudice between experts from different government agencies and different academic disciplines. Assuming information asymmetries and prejudices may be distorting the results and confounding the interpretation of the expert survey and interviews, collecting more information on expert opinions about GE technology in general and experiences with different facets of the regulatory system may help illuminate the differences in how experts rated different regulatory attributes and outcomes.

Prospects for Future Research

The authors find that there is strong agreement among experts that U.S. regulatory oversight of GE is complex. This result is not too surprising given the number of agencies involved and the variety of legislation that guides them. The authors also note that there are substantial differences across countries in regulatory oversight. Given the complexity of U.S. oversight and differences in oversight across countries, there are interesting opportunities for future studies to expand on the authors' current research and gain additional insights.

Taking a more global perspective also raises new questions regarding how a lack of harmonization in regulatory policy across countries might be affecting the outcomes of regulatory oversight in the United States.

The authors' holistic approach was in part guided by the objective to compare the attributes and outcomes of regulatory oversight in the United States across different types of technical innovation. Given the multiple dimensions of GE regulatory oversight and the complexity of the regulatory framework, future research could repeat the authors' exercise while focusing on different facets of GE regulation. For example, separate case studies that identify the attributes and outcomes of regulation could be developed for the role of the EPA, FDA, and USDA in the oversight of GE. There are also opportunities to further subdivide each agency's regulatory responsibilities. For example, the EPA has taken an active role in regulating plant-incorporated-protectants in terms of non-target effects on the environment, human health effects, and insect resistance management. These case studies could then be compared in an effort to develop further insights.

There are several benefits to be gained from taking a more in-depth look at different facets of GE regulation. There are likely to be fewer distortions due to informational asymmetries, because experts could confine their responses to the aspects of the system that are most familiar. Survey response rates could improve if some experts declined to complete the authors' sur-

vey because they were not comfortable evaluating the regulatory system as a whole given the limits of their expertise. There is also variation in how each agency has approached GE regulation. For example, the EPA treated insect-resistant crops differently from conventional pesticides because it viewed them as safer for human health and the environment,[3] while the FDA declared that GE crops were generally recognized as safe in 1992 and has since treated them the same as other crops. Understanding this variation could help explain why the authors find disagreement among experts for certain regulatory attributes and outcomes.

Additional insights are also likely to be gained from expanding on the authors' methodology to develop case studies for other countries that could be compared to the U.S. case studies. While some adaptations to the methodology would be required to make reasonable comparisons, the lessons that could emerge seem worth the pursuit because there is substantial variation in regulatory policy across countries, particularly in relation to GE. For example, the European Union (EU) has stringent labeling requirements, while the United States does not. I hypothesize that there may be more variation in GE regulatory oversight across countries than there is across human drugs and medical devices, chemicals in the workplace, and gene therapy in the United States.

A cross-country comparison of GE regulatory oversight might be particularly useful in helping to better understand how the attributes of the regulatory oversight affect research and innovation. While several experts in the authors' interviews indicated that regulatory oversight of GE was depressing research and innovation, the expert survey results suggest a neutral effect, though there was substantial variation in responses. The historical literature analysis suggested that research and innovation has slowed in the United States, but definitive links to the U.S. regulatory system have not been established. Compared to other countries, particularly those in the EU, the U.S. regulatory system has been the more enabling for GE crop research and commercialization. Therefore, more definitive conclusions on the effect of regulatory attributes on research and innovation might be obtained through the comparison of the EU and U.S. systems.

Taking a more global perspective also raises new questions regarding how a lack of harmonization in regulatory policy across countries might be affecting the outcomes of regulatory oversight in the United States. My own conversations with experts from private industry suggest that a lack of regulatory harmonization across countries is impacting research and innovation, and the distributional outcomes. These conversations suggest that the regulatory outcomes in the United States are not solely dependent on U.S. regulatory oversight. This would be another important lesson for nanotechnology oversight if it is supported by further research.

Concluding Remarks

Jennifer Kuzma, Pouya Najmaie, and Joel Larson provide the most comprehensive overview of GE regulation in the United States that I have had the opportunity read. They use a three-pronged policy analysis approach to develop a rich set of expert information that provides new insights into the attributes of GE oversight in the United States and its outcomes. These insights lead to well-formulated hypotheses for comparison to other case studies and to policy recommendations for nanotechnology oversight that are well worth considering.

There are opportunities to further exploit the authors' expert information and to develop more information from new research. These opportunities could provide additional insights, help develop new hypotheses, and refine recommendations for nanotechnology oversight. By collecting supplemental data from the experts on their general opinions about GE and their experiences with different facets of GE regulation, some of the disagreements the authors find among experts should be easier to interpret. Developing new case studies for the role of different agencies in GE oversight in the United States and for GE oversight in other countries would improve understanding of the attributes and outcomes of GE oversight in the United States, and the relationship between U.S. oversight and oversight in the rest of the world.

Acknowledgements

This article is based upon work supported by the National Science Foundation (NSF) under Grant No. 0608791. Any opinions, findings, and conclusions or recommendations expressed in this article are those of the author and do not necessarily reflect the views of the National Science Foundation. I would like to thank Susan Wolf, Efrosini Kokkoli, Jennifer Kuzma, Jordan Paradise, and Gurumurthy Ramachandran for providing me the opportunity to contribute to their efforts to better understand what lessons previous technological advances provide for active nanostructure and nanosystem regulation.

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