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Final Report of the UNIDO/MBI Workshop

Regulations and Safety Aspects of Engineered Plants and Microbial Species

(Project No. UC/RLA/89/205)

by

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and
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The workshop was held during December 5 - 7, 1989 at the Center of Marine Biotechnology, Maryland Biotechnology Institute, Baltimore, Maryland, U.S.A.

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1. Introduction.

The development of the new techniques of genetic engineering, including recombinant DNA techniques, has opened up many possibilities for altering on purpose the genetic makeup of animals, plants, and microorganisms. With these exquisite tools, researchers have been able to clarify many of life's mysteries, including those pertaining to the genetic control over metabolism, growth, development, and reproduction. Further, the advanced biotechnology techniques are increasingly being used for applied ends. For example, the pharmaceutical industry has been able to harness biotechnology techniques to produce new and unique drugs and diagnostics; and in agriculture crops have been developed that possess enhanced characteristics, including improved disease and pest resistance, better tolerance to physical stresses, and enriched nutritious compositions. Soon, the chemical industry will mass produce bulk chemicals via biological processes and genetically engineered microbes will be employed to clean up the environment by degrading persistent pollutants.

One consequence of the applied sector having adopted advanced biotechnology techniques is that genetically engineered microorganisms are being used on a large scale in industry, while in agriculture transgenic plants, microorganisms, and insects are under development. Successful research and development give rise to products, and these inevitably have to be tested in the field. The prospect of extensive field tests of genetically engineered organisms and products produced via genetic engineering has given rise to concern about possible hazards these activities may pose to humans and the environment.

Responding to concerns voiced by scientists and the informed public, several developed countries have formulated more or less elaborate statutory frameworks of laws and regulations designed to protect the health and safety of workers, the public, and environment. Regulatory frameworks typically includes laws and regulations controlling activities in agriculture, health, industry, food, and the environment. Each is tailored to fit the specific conditions of the country in question; nevertheless, the underlying scientific basis for regulations remain the same wherever they are promulgated. However, this basis is still in its early developmental phase because data on potential risks posed testing activities is insufficient or lacking. Further, many countries do not possess the expertise or resources to develop their own regulatory frameworks.

In Latin America, the majority of countries are conducting extensive research in health and agriculture; some research units employ genetic engineering techniques in their work. This number is certain to grow as an ever increasing number of Latin American scientists receive training in the new biotechnology techniques.

For example, the Regional Biotechnology Programme for Latin America and the Caribbean has an extensive training component. As more research institutions adopt genetic engineering techniques, and as they develop genetically engineered microorganisms and plants, there will be a need to elaborate statutes and guidelines for the safe testing and applications of its products. Aware of this problem, Latin American scientists and representatives from governments and regulatory bodies of the region have publicly expressed the need to elaborate measures for making certain that biosafety techniques will be applied in field experiments and applications. Within the framework of the UNIDO Regional Biotechnology Program, during its Board of Directors meeting held in 1989, the official representatives of the participating countries identified this subject as a priority for the region and urged UNIDO to take action whereby a set of biosafety guidelines appropriate for the region may be elaborated for dissemination to the governments.

In order to lay a basis for the rational elaboration of appropriate regional guidelines, as a first step it was proposed to organize a three day workshop on biosafety in cooperation with the Maryland Biotechnology Institute, University of Maryland. During the course of the workshop, specialists from industries, regulatory agencies, and universities, would provide conferees with information relevant to all aspects of biosafety, including risk assessment techniques, means of communicating risk information, and elements for elaborating rules and guidelines. The primary objectives of the workshop were to inform selected scientists and industrialists from Latin America governments of: (1) current methods of calculating risk associated with work where genetically engineered organisms are used; (2) issues involved in communicating information about possible risks to governments and the public; (3) elements required for formulating national laws and/or regulations for managing research and applications where genetically engineered organisms are used; and (4) specific examples of cases where products and organisms have been tested in the field.

2. Workshop Activities.

A. Day One

Following introductory remarks, the workshop began with descriptions of the biotechnology industry. The general topic of issues in safety was then approached by considering three of its subareas; pre-release considerations, field activities, and risk assessment. These considerations were followed by presentations dealing with specific methods (models) for data analysis, data sources, and public perception of the risks and risk analyses. All presentations made during the first day were video taped. The specific topics presented were as follows:

i. Biotechnology industry.

The representative from biotechnology industry discussed the general scope and potential of the industry, safety in the laboratory and workplace, and safety issues pertaining to the testing of new products.

ii. Basis for risk assessment.

Two speakers discussed the many aspects of pre-release considerations, which comprise the process a company must go through before testing, including pre-planning, site selection, preliminary data collection and information needs. Specific activities in conducting a field test includes site activities, protocol development, monitoring, containment, and data analysis. The speaker on risk assessment described how to assemble detailed information about the engineered organism so that a framework for a decision about releasing or using the organism can be developed.

iii. Data analysis and presentation.

The fifth speaker described the use models for estimating the outcome of field trials, including their availability, utility and credibility; he was followed a speaker who explained the compilation of information requirements for testing and sources of data for planning, releasing and evaluating a field test. The final presentation of the day dealt with the perception and acceptance of biotechnology risk by the public and its representatives and how to efficiently communicate information about risks to the public.

B. **Day Two**

The second day was devoted to three general sessions; a description of existing regulatory structure in the U.S., a discussion of the costs of regulation of the industry, and the presentation of the first of a series of four case studies dealing with the actual development and registration of a particular product.

i. U.S. regulatory structure.

The rationale and description of existing regulations for the release of engineered plants and animals was presented from the perspectives of the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, and the U.S. Federal Drug Administration. The subject was concluded with a fourth speaker describing attempts to coordinate the efforts of the key agencies.

ii. Biotechnology regulatory burden.

The burden and impact of regulations pertaining to biotechnology was examined both from a government perspective - the cost of implementation - and from an industry perspective - the cost of compliance.

iii. Case study.

The second day's formal presentations were concluded with the seventh speaker presenting the workshop's first case study, which focussed on the development and testing of a fish with enhanced growth characteristics.

Day Two concluded with a dinner for the participants during which the speech "The New Biology in Latin America: An Alternative Viewpoint" was presented.

C. **Day Three**

Day Three had three parts. During the first, three case studies were presented. The second part included descriptions of the regulations of European countries and the involvement of intergovernmental organizations in the safe practice of biotechnology. The third part was a round-table during which the participants discussed biotechnology regulations in Latin America and voiced opinions on regional regulatory needs.

i. Three case studies.

The three case studies consisted of discussions of genetically engineered Rhizobia for use as crop enhancers; a bacterium which has been altered to enhance its insecticide ability; and the field testing a recombinant viral vaccine.

ii. Regulations in the international arena.

Two speakers described and discussed biotechnology regulation and safety research in the international arena, including select European countries and the European Communities, as well as relevant activities by UNIDO, UNEP and WHO. Unscheduled representatives from the U.S. Agency for International Development discussed that Agency's concerns about biotechnology testing in countries receiving AID support.

iii. Round-table on Latin American regulations.

The session opened with a presentation that provided an overview of Latin American regulations that bear on biotechnology. It was followed by a round-table during which workshop participants discussed their personal experiences with regulations and stated their ideas as to needs and specific

activities for Latin America in the area of biotechnology regulations (see below).

3. Discussion

The last session of the workshop consisted of a round-table discussion on the status of regulations that affect biotechnology research and industry in Latin American countries. Since workshop participants originated from 12 of these countries, the scope of the discussion was wide and many salient comments were made. The following paragraphs sum up the important points made during the round-table:

* Researchers in developing countries are usually knowledgeable about training possibilities in the various scientific areas they work. Thus, they know where they could apply for training in cloning techniques, monoclonal antibody construction, DNA sequencing, and so on. However, they are often not aware of courses or training in topics that are not directly related to the carrying out of research, but that are nevertheless important to their work. Specifically, they are mostly unaware of safety considerations relevant to performing research, the carrying out of field testing, product testing, and safe biotechnology industrial practices. The consensus among the participants was, therefore, that the UNIDO/MBI initiative to offer this workshop was important, timely, and necessary.

* The development of biotechnology safety practices, risk assessment, field testing, and product testing is fairly well advanced in several developed countries. Developing countries can and should learn from this experience, but then need to develop their own regulations or rules taking into account indigenous concerns and conditions. However, the information and knowledge basis for such development does not exist in most countries. This type of workshop helps develop such a basis.

* Living organism, especially microorganisms, do not respect political boundaries. Therefore the potential exists of a mishap or negative side effect originating in one country affecting other countries. Mishaps are more likely to arise in countries where regulations or rules governing safety practices in laboratories and industry are inadequate, missing, or ignored. This fact argues for nations harmonizing rules and regulations that govern these activities, and enforce them at some agreed on level of strictness. Intergovernmental organizations possessing the requisite expertise should take the initiative for bringing such a harmonization about.

* To some extent, harmonization of testing schemes and regulations depends on the availability of appropriate data to regulators, researchers, and industrialists. Data pertaining to field trials, dispersion of microorganisms and plants in the environment, long terms effects of biotechnology products, and so forth is especially important. Intergovernmental organizations could act a clearing houses, providing data available on these subjects to those who need it. They could also publicize available information sources, including data banks, and collect ecological data on individual countries and regions that could be useful to researchers and regulators when they plan field tests.

* Regarding testing and issuance of biotechnology products, the appropriate intergovernmental organization could take the initiative to develop and put into effect a tracking system for future tests and products. Such as system would be useful to government regulators, researchers, and industrialists because it would allow them to assess the possible long-term effects that products may give rise to; incrementally improve over time on testing schemes; avoid duplicating testing already done; and harmonize testing schemes between nations.

* It is difficult to strike a balance between, on the one hand, the freedom of researchers to perform research and industrialists to test and market products and, on the other, governments to take steps to ensure that research and testing is carried out safely and products are not harmful. Striking an equitable balance between these at times competing demands will take a coordinated effort by these three groups. Such an effort will to a large extent be dependent on the availability of adequate information (as mentioned above) and the availability of risk assessment and risk communication experts (trained at workshops such as this).

* Governments should recognize that after they promulgate rules and regulations, laboratories and industries will inevitably have to devote significant resources to make certain these are followed. Therefore, while governments are formulating rules and regulations they should simultaneously determine the burden these will place on laboratories and industries and make certain this burden is not excessive.

As the final activity, the Latin American participants were asked to evaluate the workshop. An questionnaire had been previously prepared; it consisted of four parts. Part 1 referred to the workshop's first day; part 2 to the second day; part 3 to the third day; and part 4 was of a general nature, containing

questions about logistics and the workshop as a whole (see Annex 1 for a sample questionnaire and a summation of replies). Summing up the 12 replies (some participants did not answer all questions):

Day 1: Most participants felt that the presentations were pegged at about the right technical level and that they struck a good balance between being too detailed or general. Some participants suggested adding topics on biodiversity and safety research. Six participants felt that the first lecture could be improved.

Day 2: Most participants felt that the presentations were pegged at about the right technical level and that they struck a good balance between being too detailed or general. Some participants suggested adding topics on transgenic insects and Latin American legislation; a few felt that less emphasis should be placed on the U.S. regulatory situation.

Day 3: Most participants felt that the presentations were pegged at about the right technical level and that they struck a good balance between being too detailed or general. Some participants suggested adding case studies on the patenting of transgenic mammals and plants; one questioned the need to discuss the regulatory situation in Europe.

General Comments: Almost all participants felt that more time should be allocated to discussions of the presented material; some believed that extended discussion periods should be scheduled every half day. Most thought that the duration of the workshop was about right. Only one participant felt that the workshop would have been enhanced by having simultaneous English-Spanish translation. Participants were asked to "grade" certain aspects or activities of the workshop; in general the approval rate was high. Specifically, on a scale of 1 - 10 (with 10 representing perfection) the participants rated the quality of the presented material at 8.1; workshop facilities at 8.6; organization of the workshop at 8.95; hotel accommodations at 8.9; quality of catered lunches at 7.95; and the helpfulness of MBI staff at 9.4.

4. Conclusion and Recommendations

At the conclusion of the round-table, the workshop participants collectively recommended the following:

* There is a need in Latin America for designing and implementing a regulatory framework for the safe carrying out of biotechnology research, development, and testing. Considering the limited resources of the concerned countries, a regional approach to the problem makes best sense. The Regional Program in Biotechnology for Latin

America and the Caribbean is the appropriate organization to take the lead in this effort.

* The present workshop helps provide the scientific and technical basis on which regulations can be structured. It is recommended that UNIDO, together with the MBI, organize a second such workshop, to be held in Costa Rica during September 1990.

* The workshop in Costa Rica should largely follow the format of this workshop, but should allow more time for discussions and take more into account the Latin American context. Specifically, as a preparatory activity to the Costa Rica workshop, an attempt should be made to collect information on laws and regulations in Latin American countries that bear on biotechnology and collate that information in one document that would be made available to researchers, industrialists and government officials.

* UNIDO is asked to explore the possibility of converting this type of workshop into an annual event. This would ensure the ability of participants to stay abreast with developments relating to biosafety, risk assessment, and regulations.

ANNEX II

LIST OF PARTICIPANTS AND OBSERVERS

UNIDO/MBI WORKSHOP

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WORKSHOP AGENDA

Day One: Problems/Science

8:45 Welcome by Dr. Fred Singleton, Director, Center of Marine Biotechnology (COMB).

Welcome by Ms. Maria Quintero de Herglotz, UNIDO.

9:00 Introduction and Overview by Workshop Director.
Dr. Morris Levin, Center for Public Issues in Biotechnology (CPIB)

9:10 Biotechnology Industry: Trends and Potential Problems.
The general scope and potential of the industry including safety in the laboratory and workplace, as well as safety issues pertaining to the testing of new products.
Dr. Alan Goldhammer, Industry Biotechnology Association

9:50 Issues in Safety: Pre Release Considerations.
The process a company must go through before testing, including pre-release considerations, pre-planning, site selection, preliminary data collection and information needs.
Dr. Robert Colwell, University of Connecticut

10:30 COFFEE BREAK

11:10 Issues in Safety: Field Activities.
Specific activities in conducting a field test including site activities, protocol development, monitoring, containment, and data analysis.
Dr. Jane Rissler, National Wildlife Federation

12:00 Risk Assessment.
Risk assessment framework for releasing engineered organisms.
Dr. Harlee Strauss, H. Strauss Associates

12:50 LUNCH

14:30 Issues in Safety: Modeling.
Description of models for estimating the outcome of field trials, including their availability, utility and credibility.
Dr. Charles Hagedorn, Virginia Polytechnic Institute

15:20 Issues in Safety: Information Requirements for Testing.
Data requirements for planning, releasing and evaluating a field test as well as identification of data sources.
Dr. Mark Segal, US Environmental Protection Agency

16:10 COFFEE BREAK

16:30 Risk and the Public.
The perception and acceptance of biotechnology risk by the public and its representatives.
Dr. Robert Wachbroit, CPIB

17:20 Social Hour.

Day Two
Regulatory activity by Industrial Sector/
Costs and Benefits of Regulation

8:45 Summary and Overview of Agenda for Day Two.
Dr. Morris Levin

9:00 Agricultural Sector.
Rationale and description of existing regulations for the release of engineered plants and animals.
Dr. Sally McKammon, US Department of Agriculture

9:50 General Industry Sector.
Rationale and description of existing regulations for the use and release of genetically engineered products.
Dr. Elizabeth Andersen, US Environmental Protection Agency

10:40 COFFEE BREAK

11:10 Pharmaceutical Sector.
Rationale and description of existing regulations for the review of genetically engineered products.
Dr. Edward Korwek, Hogan & Hartson

12:00 Case Study of Regulations.
US Regulatory structure and an analysis of its rationale.
Dr. Marvin Rogul, CPIB

12:50 LUNCH

13:40 Biotech Regulatory Burden.
Government perspective on calculating costs and benefits of regulatory activity.
Ms. Katherine Devine, US Environmental Protection Agency

14:30 Biotech Regulatory Burden.
Industry perspective of the impacts of regulations.
Dr. Pamela Bridgen, American Biotechnology Association

15:20 COFFEE BREAK

15:50 Case Study: Developing and testing a fish with enhanced growth characteristics.
Dr. Tom Chen, COMB

16:40 Social Hour

19:00 Dinner.
"The Ideal Law for Regulating Biotechnology"; Dr. Jack Doyle, Environmental Policy Institute

Day Three
Case studies /International Regulatory Activity

8:45 Summary and Overview of Day Three
Dr. Morris Levin

9:00 Case Study: Testing an engineered microbe designed to improve nitrogen fixation.
Dr. Gary Glass, Biotechnica of America, Inc.

9:50 Case Study: Testing an engineered microbe designed to enhance insect resistance in a crop.
Mr. James H. Davis, Crop Genetics International

10:40 COFFEE BREAK

11:10 Case Study: Vaccine Development.
A description of the development and testing of a recombinant vaccine.
~~Dr. Zsolt Harsanyi, Porton International~~
MR. STEVEN BUSH,

12:00 LUNCH

13:30 Biotechnology Regulation in the International Arena.
Overview of biotechnology regulatory activities of intergovernmental organizations including UNEP, UNIDO, WHO and others.
Dr. Harlee Strauss, H. Strauss Associates

14:20 Biotechnology Regulation in Europe.
Discussion of regulatory activities of the European Communities, Organization for Economic Cooperation and Development, and selected European countries.
Dr. Raymond Zilinskas, CPIB

15:10 COFFEE BREAK

15:30 Biotechnology Regulation in Latin America.
A consideration of the regulatory regime that exists in Latin American countries that pertain to biotechnology. (The talk will be followed by a group discussion.)
Dr. Rodolfo Quintero, UNDP

16:20 Summary and Conclusions.
Identify needs and specific activities for Latin America in the area of biotechnology regulations.
Drs. Morris Levin and Raymond Zilinskas

Presentation of course certificates and farewell.
Dr. Rita Colwell, Director, Maryland Biotechnology Institute

WORKSHOP ON REGULATION OF ENGINEERED ORGANISMS AND PRODUCTS

DECEMBER 6 - 8, 1989

OBJECTIVES

The workshop will review biotechnology regulatory procedures with an emphasis on field testing, their rationale, and how experience reviewing biotechnology products in other countries could serve as examples to Latin American countries which are considering the need for a regulatory mechanisms to deal with biotechnology products.

The workshop will cover the rationale for risk assessment, the science base required for evaluating biotechnology products, how various countries have devised a regulatory framework and case studies of products which have been approved for release.

LOCATION

The workshop will be conducted at the Center for Marine Biotechnology in Baltimore, Maryland.

WHO SHOULD ATTEND

- Scientists working in areas where field testing of engineered products will be necessary.
- Scientists who could be involved in biotechnology product review as expert witnesses or panelists.
- Government personnel involved in developing regulations governing testing and use of biotechnology products.
- Regulatory affairs personnel in industry responsible for regulatory compliance.

PRESENTED BY

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