Biotechnology and the Environment

Research Needs

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BIOTECHNOLOGY AND THE ENVIRONMENT

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BIOTECHNOLOGY AND THE ENVIRONMENT

Foreword

This book discusses research needs relating to the effects of biotechnology on the environment. The material presented is based on, and the result of, a workshop convened by the American Association for the Advancement of Science and the U.S. Environmental Protection Agency at Berkeley Springs, West Virginia in 1984.

The manner in which the release of genetically-altered organisms will effect the environment, and indeed whether they should be released at all, has been a subject of great interest for many years. That it has become a highly controversial issue recently is only a small indication of the enormous advances being made almost daily in the field of biotechnology. Many questions must be answered and numerous problems solved–among them how to monitor and control the environmental effects of the release or synthesis of novel organisms. This should be a valuable document for those concerned with the release of genetically-altered organisms to the working or general environment.

The book presents a workshop summary and four papers which cover major areas of concern–environmental effects, health effects, monitoring and quality assurance, and control technologies–as each of these applies to research needs in biotechnology and the environment.

The information in the book is from *Research Needs in Biotechnology and the Environment,* edited by Gilbert S. Omenn of the University of Washington School of Public Health and Community Medicine and Albert H. Teich of the American Association for the Advancement of Science, Office of Public Sector Programs, prepared for the U.S. Environmental Protection Agency by the American Association for the Advancement of Science, November 1985.

The table of contents is organized in such a way as to serve as a subject index and provides easy access to the information contained in the book.

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Many people contributed to the workshop and to this report and deserve thanks for their contributions. Among them are, of course, the paper authors, and other workshop participants, who gave generously of their time and whose names are listed in an appendix at the end of this report, and, especially, the workshop chairman, Gilbert S. Omenn. EPA officials, led by John R. Fowle III and Morris A. Levin, were most supportive and helpful in arranging and conducting the workshop and in preparing this report. We also appreciate the assistance of the consultants who prepared the two commissioned papers following the workshop, Marvin Rogul and David Glaser and his colleagues. Finally, many current and former AAAS staff members contributed their time and energy to the project in its various stages, including Jill H. Pace, Barbara Dworsky, and, especially, Mary I. Haddock.

NOTICE

Contents and Subject Index

PART I
WORKSHOP SUMMARY

PART II
PAPERS

Part I

Workshop Summary

WORKSHOP SUMMARY

Prepared by Gilbert S. Omenn, Workshop Chairman and
Albert H. Teich, Project Director

A. Introduction and Background

Approximately 60 people, including outside peer reviewers and EPA and AAAS staff, participated in the AAAS/EPA Biotechnology Workshop at Coolfont Conference Center, Berkeley Springs, West Virginia, 29 April - 1 May 1984. As noted by EPA Assistant Administrator for R & D, Bernard D. Goldstein in the opening session, the charge to the workshop was to assess the scientific needs and researchable problems facing the agency as it prepares to deal constructively and responsibly with proposals that might lead to release of genetically-altered organisms to the working or general environment.

The project began with a workshop on 14-16 December 1983 at EPA. Attendees at this meeting included over 50 representatives of EPA program offices (including Pesticide Programs; Toxic Substances; Policy and Resource Management; Drinking Water; Solid Waste; Water; and Air, Noise and Radiation), the Office of Research and Development, and EPA field laboratories. AAAS's role in this first meeting consisted of assisting EPA with the meeting's logistical arrangements and suggesting means of facilitating session deliberations. Most importantly, AAAS involvement in the first workshop facilitated translating the results of that meeting into the basis for the second workshop, as described below.

Based on the deliberations at the first workshop, EPA laboratory and office representatives prepared documents suggesting research approaches which might be necessary to support EPA regulatory efforts in four major areas, which generally paralleled the working groups from the first workshop: health effects, environmental effects, monitoring and quality assurance, and containment and control technologies. Taken as a whole, the four papers constituted elements of a draft biotechnology research agenda.

The second workshop, held at the Coolfont Conference Center in Berkeley Springs, West Virginia, 29 April to 1 May 1984, was convened to subject these papers to an intensive peer review by researchers from outside the agency and by EPA staff, to further define the agency's research plans, needs and capabilities, evaluate them, and modify them to produce an appropriate and feasible research agenda. Names of participants in the Coolfont workshop may be found in the Appendix.

Workshop participants were selected to represent a range of backgrounds, and affiliations. EPA laboratory representatives and headquarters staff brought to the meeting their knowledge of relevant research areas, their understanding of laboratory capabilities, and their own scientific interests and expertise. They represented the interests of those who will actually carry out the research planned at the workshop.

Program office staff represented the perspectives of the clients of users of the research. They brought to the meeting their knowledge of

EPA's regulatory mission, their understanding of its needs and priorities, and their views of what needed to be learned in order to carry out the agency's mission and address its priorities.

The outside experts, drawn from universities, government agencies and industrial firms, lent to the deliberations their special expertise regarding scientific aspects of the problems under discussion, their knowledge of other research being conducted in these areas, and their informed opinions regarding the feasibility of proposed efforts.

Participants were assigned to each of the four working groups, and were sent draft documents in advance of the meeting. Each participant brought to the workshop a written review of the paper closest to his or her area of expertise. The workshop began with a plenary session at which summaries of all the draft documents were presented. Brief scenarios of possible EPA involvement in biotechnology, and a summary of the NIH experience were also presented to stimulate discussions.

Most of the meeting was devoted to discussions in four workgroups (panels) corresponding to the four draft papers prepared by EPA scientists:

(1) "Proposed Biotechnology Research Plan for Test Methods Development for Risk Assessment of Novel Microbes Released into Terrestrial and Aquatic Ecosystems" (environmental effects group);

(2) "Proposed Biotechnology Research Plan for Test Methods Development for Risk Assessment of Health Effects Associated with Biotechnology" (health effects group);

(3) "Proposed Biotechnology Research Plan for Monitoring Systems and Quality Assurance" (monitoring and quality assurance group);

(4) "Proposed Biotechnology Research Plan for Environmental Engineering and Technology" (control technologies group).

Plenary sessions were held at the beginning, middle and conclusion of the workshop. The discussions throughout were lively and provocative, going to the root of EPA's role, as well as providing a rigorous review of the proposed data gathering and research projects.

Following the workshop, revised drafts of the papers were prepared and circulated to all participants for comment. Reviews were also solicited from a variety of other individuals who had not attended the workshops. Following this review, it was determined that two of the revised papers did not serve the purpose intended by the workshop organizers, and AAAS and EPA staff agreed to commission new papers to better address the issues. These replacement papers were submitted in draft form and reviewed by EPA and AAAS staff subsequent to the workshop. A preliminary report was prepared by AAAS immediately following the workshop, highlighting the main ideas of the papers and identifying areas for EPA emphasis and attention. Part one of the final report, contains a AAAS summary of the key recommendations and concerns expressed at the workshop. Part two includes revised versions of two of the workshop papers and the two replacement papers: "Monitoring Techniques for Genetically Engineered Microorganisms," by David Glaser and colleagues of Harvard University, and "Biotechnology

Health Risk Assessment Research Plan," by Marvin Rogul of The Rogul Group and John R. Fowle III and David Kleffman of EPA.

B. Key Concerns and Recommendations

Workshop deliberations resulted in identification of a number of areas of concern and recommendations for EPA research activities. No attempt was made to force consensus among workshop participants, but several items were considered high priority for EPA attention. These are enumerated below, and are followed by highlights from the discussions of each working group.

(1) EPA's primary emphasis in biotechnology research should be on potential environmental and health effects of deliberate or accidental release of genetically-altered organisms to the environment. EPA's mandate establishes its lead-agency role in this important area.

(2) Attempts at risk assessment should begin with well-selected specific cases, including, especially, the applications being developed within EPA to control certain pollutants or contaminated sites. A major regulatory need, particularly for OTS, is predictive risk assessment models for products of biotechnology, analogous to the structure-activity relationship models employed for predicting chemically induced effects. It

is, however, premature to attempt development of a general predictive model for assessing the risks of release of genetically altered organisms. Because of the vast number of biological possibilities for biotechnology products (e.g., organisms, vectors, gene sequences, products), it is not possible to predict potential effects without specific knowledge of a number of important parameters. Thus, experience must be gained first on a case by case basis.

(3) Much information pertinent to EPA's biotechnology activities may already be available. The currently available literature should be systematically reviewed, analyzed and used to focus and set priorities for EPA's future efforts. This review will also help foster complementary efforts, and avoid duplication of work performed by other organizations. The scope of the search should include published microbiological and public health information, NIH/RAC sponsored risk assessment efforts, and reports on recent and current molecular biological and ecological studies. The literature should be continuously monitored and collaborative efforts with organizations such as NIH/RAC should be encouraged to keep EPA abreast of developments in the field.

(4) There is a clear need to enhance EPA's molecular biology capabilities and its in-house expertise in biotechnology. A strategy should be developed for gradual, long-term development