OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

18004

UNIDO/WHO/UNEP INFORMAL WORKING GROUP ON BIOTECHNOLOGY SAFETY

Report on Fourth Meeting

Vienna, 18 - 19 December 1989

Sponsored by

United Nations Industrial Development Organization;

International Centre for Genetic Engineering and Biotechnology

TABLE OF CONTENTS

This Report has been prepared by Dr. T.G.B. Howe, University of Bristol, U.K. The assistance of Dr. J.L. Zelibor, Biotechnology and Genetic Engineering Unit, UNIDO, in commenting on the draft Report is gratefully acknowledged.

I. BACKGROUND TO FOURTH MEETING.

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

The first meeting of the Working Group was held at UNIDO headquarters in Vienna, Austria (January 1986) and addressed several aspects of biotechnology safety (see Annex I, Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, 27-29 January, 1986) including:

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

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

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

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

v. To consider what elements are required for a set of minimal guidelines useful to developing countries that may wish to regulate bioscience-based industry and industry that utilizes, or will utilize, biotechnology;

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

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

The second meeting of the Working Group 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 1986 (see Annex I, Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, 3-5 November 1986). The participants reviewed in detail the purpose and content of proposed guidelines and a general outline was agreed for (a.) safety guidelines for laboratory scale practice, (b.) safety guidelines for large scale practice, and (c.) safety and risk assessment for release of genetically engineered organisms into the environment. It was recommended that all United Nations organizations should, in programmes relating to the environment, aim at (a.) standardization and validation of microcosm, mesocosm, and controlled field test protocols suitable as predictors of responses of natural ecosystems, (b.) development of simple predictive measures, including predictive models for estimating field effects from controlled laboratory or other enclosed studies, and (c.) development of accurate methods of extrapolating results of risk assessment testing from laboratory to field and from one field site type to another. Also, the Food and Agriculture Organization (FAO) was encouraged to make a formal request to join the Working Group as a member.

The third meeting of the Working Group was in Paris, France (December 1987) and was hosted by UNEP. The meeting was held for the purpose of determining the need for and scope of guidelines for practices for research, development and applications of biotechnology. Recommendations (see Annex I, Report of the Informal UNIDO/WHO/UNEP Working Group on Biotechnology Safety, 15-17 December 1987) were made for (a.) development of biosafety training, (b.) establishment of an international data base for information on industrial, agricultural, and environmental applications and impacts of biotechnology, (c.) development of minimal global guidelines for industrial, environmental, and agricultural applications of natural and genetically modified organisms, and (d.) development of notification schemes for field testing and use of certain categories of organism.

The fourth meeting was held at UNIDO headquarters, Vienna, Austria (December 1989) and was co-sponsored by UNIDO and the International Centre for Genetic Engineering and Biotechnology (ICGEB).

A draft report prepared for UNIDO in April 1989 was adopted as the basis of the agenda for the fourth meeting of the Working Group (see Annex II). This report noted that several of the original objectives of the Group have since been the subject of intensive study by international as well as national regulatory and advisory bodies. The activities of these bodies have led to the drafting of several codes of practice, some of them since embodied in law, and among the supra-national groupings which have addressed the question may be noted the EC, whose draft directives are now nearing completion, and the OECD, which is currently revising its own guidelines first drafted in Paris in 1986. The report therefore stressed the need for the Group to consider whether it should continue to develop its own guidelines, or whether it would be more useful to prepare guidelines based on existing codes.

None of these codes has considered specifically the special problems that biotechnology might pose for the developing world, where there is now frequently great awareness of the advantages to be gained from acquiring new technological skills in gene manipulation and also the acquisition of non-indigenous organisms. These countries are also concerned that they might, without their own knowledge or agreement, become the sites for experimental work that for safety reasons is prohibited or tightly controlled in the developed world. Concerns have also been expressed that these countries might be presented with codes of practice devised in and suited to the developed world but to which they themselves have had no opportunity to contribute. Any attempt to provide a framework that might subsequently be adopted as a basis for legislation is beyond the remit of an informal Working Group, but the recommendations of such a group should at least have a reasonable chance of acceptance by governments and informed public opinion in the countries concerned.

The formulation of codes of practice in the developed world has benefitted greatly from an interaction between scientists on the one hand and advisory bodies and public interest groups on the other. A further question, therefore, is whether the ICGEB might be an appropriate body through which scientific advice could be focussed, and perhaps also whether it might provide limited laboratory facilities for the evaluation of safety measures.

The report finally directed attention to the need for any recommendation to be accompanied by an indication of how it is to be implemented, including a timetable for implementation, and a statement of the criteria according to which implementation may be seen to have succeeded.

II. MEETING ACTIVITIES.

A. OPENING STATEMENTS

Dr. Venkataraman (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 the developing countries.

Dr. Falaschi (Director, ICGEB) outlined the role of ICGEB whose main function would be in research rather than safety work.

Dr. Zelibor (UNIDO) described the background information that was provided for the meeting. This included the *Report of the Third Meeting of the UNIDO/WHO/UNEP Working Group on Biotechnology Safety* (see Annex I); *Draft Report of the UNIDO/WHO/UNEP Working Group on Biotechnology Safety* (see Annex II); *The Use of Artificial Intelligence to Facilitate Compliance with U.S. Federal Biosafety Regulation* by MacKenzie et al., 1989; *The Perception and Acceptance of Biotechnology Risk* by R. Wachbroit, December 1989 (see D below); *An International Approach to Biotechnology Safety* by G.M. Karny (UNIDO/IS.617, April 1986).

B. ELECTION OF A CHAIRMAN AND RAPPORTEUR

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 UNEP, UNIDO, WHO and ICGEB, invited experts, and observers from UNCTAD, USDA, UKHSE, EC and FAO and others were present (see Annex III) and were introduced by the Chairman.

C. ADOPTION OF THE DRAFT AGENDA

The draft agenda (see Annex IV) was adopted by the meeting.

D. REPORTS ON IMPLEMENTATION OF PREVIOUS RECOMMENDATIONS

a. Development of Biotechnology Training Courses. The WHO representative drew attention to training courses that were now operating in Australia, Canada and the United States.

The UNIDO representative reported on a workshop co-sponsored by UNIDO and the Center for Public Issues in Biotechnology (CPIB) at the Maryland Biotechnology Institute, Baltimore, Maryland, U.S.A. (December 1989) entitled "Dealing with Field Test Regulations and Public Acceptance of Engineered Plants and Microbes." This workshop focussed on issues in biotechnology for the benefit of Latin American countries.

Although a need for training was clearly identified there was difficulty in securing resources, and it was suggested that less costly guidance packages would often be suitable.

b. Development of an International Data Base. Relevant data bases have been established by USDA and the World Bank / Government of Australia; the ICGEB considers that these are of greater importance than safety courses and is working on a network of existing data bases. It was noted that such data bases are often expensive to maintain and difficult to validate.

c. Development of Minimal Global Biosafety Guidelines; Safety Principles for Environmental and Agricultural Practice. These two matters were considered jointly and further reference is made to them later in this Report (see G and H below). The WHO drew attention to its own health manual which had achieved wide international acceptance and is currently being updated.

d. Code of Practice for Large-scale Utilization of Microorganisms. The 3rd meeting had recommended consideration of the OECD code but no further progress was reported.

e. Safety Evaluation and Notification Schemes. No reports were presented to the meeting on these topics.

E. CONCEPT PAPERS BY INVITED EXPERTS

a. The Intentional Introduction of Organisms to the Environment: Dr. John E. Beringer, Department of Microbiology, University of Bristol, U.K.

Professor Beringer reviewed the historical background to agricultural development and noted that although from a human point of view this had usually 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 the laboratory. The present guidelines and regulations for release of genetically engineered organisms have developed in advance of the technology they are intended to control and are in places 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, perhaps mainly in response to what is perceived as public concern.

There must be considerable concern about countries that do not yet have regulations. The only realistic approach for such countries is for them to participate in regional schemes for assessment and monitoring: such regional bodies will require authority and adequate finance, and they could well use existing sets of regulations that are internationally accepted. Those of OECD are especially suitable. The regional committees will require a good balance of scientific disciplines and of members with a knowledge of local environmental conditions, with individual countries represented. The main problem will be risk assessment since risk may differ in different environments.

b. The Concepts of Risk Assessment: Dr. Alvin G. Lazen, Commission on Life Sciences, National Academy of Sciences, Washington D.C., U.S.A.

Dr. Lazen emphasized the distinction between risk assessment and risk management: the former is a matter of scientific assessment and the latter is a value judgement that should ideally begin only after the scientific assessment has been performed. Decisions to regulate organisms made by the process of genetic engineering rather than the products themselves exemplify the confusion between societal value judgement and scientific assessment. He discussed the variety of assessment regimens for ecological risks associated with the release of genetically modified organisms, mainly as they have evolved in the U.S.: the latter identify four separate areas for consideration - attributes of the genetic alteration, attributes of the parent organism, phenotypic attributes of the derived organism in comparison with its parent, and attributes of the environment. Many of these issues can be approached in a "decision tree" framework.

Dr. Lazen concluded by outlining the components of a practical scheme for assessing risks and considering how such a scheme might be applied in developing countries. Practicality itself can be viewed as a scientific matter or as one implying public acceptability and capacity for incorporation into a country's legal framework.

c. Biotechnology: European Policy and Industrial Needs: Dr. Dieter Brauer, Hoechst AG, FRG.

Dr. Brauer reviewed the history of the European Community (EC) which finances 37% of global governmentally funded economic aid and contributes 41% to global trade. The intended establishment of a single EC market by 1992 will have widespread effects and the safety of man and the environment must have the highest priority. He outlined the industrial and other areas likely to benefit from biotechnology and 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 and plants. A sound science-based risk assessment should continue to be based on physical and biological containment.

The EC is currently developing about 15 directives to regulate and harmonize modern biotechnology many of which pose problems for the continued competitiveness of European biotechnology. Dr. Brauer considered that the directive for contained use should be based on Article 100 A of the Treaty and that the OECD classification system should be adopted; that suggested for deliberate release is unfavourable, and legislation for worker protection should be based on scientific criteria. There are currently wide differences between the EC countries with respect to the stringency of procedures for contained use and deliberate release applications. It is clear that the world's needs generally cannot be tackled without modern biotechnology.

d. Biosafety Regulations in Developing Countries:
Dr. Eduardo J. Trigo, Director, Technology Generation and Transfer Program, Inter-American Institute for Cooperation on Agriculture, Costa Rica.

Dr. Trigo considered that the creation of a climate of public trust is essential in order that the great promises which biotechnology offers for industry, agriculture, health and other sectors will be realized. The risks that might be posed by biotechnology have generally been seen by scientists as being probably 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 exists 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.

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 scientists are aware of the importance of biotechnology for their countries and this awareness tends not to influence policy making. The severe external debts of many constrains development and also results in a loss of scientists by emigration and to other professions, but some small locally-owned high-technology firms are 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.

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

F. INFORMAL PRESENTATIONS BY OBSERVERS

Ms. Joanna 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 in the next two months.

Dr. Roger Nourish (UKHSE) advised the Meeting of modifications to the OECD booklet "Recombinant DNA Safety Considerations" (Paris, 1986) of which a revised version is expected shortly.

Dr. L. Val Giddings (USDA/APHIS/BBEP) outlined the relevant work of USDA Agencies which includes guidance for the World Bank, an important lending organization for developing countries.

Dr. Jens C. Tjell (FAO/IAEA) indicated that FAO was willing to join the three UN agencies sponsoring meetings of the Working Group.

G. POINTS ARISING FROM DISCUSSION BY THE WORKING GROUP

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

a. Applications for field testing have already been received, and countries are delaying acceptance of these applications pending advice on safety measures. There is an urgent need for such advice to be forthcoming; this can be done on a case-by-case basis.

b. From the point of view of a developing country, should an existing international or national code be adopted or modified, or should a new one be devised? The views of the countries involved should be sought, and whatever is recommended must be practical. It is best to adapt existing codes: many might be suited to particular countries with very little amendment, and that of the OECD was supported as providing a good base from which to work. Working groups might be established to consider reports such as this with a view to making them practicable in developing countries. The International Code of Conduct for the Distribution and Use of Pesticides (FAO; Rome, 1986) may be a useful model in preparation of a code of conduct for the distribution of biotechnology products in developing countries.

c. A dual approach might be best: a code of conduct from the developed countries could be adopted with suitable modification immediately, while a longer term strategy more suited to the developing countries is worked out.

d. Dr. Beringer's proposal of regional committees was widely supported. It would be particularly useful in dealing with problems arising as a result of diversity. How might such committees be organized? Should they be language-based? Should the UNDP be involved in their funding? These and other questions should be addressed at a subsequent meeting of the Working Group.

e. The role of the Working Group itself should be clarified. It is not good that no action has apparently been taken on some matters recommended for action at the 3rd Meeting. UNEP favoured maintaining the Group on an informal basis, and this was favoured by other members of the Group.

f. Role of the ICGEB. It was commented that the ICGEB might be a suitable body to assist with several matters: provision of laboratory facilities for evaluation of safety measures, provision of safety courses, and advice on risk assessment and other scientific matters. Dr. Falaschi (Director, ICGEB), however, had commented that the ICGEB's priority was research, and that safety evaluation is not within the five-year programme budget.

g. Safety considerations should not be different in developing as opposed to other countries, and risk assessment procedures should be consistent. The guidelines eventually recommended should not contain differences of principle from those in use elsewhere.

h. Several Observers indicated that their organizations, in particular USDA / APHIS, EC, UKHSE, Ministry of Environment of The Netherlands, and others known to them were willing to assist the Working Group with regard to field testing of genetically modified organisms in the environment in developing countries. The use of such assistance would promote credibility of the guidelines subsequently recommended.

i. There were few present at the Meeting with direct experience of developing countries. Representatives of these countries should be more fully involved in future discussions.

j. Guidelines will have little value without adequate monitoring. IAEA has considerable experience in international monitoring: it would help if a representative could attend meetings of the Working Group.

k. The responsible authority(s) in developing countries should be identified. The Economics or Health Ministry might be most suitable.

l. The analysis of the response to the UNEP questionnaire should be circulated to interested parties.

H. RECOMMENDATIONS

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

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 Group convening annually to meet all these requirements in a reasonable period of time. The following recommendations are accordingly made:-

1. The Working Group should continue to meet to provide a forum for discussion by UNIDO, UNEP, WHO, and FAO (see 2. below). It should engage Consultants to prepare a Manual whose purpose will be educational. This should be directed initially at those responsible for giving advice within the developing countries, and it should both raise awareness of the problems arising from the practice of biotechnology and the distribution of biotechnological products in the developing countries and also work towards the preparation of a code of practice. The manual should have annexes summarizing the current biosafety guidelines in the following areas:

   a. Laboratory health and safety (WHO);

   b. Environmental safety (UNEP, FAO);

   c. Industrial practice (UNIDO).

   It is hoped that sufficient progress will have been made on the Manual to enable the Working Group to discuss progress at its next meeting to be hosted by WHO in late 1990, and for a full draft to be available for critical evaluation in 1991. The environmentally sound management of biotechnology has been highlighted as a major concern by the Chairman of the UN Conference on Environment & Development (General Assembly document A/C.2/44/L.86, page 4, para. 12f). It should be possible for completion of the Manual to be reported at the Conference scheduled for 1992.

2. The FAO requested membership in the Working Group and this request was welcomed by the meeting.

3. A Standing Committee for the assistance of developing countries in the safe practice of biotechnology and use of biotechnological products should be established under UN auspices at an early date. Its first role, for which it should be ready if necessary to engage Consultants to give guidance within 2 - 3 months, should be to assist those countries that have already requested advice by directing their attention to existing guidelines, suitably modified where appropriate. It should ascertain the appropriate agency in each country through which advice can be channelled and, in turn, advise the agency in each country of its own 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 Standing Committee should be given wide publicity as soon as possible.

The Standing Committee 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 organisms. These sub-groups will need representation of the local countries involved and also of existing scientific expertise. The Inter-American Study Group on the New Biotechnolcgy in Agriculture and Health, which is to meet in Brasilia in May / June 1990, could provide the basis of such a grouping for the Latin American and Caribbean countries.

The initial setting up of the Standing Committee will require funding from existing UN sources. Once it is established, however, it should be possible for its activities to be funded at least in part by fees payable by companies wishing to undertake large-scale work or field testing in developing countries. Such companies themselves have an interest in the presence of guidelines to which they can work.

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

5. The sponsoring agencies should consider (a.) the extent to which the above activities can be funded from within existing identified UN budgets and also (b.) the fee structure for long-term developments (see 3. above).

6. Other items suggested for discussion at a future meeting of the Working Group include (a) the problems arising from applications of released organisms on a wide scale; (b) the UNEP report and questionnaire; (c) the new training programme initiated by WHO; and (d) the social and economic impact of biotechnology.