Problem Formulation and Option Assessment (PFOA) Linking Governance and Environmental Risk Assessment for Technologies: A Methodology for Problem Analysis of Nanotechnologies and Genetically Engineered Organisms

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Societal evaluation of new technologies, specifically nanotechnology and genetically engineered organisms (GEOs), challenges current practices of governance and science. When a governing body is confronted by a technology whose use has potential environmental risks, some form of risk analysis is typically conducted to help decision makers consider the range of possible benefits and harms posed by the technology. Environmental risk assessment (ERA) is a critical component in the governance of nanotechnology and genetically engineered organisms because the uncertainties and complexities surrounding these technologies pose such risk potential.[1] However, GEOs are unique technologies, and there is widespread, international recognition (e.g., the Cartagena Protocol on Biosafety of Living Modified Organisms) that many traditional forms of ERA are not well-suited for evaluating them.[2] Nanotechnology products are also likely to need different models of risk assessment, as there is very little information on their fate, transport, and impacts in the environment.[3]

ERA was originally developed approximately 40 years ago to address the effects that pesticides and other point-source[4] environmental pollutants could have on the environment, and was patterned on human health risk assessments.[5] It assumed that the adverse environmental effects of these chemical pollutants could be best evaluated by examining the toxicity of the pollutant on a few species to ascertain the kinds of adverse effects considered possible.[6] Employing an ERA for governance and oversight assumes we have a reasonable ability to understand consequences and predict adverse effects. Basically, the traditional ERA involved choosing a few species, estimating likely maximum environmental exposure, conducting acute toxicity tests, and devising management restrictions to reduce the expected risk. In recent decades, the scope of ERA has expanded substantially to consider non-point pollutants, multiple pollutants from multiple sources, invasive species, environmental hormones, land use

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practices, and others.[7] As part of this expansion, ERA has been applied to genetically engineered organisms and nanotechnology. In addition, the purpose of ERA has expanded. Originally considered a decision-support tool, it is now sometimes used to legitimize a decision to stakeholders or society-at-large.[8] Consequently, the traditional ERA has come under considerable criticism for its many shortcomings.[9]

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One shortcoming of many traditional ERA processes is the inability to effectively involve societal perspectives in a practical way that interacts with and informs the ERA throughout its entire process and places the science within a social deliberation over the values that frame policy. There is a tendency in traditional ERA models to focus primarily on scientific understanding of environmental issues.[10] This understanding is clearly essential to effective governance, but in the case of nanotechnology and transgenic organisms, ERAs need to be responsive to broader societal values and issues. In particular, the complexity and uncertainty associated with GEOs often leads to polarizing debates, influences their societal acceptance, and ends in governance deadlock.[11] Considering these technologies demands the inclusion of information about political, ethical, social, and economic factors in order to bridge science and governance. Uncertainty and complexity require a more profound and inclusive deliberation that allows participants to consider the acceptability of risks in relation to their values.[12]

Several international efforts suggest that an ERA of emerging technologies will be more informative for decision makers if broadened to focus not just on the ecological risks posed by the technology, but also on the critical societal needs that the technology is being proposed to address.[12] When such a technology is being considered for introduction in a country, it is being evaluated as a solution to some problem. Ideally, a societal problem will be addressed with the solution most suited to that problem; however, to do so demands that a country have an adequately broad understanding of the problem, so that all of the possible alternative solutions can be evaluated. This requires social reflection and discussion.

To successfully integrate ERAs, governance, and societal reflection, a deliberative process involving multi-stakeholder participation is one method that is becoming increasingly common throughout the world; many view it as the most robust method.[13] A deliberative process is one involving careful consideration and evaluation of available options. Multi-stakeholder participation means directly involving the voices of those people likely to be most affected by a particular decision. Integrating a deliberative multi-stakeholder process into ERA procedures for a nanotechnology or transgenic organism is a way to allow a relevant cross-section of society to evaluate the critical needs and risks involved cooperatively and comparatively. Doing so — if the process is taken seriously — can help overcome deadlock and actually move parties forward on legitimate grounds to make a decision.[14]

In this article, we briefly review the challenges posed by genetically engineered organisms and nanotechnology, leaving an extensive analysis of these problems to other authors in this symposium, and then present the Problem Formulation and Option Assessment (PFOA) methodology as a flexible approach linking environmental risk assessment with decision making, thereby enhancing governance of these technologies. Finally, we focus on the key concepts underlying PFOA that strengthen both ERA and governance.

Unique Challenges Posed by the Technologies

Nanotechnology

Nanotechnologies are emerging technologies that present unique challenges to countries struggling to keep pace with the broad range of products, both potential and already commercial, and the necessary oversight responsibilities and ethics of good governance. Those challenges include:

- Business projects an astronomical growth in applications.
- Nano results in complex technologies, for example, those that move across traditional biophysical boundaries.
- Some nanotechnologies are active and continue to be active, with unknown consequences.
- Science is playing catch-up with each new discovery, resulting in a dearth of information.
- Currently, in the United States nanotechnology is governed with a quilt of preexisting laws, policies, and agencies.

Scientists and scholars have been documenting the incredible range of products that could be considered nanotechnologies or nanosystems.[15] These products provide numerous services from drug delivery to strengthening structures, from improved sunscreen to illumination that allows us to see previously unexplained molecular processes.[16] In response to these discoveries, patent numbers are increasing and along with them the related oversight challenges.[17]

Complex nanotechnologies multiply uncertainties as we work with their attributes, stretching our previous understanding of the way the world functions and what we can predict. The foundational difference is the size, at the nanometer scale. Nanometer particles can move through a biological organism, crossing membranes and even into cells. This tiny size allows for molecule-to-molecule interactions to dominate their dynamic properties, a realm in which we have only poor statistical understanding. Scientists and public officials do not yet have sufficient information to track nanotechnology production and confidently monitor nanotechnologies into the future.

These technologies defy our governance assumption that we have a reasonable ability to understand consequences and predict adverse effects. In the United States we are currently using laws, risk assessment methodologies, and agency structures designed for other technologies.[18] While a practical approach, this patchwork causes some to question whether we have sufficient oversight to satisfy our legal responsibilities, ethical obligations, or status as global leader in nanotechnology.[19]

Each country has the right and responsibility to design its own policies and regulatory systems to address nanotechnology. However, navigating the complexity and uncertainty surrounding this technology requires that countries have the capacity to conduct a reliable assessment of the technology. If a country has poor chemical, medical, or consumer product regulatory systems, then it will be a major challenge to address nanotechnology oversight.

Genetically Engineered Organisms

GEOs pose some unique challenges to any country working to determine whether or how they will be allowed and managed within the county's borders. Those challenges include:

- GEOs may have widespread impacts.
- They are alive and therefore able to spread and evolve on their own accord.
- Every unique instance of proposed GEO technology may need to be considered individually.
- Evaluating GEOs requires particular scientific and institutional capacities.

GEOs may have broad, unintended effects on people and environments. GEOs can be easily transferred within regions and across borders through trade or environmental processes, such as pollination. Once a GEO is introduced, a country's ability to control exposure and movement may be limited.[20] Thus, the effects of using GEOs may not be isolated to the intended area of use. One country's decision to allow and manage GEOs within its borders, even if only in one particular region, may unintentionally impact other regions inside its borders or, of greater political significance, other countries. As the existence of GEOs becomes more pervasive, especially given the potential for trans-boundary movement, the capacities of countries to intentionally and autonomously decide whether or how GEOs will be allowed and managed within their borders could become diminished.

A GEO technology should be considered for its own unique benefits and harms to the ecological and societal contexts into which it is introduced.[21] A GEO is the product of one or more in vitro modifications to the genetic structure of a naturally occurring species or subspecies. GEOs are usually genetically similar to the species or subspecies from which they originate. However, the genetic modifications in a GEO create potential for the organism to act differently than its naturally occurring counterpart in a particular environment. Ecologically, these differences could manifest in patterns of survival and reproduction, interactions with other organisms including humans, or roles in ecosystem services. For society, these differences could manifest in any number of social, cultural, or economic systems. Furthermore, the consequences of these differences could be beneficial or harmful, benign or significant, geographically restricted or widespread. The only way to understand with reasonable certainty what effect the differences may have is to specifically examine a proposed GEO in the particular contexts into which it might be introduced.[22]

To meet governance responsibilities for GEOs, each country will design policies and regulatory oversight, but the complexity and uncertainty associated with GEOs require a reliable assessment of the technology.[23] This demands the scientific capacity to conduct an environmental risk assessment (ERA) and the institutional capacity to integrate socio-economic considerations into the overall decision-making process. Some countries already have the infrastructure in place to accommodate an assessment of GEOs that can effectively balance safety, competitiveness, and existing societal and ecological contexts. Other countries have faced difficulties in providing the infrastructure needed.[24]

Problem Formulation and Options Assessment (PFOA)

Problem Formulation and Options Assessment (PFOA)[25] is a methodology that we initially designed for deliberative formulation of problems and comparative assessment of future alternatives relative to the biosafety evaluation of genetically engineered organisms.[26] This is a methodology we have used and refined in many countries, including Kenya, Brazil, and Vietnam. The methodology was developed within the GMO ERA Project[27] to help deal with the traditional deficiency of societal deliberation in ERA and integrate societal perspectives throughout the ERA process. Though designed for transgenic organisms, it can be modified for nanotechnology to address either the introduction of new technologies or the development of monitoring plans and risk management for existing nanotechnology.

A PFOA is a multi-step, interactive process that directly involves stakeholders in an assessment of the positive and negative effects of a technology. The process asks relevant stakeholders to conduct an ERA by collaboratively identifying, analyzing, and advising on the reduction of possible harms and the enhancement of potential benefits within the specific contexts for which a technology is being considered. To this end, a PFOA relies on being transparent, inclusive of all appropriate stakeholders, and informed by the best available science. It serves to strengthen an ERA by incorporating deliberation into scientific assessments as a means of linking risk assessment with governance.

A PFOA process can be a core component for any biosafety assessment of a transgenic organisms and nanotechnology. It uniquely and necessarily puts all people potentially affected by a proposed use of a technology (i.e., stakeholders) at the center of risk assessment in a way that they can influence and contribute to the assessment. The healthy debate it can engender provides a forum for considering a technology at multiple scales, across disciplines, by policy makers and regulators, and among stakeholders. It provides a viable means of combining public deliberation and science-based analysis within a decision process. The major contributions that the PFOA process potentially can make to an ERA include:

- improving the use of science in ERA;
- providing an arena for considering societal values and ethics along with science;
- providing for the possibility of a responsive relationship among citizens and between citizens and scientists in the ERA process;
- strengthening the legitimacy of the ERA and governance of technologies;
- better linking ERA with the entire system of regulating and managing technologies; and
- helping society evaluate technologies in light of alternative futures.

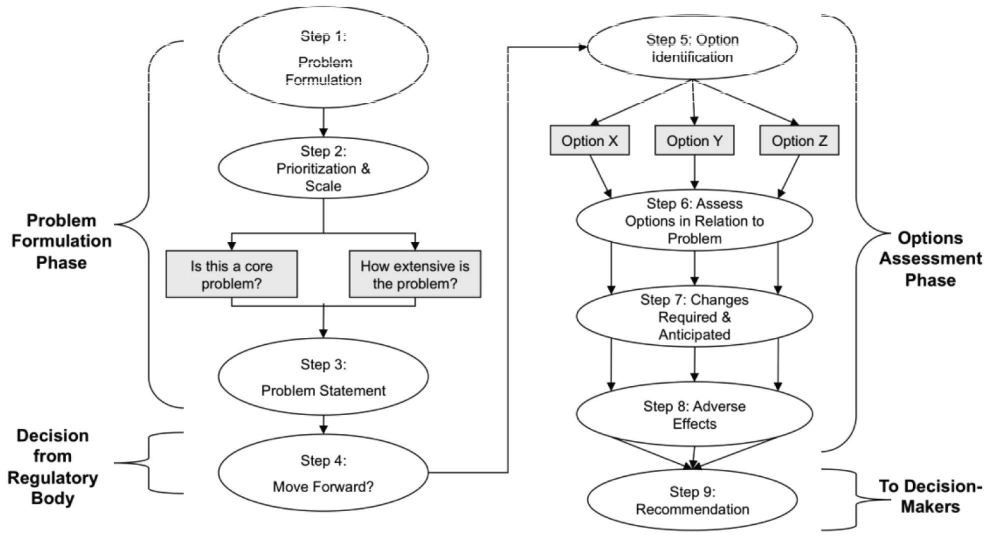
The PFOA process emphasizes engagement with stakeholders in an iterative series of stages, from identification of the problem(s) through comparison of multiple technology solutions that could be used in the future with their relative benefits, harms, and risks. It provides upstream public engagement, as opposed to consultation only when a product is being considered for release to the market.

Someone must propose that a particular technology, such as a GMO, would be a beneficial alternative to the way things are currently being done in a particular system. These proposals may come from a variety of actors, and each nation will have its own process for moving such a proposal through a common review process.

The PFOA Methodology

The PFOA process is comprised of brainstorming, discussion, and analytical components. The following sections outline the specific steps and phases involved in the PFOA process (Figure 1). The PFOA steps do not correspond uniformly to the steps or tiers in classical risk assessment because each country organizes its risk analysis differently. For example, a country may use the PFOA at a policy level for a technology needs assessment that would guide research and development decisions about nanotechnology or transgenic organisms (Steps 1-3), or the PFOA may be used for

Figure 1
Problem Formulation and Option Assessment (PFOA) Methodology for Environmental Risk Analysis of Nanotechnologies and Genetically Engineered Organisms (Nelson and Banker 2007)



environmental risk assessment of a specific GMO (Step 1-9 with an emphasis on Step 9). In addition, decisions will have to be made about whether to develop a basic PFOA involving a few essential meetings for deliberation, or a highly interactive PFOA with many meetings for exchange between stakeholders and scientists and/or regional consultations.[28]

Pre-PFOA: Initiating Proposal

Proposal to Use the Technology

First, someone must propose that a particular technology, such as a GMO, would be a beneficial alternative to the way things are currently being done in a particular system. These proposals may come from a variety of actors, and each nation will have its own process for moving such a proposal through a common review process. For example, a PFOA designed for policy-level recommendations may be initiated by the government research and development branch as a needs assessment, considering current problems and possible technology solutions, including nanotechnology. A PFOA designed for environmental risk assessment of a specific transgenic organism may be initiated by a national research institute developing a new technology or a company proposing importation of a GEO. In this case, the PFOA uses Steps 1-3 to understand the societal needs and problems that would be addressed by the new technology. These steps inform the system analysis and adverse-effects questions in the options assessment.

Decision by Policy or Regulatory Body

Before launching the PFOA process, the relevant policy or regulatory body must consider whether there is merit in moving forward to evaluate the GMO as a possible option. If the relevant body finds that there is indeed merit and the proposal to be considered is not premature, then the PFOA process is appropriate.

PFOA Process

Step 1: Problem Formulation

Formulating the problem that will be addressed by the new technology is the initial step in a PFOA that must be done by a multiple-stakeholder group in an open deliberation considering diverse perspectives. The problem is defined as an unmet basic human need that requires change. Basic human needs are most commonly identified as food, shelter, and safety. Other human interests are stakeholder-specific, such as enhanced economic opportunity, positive social interactions, and cultural richness. For example, individuals have a basic need for a certain amount of calories per day as a minimum foundation for well-being. Once the needs for food, shelter, and safety are met, an individual can expand his or her interests to include other options for well-being. These interests will differ from one individual to another and from one group to another. An example question in this step is:

- What needs of the people are not being met by the present situation?

Step 2: Prioritization and Scale

Systems research indicates the importance of first considering whose problem we are addressing (the positive question), and whose problem we should be addressing (the normative question). There may be more than one "who" identified. The next step is to determine the needs of the identified people that are not being fulfilled by the present situation. This statement of unmet needs is a statement of the problem addressed by the technology. Changing the present situation to meet those needs is a statement of the "solution" to the problem. In developing protocols for these questions, it will be essential to detail the sources of information (kind of data, opinions, etc.) necessary to answer the questions.

Representatives of stakeholder interests present their perspectives on the problem and priorities. Through the deliberative process, the needs of each stakeholder sector will be clarified. Example questions in this step include:

- Is this problem a core problem for the people identified?
- How extensive is the problem?

Step 3: Problem Statement

A problem statement is a shared understanding of the unmet need addressed by the technology and its relative importance for diverse groups of people. This stage of the multi-stakeholder process ends with a commonly agreed upon problem statement as well as articulation of differences. An assessment of the merits of continuing the process or not proceeding further informs the decision made by the appropriate regulatory group: should the PFOA process advance to develop the options assessment for addressing this problem or not? Reasons for not proceeding may be the limited scale of the problem, the lack of importance to stakeholders, or the unclear need for change, among others.

Step 4: Recommendation to Move Forward

In a policy-level needs assessment, the group will decide if the technology should be considered as a potential solution because it may address critical societal needs. If the technology is already being used, then the environmental risk assessment will not be proactive but rather reactive, focused on monitoring for any adverse effects. In most cases a regulatory authority will oversee the environmental risk assessment. An example question in this step would be:

- Do we move forward to identify options and conduct an options assessment?

Step 5: Option Identification

This step involves the identification of potential solutions for the identified problem (policy and technical options and potential alternative solutions). This is one of the most creative moments in a PFOA. It involves brainstorming about the multiple ways in which the defined problem could be solved or addressed. It is not a commitment to one option or another, but rather an open generation of ideas. It is an effort to think about a problem in a new way or suggest how new resources can be brought to bear to solve a problem. The entire group generates options without concern about defending them or endorsing them.

This step can be undertaken by the multi-stakeholder group for the initial identification of options, then a technical committee can develop a pre-report that covers information for Steps 6-8, and the multi-stakeholder group can use the document to further evaluate options. Moving through Steps 6-8 can be an iterative process, designed with multiple opportunities for exchange among the PFOA group, risk-assessment scientists, and decision makers. The number of exchanges will be country-specific with a minimum of two to three, but could be designed to provide numerous interactive meetings. An example question for this step is:

- What are the options for solving the problem?

Step 6: Assessment in Relation to the Technology and the Problem

Identification of the attributes of each option provides the data necessary for a comparative assessment of potential alternative solutions. This begins the analysis of the merits of each option and how implementation would be conducted. Example questions for this step are as follows:

Technology attributes:

- What are the characteristics of the technologies involved?
- What is the efficacy of the technology relative to the target?
- What is the cost of the technology within the production system?

Sociopolitical attributes:

- What social and economic organization will be required?
- What values or norms will be affected?
- What laws, regulations, policies, or programs currently exist that would regulate the option?

Production attributes:

- What current advantages do we have for implementing this option?
- What barriers to use exist?
- How does this option fit with current practices?

Summary of how each option might be evaluated:

- What is the current state of information and science related to this option?
- How will anticipated changes in practices affect the needs identified in Steps 1 and 2?

Step 7: Changes Required and Anticipated

Based on the identified attributes of each option, the group proceeds to define the extent of changes required to implement each option. The main focus should be on the system, but changes in the local economy, social organization of the sector, and policies will be necessary to consider as well. Changes may be necessary in order to implement the option, or they may be an indirect effect of implementing the option. Example questions for Step 7 include:

- What changes in management practices might contribute to this solution?
- What changes in the local community might contribute to this solution?
- What changes in government support might contribute to this solution?
- What changes in the structure of production might contribute to this solution?
- How do the options compare in the extent of the changes required or anticipated?

Step 8: Adverse Effects

The essential link to environmental risk assessment is identifying the potential adverse effects of the proposed options. These potential adverse consequences of solving the problem should not be more costly to society than continuing with the status quo. In general, society demands precaution when a proposed change is both adverse and irreversible. The most critical effects will be those that adversely effect the conservation or sustainable use of biological diversity in an area or that will force hardship on a disadvantaged group. By focusing on adverse effects, the group is identifying the values at risk. Example questions for this step are as follows:

- How might the potential solution affect production systems and their infrastructures?
- How might the potential solution reinforce poor practices or disrupt useful practices?
- What are the potential adverse effects/harms of these changes internally and externally to the production system?
- How will its use affect (both positively and negatively) other nearby ecosystems; the conservation of genetic variability of species and other related biodiversity; and important social, cultural, economic, or ethical values?
- What is the scale and importance of these effects?
- Are any of these effects difficult to reverse once they occur?
- How do the options compare in their potential for adverse and irreversible effects?

Step 9: Recommendation

The group can recommend an option. If no option is acceptable, then the report should clearly explain why. The PFOA report is sent to the oversight body to inform their considerations and final decision. The legitimacy of the governmental decision makers rests on their ability to reflect the interests of diverse groups within society and conduct oversight for the common good.

Key Concepts Underlying PFOA

Problem Formulation and Options Assessment (PFOA) is a methodology based on key concepts in two areas: environmental risk assessment (ERA) and governance. The foundational concepts in ERA are science-based consideration, deliberation, and multicriteria analysis. Under the umbrella of governance, concepts of participation, transparency, and accountability are most relevant. The following discussion addresses these concepts, some of which have also been addressed in critiques of nanotechnology oversight presented by authors in this symposium.[29]

All of these concepts are part of broader discussions about ERA and governance in countries around the globe.[30] Thus, they have all received extensive treatment by scholars and practitioners elsewhere. For the purposes of this article, it is not necessary to be familiar with the full scope of these discussions. However, it is worthwhile to have a grasp of each concept as it relates to PFOA. Here we provide a brief overview of each, plus an explanation of how each is embodied within PFOA.

Key Concepts Linking PFOA to ERA

An ERA is undertaken to help decision makers make socially acceptable decisions when faced with a choice involving risk.[31] A proposed activity involving risk compels decision makers to weigh the possible impacts of allowing the activity in comparison to alternative approaches, such as not allowing the activity or allowing the activity in some restricted form. It is common for decision makers to accept some degree of risk in decisions, particularly when a proposed activity offers significant benefit in addressing a societal problem. However, risk should never be accepted lightly or blindly. An ERA helps to ensure that decisions involving risk are well informed and made in the best interests of society.

Conducting an ERA always involves making judgments in the face of uncertainty. Because the judgments made in an ERA could impact critical societal decisions, it is important to clarify the options available and make the judgment as accurate as possible. There are a variety of methods and tools used in ERA to help increase accuracy in judgments. These include:

- basing an ERA in scientific knowledge, information, and analysis;
- using deliberation involving peers to determine the best responses to key questions; and
- integrating some degree of multi-criteria analysis to help compare types of information that are different or otherwise incomparable.

An additional means of increasing the accuracy of judgments made within an ERA is to deliberately include societal discussion in the process so that judgments can better respond to a society's core values, concerns, and needs. PFOA is a means of increasing accuracy in judgments within an ERA by integrating societal discussion directly into the process. PFOA also uses the same means as ERA for helping increase accuracy of judgments: science-based consideration, deliberation, and multi-criteria analysis.

Science-Based Consideration

A science-based, decision-making process uses sound interpretation of the most relevant scientific information available to inform decisions.[32] Decision makers are always challenged by the degree of uncertainty, whether smaller or larger. This is particularly true when trying to determine and weigh the consequences of a decision about a complex issue for the future. Even though science is subject to uncertainty, science can serve as an important foundation for decision-making processes because of the nature of scientific information and the way science deals with uncertainty.[33]

Science aims to determine what information about the world can be relied upon as accurate, through a systematic process of testing hypotheses about how phenomena in the world are related. Scientists generate information through the use of agreed-upon methodologies that have been developed over time, specifically to help minimize bias and promote greater objectivity. For example, scientists carefully document their work and clearly indicate the assumptions underlying it, including any known uncertainties, and then subject the work to peer review by other scientists to evaluate its quality and accuracy. These systematic methodologies can help them acknowledge the limits of their information and thus be more effective in judging the reliability of their findings. Additionally, scientific practices such as these ensure that a degree of transparency and accountability is built into science. For these reasons, scientific information can carry more credibility among some people, particularly when diverse groups of interests are involved.

There are various debates within society about science and grounding decision making in science.[34] A prominent example within governance has to do with concerns people have about the role of science in informing policy. Some question whether scientific information should be privileged over other information, especially when issues are more social or cultural in nature. Others argue that doing "good" science takes too long and that science does not provide information at the pace policy requires to keep moving forward. Some question the objectivity of science, arguing that it is a social process influenced by values and cultural norms. These are legitimate and important concerns, and the debates are ongoing. However, at least in the case of risk assessment, there is enough evidence to suggest that science can play a critical role in informing policy, including an evaluation of uncertainty. As for concerns about the pace and elaborateness of the scientific process, it is important to note that these concerns should be addressed. There are efforts to make scientific methodologies more efficient, accessible, timely, and still rigorous in their ability to produce information for policy.[35] These are the primary objectives behind the work of the GMO ERA Project mentioned above.

PFOA brings science-based information into a broader societal deliberation to help answer the socially significant questions surrounding an issue. For example, PFOA can assist an ERA with understanding the degree of acceptable risk or potential advantages that any particular option poses. Science has a history of methodology that is accepted by experts. Using the information from such commonly agreed-upon methodologies as the basis for new understanding makes these understandings more reliable. If certain scientific methodologies are challenged, a new consensus about what constitutes rigorous evaluation must evolve. For example, obtaining common agreement on a set of scientific methodologies for conducting ERAs of transgenic organisms is the overall goal of the GMO ERA Project, the effort from which PFOA has emerged. By using science to support the answers to questions framed by the values of participating stakeholders, PFOA may reduce the political fighting among stakeholders over some ecological uncertainties. Science-based information offers a mutually credible basis for discussion, leading more people to see a discussion as a reasonable dialogue rather than as positional fighting over power, which detracts from dealing with the actual issue under discussion.

Nanotechnology is an example of a technology requiring science-based consideration. This technology may not be as politicized within the United States as elsewhere,[36] but there are tremendous uncertainties about how nanotechnologies will behave, through traditionally assumed boundaries such as membranes, in the environment, and over time.[37] Science-based information in PFOA helps minimize, or at least reduce, the conflicts among stakeholders over the use of emerging technologies. Disputes among stakeholders are addressed by answering questions together supported by scientific information relating to GMOs. This grounding in science also actually helps set the stage for participants to later bring other types of information into the discussion, such as social, economic, and ethical factors. Once a dialogue has been started around scientific information, these other types of considerations can often be raised without creating as much instantaneous resistance between divergent stakeholders as discussions about value-based factors otherwise might.

Deliberation

We define "deliberation" as the means by which all participants carefully consider, as a group, all relevant sides of an issue in order to understand differences and possibly reach some shared conclusion. Deliberation differs from a positional process of assessment in which stakeholders with different interests come together to argue for their particular pre-defined positions.[38] Rather, deliberation seeks to reach a common answer, and this requires a collection of different interests coming together to openly share and listen to diverse views.[39] Deliberation differs from participation (see below) in focusing on how participants interact rather than on who should participate in the group.

Deliberation requires a collaborative process in which individuals with different interests answer questions together in order to identify and be as inclusive as possible of all relevant considerations in their process. During deliberation, disagreement and uncertainty are openly acknowledged in order to facilitate the identification of alternatives for dealing with an issue. For participants, deliberation can produce mutual understanding of different interests and where differences exist, shared learning about answers.[40] Deliberation acts as a structured means for people to exchange information, clarify their understandings, create new possibilities, and compare options. For this reason, deliberation is also capable of moving people closer to agreement on some issues and identifying differences where they exist.

Critics of deliberation express concerns about the potential for deliberation to degrade into open conflict. This is a valid concern in that a deliberation can only be effective if the atmosphere remains cooperative. Anytime conflicting interests are brought together, maintaining a cooperative atmosphere is a challenge. However, deliberation does not mean posturing or fighting. Deliberation also does not mean forcing a consensus. Differences of opinion continue to exist. Deliberation involves listening, questioning, commenting, and mutual understanding. A process intended as a deliberation needs to be designed with this in mind, by ensuring that participants have both the intent and the incentive to deliberate as opposed to simply fight.

PFOA alters traditional conceptions of ERA by incorporating deliberation. Historically, many ERAs have not gone much beyond a consultative approach: an agency might define recommendations based on conclusions from scientific evaluations, the recommendations are presented to the public, and stakeholders take positions relative to the agency's recommendations.[41] However, in this approach, the possibilities are confined by the limits of the recommendations, and typically generate adversarial positions. With PFOA, an ERA is centered on a deliberation in which stakeholders answer questions about a problem together throughout the evaluation process rather than after it has been completed. Stakeholders engage because the questions are significant and the process is beneficial to them. They can exchange information and jointly analyze topics with scientists. The idea is that in doing so, new information and organization of ideas will be brought into the process, creating new possibilities for future alternatives. As opposed to the adversarial stances that arise in a consultative approach, the deliberation in PFOA is better able to generate and add new information into an ERA. Deliberation requires stakeholders to work together, allowing for shared reflections among a broad range of interests. Additionally, new insights can be generated as stakeholders share information; something less likely to occur when stakeholders start out positioned against one another. Deliberation also allows stakeholders to identify shared points where their interests meet. Moreover, deliberation helps stakeholders clarify their understanding, such as resolving what information is relevant, and identifying areas where uncertainty exists.

Multi-Criteria Analysis Approach

A multi-criteria analysis approach assumes that PFOA will expand the scope of a traditional ERA to address wider concerns in assessing risk. The European Union regulations consider cumulative and synergistic effects, among others.[42] The National Research Council discusses effects on future generations and ripple effects.[43] Multi-criteria analysis refers to formal methods that people can use to help deal with complexity and incompatibility of views on an issue. Issues, especially related to the environment, are often complex because there are so many different factors and competing interests that people need to consider.[44] For example, a given analysis might need to consider ecological factors, social factors, ethical factors, political factors, and economic factors. Because each of these factors is valued differently by different stakeholders, they cannot be easily condensed into a common measurement, such as a dollar value, to compare them to one another. Multi-criteria analysis allows a group to create a conceptual model based on assumptions about the way something works and how different factors relate to one another. Then the group can take different and otherwise incomparable units and incorporate them into the created model to weight the units according to the assumptions built into the model. (A form of this approach is used in the case studies in this symposium.[45])

When complexity and incompatibility are not effectively dealt with in risk considerations, important information may be discarded or relevant perspectives may go ignored because they are difficult to consider or measure. For example, scientific information has certain advantages, such as greater reliability, but a disadvantage is that science might not have taken into account a people's ethical or cultural concerns. Multi-criteria analysis involves trying to bring complexity and incompatibility together. It helps people make full use of all relevant information to identify alternatives and make more informed, robust decisions that are appropriate to a particular context.

PFOA does not currently require a formal, model-based multi-criteria analysis process, but it does embody the basic elements underlying multi-criteria analysis, and it allows for the possibility of integrating a model-based analysis if desired. Like multi-criteria analysis, PFOA involves asking questions that look at changes at different scales and relationships within a system. (These might include within an organ, within the body, between people, or within an ecosystem beyond a country's borders.) As a PFOA group asks their questions, they then develop answers using the assumptions people have about the functioning of a system at appropriate scales. This involves doing analysis across different units, such as different economic, ecological, and social considerations. The key elements of multi-criteria analysis are present in PFOA, and integrating formal modeling into a PFOA is possible.

Key Concepts in Governance

Governance broadly refers to the activities carried out by individuals and institutions, public and private, to reach their shared goals and manage their common affairs.[46] Use of the term "governance" today pertains more specifically to practices intended to promote a working two-way relationship between the state and citizens, namely participation, transparency, and accountability. From the perspective of the state, governance is the capacity to learn and understand what the citizenry needs and wants, and to respond effectively and respectfully. From the perspective of the citizenry, governance is the capacity to be informed about and involved in the state's activities, and to effectively communicate and negotiate with the state about interests and concerns. There are a number of ways in which today's concept of governance is expressed in practice. Examples include efforts to involve a range of citizen perspectives in decision making, open sharing of information between the public and the state, and making sure these practices are subject to oversight and challenge. Governance is the means by which the state and the citizenry meet their responsibilities to one another and to other nations.

Relative to the concerns of this article, ERA is a state responsibility, because emerging technologies have the potential to impact society at all levels, from individual citizens to other countries. For example, with transgenic organisms, the Cartagena Protocol is meant to help individual nations manage this responsibility, and PFOA is a specific methodology designed to assist with this. As part of an ERA, PFOA transforms discussion of transgenic organisms or nanotechnology into a more horizontal, societal discussion between the government and the representatives of civil society, as opposed to a closed-door, expert-driven approach to ERA. In this way, PFOA embodies the governance principles of participation, transparency, and accountability. These criteria have been highlighted as critical components of an oversight model by other authors in this symposium and noted as lacking in several of the case studies of current regulatory systems.[47]

Participation

In governance, participation is the foundation for a two-way relationship between citizens and the state. For any given issue in society, there are various interests or stakeholders (i.e., individuals and groups who hold a stake in what happens). For citizens, participation is the means by which individuals and groups can get involved with state processes to provide input about their interests and influence decisions relating to an issue.[48] For the state, participation is the means by which governing institutions can learn about and respond to various interests.[49] Communication must be effective in both directions to support a genuine impact on policy as well as social learning. Participation helps ensure that the rights of citizens are protected, and it helps the state do a more effective job of governing. In this way, participation also helps support the legitimacy of the state.[50]

The effect that participation has on governance depends upon the extent of the citizen participation and state efforts to involve citizens. One method that has proven particularly effective in many countries is a collaborative approach in which stakeholders and state agency representatives work together to reach common agreements.[51] However, participation can occur in a number of different ways. Traditionally, participation has consisted of public comment periods, during which individuals comment on draft decisions near the end of the process through letters or public hearings. Increasingly, governments are implementing procedures that involve citizens in advisory roles, from consultation sessions at the beginning of a project, and throughout the evaluation and decision-making process. Rather than people just responding to a finalized policy, citizens instead share knowledge early in the process and shape evaluations directly by providing input and helping analyze problems and the options for solving them.

Key to participation is inclusiveness, which allows for better societal decisions. When a range of stakeholder voices, with their different backgrounds and concerns, is included in decision-making processes, decisions can be based on more complete information. Better-informed decisions generally make for better decisions. In addition, inclusive decisions can also be more durable. When all relevant stakeholders take part in the decision-making process and are allowed to express themselves or have a "voice," stakeholders are more likely to develop ownership of and commitment to the resulting decisions. Along with a voice, stakeholders must have the sense that there is the potential to contribute to the decision-making process — that their voice has the capacity to influence considerations in a decision. Through a process that provides opportunity for voice and influence, an increased ownership and commitment decreases the probability of a decision being challenged, which increases the overall legitimacy and durability of the decision. More durable decisions generally make for better decisions.[52]

A concern sometimes raised about participation is that it will take too much time or make processes too complex. There is some truth to this. Participation does take time. However, it has been repeatedly found that with thorough planning, participation can be designed to function efficiently and effectively.[53]

In risk assessment, efficiency is never a singular goal and certainly not at the expense of a sufficiently rigorous risk assessment. In fact, participation can make ERA more efficient than traditional assessment, which can get mired in prolonged legal battles and/or political conflict. Many who have had experience with participation see the points raised by these efficiency criticisms as outweighed by the greater benefits that result from participation.

> PFOA incorporates citizen voice and influence in the process of defining the problem that an emerging technological product is expected to address, in assessing the range of future options for addressing the problem, and in evaluating the relative harms and benefits.

Participation is embodied in PFOA through its involvement of stakeholders in the consideration of technologies throughout the ERA process. Traditionally, ERA is framed as a task to be carried out by scientists who assess the risks posed by whatever is being evaluated and then make recommendations to decision makers who create policy based on these findings. However, this may not be the most robust procedure for conducting an ERA. Although ERAs are traditionally based on ad hoc expert opinions and judgments, as well as scientific studies, ERAs ultimately serve a social purpose because they are conducted to inform policy. The science in ERA has an essential role in informing policy, such as quantifying the potential risk something poses to society, but it is also just one component that needs to be considered in policy making. Decision makers also need to understand information, such as the acceptability of risk, which is grounded in broader human values and societal judgments. By embedding citizen participation in the ERA process, PFOA makes

ERA more rigorous because it allows decision makers to place the science within the context of societal discussions. Through PFOA, diverse stakeholders can better inform and be informed by scientific information in the ERA. This benefits the science because it can help direct what needs to be studied, and it helps stakeholders because it allows them to directly work with the scientific information and consider its implications at an early stage in the ERA process. PFOA incorporates citizen voice and influence in the process of defining the problem that an emerging technological product is expected to address, in assessing the range of future options for addressing the problem, and in evaluating the relative harms and benefits.

Transparency

Transparency implies that governance processes are open to public review and that information is being freely shared between government and citizen. Instead of closed-door bargaining between officials and experts, a transparent system suggests that a process is visible. Traditionally, government reporting and information-sharing occur late in a process and on a more need-to-know basis. Transparency suggests that a process provides timely updates about what is happening throughout the process and that the information is available to everyone interested in receiving it, particularly the people to be most directly affected (i.e., stakeholders). This can occur through a number of different means ranging from observation and reporting procedures to participatory practices that put stakeholders in the same room together.[54]

Transparency ideally means that information is easily accessible and understandable. If information is to be useful to people, they need to be able to readily retrieve it and comprehend what is being said, especially the implications and consequences for their own lives. This is an issue of particular importance in ERA, and specifically in the ERA of nanotechnology or transgenic organisms, because ERAs often involve highly specialized scientific and technical information that many people may not have the background to adequately understand. Information accessibility and understandability are a crucial component of an effectively transparent system.

Objections raised about transparency often relate to the apparent magnitude of the tasks involved in achieving it. It is possible to pursue transparency by making information available in a few select and efficient ways. For example, increasingly the Internet is an easy way to provide information to and get feedback from different segments of society, and the Internet is relatively easy and inexpensive to use in this way.[55] In communities without Internet access, radio announcements and programs have served to inform citizens. An intent and effort to encourage and improve transparency, even in limited ways, provides a basis that can lead to further communication improvements as resources, capacities, and needs evolve.

PFOA assures transparency at a number of different levels. Foremost, a PFOA creates transparency within ERA simply through the inclusion of stakeholders in the process. So, as opposed to an expert-driven ERA that reports its findings after a conclusion is reached, a PFOA allows ERA information to be shared with stakeholders earlier in the process and at appropriate intervals. Additionally, since a PFOA group involves representatives from a range of different stakeholder interests, an ERA process can become directly visible to a greater range of the public by way of representatives reporting back to the different sectors. Moreover, for scientists and regulators, a PFOA also provides a good means for evaluating the accessibility and understandability of ERA information and processes. It offers a direct means of receiving ongoing feedback from representatives about what needs to be better explained and what information is reaching whom. The overall structure of PFOA allows for and encourages broad reporting about the ERA process to the general public; additionally, it helps make information accessible and understandable to the public.

Accountability

Accountability is created by the state's responsibilities to its citizens — the degree to which governance processes are open to external oversight and challenge by the public. Any person or institution delegated power to make decisions that will affect society is accountable to some degree to the citizens from whom that power is derived.[56] There is accountability in governance when people are free to examine and ask questions about governance actions and their consequences, and the individuals and institutions behind any given action are subject to such scrutiny.

Accountability is closely related to transparency. With greater transparency, accountability becomes more possible and without transparency, accountability is highly diminished. Accountability is the checks-and-balances aspect of government that is enhanced by openness. In fact, it is partly through transparency that a state achieves accountability. By freely sharing information about government processes in a way that is accessible and understandable to citizens, accountability is strengthened because it makes the internal work of governance visible to external parties. It is through this visibility that any external party can begin to have oversight and consider supporting an action or initiating a challenge. In this sense, like transparency, there is a practical side to accountability. To be useful for citizens, accountability practices need to be transparent, offering a clear indication of how external feedback can be provided and how such feedback will affect a given process. A benefit of ensuring accountability in governance is that it can build legitimacy. This is especially true when stakeholders are invited to participate in a process from the very beginning.

While accountability is important, those who suggest that accountability must have limits make an important point. A state exists because its citizens grant it the authority to govern. To do so effectively, a governing body needs the authority to move forward on decisions. A reasonable set of checks and balances needs to exist to encourage the larger purposes of governance, like maintaining an effective two-way relationship between the state and its citizens. However, just as accountability suggests citizens have the capacity to place checks on governance processes, there also needs to be a balancing check on citizens to ensure the state can effectively function and perform its necessary governing role assigned by the citizens.[57] Sometimes the tasks involved in governance are controversial or unpopular, and governance processes need to have some capacity to avoid becoming overly impeded by accountability. Generally this means that accountability exists within defined systems and procedures.

PFOA embodies accountability through the feedback it provides and by ensuring different interests are represented. Throughout the PFOA stages, there is feedback from various stakeholders about how they perceive information or decisions within an ERA. This might include what questions are investigated in an ERA, how potential harm is evaluated, and opinions about what a scientific study suggests about risk. As the PFOA group examines the information it receives, participants can provide feedback to administrators and scientists, which can then be used to shape the ERA process. Additionally, PFOA embodies accountability by ensuring that a breadth of interests is involved in ERA. Different stakeholders may interpret information differently. If a range of stakeholder voices is not represented in ERA (such as in an expert-dominated approach to ERA), then the process will be open to charges of bias toward particular perspectives and interests. Part of accountability is being accountable to the full spectrum of citizens. Thus, a PFOA creates legitimacy for ERA by allowing relevant stakeholders to contribute and by defining how stakeholder voices may influence the process.

> Oversight of technology is a negotiated responsibility among the producer, the state, and the citizenry. PFOA can assist in this negotiated social contract by creating an arena where science, values, and decision making come together to inform oversight through improved governance.

Development of PFOA

Since 2002, public sector scientists and agency representatives have used several workshops to vet the PFOA methodology, subjecting it to trial runs. These activities — in Kenya, Brazil, Vietnam, and Malaysia — have played a critical role in helping to refine PFOA. Each has resulted in specific findings and an evaluation of the PFOA methodology based on the unique context of each country and has produced successively refined versions of the PFOA methodology.[58]

During its initial development, the PFOA methodology underwent trial runs during workshops in Kenya, using the case of Bt maize in 2003; Brazil, using the case of Bt cotton in 2004; and Vietnam, using the case of Bt cotton in 2005.[59] A Bt crop is a genetically engineered crop that contains a gene from *Bacillus thuringiensis*, a soil bacterium that synthesizes a toxin that will kill some insects. These were not full PFOAs for the respective crops, but rather evaluations of the concepts and protocols for the PFOA model using specific cases. During these trials, participants evaluated PFOA by discussing its purpose within an ERA, testing questions from each step in its process to experience the type of discussion that might result from a multistakeholder exchange, and deliberating over how a PFOA would best fit each country's regulatory system. Later PFOA received an additional evaluation as representatives from multiple countries — Chile, Cuba, Thailand, and China — met in a workshop to consider a PFOA in an ERA for transgenic fish in 2006. Participants tested the questions, modified steps in the PFOA to fit the case of fisheries, and thought about how a PFOA would work to improve ERA and governance within their national system. Participants moved through each step, assessing its contribution to technology evaluation and ERA. These participants discussed possible answers for PFOA questions, but did not conduct a complete trial run.

The types of participants changed from one workshop to the next depending on the host planning committee's objectives, but over time the total participation provided a diversity of insights. In the Kenya workshop, participants included research scientists for Bt-corn, ecologists, rural extension workers, and non-government community development staff. In Brazil, participants were ecologists and geneticists but key national agency representatives also joined the group, including regulators from the Ministries of the Environment, Industry and Technology, Agriculture, Health, as well as scientists from national research centers. In Vietnam, the participants followed the Brazilian pattern, with the addition of a farmer's union representative.

Participants in each workshop reviewed the evaluations of previous workshops and decided whether they agreed with those evaluations. This resulted in the following summative findings about the potential for the PFOA methodology in problem analysis for genetically modified organisms:

- PFOA is a good idea for any agricultural technology, but critical for GMOs. Brazilian participants added that it should be done taking into consideration a precautionary approach on a case-by-case basis.
- PFOA proved to be particularly useful for encouraging constructive dialogue and potential agreements.
- For a successful PFOA, a nation should reduce uncertainty about GMOs when possible.
- To be effective, PFOA requires an organized and integrated database.
- The discussion of a case study provides applied insights about key issues and consensus-building areas.
- In each country, additional questions and clarifications for specific technologies will strengthen PFOA. The method has the flexibility to respond to specific situations.
- The PFOA should be organized by government authorities and discussed by a multi-stakeholder group.
- In Malaysia and Vietnam, participants suggested that PFOA serves as a good foundation for future monitoring of environmental and societal impacts of the technology.
- In Vietnam participants suggested that PFOA can assist with public education about genetically engineered organisms.

Challenges for Using PFOA in Governance of Nanotechnologies

Of course, challenges exist for the use of PFOA in the governance of nanotechnologies. These challenges relate to the technology itself, the assumptions and limitations of the methodology, and current institutionalized governance structures. PFOA was initially conceptualized for use in risk analysis for genetically engineered organisms that are difficult to define. Do transgenic processes produce organisms different from those produced through traditional breeding processes for hybrids, or through evolutionary processes that result in new species? As the workshop participants suggested, it would not matter because the PFOA methodology could assist with risk assessment of any new technology. But nanotechnologies and nanosystems are diffuse and difficult to understand. What is a nanotechnology product, and how do we frame the product in order to assess the risk? Scholars in this symposium suggest this is an important issue.

As it is currently designed, PFOA assumes risk analysis is proactive by occurring at the technology-selection stage. One challenge to using PFOA will be that nanotechnology products will be market driven — this will offer few opportunities for conscience decisions about which products to choose at a societal level. Rarely will there be oversight as to which nanotechnology product to evaluate or whether to produce the product at all. However, PFOA can be adapted to any stage of product development and commercialization. In the case of research and development of nanotechnology, especially in the case of government-led technology initiatives, PFOA could assist in selecting a technology or deciding not to invest given the viability of other options. Even if a technology is already being used, the PFOA methodology can be employed to develop a comparative monitoring and assessment program to identify emerging adverse effects on important values. Finally, PFOA is designed to evaluate environmental risk, but human health effects will be paramount for nanotechnologies due to their properties and potential uses. More work should be done to incorporate attention to these potential effects into the PFOA methodology.

Conclusion

Oversight of technology is a negotiated responsibility among the producer, the state, and the citizenry. PFOA can assist in this negotiated social contract by creating an arena where science, values, and decision making come together to inform oversight through improved governance. As documented in the articles in this symposium, there have been few opportunities in U.S. governance to implement methodologies like PFOA for other technologies. Given existing laws and administrative implementation, authors in this symposium have found shortcomings in the criteria of transparency, public input, and the capacity to bring data, values, and decision making together. PFOA, and methodologies like it, can strengthen these criteria by providing the basic functions of oversight — keeping our "eyes open" and focused on societal values, deliberating about possible harms by sharing information, asking together what do not we know, and making strategic investments in monitoring for possible adverse effects.

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