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18237

Distr.
LIMITED

IPCT.113
6 April 1990

ORIGINAL: ENGLISH

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

Fourth Meeting of the
Informal UNIDO/WHO/UNEP Working Group
on Biotechnology Safety

Vienna, Austria, 18-19 December 1989

# REPORT*

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* This document has not been edited.

V.90-83524

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## I. INTRODUCTION

1. In 1985 the United Nations Industrial Development Organization (UNIDO), World Health Organizations (WHO), and United Nations Environmental Programme (UNEP) organized an informal Working Group to consider all facets of biosafety pertaining to research institutions, industry and the environment. The purpose of the Working Group is to establish a process through which the potential risks arising from biotechnology can be assessed and appropriate safety measures designed.

2. The first meeting of the Working Group[1/] was held at UNIDO headquarters in Vienna, Austria (January 1986) and addressed several aspects of biosafety including:

i. review existing safety practices as they apply to biotechnology industry and research & development;

ii. review existing safety rules and regulations that serve to manage biotechnology research and development institutions and bioscience-based industry;

iii. review existing practices which attempt to ensure safety of genetically engineered organisms into the environment;

iv. consider what elements are required for a set of minimal guidelines useful to the managers of research and development institutions, especially in developing countries;

v. consider what elements are required for a set of minimal guidelines useful to developing countries wishing to regulate bioscience-based industry and industries which utilize, or will utilize, biotechnology;

vi. determine whether guidelines should be formulated which seek to assure safe practices when genetically engineered organisms are, or will be, released into the environment.

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[1/] Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, Vienna, Austria ID/WG.463/3 27-29 January 1986.

3. Among the recommendations of this meeting, two continue to be of key interest to the Working Group i.e., the development of guidelines for laboratory and industrial facilities and for field testing genetically engineered organisms as well as improvement and continued development of an awareness of biosafety in developing countries.

4. The second meeting of the Working Group[1/] took place in Geneva, Switzerland (November 1986) and was hosted by WHO. The purpose of this meeting was to review progress of the programme of work developed in January 1986. The participants reviewed in detail the purpose and content of proposed guidelines and a general outline was agreed to include:

i. safety guidelines for laboratory scale practice;

ii. safety guidelines for large scale practice, and;

iii. safety and risk assessment for release of genetically engineered organisms into the environment.

5. The Food and Agriculture Organization (FAO) was encouraged to make a request to join the Working Group as a member.

6. The third meeting of the Working Group[2/] was held in Paris, France (December 1987) and was hosted by UNEP. The meeting was to determine the need for and scope of guidelines for practices for research, development and application of biotechnology. Recommendations included:

i. development of biosafety training;

ii. establishment of an international data base for information on industrial, agricultural and environmental applications, as well as the impacts of biotechnology;

iii. development of minimal global guidelines for industrial, environmental, and agricultural applications of natural and genetically engineered organisms, and;

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[1/]Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, Geneva, Switzerland CDS/SMM/86.26 3-5 November 1986.

[2/]Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, Paris, France 15-17 December 1987.

iv. development of notification schemes for field testing and use of certain categories of organisms.

7. The fourth meeting, of which this is the report, was held at UNIDO headquarters, Vienna, Austria (December 1989) and was sponsored by UNIDO with the participation of the International Centre for Genetic Engineering and Biotechnology (ICGEB).

8. A background draft report prepared for UNIDO in April 1989 was adopted as the basis of the agenda for the fourth meeting of the Working Group. This report noted that several of the original objectives of the Working Group have since been the subject of intensive study by international as well as national regulatory and advisory bodies. The activities of various regulatory and advisory bodies have led to the drafting of directives and guidelines in biosafety. The report stressed the need for the Working Group to consider whether it would be more useful to suggest biosafety guidelines based on existing codes.

## II. MEETING ACTIVITIES

### A. Opening Statements

9. The Director, Industrial Technology Development Division, UNIDO, welcomed the participants to the meeting and stressed the role of the Working Group as a forum for common participation and action in assisting developing countries in biosafety. Prof. A. Falaschi, ICGEB, outlined the role of ICGEB whose main function would be in research with limited efforts in development of biosafety guidelines. Background information[1/] provided for the meeting was described by UNIDO staff.

### B. Election of a Chairman and Rapporteur

10. It was agreed by members of the Working Group that Dr. T.G.B. Howe, University of Bristol, act as Chairman and also serve as the rapporteur for the meeting. Dr. Howe was asked to prepare the final report with the assistance of UNIDO staff. Representatives of UNIDO, WHO, UNEP, ICGEB, invited experts, and observers were present (see Annex I) and were introduced by the Chairman.

### C. Adoption of the Agenda

11. The agenda (see Annex II) was adopted by the participants of the meeting.

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[1/] "An International Approach to Biotechnology Safety" (UNIDO, Vienna, 1989).

## D. Reports on Implementation of Previous Recommendations

Development of Biotechnology Training Courses

12. The representative from WHO drew attention to training courses that were now operating in Australia, Canada and the United States.

13. The representative from UNIDO reported on a workshop[2/] co-sponsored by UNIDO and the Center for Public Issues in Biotechnology (CPIB) at the Maryland Biotechnology Institute. This workshop focussed on issues in biosafety for the benefit of Latin American countries.

14. Although a need for training was identified, it was pointed out that there would be difficulty in securing resources and it was suggested that less costly guidance packages may be more suitable.

Development of an International Data Base

15. Relevant data bases have been established. ICGEB has capability through its network to access public domain data bases and could potentially act as a central hub for exchange of information. It was noted that such data bases are often expensive to maintain and difficult to validate.

Development of Minimal Global Biosafety Guidelines; Safety Principles for Environmental and Agricultural Practice

16. These two matters were considered jointly and further reference is made to them later in this Report (see G and H below). WHO drew attention to its own Laboratory Safety Manual[3/] which had achieved wide international acceptance and is currently being updated.

Code of Practice for Large-scale Utilization of Microorganisms

17. The third meeting had recommended consideration of the OECD safety and regulations in biotechnology[4/] but no further progress was reported.

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[2/] "Dealing with Field Test Regulations and Public Acceptance of Engineered Plants and Microbes" (Center for Public Issues in Biotechnology, Maryland Biotechnology Institute, Maryland, December 1989).

[3/] "Laboratory Biosafety Manual" (Geneva, World Health Organization, 1983).

[4/] "Safety and Regulations in Biotechnology" (OECD, February 1986).

Safety Evaluation and Notification Schemes

18. No reports were presented to the meeting on these topics.

## E. Concept Papers by Invited Speakers

The Intentional Introduction of Organisms to the Environment (Dr. J.E. Beringer, Department of Microbiology, University of Bristol, UK)

19. Prof. Beringer reviewed the historical background of agricultural development and noted that although from a human point of view, agriculture had been highly beneficial, the environmental consequences of human intervention had generally been very damaging. Introduction of new species is controlled in many national regulations and the Geneva Convention (1984) serves to control the movement of non-indigenous species. Although existing regulations adequately control most aspects of laboratory genetic manipulation work, there is still an uncontrolled risk for the environment in the use of the products of such work outside of the laboratory. The present guidelines and regulations for the release of genetically engineered organisms were prepared before the technology they are intended to control and are in some instances inconsistent. The US regulations tend to address the products of genetic manipulation rather than the method of production, whereas the EC intends to regulate the method, mainly in response to what is perceived as public concern.

20. There should be considerable concern for those countries which do not yet have regulations and the only realistic approach for them is that they participate in regional schemes for assessment and monitoring. Such regional bodies will require authority and adequate financing and they may consider using existing sets of regulations which are already internationally accepted. For example, those of the OECD are especially suitable. The regional committees will require a good balance of scientific disciplines and members with a knowledge of local environmental conditions, with individual countries being present. The main problem will be risk assessment since risk may differ in different environments.

The Concepts of Risk Assessment (Dr. A.G. Lazen, Commission on Life Sciences, National Academy of Sciences, Washington D.C. USA)

21. Dr. Lazen emphasized the distinction between risk assessment and risk management: the former being a matter of scientific assessment and the latter a value judgement which should ideally begin only after the scientific assessments had

been performed. Decisions on regulating organisms made by the process of genetic engineering rather than the products themselves exemplify the confusion between societal value judgement and scientific assessment. Dr. Lazen discussed the variety of assessment regimens for ecological risks associated with the release of genetically modified organisms, mainly as evolved in the USA: the latter identify four separate areas for consideration - attributes of genetic alteration, attributes of the parent organism, phenotypic attributes of the derived organisms in comparison to its parent, and attributes of the environment. many of these issues can be approached by a "decision tree" framework. Dr. Lazen concluded by outlining the component of a practical scheme for assessing risks and considering how such a scheme might be applied in developing countries.

Biotechnology: European Policy and Industrial Needs (Dr. D. Brauer, Hoechst AG, FRG)

22. Dr. Brauer provided an historical review of the European Community (EC) which finances a significant percentage of governmental funded economic aid that contributes to world trade. The European development, and in particular, the regulatory measures to achieve harmonization towards a "single market" should result in advantageously placing the benefits of biotechnology and recombinant DNA applications into the market. There is concern, that in public and official statements, environmental aspects are overemphasized to the expense of urgent health, food and energy needs. Safety for mankind and the environment should be given the highest priority. The industrial and other areas likely to benefit from biotechnology were outline and it was noted that in almost 15 years of research, recombinant DNA techniques had not been found to add to the risk posed by organisms to humans, animals or plants. A sound science-based risk assessment is possible which should continue to be based on physical and biological containment as well as scientific principles in general. The OECD Report (1986), which recommends that recombinant DNA organisms should not be treated as a separate class and that any regulation should encompass work with all organisms, independent of their origin, and that the prime consideration is safety, should be adopted as sound basis for the legislative action required.

23. The EC is currently developing a number of directives to regulate and harmonize modern biotechnology, several of which are close to "final drafts", some have passed the European parliament. Dr. Brauer suggested some modifications to directives concerning contained use, deliberate release and worker protection. There are currently wide differences between the EC countries with respect to the stringency of procedures of contained use and deliberate release applications.

Biosafety Regulations in Developing Countries (Dr. E.J. Trigo, Director, Technology Generation and Transfer Program, Inter-American Institute for Co-operation on Agriculture, Costa Rica)

24. Dr. Trigo considered that the creation of a climate of public trust is essential for the great promises which biotechnology offers for industry, agriculture, health and other sectors to be realized. The risks which could be posed by biotechnology have generally been seen by scientists as probably being small, at worst, and as not precluding further development; there has been broad agreement on the level of control appropriate to laboratory work and to large-scale use of genetically engineered products and organisms, although no such consensus yet exist for environmental release. On the political level, opposition both in the US and Europe has sometimes been based on moral grounds and in some instances has resulted in delays by regulatory bodies.

25. The debate on biotechnology has not yet become an issue in developing countries, although there have been some incidents related to safety. Few of these countries have yet recognized medium-term development as an issue; usually only small groups of scientist are aware of the importance of biotechnology for their countries and this awareness does not tend to influence policy making. The severe external debt situation of many constrains development and also results in a loss of scientists through emigration to countries and professions, but some small locally-owned high-technology firms are nonetheless successfully operating. Biosafety regulations are one aspect of a national or regional development strategy. The experiences of developed countries should be monitored before developing countries formulate detailed guidelines, although ad hoc rules should be established where these are needed urgently. A multilateral mechanism is needed to address the international character of some developments initiated by industrialized countries and multinational companies.

26. Particular difficulties in establishing a control framework for developing countries include the traditional lack of public or private accountability in some, a lack of awareness and information, and a lack of resources to enforce regulations. Any regulatory mechanism will have to strike a balance between the need to protect local public interests and the desire to attract investment in order to develop a capability in biotechnology. An international or regional approach would be very attractive.

## F. Informal Presentations by Observers

27. Ms. J. Tachmintzis (EC) presented a summary of the current position on progress towards EC legislation. It was noted that draft directives, possibly subject to minor amendment, were likely to be presented to the European Parliament within the next two months.

28. Dr. R. Nourish (UKHSE) advised the meeting of modifications to the OECD booklet[2/] of which a revised version is expected shortly.

29. Dr. L. Val Giddings (USDA/APHIS) outlined the relevant work of USDA Agencies, which includes guidance for the World Bank, and important organization that provides developmental aid for developing countries.

30. Dr. J. Tjell (FAO/IAEA) indicated that FAO was willing to become a full member of the Working Group.

## G. Points Arising from Discussions by the Working Group

31. The meeting affirmed the potential benefits of biotechnology for the developing countries and raised the following points in its discussions:

i. The participants noted that assistance to evaluate applications for field testing genetically modified organisms has been requested by some developing countries. However, these countries may be delaying acceptance of these applications pending advice on safety measures. There is an urgent need for such advice from international organizations. This can be done on a case-by-case basis.

ii. From the point of view of a developing country, should existing biotechnology safety guidelines prepared by international or national organizations be recommended, modified, or should a new one be devised? The views of countries involved should be sought and whatever is recommended must be practical. Safety considerations should not differ for developing countries as to other countries and risk assessment procedures should be consistent. Adaption of existing biosafety guidelines was viewed as favorable because many may be suitable to some countries with very little amendment.

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2/"Recombinant DNA Safety Considerations" (OECD, Paris 1986).

iii. A suggestion to establish regional advisory groups to deal with problems arising as a result of diversity in biosafety guidelines was widely supported by the participants. Advisory groups may be useful to consider existing guidelines with a view of making them practicable in developing countries. Matters of how such advisory groups can be organized, whether they should be language-based and whether UNDP should be involved in their funding should be addressed to future meetings of the Working Group.

iv. A dual approach may desirable. Biosafety guidelines from international and national organizations could be immediately adopted, with suitable modification(s), while a longer term strategy such as a international code of conduct is developed. The code of conduct prepared for the distribution and use of pesticides[2/] may be useful as a guide in preparing a code of conduct for the distribution of biotechnology products in developing countries.

v. The role of the Working Group itself should be clarified. It was noted that no action had apparently been taken on some matters recommended for action at the previous meeting of the Working Group. Members favored maintaining the Working Group on an informal basis.

vi. It was noted that ICGEB may be a suitable body to assist in several matters, i.e., provision of laboratory facilities for evaluation of safety measures, hosting safety courses, advice on risk assessment and other scientific matters. The Director of ICGEB commented that research was their priority and resources for the development of guidelines were not foreseen in the Five-year programme budget.

vii. There were only a few present at the Meeting that had direct experience in developing countries and it was considered that in the future these countries should be more fully involved.

viii. Safety guidelines will have little value without adequate monitoring. IAEA has considerable experience in international monitoring and it was considered useful if a representative were to attend future meetings of the Working Group.

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[2/]"International Code of Conduct on the Distribution and Use of Pesticides" (Food and Agriculture Organization of the United Nations, Rome, 1986).

ix. The responsible authorities in developing countries should be identified.

x. An analysis of responses to a UNEP questionnaire on biosafety in developing countries should be circulated to interested parties.

## H. Recommendations

32. There is an immediate need to advise countries, at their own request, on suitable safety guidelines for field testing genetically modified organisms in the environment. There is also a longer term need to evolve practical safety guidelines, whether new or adapted from existing codes, which will meet the needs of developing countries and also win the support of the industrial community. It will be necessary to assess whether these guidelines work in practice and to balance the requirements of different countries against the needs for uniform standards of safety.

33. The UN agencies sponsoring the Working Group can play a valuable role in discussing strategic issues. However, it is not feasible to expect an informal Working Group convening annually to meet all these requirements within a reasonable period of time. The following recommendations were accordingly made:

i. The Working Group should continue to meet in order to provide a forum for discussion by UNIDO, WHO, UNEP, and FAO. It should engage consultants to prepare a manual on biosafety whose purpose will be purely educational. This manual will be initially directed towards those who are responsible for giving advice within the developing countries, and it should raise both an awareness of the problems arising from the practice of biotechnology and the distribution of biotechnological products in developing countries, and also work towards the preparation of an international code of conduct. The manual should have annexes summarizing the current biosafety guidelines in the areas of industrial practice (UNIDO), environmental safety (UNEP, FAO), laboratory health and safety (WHO). It is hoped that sufficient progress will have been made on the manual to enable the Working Group to discuss its progress at its next meeting to be hosted by WHO in late 1990. A full draft should be available for critical evaluation in 1991. The environmentally sound management of biotechnology has been emphasized as a major concern by the Chairman of the UN Conference on Environment and

Development[10/].

ii. The FAO requested membership in the Working Group which was endorsed by the members of the Group.

iii. An advisory group for the assistance to developing countries in the safe practice of biotechnology and use of biotechnological products should be established as soon as possible. Its first role should be to assist those countries which have already requested advice, by directing their attention to existing biosafety guidelines, suitably modified where appropriate. If necessary, short-term consultants to give on the spot advice may be engaged on behalf of the advisory group. The advisory group should ascertain the appropriate authority in each country through which advice can be channelled and, in turn, advise such authorities of the group's procedures for processing requests for advice. The views of developing countries on the utility and mode of operation of such a committee should be solicited. The establishment of the advisory group should be given wide publicity as soon as possible. The advisory group may find it appropriate to establish regional sub-groups to advise on the problems of particular countries and regions, especially for activities involving the intentional release of genetically modified organisms. These regional sub-groups should be represented by members from each of the countries involved and also by existing scientific expertise. The Inter-American Study Group on New Biotechnology in Agriculture and Health, which is to meet in Brasilia in 1990, could provide the basis for such a grouping of Latin American and Caribbean countries. The initial establishment of the advisory group will require funding from existing UN sources. Once this is secured, it should be possible for the group's activities to be funded, at least in part, by fees payable to by companies wishing to undertake large-scale work or field testing in developing countries. Such companies themselves have an interest in the presence of biosafety guidelines according to which they can work.

iv. Consideration should be given to the extent of ICGEB's role in safety evaluation and the funding of such work.

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[10/]UN conference on Environment and Development (General Assembly Document A/C.2/44/L.86, 1989)

v. The sponsoring agencies should consider the extent to which the above activities can be funded from within existing identified UN budgets and the fee structure for long-term development.

iv. Other items suggested for discussion at a future meeting of the Working Group include:

i. problems arising from deliberate release of genetically modified organisms into the environment on a wide scale;

ii. the UNEP report and questionnaire;

iii. the new training programme initiated by WHO, and;

iv. the social and economic impact of biotechnology.

**ANNEX I**

# LIST OF PARTICIPANTS

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**ANNEX II**

**AGENDA**

Monday, December 18, 1989

Conference Room VII, 7th Floor, C-Building

0900 Informal Discussion (UNIDO/WHO/UNEP Representatives Only)

0930 Introductory Remarks (Venkataraman, Zelibor, UNIDO; Tzotzos, ICGEB)

Introduction of Chairman

1000 Adoption/Modification of Draft Agenda (Chairman)

1045 Roundtable Discussion on Implementation of the Recommendations of 3rd Meeting (Chairman)

Tentative Topics:

(a) Development of Biosafety Training Courses

(b) Development of International Data Base

(c) Development of Minimal Global Biosafety Guidelines

(d) Code of Practice for Large-Scale Utilization of Microorganisms

(e) Safety Evaluation

(f) Code of Practice for Environmental and Agricultural Practice

(g) Notification Schemes

(h) Information from Observers

1330 Overview of the Presentations by Experts (Chairman)

1345 Environmental Release: Recent Developments (J. Beringer, University of Bristol, U.K.)

1415 Risk Assessment (A. Lazen, National Research Council, National Academy of Sciences, Washington D.C.)

1515 European Policy and Industrial Interests (D. Brauer, Hoechst Aktiengesellschaft, FRG)

1545 Guidelines for Developing World (E. Trigo, Inter-American Institute for Cooperation on Agriculture, Coronado, Costa Rica)

1615 Discussion

1730 Adjourn

Tuesday, December 19, 1989

Conference Room VII, 7th Floor, C-Building

0900 Informal Discussion (UNIDO/WHO/UNEP Representatives Only)

1000 Opening Remarks (Chairman)

1015 General Discussion (Chairman)

1430 Recommendations and Criteria for Implementation (Chairman)

1600 Suggestions for Future Agenda Items (Chairman)

1700 Close of Meeting