Mobilizing Science for Risk Assessment

The case of genetically modified organisms

Little systematic research has looked at how science is mobilized to inform risk decisions, especially under conditions of scientific uncertainty, as with agricultural biotechnology. To address this gap we review the case of risk assessment research priorities for genetically modified organisms (GMOs) at the United States Department of Agriculture (USDA).

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Purpose

To answer questions of mobilizing science for risk policy, we look at ten years of the United States Department of Agriculture Biotechnology Risk Assessment Research Grants Program (BRARG), the longest running, most accessible of the US biosafety research programs, and talking to academic and industry scientists involved in biotech risk research.[1] We ask what hypotheses are prioritized; when and how they change; who is represented in funding committees; what are the funding criteria; and what are the wider regulatory, research, and discursive contexts that frame their approaches.

Introduction

Risk can seem quite straightforward. Figure out how likely something is to happen, and if it happens, what effects it will have. It is a simple equation: Risk = Probability x Hazard. First, quantify the risk (risk assessment). Next, determine the policies for addressing it (risk management). Scientists do the first part, politicians the second. The system is contained. The participants' roles are clear. Facts are facts, values are values. Conventional risk analysis can be an effective technique for dealing with quantifiable issues. With high degrees of scientific uncertainty, however, this form of risk analysis breaks down. After all, if data gaps make it difficult to insert known quantities into the right-hand side of the equation, there cannot be a solution. This has been the case with GMOs introduced for commercial agricultural use.

The USDA Program recognized that the "traditional risk assessment process, which was developed primarily to assess the hazards associated with chemicals, cannot be easily applied to agricultural biotechnology. Thus, it was necessary to develop new approaches" (USDA 1995:1). How, then, did the USDA address the problem of finding "new approaches?" To answer this question, we look at information from the BRARG program to discover how the USDA characterized risks, what specific areas of research it prioritized, and what kind of research it funded. We also asked individuals involved in biotechnology risk research about their views of the process. How does the federal government, through a program that is a very small part of its overall biotechnology policy and development framework, decide what risk is and how to assess it? Who is involved? What is ignored? What is prioritized? And how do the actual "risky objects," the GMOs themselves, affect what decisions are made?

USDA and BRARG

In the 1990 Farm Bill, Congress set aside one percent of all federal biotechnology research funding for the USDA program for risk assessment research to "support science-based regulatory decisionmaking" (USDA 1995), increase baseline knowledge, and thereby improve risk assessment. Environmental and consumer groups lobbied to include this set aside. In the 2002 Farm Bill, Congress doubled the funding to two percent. The USDA program also changed over the years in two main areas: the program description has become much more detailed, and the research funded has moved from a focus on small organisms like microbes to larger organisms and ecosystems. A USDA-prepared program assessment (Hamernick 2003) summarized the funded proposals from 1992 to 2002, noting both shifts and continuities. Certain elements remained emphasized throughout; for example, viral recombination is listed in every solicitation. Studies of unintended

effects, including impacts on non-target organisms, have increased, particularly since 2000.
Later projects also focused more on broader effects and on larger organisms, like corn. Most of the research on corn has come in the last five years, despite its being one of the earliest commercial crops, reflecting the increased emphasis on unintended consequences since 2000.

BRARG Solicitations: Program Description and Evaluation

Also, the language in the solicitations has become more detailed and more specific. In 1992, the research areas section included only five sentences, one for each research area. By 2005, this section expanded to three pages. There are still only five research areas, but each has from two to seven subareas. Priorities changed as well. The 1992 solicitation highlighted the "potential to advance the safe application of biotechnology to agriculture." By 1996, the focus on advancing the application of biotechnology disappeared, and the evaluative criteria centered on "scientific merit, qualifications of project personnel, adequacy of facilities, and relevance for current regulatory issues" (FR 1995). The 1997 solicitation reflected changes based on comments the USDA received in a 1996 program evaluation. These included adding definitions for risk assessment and risk management while emphasizing that the program focus was to be risk assessment only. The 2000 solicitation defined the risk assessment process as well, saying research should address at least one of four risk assessment questions:

- hazard identification;
- probability of occurrence;
- quantifying the effects; and
- is there an effect above and beyond what might occur with an organism, with similar traits, developed using other technologies?"(FY 2000).

The solicitations have also changed in response to comments and concerns about the program as well as about risk issues related to GMOs more generally. The organisms, too, have inserted themselves into the process, as with a study that showed GM corn pollen was toxic to monarch butterfly larvae (Losey et al. 1999).
The USDA program had not anticipated this kind of nontarget effect. Losey's larvae created a surprise. Similarly, a series of contamination events elevated risk management concerns, including containment.
The 2002 Farm Bill, the next incarnation of the Farm Bill after these incidents, reflected increased concern with biosafety issues in its doubling of the amount of funding for the USDA risk research program and its inclusion of risk monitoring and risk management research as areas suitable for funding. It maintained the idea of a distinction between the science and policy processes, but the boundary between information considered important for risk assessment and risk management began to shift. Different actors insert themselves into the process and what matters changes, even within a framework that appears rigid.

Who can talk?

The list of admitted stakeholders who affect research priorities of GMOs for regulatory agencies is very limited: agribusiness or industry scientists, government or academic researchers, and NGOs. Only one to two dozen individuals – from each one of these stakeholder groups – can be counted as long-term participants in the arena of GMO crop regulation and ecological risk assessment research.
Individual ecologists and industry scientists have similar views of the environmental and human health risks of pesticides. Reducing the use of agrochemicals by replacing them with a "safer" technology is a primary motivation of scientists producing and promoting GM crops. But ecologists hold a more cautious view of the "safety," or risks of GM crops: "There is a fundamental difference ... and that is that genes are not easy to get rid of. You can get genes into a population and never get them out and so these are changes that are forever. ... It is totally and fundamentally different to introduce genes than to introduce a chemical into the environment." Divergent views between industry scientists and ecologists on the inherent risks of GM crops lead to different perceptions of the adequacy of regulatory research priorities.
It is common to hear that seed biotechnology companies have the ear of regulatory agencies. One reason this perception exists is that the commercialization process includes intensive discussion between agencies and the companies applying for product testing and commercialization. Among other things, this dialogue results in there being no applications that are rejected by the agencies; they are always withdrawn if it becomes clear that there are too many risk questions for the company to continue investing in the product. This close association has been cause for suspicion among those critical of the rigor and standards of the regulatory process.
From the companies' perspective, however, this close association with industry does not result in undue influence on research priorities within the agencies. In fact, they are remarkably in the dark about any agency initiatives to develop data or models to aid in the risk assessment of GM crop plants. One industry scientist admitted, "It's a complete void to me." While the close association between applicants and agencies certainly results in agency employees hearing a lot from industry, this relationship has not been overruling; otherwise there would have been no change in priorities to include ecological risk questions as described earlier.
Given that industry scientists barely have ecological risk assessment questions on their radar at all, it follows that these companies are not very influential in driving risk assessment research priorities; otherwise, the questions of ecological risk being pursued today would be supplanted by areas of marketing concern for industry, such as allergenicity. Some of the industry personnel interviewed admit to knowing less about some risks than others, and especially absent are questions of ecological risk. So if the changes to priorities have not been driven mainly by industry, then by whom?
All the interview subjects observed that political pushback has brought increased scrutiny to risk assessment and regulation of GM crops. There are now more checks and balances throughout the life of a GM crop line, from conception through commercialization and beyond. Those scientists and agribusiness managers involved in developing new GM crops have had to shift their focus over time: away from just genes that deliver desirable crop traits, to looking down the line at foods and at consumers.
Such changes are seen unfavorably by industry scientists whose view is that much of the increased burden is politically motivated as opposed to driven by biological rationale or science-based assessment.
The current view among these scientists is that risk assessment standards in the US

go "well beyond what is reasonable ... to show product safety." Their critique goes on to imply that regulatory agencies have been highly susceptible to political influence.

Ecologists agreed that there has been some movement toward accepting and validating questions of ecological risk, noting that the USDA has gotten more ecological, moving from outright dismissal to actually asking some ecological questions. One concrete example of how the agency culture is accepting more ecological enquiry is a shift in language from considering only field crop weeds to considering biodiversity. However, ecologists involved in risk assessment research are also critical of the progress agencies have made in prioritizing questions of ecological risk. The general consensus among ecologists is that the risk assessment analyses that have been done are fairly weak and more attention needs to be given to system-level, whole-farm studies and investigations into global impacts on agricultural systems. While agency research priorities have moved somewhat from gene flow and containment, the thinking of ecological researchers also has moved forward: accepting gene flow as imminent, containment as impossible, and moving on to evaluating the magnitude of hazards like threats to biodiversity, and thinking about management and monitoring.

Discussion

The idea of a neutral science to inform rational policy gives way to a more complex construction. The discovery of new techniques to make commercial applications of agricultural biotechnology possible created several new actors to reckon with, to adjust to, to admit. The USDA program offers a glimpse at some of the actors and processes involved, from the organisms being modified, to the transgenes, to non-target insects, to resistant pests, to agency scientists, academic scientists, environmental activists, consumers, farmers, agency officials, and politicians.

The USDA program offers a perspective into how power asymmetries are built up and what factors might be involved in breaking them down. The program may add to existing structures, but it may also offer venues for breaching them. Examining the interconnections of actors helps show how, by whom, and why boundaries are set and change. It creates a baseline for understanding the construction of risk assessment for GMOs, who/what is admitted to help build it, and who/what comes onto the construction site unannounced. Whether these unannounced presences can turn from enemies to guests within existing regulatory structures is not completely clear.[2] Isabelle Stengers in The Cosmopolitical Proposal (2005) describes a cosmopolis that offers membership, rights, and responsibilities to more than just experts, and, indeed, more than just humans.[3] Stengers suggests a slowing down in the face of resistance or a forcible slowing down by the resister. She highlights the role of the "idiot," the outsider, the one who, as with the related "idiom" speaks peculiarly, in a private language. Indeed, the Greek term "idiótes" referred to an uneducated or ignorant person, but also to the common man or layman.

In the case of scientific research for risk assessment of genetically modified organisms, the process is nearly bereft of idiots. In some ways, this is a very good thing. The scientists involved have substantial experience and insights regarding the transformation processes and organisms. The USDA also makes an effort to bring in scientists from outside the academy or regulatory agencies in prioritizing risk assessment research, as is evident from the participant lists for stakeholder workshops. It is also evident in the changes that have occurred in risk research priorities – and in that changes have occurred at all.

Nonetheless, these selected participants – "stakeholders" and "scientific peers" – will have difficulty serving as idiots, as strangers, as resistant actors. Even the opponents or skeptics of agricultural biotechnology who are involved in the process are exactly that – already involved, wrapped up, enrolled. The disciplinary interests and networks of the participants have been expanding, but are still fairly tightly centered around a few core areas (Bonneuil 2004). The question then becomes how to enroll new actors, how to take into account new perspectives, how to let in parties from outside the collective (Latour 2004).

References

1 All quotations are from interviews conducted by Joy Hagen.

2 The word "guest" comes from the same root as "hostile" – Latin "hostis," a stranger or enemy.

3 See also Latour (2004).

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