



Safety First:

Making It a Reality for Biotechnology Products

Final Report of the First meeting of the Executive Advisory Board
and Steering Committee of the Safety First Initiative

Convened by
Institute for Social, Economic and Ecological Sustainability

Weisman Museum
University of Minnesota
April 22, 2002

Co-Sponsored by:
Pew Initiative on Food and Biotechnology and
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An Agenda for Action: Making Safety a Credible Priority

Around the world, a primary concern of consumers and scientists is the safety of development and use of genetically engineered agricultural products. The recurrent questions are by now familiar: Will genetically modified organisms irreparably harm genetic diversity? Will they introduce potential harms to human health and ecosystems? Public opinion research suggests that anxiety about the safety of genetically engineered products is now widespread in the United States.

The Safety First Initiative proposes a “safety first approach” toward genetic engineering and other innovations in biotechnology as a means for transcending the currently polarized debates and producing a publicly credible and scientifically reliable industry-wide safety program. Concerns about biotechnology can be addressed with a bold solution - making safety the first priority in the development of biotechnological products.

The Safety First Initiative proposes a transparent process that incorporates a representative range of responsible perspectives on biotechnology in a series of working groups to design the standards for a publicly credible industry-wide safety program. This representative and consultative process would deliver the kind of independent and verifiable recommendations that would be credible with consumers and other groups, a credibility that has thus far eluded those biotechnology companies that have made serious efforts to ensure safety. Involvement of scientists and safety experts from multiple disciplines will assure that industry safety programs are also scientifically reliable. This representative and transparent process offers a path toward effective, responsive, and responsible safety programs that can improve public trust in the multiple industries involved in genetic engineering and other biological technologies.

The purpose of the April 22, 2002 meeting was to initiate a creative and collaborative process among the Executive Advisory Board, the Steering Committee, and the Institute for Social, Economic and Ecological Sustainability (ISEES). Together, meeting participants explored the rationale for a safety first approach and the practical possibilities of creating it. This meeting, and subsequent discussions among participants, are shaping the next steps in making the Safety First Initiative a reality.

I. Designing an Industry-wide Safety First Program

The Initiative is proposing a model for pro-active, industry-wide biosafety standards. This pro-active approach uses science and representative public deliberation to: anticipate and resolve biosafety issues as far upstream of commercialization as possible before developers seek regulatory approval of a product; stress public-private partnerships beyond government regulation; and produce biosafety policies that are financially and administratively feasible. Towards this end, the Initiative proposes moving forward to establish the standards and framework for an industry-wide safety program for genetic engineering (and other biotechnology) products, using a process that utilizes the principles of safety engineering that have been successful in other industries.

A. The Focus and Process for Making Safety First a Reality

Making safety first a reality will require the formulation of broad standards for the entire industry and for genetically engineered products; it will also require individual firms to adapt these standards to their own operations and products. At the meeting held April 22, 2002, the Safety First Initiative's Executive Advisory Board and Steering Committee discussed the difficulties of formulating standards for all genetically engineered products. Discussants agreed that the Initiative should begin by focusing on the safety issues for two classes of products that are currently under development: non-food uses of food crops and food uses of genetically engineered fish and other aquatic species. Concerns about the environmental and human health safety, and related regulatory complexity, of non-food uses of food crops (1,2,3,4) and food uses of genetically engineered fish and other aquatic species (5,6) have been an increasing focus of discussion for scientists, policy makers, developers and consumers. These products clearly promise benefits to a large number of consumers, while posing new and complex safety management issues - a situation that highlights the urgency for addressing the formulation of safety standards in these two cases. In both cases, development programs are such that, in some instances, safety programs can be developed at the earliest stages.

Workshop participants agreed on a process for making safety first a reality in these classes of products that would serve as a model for safety standard development programs in the industry. The Initiative would formulate industry-wide standards (first two levels in Figure 1) by forming representative working groups. A two-step process will produce the standards and framework for an industry-level safety program.

First, the Steering Committee, with oversight from the Executive Advisory Board and the operational assistance of the Institute's staff, will constitute four Working Groups, assign them responsibilities, monitor their progress, review the standards they produce, and ultimately approve and release agreed-upon industry standards. Figure 2 shows the relationships among the leadership and the working groups; the Executive Advisory Board and Steering Committee will oversee and interact with the Working Groups, and the Working Groups will communicate among each other. Figure 3 shows a deliberate sequence for establishing, staffing, formulating, and releasing industry-wide standards over time.

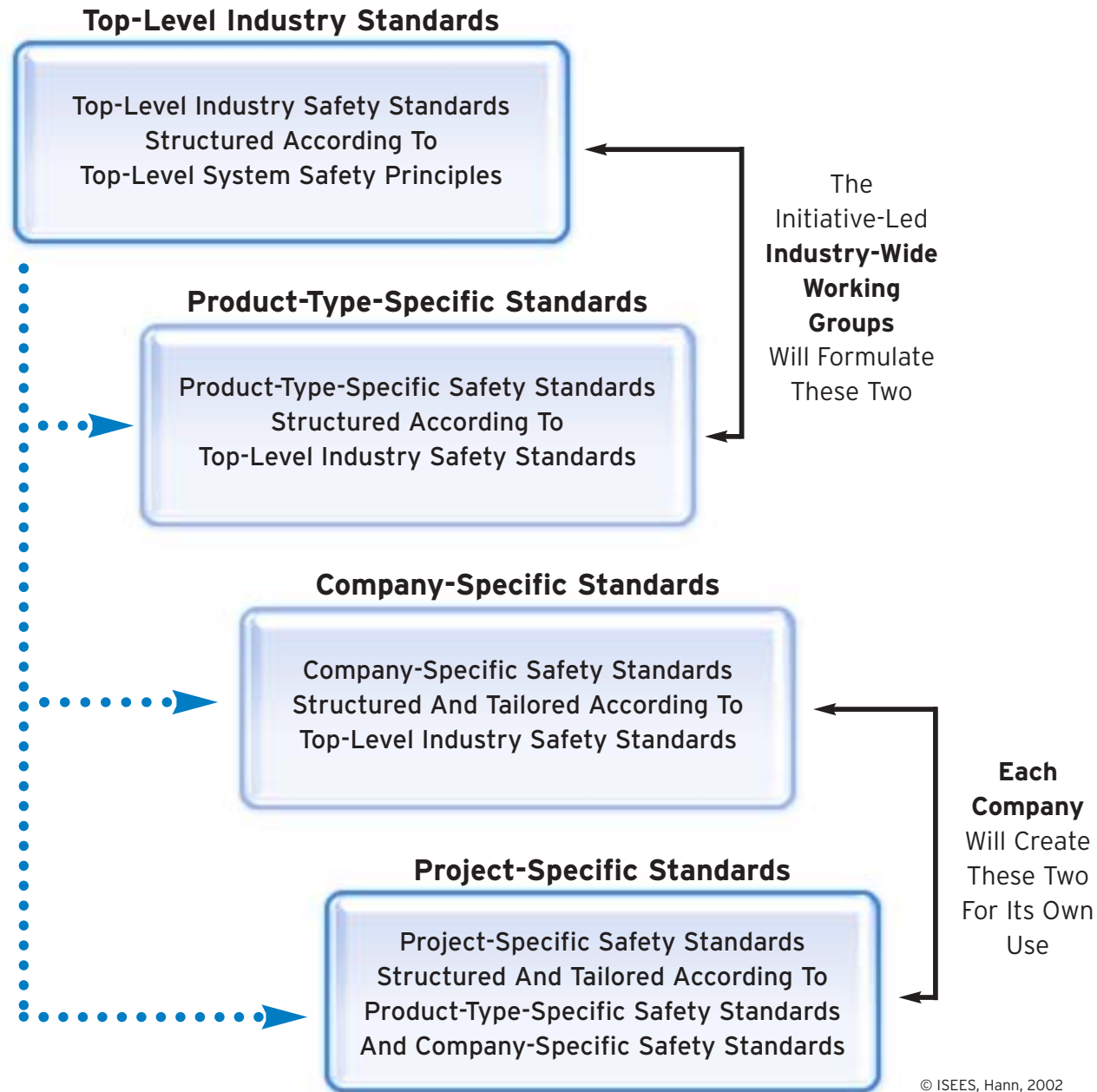


Figure 1. The goal of the Safety First Initiative is to formulate the framework and standards for a hierarchy of safety standards at four levels, from industry top-level down to project-specific, for each of the essential elements of safety.

Second, the Steering Committee and four Working Groups will focus on these essential elements of safety programs in the two selected cases:

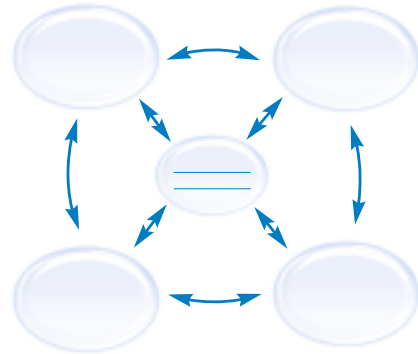
- a. Criteria setting:** Designing safety criteria requires systematic analysis of possible harm, which involves the rigorous identification of hazards, the assessment of risk, and planning to reduce and control risk. Establishing a complete and scientifically reliable set of safety design criteria rests on two requirements: establishing rigorous criteria at the outset of development of a new product and independently validating that criteria before it is used.
- b. Verification:** Rigorous tests need to be designed that will fully challenge the product and credibly demonstrate that the product meets the pre-set government approved safety criteria. Designing these tests requires the application of the best available scientific methodologies and information, from all relevant fields.
- c. Follow-up:** The processes of setting criteria and conducting tests to verify that the product meets safety criteria cannot anticipate all problems. Open-minded and scrupulous monitoring of the product in all its uses is also required; the discovery of problems needs to be followed-up with meaningful and timely corrective action.
- d. Safety Leadership:** A well-designed set of safety criteria, verification process, and follow-up procedures will only be meaningful if they are implemented consistently and properly. This requires responsive and responsible safety leadership in three areas. The first area is the establishment of rigorously trained and independently certified safety engineers who would be valued employees of industry firms. The second area is the encouragement of a company management style that fosters broad-thinking, application of the best scientific methodologies and information, self-imposed responsibility to make safe products, responsiveness to evidence of real hazards and problems, and independent review of all aspects of the product safety program. The third area is the creation of a framework for managing the application of industry-wide safety standards, including an independent audit function.



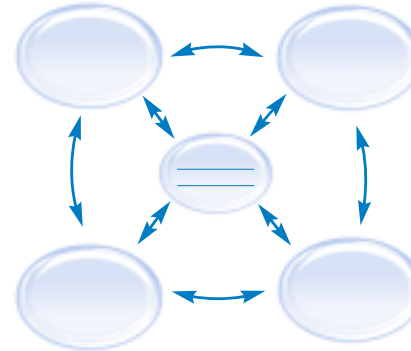
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Figure 2: Relationships among the Leadership and Working Groups.

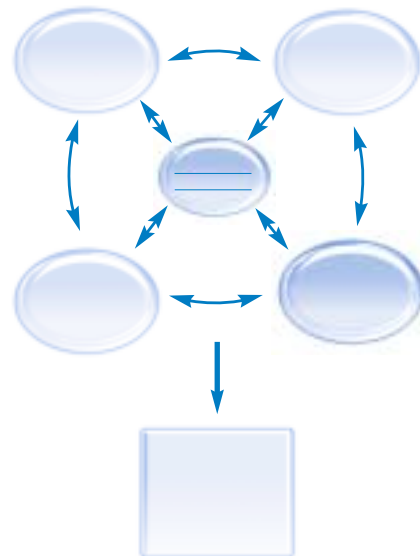
Step 1:
Initial Working Groups Are Chartered
And Begin Deliberation



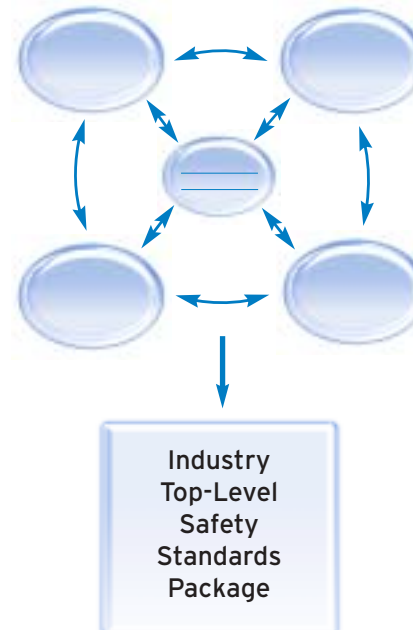
Step 2:
All Working Groups And Sub-Working
Groups Are Staffed And Are
Deliberating



Step 3:
Steering Committee Approves And
Releases First Working Group's
Standards



Step 4:
Steering Committee Approves And
Releases All Working Groups'
Standards



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Figure 3: Sequence for creation of industry top-level safety standards.

B. The Safety First Initiative Team

The Initiative integrates five critical components of a process for producing industry-wide safety standards. For the two cases selected, each component would incorporate important leaders and assume critical responsibilities. Here are the five components:

a. The Safety First Initiative Executive Advisory Board:

Members: Leaders from diverse private and public sectors who are committed to furthering the Safety First Initiative

Charge: Provide oversight of the Steering Committee and the Initiative's outcomes

b. The Safety First Initiative Steering Committee:

Members: Leaders from diverse private and public sectors who are committed to furthering the Safety First Initiative

Charge: Provide oversight of the four Working Groups and their output: establish charters, identify members, review outputs, advise on group negotiating processes when needed

c. Safety First Initiative ISEES Staff:

Members: Staff and consultants in the Biotechnology & Governance Program at ISEES

Charge: Provide administrative and managerial support and guidance on safety engineering and safety principles to the Working Groups, Executive Advisory Board, and Steering Committee

d. Safety First Initiative Working Groups:

Members: Stakeholders, including technical experts, from diverse interests whose knowledge is necessary to create the industry-wide Safety First standards and framework for genetically engineered products

Charge: Create and negotiate key elements, standards, and procedures of an industry-wide safety program for genetically engineered products

e. Safety First Initiative Sub-Working Groups:

Members: Stakeholders, including technical experts, from diverse interests whose knowledge is necessary to create the Safety First Initiative's detailed standards for genetically engineered products

Charge: Create and negotiate key elements, standards, and procedures of an industry-wide safety program for genetically engineered products

II. Proposed Architecture of the Safety First Initiative Working Groups

The Initiative will form four Working Groups and Sub-Working Groups that will work under the supervision of the Steering Committee, and oversight of the Executive Advisory Board, to conduct the negotiations over particular safety standards (Fig. 4).

A. Working Groups and their Sub-Groups

The Initiative will establish four Working Groups whose domains correspond to the essential elements of safety programs, each with two Sub-Working Groups focused on one of two product classes: non-food uses of food crops and food uses of genetically engineered fish and other aquatic species.

a. Criteria Setting Working Group

Objectives: Establish complete and scientifically reliable standards and processes for setting product safety design criteria, aiming to prevent the occurrence of harm

Design a systematic assessment of possible harm and corresponding safety criteria for each Sub-Group product class within global criteria setting structure

b. Verification Working Group

Objectives: Design rigorous verification and test standards that fully challenge the product and credibly demonstrate that the product meets its safety criteria

Design structure of verification tests for each Sub-Group product class within the global verification standards

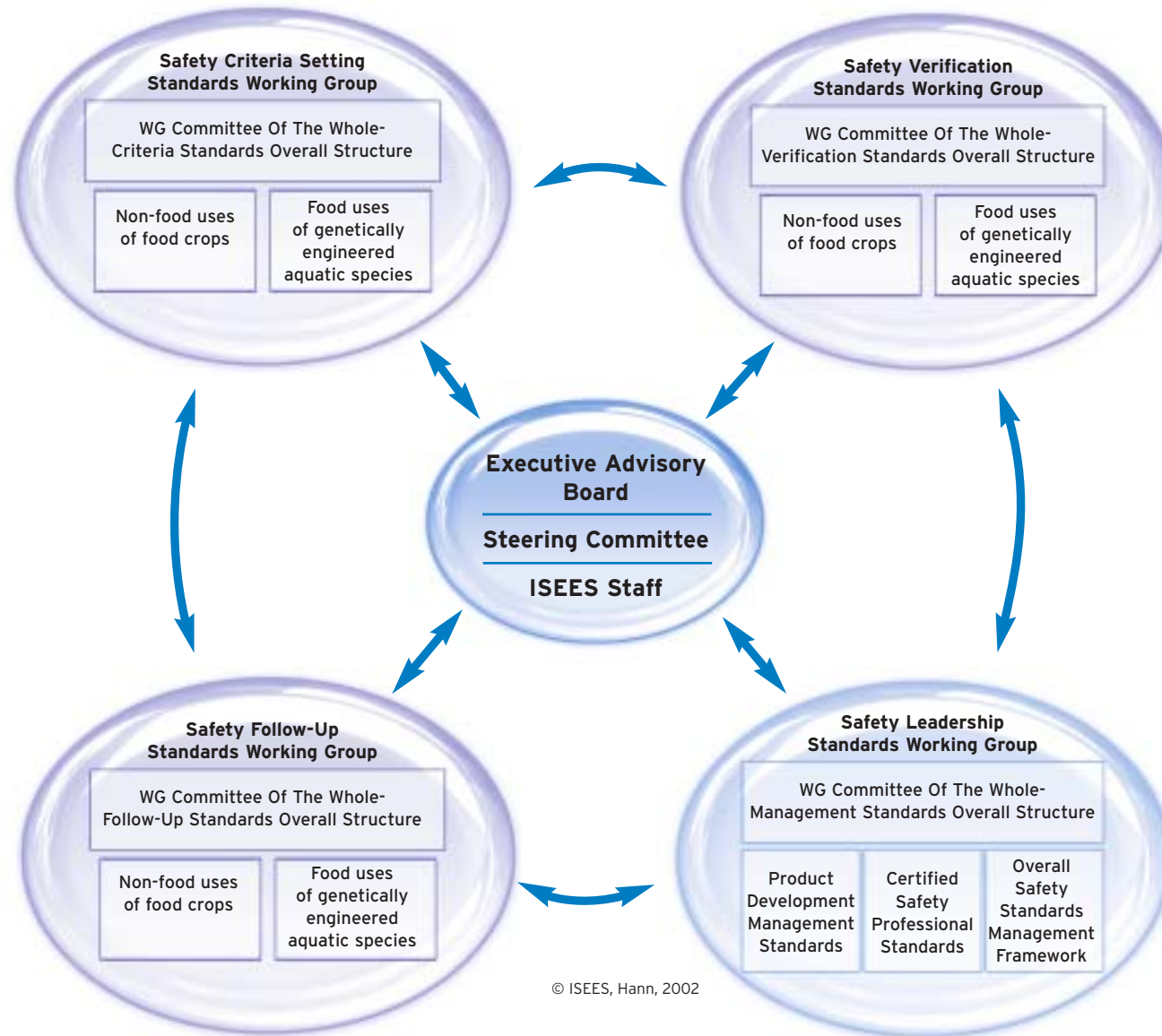


Figure 4: Proposed architecture of Safety First Initiative Team with different Working Groups and Sub-Groups.

c. Follow-up Working Group

Objectives: Design rigorous follow-up standards that will ensure effective tracking of the safety performance of the product in use and meaningful and timely corrective action in response to safety problems

Design structure of rigorous follow-up methods for each Sub-Group product class within the global follow-up standards

d. Safety Leadership Working Group

Objectives: Propose structure and standards for safety professionals program

Present structure of corporate management standards that foster support for and implementation of product safety program

Create an overall, industry-wide safety standards management framework

B. Responsibilities of the Working Groups

The Working Groups are the engine for producing the industry-wide safety standards. In particular, the Working Groups will have three responsibilities:

- a. Produce safety standards in accordance with each Working Group's charter, other Working Group's standards, and system safety engineering principles
- b. Coordinate with Sub-Groups and with other Working Groups, and report on progress to Steering Committee
- c. Submit safety standards, when completed, to Steering Committee for approval

III. Next Steps for Safety First Initiative

In the next six months, ISEES staff, in conjunction with Steering Committee members, will invite individuals to participate in the Safety First Initiative as members of the Working Groups. Shortly thereafter, ISEES staff will organize the inaugural Working Group meetings, bringing the Executive Advisory Board, the Steering Committee, and the Working Groups together.

As the steps above unfold, the Executive Advisory Board and ISEES leadership will focus on securing the continuing organizational resources necessary to sustain the Safety First Initiative through the next phases of implementation.

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