Institute for Social, Economic & Ecological Sustainability
A program of the Interdisciplinary Center for the Study of Global Change
at the University of Minnesota

Making Safety First a Reality

Final Report
of the March 2–3, 2001 Workshop

Safety First: Active Governance of Genetic Engineering for Environment and Human Health Worldwide

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Workshop Summary

The Institute for Social, Economic and Ecological Sustainability (ISEES) is pioneering an alternative approach to governing the safety of biotechnology that transcends the currently polarized debates. The Institute is proposing to combine the initiatives of business with government, consumer and public involvement in shaping, reviewing, and overseeing the formulation and implementation of scientifically reliable and socially credible safety standards for genetically modified organisms and derived products. This "Safety First" approach would address both human and environmental safety.

The objective of the Safety First Initiative is to produce a cross-industry safety program (e.g., life science, food manufacturing and food retail) for designing, verifying and monitoring the safety of agricultural biotechnology products from the lab bench through production to the dinner plate. This safety program will be credible because it will be produced through negotiations among business, government, and consumer and public interest groups. Two of the major outcomes of these negotiations would be to generate agreement on safety objectives and what is "safe enough" in the products of agricultural biotechnology. Involvement of scientists and safety experts from multiple disciplines will assure that the safety program is also scientifically reliable.

Our international Safety First Workshop convened in March 2001 indicated that a safety first approach offers the potential for a rare and extraordinary convergence among previously acrimonious participants in the biotechnology debate: 1) businesses that produce and market biotechnology products are concerned about consumer uncertainty, potential legal liability, and the skittishness of investors, which has prompted several companies to take the lead in developing components of a safety program and to welcome collaboration in developing an industry-wide safety program; 2) consumer and other public interest groups are eager to enhance the safety of products and to achieve durable public trust in safety decision-making processes in the biotechnology industry; and 3) the core principles of safety engineering have already been established in other industries.

A deliberative process, in which the Institute serves as an honest broker to bring together legitimate representatives of potentially affected parties, is integral to our work to date and in the future. Our workshop was a culmination of a year-long process during which we assembled a multi-stakeholder Steering Committee and promoted negotiations among diverse and contending groups representing business, government, public interest, consumer and academic interests. The Institute's Safety First Initiative has garnered substantial support, illustrated by the wide participation in the Workshop, the prominence of its Steering Committee, and the post-workshop planning with several organizations in designing future steps. The Institute welcomes the opportunity to discuss our Safety First Initiative with potential partners in the business, foundation, and public sectors at the national and international levels.

The core of our approach is to create an industry-wide and industry-run Safety Program that defines premarket safety design and verification as well as post-market safety follow-up in order to adequately govern genetically modified organisms (GMOs) and other products of biotechnology. This Safety Program would be comparable to the systems in place in aircraft and other industries that engineer complex systems and that pose the potential of public harm. This approach is built on the assumption that the safety program and the process by which it is developed would not result in the erosion of existing national and transnational regulatory regimes. Furthermore, credible safety approaches in other industries have demonstrated that broader governance activities, beyond government regulation, are needed to create an effective industry-wide and industry-run Safety Program (see discussion in Appendix 1). Indeed, Workshop discussions focused on these broader governance approaches to safety.

At the Workshop, discussion among national and international participants from industry, public interest groups, academia, and government revealed widespread interest in further investigating Safety First approaches for agricultural biotechnology. Although these discussions focused primarily on agricultural biotechnology products that are in the market or are approaching commercialization in the context of the

United States, participants recognized that this approach could be useful internationally for evaluating a broader array of biotechnology products being developed in both public and private research facilities.

The feedback we received at the Workshop broadly encouraged the Institute to move forward in the following directions:

- **Establishing cross-sectoral working groups to negotiate the development of a safety program was welcomed as a constructive way to move past the polarized GMO debates.** The historic experience of American industry as well as the current practices in the aircraft and nuclear energy industries showed that the focused involvement of reasonable critics in the iterative analysis and deliberation throughout the formation of safety programs is one of the most successful methods for identifying and addressing possible shortcomings of safety criteria and monitoring practices, and consequently winning durable consumer trust.
- **There was some recognition that certain companies that utilize genetic engineering have already established components of a safety program** and offer the foundation for building an industry-wide program of safety leadership. Pioneering firms have not received appropriate recognition for their efforts because they are not industry-wide and have not been fully implemented. The experiences of other industries, such as aircraft and steel, demonstrate that safety pioneers can play a critical trail-blazing role. These experiences also offer valuable models for building a scientifically sound and publicly trusted safety program for products of genetic engineering.
- **We learned about a myriad of potential benefits derived from the development of safety programs** for industry, the government and the public. The development of effective, responsive and responsible safety programs can improve public and industry-wide trust in the use of genetic engineering and other biological technologies and can improve product utility for consumers, as evidenced by lessons learned in other engineering industries. Benefits to companies and the industry derived from safety programs included decreased risks of product failure, enhanced market competitiveness, higher investment ratings, and an improvement in inter- and intra-industry relations.
- **Diverse participants welcomed the notion of safety and scientifically reliable industry standards for ensuring safety from the lab bench to the dinner plate.** The history of other large American industries (aircraft and nuclear energy industries, in particular) reinforced the conclusion that safety is a useful organizing concept for implementing rigorous environmental and human health standards in the production and use of commercial technologies.
- **Lessons learned historically in other industries provide a wealth of experience to draw upon** regarding how to design and improve upon safety programs in a new industry. Safety programs in industries that make inanimate products, such as airplanes, differ from self-replicating, biological products made by the GMO industry. Discussion revealed that there were, however, important similarities between inanimate and animate products, because inanimate products also pose complex and seemingly intractable safety issues.
- **Safety First initiatives require a system-wide analysis of the genetic engineering processes and product usage.** We learned in other industries, complex products have multiple-site damage or system-level failures that cannot be predicted by looking at single components or single instances of failure. Therefore, an effective safety program needs to address interactions between components at a systems-level using an interdisciplinary team of experts.
- **Social, economic and cultural systems contribute to the safe or unsafe development and use of a product.** We learned that there are innovative examples from other industries that bring relevant social, economic and cultural factors from these systems into a safety program, which reduces unexpected long-term costs such as consumer boycotts, expensive recalls and environmental clean-ups.

- **Some participants welcomed the Safety First approach as a mechanism for addressing the next wave of biotechnology products.** The same process that would be established for genetic engineering of organisms in agricultural biotechnology would be readily adaptable for other biotechnological innovations in agriculture (e.g., genomics) and in other industries (e.g., pharmaceuticals, industrial materials bioengineering, etc.).
- **We learned that safety is not exclusively the responsibility or concern of the biotechnology industry.** Governance activities to achieve safety is a shared responsibility—there are not certain individuals or groups of individuals who are the owners of safety in the application of a technology. Everyone shares a role in developing safety. The challenge to all the stakeholders in the biotechnology discussion, therefore, is establishing ways to demonstrate product safety that address human and environmental health in a community that shares an interest in ensuring that development, use and performance of these technologies occurs in a manner collectively viewed as safe enough.

Agenda for the Future

I. The Institute's Initiative for Implementing a Safety First Approach

The Institute is moving forward to capitalize on the exciting potential convergence of industry, consumer groups, and government around the development of an industry safety program. The work ahead is to develop a collaboration with the pioneering companies that are already committed to creating an industry—wide and publicly trusted safety program, consumer and other public interest groups that are receptive to establishing a credible safety program, and safety engineers in other industries who have prepared the safety principles and processes that can be adapted for building rigorous and verifiable safety programs in the genetic engineering and biotechnology industries.

The Institute proposes an ambitious three-pronged approach to establish an industry safety program. The three prongs are the following:

1. **Product Safety**—(a) industry-wide, product safety standards, processes, and leadership with (b) recommendations for reinforcing government policies;
2. **Safety Training/Education**—(a) biosafety professional training and certification, aimed at building a recognized safety professional career path; and (b) biosafety literacy education modules for business, government, consumers, the public, and university clientele; and (c) a forum for professional and scientific exchange (e.g., professional society on biotechnology product safety).
3. **Safety Research**—agenda for research on (preventative) safety design, verification, and monitoring.

The Institute welcomes the opportunity to discuss its agenda for establishing an industry safety program with potential partners in the business, foundation, and public sectors. These ideas are a point of departure for building a coalition of interested groups to work with us on implementing a Safety First approach to the proactive governance of agricultural biotechnology products around the world.

First Steps: Moving Forward on Industry-wide Safety Program

Building on the positive feedback from our March Workshop, we propose to move forward to establish an industry safety program for genetic engineering (and genomic) products, where the agricultural biotechnology industry plays a leading role in the development and management of the safety program. The purpose of this initiative will be to enhance safety programs in product design, verification, follow-up, and overall company leadership, focused primarily on human and environmental health. The Institute's success with its work-

shop, as well as the recent experience of the aircraft and nuclear energy industries and historic experiences in other industries, lead us to recommend organizing cross-sectoral working groups—including participants from business, consumer and public interest groups, and government agencies¾that will negotiate key elements and procedures of industry-run safety programs. These working groups will address the technical details of applying elements of a safety program to specific GMOs.

The Institute proposes to form diverse working groups to discuss the following elements that participants at our Safety First workshop reviewed:

- **Criteria Setting**—complete and scientifically reliable product safety design criteria, established and vetted through transparent interdisciplinary review at the outset of development of a new product. Safety design criteria aim to prevent the occurrence of harm, but establishing them requires going through a systematic analysis of possible harm, that is, hazard identification, risk analysis, setting the safety criteria, and risk reduction planning.

  Workshop Feedback on Criteria Setting: Our Workshop identified some of the greatest difficulties expected in the safety criteria process, including: establishing a hazard or risk in terms of environmental and human health safety; incorporating socio-economic costs and benefits into a broader safety assessment; incomplete knowledge about potential risks of GMOs; establishing criteria internationally; establishing a broad enough base of stakeholders to be effective at addressing highly complex safety problems that occur at multiple levels, along with the designers of GMOs themselves.

- **Verification**—application of the best available scientific methodologies and information, from all relevant fields, in rigorous tests that challenge the product and credibly demonstrate that the product meets the pre-set and government-approved safety criteria.

  Workshop Feedback on Verification: Participants made specific recommendations regarding what verification procedures might be comprised of, including verifying the safety program as well as the product; making verifications in discrete performance categories so that improvements needed for enhanced safety could be more precisely located and realized; making verification tests frequently; making verification data publicly available in lay language; allowing a verification rating of "unacceptable"; involving people who are on "the inside" of design of the product alongside those who are on the "outside" wanting to verify safety; developing means to share certain confidential business information that provides key safety information while maintaining the integrity of both industrial research and public interest; and developing international standards for verification of safety criteria.

- **Follow-up**—in recognition that criteria setting and verification cannot anticipate all problems, open-minded and scrupulous monitoring of the product in all its uses, with meaningful and timely corrective action upon discovery of problems.

  Workshop Feedback on Follow-up: In the workshop, participants noted that monitoring is expensive and there are no strong incentives to do it at the proper scope to assess these products in the environment. Therefore, some suggested that we should look at building in mechanisms to create incentives for better monitoring. The follow-up, it was suggested, has to be forged with the same deliberative process as the other processes mentioned before. One possibility that was raised but that requires further discussion is the establishment of an independent audit done by cross-representational task forces that could suggest safety-enhancing changes to product design and use. Follow-through on these recommendations would improve safety performance.

- **Safety leadership**—rigorously trained and independently certified safety engineers and a style of company management that fosters broad-thinking, application of the best scientific methodologies and information, self-imposed responsibility to make safe products, responsiveness to each real hazard and evidence of problems, and independent review of all aspects of the product safety program.

The Institute's Initiative starts with a foundation in current corporate practice: existing exemplary cases of safety leadership to work with in promoting and developing safety programs in the biotechnology industry.

Workshop Feedback on Safety Leadership: Historic experience as well as the presentations by safety officials in biotechnology firms indicated that the commitment of corporate leaders with safety in their own companies was necessary to create a "climate" of prioritizing safety throughout the company. Innovative companies, in turn, influenced the development of higher safety standards throughout entire industries. Some participants indicated that that the success of safety programs historically depended on their implementation by the top management and institutionalization throughout the organization, instead of being compartmentalized in a "safety wing" of the organization.

- **Certification of safety professionals**—Rigorously trained and independently certified safety engineers foster broad-thinking, apply the best scientific methodologies and information, help to focus response to each real hazard and evidence of problems, and direct independent review of all aspects of the product safety program.

  Workshop Feedback on Certification: The workshop demonstrated that historically, safety officers are primarily responsible for making sure that safety is perceived as the responsibility of every manager throughout the company. In order to staff such organizations, formal certification of safety experts trained for specific industries was necessary. Safety professionals were instrumental in the establishment of safety networks that had been developed to support safer corporate practices and install safety standards—as evidenced by the National Safety Council, National Bureau of Standards, and other organizations. Historically, some companies came to welcome these extra-corporation organizations as a means to reassure consumers and investors, and as a guard against potential legal liability. Extensive historical precedent suggested that the principle of safety professionalism is essential to an effective safety program for the biotechnology industry.

- **Government Oversight**—review of first, the safety criteria set, followed by review of the safety verification data submitted in commercialization applications for demonstration that the GMO product meets the pre-set safety criteria, review of independent audits of compliance with government-approved industry-led safety programs, scientifically sound certification and de-certification of safety professionals who would prepare safety reports, and review of industry efforts to learn from and promptly correct post-marketing problems.

  Workshop Feedback on Government Oversight: Workshop participants discussed primarily two roles for government in the formation and implementation of safety programs: securing public participation in safety oversight programs, and evaluating compliance with safety programs (e.g., based on a company's track record with verification reports, professional certification and audits). Government, some suggested, should address the imbalance of resources and access by providing information about safety of genetically engineered products, by sponsoring diverse, broad public participation throughout the various levels and stages of safety programs (including, for example, an enhanced role of the public in post-market monitoring); by verifying the participation of the public in industry-led safety programs; and by sponsoring research on preventative safety design and verification of GMOs. Participants at the workshop who had extensive experience with safety programs in industry noted that there were recent, efficient, and effective innovations regarding the government role in industry safety programs in other industries (e.g. aircraft and nuclear energy) to consider as potential models for government's participation in a safety program led by the biotechnology industry.

- **Public Participation**—mutually agreed upon involvement of legitimate representatives of consumers and other potentially affected parties in industry-led formulation and periodic updating of safety programs, and in establishment and review of government oversight.

  Workshop Feedback on Public Participation: There was considerable discussion during the workshop on the public's role in the development of a safety program for GM products and processes. Participants noted that a key component in an effective safety program was the production, sharing, and analysis of safety research data with the public. Some participants stated that the safety program should also provide some means for the public to air safety concerns after the product has been marketed. For companies that already have extensive safety programs, there were suggestions that companies openly discuss and promote their proactive safety approach in a way that would present a challenge to other companies in the biotechnology industry that have not invested substantially in safety programs.

II. Additional Participant Suggestions Regarding Safety First Approach

In addition to comments and ideas specific to the Institute's Safety First Initiative, participants made additional suggestions to improve safety of genetically modified organisms, such as enhancing:

1. Corporate ethics and leadership that builds and promotes safety programs
   - Implement safety programs quickly while the biotechnology industry is young. Success of the safety program is dependent on early adoption in order to avoid the more costly and difficult process of late-stage development, after industry practices have formed and the costs of legal battles and lost consumer trust have already been incurred.
2. Government participation in safety programs
   - Provide additional support for safety research that is applicable to products of genetic engineering and other biotechnologies.
   - Run a pilot test of new safety programs at a few companies to allow extensive public and business comment on the safety program's testing procedure and create a standard for transparency in the testing process.
   - Propose government activities that level the playing field so that all companies in the genetic engineering and biotechnology industries meet minimal industry-set safety standards. Further discussion is needed to identify fair and effective methods of achieving such a goal.
   - Develop a cooperative approach with public interest groups and industries to avoid a reliance on government inspection as the primary tool for safety assurance. Successful establishment of a proactive industry-wide safety program requires participation from the "inside" of the system.
   - Evaluate the efficacy of existing risk and safety analysis procedures. For example, once a safety program has been proposed, federal agencies could use that program to support a research effort to back-test products that have failed to perform safely in the past. By way of comparison, the Federal Aviation Administration funds research on problems that afflict the entire aircraft industry.
   - Support safety research that includes assessment of costs and benefits of biotechnology products in cultural, social and economic spheres.
3. Public participation in safety programs
   - Research public opinion and media reporting to track public understandings and confidence in genetic engineering.
   - Explore ways to incorporate consumers and civic groups in safety programs as those who are often the first to see problems with products or processes. End users, manufacturers on the factory floor,

maintenance workers, and people who live nearest to the production facilities have historically become aware of safety problems before the designers themselves, despite the designers' expertise in the structure and function of the product. This participation would enhance transparency and trust in the safety process.

- Provide educational opportunities and encourage educational institutions to enhance literacy in biotechnology science and policy issues. One of the greatest needs moving forward is to encourage high quality and informed decision-making and civic engagement in safety issues.
- Employ biotechnology centers at universities to serve broader educational goals of improving biosafety and facilitating development of safety programs for genetically engineered organisms and their products.
- Encourage foundations to play a role in the promotion of safety programs by: catalyzing innovative, outside-the-box thinking necessary to initiate safety thinking in industry; undertake investigations of issues in current trade, regulatory policies, and real-world applications with regards to GMO products and then analyze these with a safety-first approach.
- Invite non-governmental organizations to address the creation of mechanisms and structures for transparency in safety programs, and to act as independent auditors of transparency.

Schedule for Safety First Workshop

Friday, March 2

8:00–12:00 Registration Table Open

8:45–8:50 Welcome

Robert Bruininks
Provost and Executive Vice President
University of Minnesota

8:50–8:55 Introduction
Al Sullivan
Dean, College of Natural Resources
University of Minnesota

9:00–9:10 Speaker: Workshop Goals
Anne R. Kapuscinski
Director, ISEES
Professor of Fisheries and Conservation Biology
University of Minnesota

9:10–9:30 Speaker: Workshop Process
Brian Stenquist
Facilitator
Meeting Challenges, Inc.

Section 1: *Exploring Safety in Engineering*

9:35–10:00 Speaker: History of Safety First Movements
Mark Aldrich
Professor of Economics
Smith College
Author of Safety First: Technology, Labor, and Business

10:00–11:30 Panel: Learning from the History of Safety First Movements

Rebecca Goldburg
Senior Scientist
Environmental Defense

Jeff Wolt
Global Exposure and Risk Assessment
Dow AgroSciences

David Andow
Professor of Entomology
University of Minnesota

Section 2: *Safety Second*

1:10–1:30 Speaker: Introduction to Safety Second
Lawrence Jacobs
Associate Director, ISEES
Associate Professor of Political Science
University of Minnesota

1:30–3:00 Panel: Pitfalls and Successes From Other Industries

David Rosner
Professor of History and Public Policy
Mailman School of Public Health
Columbia University

Stu Hann
Airplane System Safety Engineer
FAA System Safety Designated
Engineering Representative

Gerald Markowitz
Professor of History
John Jay College of Criminal Justice

David Lochbaum
Union of Concerned Scientists
Nuclear Safety Engineer

Frank Busta
Professor of Food Science and Nutrition (retired)
University of Minnesota

3:30–5:30 Panel: Problems in the Management of Genetic Engineering Processes and Products for Safety

Peter H. Schuck
Simeon E. Baldwin
Professor of Law
Yale Law School

Leigh Henderson
Expert Toxicologist
Unilever Research

Karen Oberhauser
Assistant Professor
Ecology, Evolution and Behavior
University of Minnesota

Robert M. Goodman
Professor of Plant Pathology
University of Wisconsin–Madison
Chair, The McKnight Foundation
Collaborative Crop Research Program

5:30–6:00 Speakers: Reflections on Safety Systems

Stu Hann

Anne Kapuscinski

Saturday, March 3

Section 3: Principles of Safety

9:30–9:45 Speaker: Introductory Statement on Governing Genetic Engineering

Lawrence Jacobs
Associate Director, ISEES
Associate Professor of Political Science
University of Minnesota

9:45–10:15 Speakers: Deliberative Approaches for Safety Decision-Making

Anne R. Kapuscinski

Brian Stenquist

Section 4: Workshop Groups

10:30–12:30 Group Discussions: Solutions for Active Governance

Section 5: Plenary Session

2:00–3:30 Reporting by discussion groups

3:00–3:30 Plenary discussion

3:30–4:00 Reflections by Steering Committee Members

Steering Committee for Safety First Workshop

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Director, Consumer Policy Institute
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Appendix 1

A "Safety First" Approach to Active Governance of Genetic Engineering: An ISEES Perspective

A.R. Kapuscinski, E. E. Pullins, S. D. Hann, L. Jacobs, and B. J. Sewall

Although safety programs for inanimate products are not directly transferable to the challenge of demonstrating safety of *self-replicating, living* systems, they provide a conceptual precedent and proven framework for shaping an industry-wide safety program for genetically modified organisms (GMOs). Participants in the March 2001 "Safety First" Workshop will review the histories of safety movements and explore the lessons for governance of GMOs. How can these histories of successes and pitfalls inform the design of safety programs that achieve safer genetic engineering worldwide?

Genetic engineering has emerged at the tail end of the 20th century, claiming precision and expertise matching that of other engineering industries. But this industry has yet to fully adopt the lessons learned and scientific techniques developed by safety engineering professionals in other industries over the last century (Aldrich 1997). The maturation of these industries has been marked by credible internal industry initiatives that apply scientific methods to empirically test and verify product safety, from pre-market design and development through post-market monitoring, and incorporate government oversight and public involvement in ways that reinforce industry responsibility and responsiveness. Histories of safety work also recognize that labor organizations, consumer and public interest groups provided a motive force for safer engineering practices and more responsible, responsive governance of industrial activity (e.g., Adato et al. 1987). Some analysts have also documented organizational sources and causes of safety failures (Maurino et al. 1995, Perrow 1999). These analyses further delineate characteristics of organizational systems that enable identification of the most suitable safety management options for the technology at issue.

Consider the aerospace industry as an illustrative point of departure for strengthening safety programs in genetic engineering. Decades of debates over problems and catastrophes that could have been avoided stimulated this industry to take the lead in demonstrating the safety of its products to government and consumers, using rigorous and unambiguous government approved safety criteria (Lloyd and Tye 1982, Anonymous 1996, Hann 2000). Interdisciplinary safety thinking permeates the entire process of producing and operating components and entire airplanes, from blueprint designs through pre-market tests at key points in development and finally in ongoing post-market monitoring of aircraft performance and maintenance. The rise of these comprehensive safety programs also involved the establishment of a profession of safety engineers who collaborate with engineers in other specialties, through an interactive and interdisciplinary process, to make company products comply with industry-wide safety standards. In the United States, for example, the Federal Aviation Administration certifies and decertifies safety engineers, based on a program of training, on-the-job demonstration of competency, examinations, and in-service training at regular intervals. Government oversight then focuses on review of the safety verification data presented in applications to commercialize a new product; audits of company compliance with government-approved safety programs; certification of safety engineers; and, when problems and catastrophes occur, credible review of identified causes and corrective actions.

This history of safety work, along with histories in other engineering industries, point to common elements of industry-wide safety programs that, as Gibbons (1999) would say, are scientifically reliable and socially robust. This history also strongly supports the merits of applying an analytic-deliberative framework of decision making that involves all potentially affected parties in the private and public sectors (Committee on Risk Characterization 1996). In our view, this analytic-deliberative process should entail the airing of different perspectives and refrain from imposing a false consensus. The following outline assumes no erosion of current national and transnational regulatory regimes for genetically modified organisms. Major elements of a credible industry-wide safety program include (Hann 2001, Kapuscinski 2001):

- **Criteria setting**—complete, rigorous and unambiguous product safety design criteria established and vetted through transparent interdisciplinary review at the outset of development of a new product. Safety design criteria aim to prevent the occurrence of harm but establishing them requires going through a systematic analysis of possible harm, that is, hazard identification, risk analysis, and risk reduction planning (Table 1).[1]
- **Verification**—application of the best available scientific methodologies and information, from all relevant fields, in rigorous tests that fully challenge the product and unambiguously demonstrate that the product meets the pre-set and government approved safety criteria.
- **Follow-up**—in recognition that criteria setting and verification cannot anticipate all problems, open-minded and scrupulous monitoring of the product in all its uses, with meaningful and timely corrective action upon discovery of problems.
- **Safety leadership**—rigorously trained and independently certified safety engineers and a style of company management that fosters broad-thinking, application of the best scientific methodologies and information, self-imposed responsibility to make safe products, responsiveness to each real hazard and evidence of problems, and independent review of all aspects of the product safety program.
- **Government oversight**—thorough review of safety data submitted in commercialization applications for demonstration that the GMO product meets the pre-set safety criteria, government audits of compliance with government-approved industry safety programs, rigorous certification and decertification of safety professionals, and oversight of industry efforts to learn from and promptly correct post-marketing problems.
- **Public participation**—mutually agreed upon involvement of legitimate representatives of consumers and other potentially affected parties in industry-led formulation and periodic updating of safety programs and in establishment and review of government oversight.

The genetic engineering industry, operating in different social and ecological contexts around the world, has yet to take the lead in establishing industry-wide safety programs characterized by the elements outlined above. Instead, the dominant approach to biosafety governance involves a reactive approach of placing the burden on government or consumers to demonstrate risk. The United States, for instance, relies on a patchwork of risk-based government regulations for addressing environmental effects of biotechnology products (Office of Science and Technology Policy 1985, 1986, 1992). The focus on assessing risks occurs long after the multiple steps of design and development of a specific line of a GMO are completed. The appropriate federal government agency reviews risk assessments of the GMO at issue when a party seeks approval for field tests, which concentrate on demonstration of agronomic benefits and largely ignore rigorous testing for ecological safety. The appropriate agencies also review environmental and food safety assessments when a party seeks commercial approval, but there are important exceptions.[2] At either point, developers of the GMO product have already invested considerable resources and are under pressure to gain market approval and generate new revenue. In a further departure from credible, industry-wide safety demonstration, the United States lacks a system of post-market safety monitoring of GMOs and derived products, despite the existence of product monitoring in other engineering industries.

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[1] Some scientifically peer-reviewed tools exist to help guide this process, for instance, the *Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms* (Scientists' Working Group on Biosafety 1998) provides thorough guidance for hazard identification and more limited guidance for risk analysis and risk reduction planning.

[2] For example, for plant GMOs that come under the jurisdiction of the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, commercialization proceeds by default, once the agency approves a petition to *deregulate* a GMO that it previously regulated during the phase of agronomic field-testing. From this point onwards, the government does not pro-actively oversee the ecological effects of production or use of the GMO.

Table 1. The systematic steps of risk assessment and management, essential but not sufficient parts of an analytic-deliberative framework of risk characterization and decision-making.

Step in risk assessment and management	Key question addressed at this step
Hazard Identification	What could go wrong?
Risk Analysis	How likely is the hazard?
	What would be the consequences of realization of the hazard and how severe are they? What is the risk assessment, i.e., a matrix of likelihood plotted against severity of consequence? Each cell of the matrix should be accompanied by a qualitative assessment of the response and level of assurance needed to reduce harm if the cell's conditions were to occur. How certain are the knowledge used to identify the hazard, estimate its likelihood, and predict consequences?
Risk Reduction Planning and Implementation	What can be done to reduce risk, either by reducing the likelihood or mitigating the consequences of hazard realization?
Risk Tracking (Monitoring)	How effective are the implemented measures for risk reduction? Are they as good, better or worse than planned for? What follow-up / corrective action / intervention will be pursued if findings are unacceptable? Did the intervention adequately resolve the concern(s)?

The world needs pro-active, industry-wide, and scientifically authoritative programs that place safety first in the development, pre-market testing, commercial approval and post-market monitoring of genetically engineered organisms and products. The private sector, with assistance from foundations, national governments and multilateral institutions and with legitimate participation of affected and interested parties, needs to direct its efforts towards establishing credible safety programs. Such safety programs will necessarily operate in a global economic context, raising the challenge that their structure and operation assure effectiveness in different social and ecological settings without exacerbating existing disparities between nations in their capacities to govern genetic engineering.

In proposing the above approach to industry-wide safety programs for genetic engineering, we are well aware that safety failures in particular applications of some genetically modified organisms will still occur due to complex interactions among people's behavior, the technology, human social institutions and environmental factors. Genetically engineered organisms are themselves complex, their potential interactions with and effects on the environment and human health are diverse and complex, and their present-day management—from the idea stage to final use—involves diffuse sites of leadership and responsibility. Acknowledging this complexity while focusing on making safety the first priority will require integrity, pragmatism and wide participation. We, at ISEES, welcome critical review and suggested changes to this proposal. What motivates us is a desire to achieve the best attainable level of scientifically reliable and socially robust pro-active safety governance of the GMO industry.

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Appendix 2

Safety First Workshop Participant Perspectives

The Workshop aimed to allow an airing of different perspectives on the ISEES proposal for an industry safety program, not to reach a group consensus. We invited the 140 participants at the workshop to submit their own perspective on the workshop for publication in the Safety First Final Report. Below is a compliation of the written individual perspectives submitted at the end of or after the Workshop. Additional comments regarding the workshop process and feedback are posted on the isees website, www.fw.umn.edu/isees.

◆

Safety First—good, proactive word choice that:

a. Stress safety and a much more slow, cautious perspective on GMO.

b. Utilizes language of business/economics as Steve Young may have eluded to —that is the importance of framing the argument—word choices *would* be most persuasive given words like safety, risk, hazard, liability, etc.

c. Shouldn't be confused by opponents' claim as to argument being neo-Luddite.

◆

- What about pushing for a GEIS (generic environmental impact statement) for GMOs—medium for many voices.
- Safety First—very important to establish concern paradigm so other problems can be viewed through this lens of not *knowing everything* (uncertainty)...caution in the air of uncertainty.
- For the future, I would second the idea to expand even more from a line of experts. The panel was incredibly diverse (accolades!) with all good insights to lend to this pile of clay issue of GMO, though it would be interesting to hear from the makers (more than Jeff Wolt, who seems to be a risk analyzer), like biotech scientists (gene-splicers) from Monsanto, Novartis; perhaps a panelist on *intellectual property rights*; a *farmer*; *traditional plant breeder* (hybrid or OP).

◆

I like the Safety First approach and believe it could really help. My main concern is that I don't see a coherent GMO "industry" but an amalgam of very big companies with lots of small companies, driven by venture-capital in hopes of being bought by the big companies. I trust the regs less with these little companies. The history of Safety First suggests that only in the face of *great* harm are such programs adopted.

◆

Safety First is fine. But here is my consumer problem and that of many folks I talk with: Corporations/Monsanto has, starting with rBGH/rBST delivered GE food to my grocery store to the tune of 60–80% of all food on the shelves now...without public debate or notice. With great arrogance and malice for my opinions and concerns. They have overtaken the conventional food system without regard for anyone but their own greed.

◆

My perspective on the workshop was that it was an awesome opportunity for a mixture of people from different disciplines to come and offer their views on mechanisms of safety. It was greatly facilitated and provided a civil environment for debate and discussion. The utilization of historical events as analogies as to what not to do was brilliantly used to further illustrate the need for safety protocols.

◆

One key message that I didn't have the chance to express: To publicize and promote "Safety First," ISEES will need to definitively demonstrate its benefit by working with a leading company, perhaps best a crop biotech firm. This would be like US Steel taking the leading role in worker safety. Make an alliance with a leading company, and work to incorporate safety first in development of a useful, environmentally friendly product, publicizing as appropriate key accomplishments in the Safety First process. Should this be a multinational, this transcending on national boundaries (and national regulatory systems) would do much to internationalize the findings, procedures, and accomplishments of Safety First.

◆

A key stakeholder missing was farmers. They are the first link in the food chain.
The talk on monarch butterflies was very incomplete. Forty studies have been done and the net result is that Bt corn pollen concentration on milkweed is far below the level that may have a negative effect.

◆

It seemed that a common goal of the workshop was to figure out the system or process through which all affected parties could reach consensus on setting appropriate safety levels for genetic engineering. While indeed an admirable goal, it seems an unattainable goal. Instead, it seems that the effort should focus on describing the system or process for ensuring that all affected parties can provide meaningful input that is sincerely considered by the decision-makers. If decision-makers had thorough understanding of all views, they would be better equipped to make decisions that addressed these views. For example, the decision-makers might chart out a strategy that included elements to appease the minority.

◆

Thanks for all your hard work and organizing of the conference. I really can't thank you enough. My participant perspective is: there is always the need for all decisions being made democratically, that is, by consensus (thumbs up = agree; thumb to side = stand aside; thumbs down = block), through synthesis of ideas. A review of *consensus process* may be advisable since none of us has a lot of experience with participatory direct democracy. Perhaps it's too late to fashion the Workshop Report into a consensus development conference with the results disseminated to the community and beyond, perhaps even the newspaper (which happens not infrequently, as you know).

The conference *included* experiences with airline, nuclear and other industries, but didn't include safety concerns of more closely related technologies such as prescription drugs and dietary supplements. For example, food additives' safety is regulated by the 1958 amendment to the 1938 Food, Drug, and Cosmetic Act, which essentially uses the *precautionary principle.* Should the FDA have declared GM foods as food additives, which do require testing, rather than as generally recognized as safe (GRAS) category, which doesn't require testing? Not much was said about the distinction between *agricultural biotech* and *medical biotech,* the latter case posing much more *harm* to the public. How reliable and valid is recombinant DNA methodology itself, given the implication from the human genome project's unexpected findings that we humans have only one-and-one-half times the number of genes as the earthworm? This finding may invalidate the "central dogma" of "DNA⇢RNA⇢protein" as a one-way causality. Some *popular education* in this area would be useful.

Suggestion:

1. Establishment of a food and drug safety commission that is independent of the FDA, analogous to the F.A.A., which sets standards for airline industry, and the National Transportation Safety Board, which investigates airline accidents and can find fault with the airline or with standards of the F.A.A. and suggest changes when necessary. Such independence is essential to ensure objectivity and to avoid conflicts of interest. It is important that such a body be independent of both manufacturers and the FDA, both of which have clear conflicts of interest.
2. Because biotech issues compete with many other issues, networking and relationship building among grassroots, scientific groups, etc. is essential. Step One could be developing an email directory, or list-serve

for different groups to endorse, sponsor, petition, redress, issues statements, mass actions, etc. Communication format could be Dr. Horn's cognitive maps, cartoons, and timelines.

3. A suggestion from the "Designing Research for Change" conference was to establish or build on any existing interdisciplinary clearinghouse that connects and allows the community groups and the University of Minnesota researchers to interact on an equal basis, where people can plug in without fear of elitism and selective discrimination, and analyze our realities for democratic social change.

I was expecting to discuss research methodology as it pertains to Safety First, such as relative risk, absolute risk, confidence intervals and other levels and strengths of evidence as we do in *evidence-based medicine.* I'm glad we discussed the issue in the overall context, which showed the uphill battle that building democracy is, and where the starting point is.

◆

The Safety First approach needs to be implemented as soon as possible. This workshop has really clarified the meaning and necessity of such an approach to decision making of GMO use and release. I would suggest the Precautionary Principle as a crucial element of the Safety First approach. Release of GMOs into the environment, and the use of food ingredients from GM sources, raises concern about environmental and health effects. Scientific information on environmental and health effects is limited, both from the industry and from public research institutions. No long-term studies to elaborate environmental and health effects of GMO use and release have been performed. Scientific literature contains hypotheses and preliminary results indicating possibly adverse effects. Particularly, questions related to secondary effects on non-target organisms and unwanted gene transfers have been discussed. Genes, and parts of genes, may be spread by cross-pollination and by horizontal gene transfer. Secondary effects may also arise from the expression products of the transgene(s), or the insertion(s) of transgene(s) may cause pleiotropic effects of the recipient organism. The obvious lack of data and sufficient information calls for application of the Precautionary Principle (PP). Application of the PP in the decision process demands that scientific uncertainty is made explicit. Hence, the PP addresses the importance of scientists' responsibility, both with regard to clarification of uncertainty and communication of uncertainty to the public policymakers.

Application of the PP entails, as a Safety First approach, a shift from a reactive practice that demands scientific evidence prior to preventative actions. However, the relation of the PP to science-based risk assessment is causing considerable controversy. The disputes among scientists center on the issue of whether the PP should be involved when proofs of a cause-effect connection is lacking. Many scientists have learned that initiatives to involve the PP in some instances may imply calling a halt to research. The opposite might, however, often be the case and acting on the basis of PP might automatically trigger research. In addition, might the precautionary measures to be taken in given situations vary from restricted ones, based on requirements to monitor impacts or to label the product, or to delay action as by moratoria.

Thank you for a very interesting workshop!

◆

1. Some scientifically peer-reviewed tools exist to help guide this process, for instance, the Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms (Scientists' Working Group on Biosafety 1998) provides thorough guidance for hazard identification and more limited guidance for risk analysis and risk reduction planning.

2. For example, for plant GMOs that come under the jurisdiction of the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, commercialization proceeds by default, once the agency approves a petition to de-regulate a GMO that it previously regulated during the phase of agronomic field-testing. From this point onwards, the government does not pro-actively oversee the ecological effects of production or use of the GMO.