Biotechnology Safety

Enabling the Safe Use of Biotechnology: Principles and Practice and *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests*

Reviewed by Sheldon Krimsky

Biotechnology earned its place on the global environmental agenda at the United Nations Conference on Environment and Development (UNCED) held in 1992. Agenda 21, the plan of action that grew out of UNCED, specifically called upon the community of nations to ensure the safe and sustainable use of emerging biotechnologies. This rapidly expanding area of science, with widespread applications in agriculture, mining, pharmaceuticals, manufacturing, and human diagnostics, was of special concern both for its potential benefits and its potential risks. Two recent reports—*Enabling the Safe Use of Biotechnology: Principles and Practice*, by the World Bank, and *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests*, endorsed by the elected leadership of 11 scientific societies and distributed by the Institute of Food Technologies in Chicago—attempt to provide guidance to nations seeking to carry out UNCED's Agenda 21 by developing protocols for the safe use of biotechnology.[1]

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Mention of the World Bank, of course, conjures up images of an international agency exporting the economic agenda of the industrialized countries to developing nations. In recent years, however, criticism of the Bank has raised its awareness about the role of environmental quality in economic development and led it to publish a series of reports entitled the "Environmentally Sustainable Development Studies and Monograph Series." *Enabling the Safe Use of Biotechnology* is the tenth such report. Its stated goal is to provide "a practical guide for policymakers and research managers who are responsible for making decisions on ensuring the safe use of modern biotechnology."[2]

The report is a curious mixture of recommendations for governmental institutions that wish to address the "concern" about biotechnology risks and claims that the risks are, for the most part, negligible or entirely hypothetical. Among its recommendations for an "enabling environment" to exploit the full potential of biotechnology, the report cites "policies, regulations, and enforcement mechanisms for the control of introductions, methods for field testing, export and import, and commercial releases of organisms with novel traits."[3] The report recommends establishing a national biosafety committee, a national technical advisory committee, and institutional biosafety committees at the sites of experiments related to risk assessment, updating guidelines, monitoring workers and the environment, and training personnel. These recommendations represent a composite of measures already adopted by countries like Canada, Australia, and the United States. In many cases, however, developing countries will probably be the testing ground for new biotechnology products. The report neglects to address the important concern that such nations lack the infrastructure and expertise to establish appropriate social guidance systems for biotechnology. It

also gives no credible sources of evidence regarding the risks associated with biotechnology, leaving the reader with the impression that the risks are hypothetical while the benefits are real.

Enabling the Safe Use of Biotechnology asks what the impact on biodiversity would be if all the products currently being researched were put on the market. It argues that the most important factor contributing to the loss of biodiversity is the conversion of native lands to agriculture as a result of population pressure. New, higher yielding crops, it claims, could prevent habitat loss by increasing the efficiency of existing agricultural land. However, the report neglects to discuss the role of biotechnology in spreading monoculture, in fostering larger, corporate-style farms, and in providing the scientific and economic rationale for the development of chemical-seed conglomerates. The preferred alternative is to modify indigenous crops so that they are more productive, more adaptive to local conditions, and less demanding of chemical inputs.

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Another section of the report addresses precautions against the uncontrolled introduction of organisms with novel traits. However, the suggestions given for hazard assessment are either strictly formal, dealing with the responsibilities of various officers and committees, or highly generalized canons that avoid the complex questions involved in evaluating genetically modified organisms. They do not indicate, for example, how to address the problem of transgenic crops that can spread herbicide-resistant genes to weedy relatives or how to evaluate the impacts of genetically engineered microorganisms on microflora prior to their actual release.

The report states, however, that "accumulating evidence from studies in greenhouses or contained animal facilities, as well as in field trials, indicates that many of the perceived risks are remote."[4] Nowhere does it refer to the growing number of real or probable hazards discussed in the literature. In 1995, the United States and the members of the European Union gave several companies permission to market herbicide-resistant soybeans and corn, cotton, and potato seeds that had been genetically modified with an insecticidal toxin from the soil bacterium *Bacillus thuringiensis* (Bt). The widespread cultivation of such crops, however, could accelerate insect resistance to Bt and compromise its use as one of the most popular biological control methods in sustainable and integrated pest management (IPM) agriculture.[5] Environmental groups are concerned that the development of herbicide-resistant crops is a retreat from sustainable, low-chemical-input agriculture.

Last year, it was reported in the *New England Journal of Medicine* that a gene transplanted from Brazil nuts (a known allergenic food) to soybeans carried the allergen to the soybeans.[6] This provides concrete evidence that genetically modifying plants can have human health effects. Current U.S. regulations, however, leave it up to companies to assess the risks of transgenic crops using a set of federally provided guidelines.

Equally worrisome, a study published in *Nature* in March 1996 reported that genes from transgenic oilseed rape (*Brassica napus*) spread rapidly under field conditions to wild relatives. According to the study, 42 percent of the non-genetically modified weedy relatives located near the engineered crops had developed herbicide tolerance by the second generation.[7] This clearly demonstrates that transferring the genes for herbicide tolerance to food crops could create new strains of weeds that are themselves resistant to herbicides, which would necessitate the use of newer and less benign herbicides. Another example of too much of a good thing can be found in crops that have become resistant to sulfonylurea herbicides. Because this class of herbicides has low toxicity to humans and other animals but high toxicity to plants, it might appear to be a desirable innovation. However, there have been reports that low concentrations of sulfonylurea disrupt reproduction in nontarget crops. As a result, expanded use of these chemicals around the world could decrease the productivity of such crops and alter the makeup of natural plant communities and wildlife food chains. These examples are not silly hypotheticals but rather distinct possibilities supported by preliminary data.

On the plus side, *Enabling the Safe Use of Biotechnology* does offer some useful recommendations for a national regulatory framework that incorporates risk assessment of transgenic organisms. For example, it suggests that empirical data on novel organisms be part of risk assessments. This is not typically the case: A study of the U.S. Department of Agriculture's assessment for the first generation of transgenic crops showed that experimental data on the novel organisms played an insignificant role in the evaluation.[8]

The critical issue is not the risk assessment guidelines themselves, but how many crops and microorganisms will be exempt from the assessment process. With more than

2,000 approved field-trial releases of genetically engineered plants worldwide and little or no research on the plant-environment interactions,[9] the prevailing regulatory view (release first and wait until a problem arises) is playing Russian roulette with nature.

The second report, *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests*, recommends some principles for regulating genetically modified plants. Among these are three that lie at the heart of the current debate about the release of genetically modified organisms into the environment: First, that the level of risk a plant variety poses should be determined by the characteristics of the plant, not our lack of familiarity with the innovation, the source of the introduced genes, or the method by which the genes are transferred to the plant. Second, that genes and the substances encoded by them that confer insect resistance are not pesticides and thus should not be subject to the Federal Insecticide, Fungicide, and Rodenticide Act. And third, that concepts such as GRAS (i.e., "generally regarded as safe") that are applied to food additives should also be applied to new varieties of plants. (Substances with this classification are exempt from the standard risk assessments required by the Federal Food, Drug, and Cosmetic Act.)

As these principles suggest, *Appropriate Oversight* argues that the U.S. Environmental Protection Agency's (EPA) proposals for regulating "plants with modified inherited traits" (a euphemism for transgenic plants) are too burdensome. It builds on a 1987 study and subsequent reports by the National Academy of Sciences that state there is no evidence that unique hazards exist either in the use of recombinant DNA techniques or in the movement of genes between unrelated organisms,[10] and, as a consequence, that the properties of a plant product and not the methods of production should serve as the criteria for regulation.

EPA has made an effort to frame its regulations in accordance with the Executive Office of Science and Technology Policy's scope principles for the oversight of biotechnology, which were issued in 1992.[11] These principles state that any regulations pertaining to "genetically modified organisms" should be based exclusively on the characteristics of the product and should not assume that a process that modifies hereditary traits is inherently riskier than any other. They also state that planned introductions of biotechnology products should not require oversight unless scientifically based information indicates that the risks are greater than those of existing practices utilizing the parent organism. However, EPA's rules still give special consideration to genetic transfers across wide species barriers. Furthermore, because current legislation is not specifically tailored to biotechnology, the agency has had to retrofit existing rules for chemical agents to use in the oversight of microorganisms and plants. (The authors of *Appropriate Oversight* fail to appreciate the fact that any regulations an agency issues have to be grounded in specific legislation.)

Appropriate Oversight is a detailed, scientifically informative, and accessible report that provides an alternative perspective on EPA regulation of biotechnology products. But it gives only one side of a complex scientific and regulatory story and should be read alongside a work that presents the other side.[12]

Although both reports are informative and provide important perspectives, they pay little or no attention to the global divisions over the introduction of bioengineered organisms into agriculture that have become quite apparent in recent years. Nongovernmental organizations throughout the world have called for greater regulation, risk assessment, and labeling of genetically engineered products. Some, like the Third World Network, have developed their own scientific consensus positions, which recommend more extensive ecological studies on a case-by-case basis before large-scale releases are approved.

The two reports are clearly more concerned that regulations will slow innovation than they are that the rapid deployment of thousands of novel organisms will disrupt natural systems and derail efforts to achieve a sustainable agriculture.

In the next few years, the critical balance between innovation and protection will be set for generations to come. The United States is now aggressively using international trade agreements to break down the barriers to its biotechnology exports imposed by some European countries. While theoretically autonomous, in practice each country's regulation of biotechnology reflects the pressures of trade harmonization and open markets. The two reports reviewed here are clearly more concerned that regulations will slow innovation than they are that the rapid deployment of thousands

of novel organisms will disrupt natural systems and derail efforts to achieve a sustainable agriculture or that the overwhelming public demand for labeling bioengineered food crops has been ignored.

Sheldon Krimsky is professor of urban and environmental policy at Tufts University. He may be reached at the Department of Urban and Environmental Policy, Tufts University, Medford, MA 02155 (telephone: 617-627-3394; e-mail: skrimsky@emerald.tufts.edu).

NOTES

1. J. C. Doyle and G. J. Persley, eds., *Enabling the Safe Use of Biotechnology: Principles and Practice* (Washington, D.C.: World Bank, 1996); and *Appropriate Oversight for Plants with Inherited Traits for Resistance to Pests* (Chicago: Institute of Food Technologies, 1996).

2. Doyle and Persley, note 1 above, page 1.

3. Ibid., page 16.

4. Ibid., page 13.

5. S. Krimsky and R. Wrubel, *Agricultural Biotechnology and the Environment: Science, Policy and Social Issues* (Champaign, Ill.: University of Illinois Press, 1996).

6. J. A. Nordlee, S. I. Taylor, J. A. Townsend, L. A. Thomas, and R. K. Bush, "Identification of a Brazil-Nut Allergen in Transgenic Soybeans," *The New England Journal of Medicine* 334 (1996): 688–92.

7. T. R. Mikkelsen, B. Andersen, and R. B. Jergensen, "The Risk of Crop Transgene Spread," *Nature* 380 (7 March 1996): 31.

8. R. P. Wrubel, S. Krimsky, and R. E. Wetzler, "Field Testing Transgenic Plants," *BioScience* 42, no. 4 (1992): 280–99.

9. M. G. Paoletti and D. Pimentel, "Genetic Engineering in Agriculture and the Environment," *BioScience* 46, no. 9 (1996): 668.

10. National Academy of Sciences, Committee on the Introduction of Genetically Engineered Organisms into the Environment, *Introduction of Recombinant-DNA Engineered Organisms into the Environment: Key Issues* (Washington, D.C.: National Academy Press, 1987); and National Research Council, Committee on Scientific Evaluation of the Introduction of Genetically Modified Microorganisms and Plants into the Environment, *Field Testing Genetically Modified Organisms: Framework for Decisions* (Washington, D.C.: National Academy Press, 1989).

11. Office of Science and Technology Policy, "Exercise of Federal Oversight Within the Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment," *Federal Register* 57 (1992): 6753–62.

12. See, for example, J. Rissler and M. Mellon, *The Ecological Risks of Engineered Crops* (Cambridge, Mass.: MIT Press, 1996).