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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

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United Nations Industrial Development Organization

Informal UNIDO/WHO/UNEP Working Group
on Biotechnology Safety

Vienna, Austria, 27-29 January 1986

REPORT*

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TABLE OF CONTENTS

I. Background

1. While UNIDO for reasons of its mandate has an interest in industrial safety practices, it is also aware of the concerns that the World Health Organization (WHO) has in this area as they relate to health and safety. Particular note has been made of the publication Laboratory Biosafety Manual with its guidelines pertaining to laboratory practices, transfer and shipping of specimens, guide to biosafety equipment, etc., and the report by WHO's Regional Office for Europe "Health Impact of Biotechnology". Interests of the two organizations on this important subject led to the establishment in 1982 of continous communications between UNIDO and WHO's programme Safety Measures in Microbiology. During the spring of 1985 it was decided between the two to constitute an informal working group and begin a systematic study on whether a set of biosafety rules and practices could and should be elaborated, the application of which could be recommended to all countries.

2. In May 1985 UNIDO became acquainted with the interest that the United Nations Environment Programme (UNEP) has in the topics of bio-wastes disposal and the deliberate release of genetically engineered organisms into the environment. In view of the obvious overlap of interest, UNEP was informed of the planned UNIDO/WHO working group and asked if it would be interested to partake in its activities. The response was positive and after consultations between UNIDO and WHO, it was decided among the three organizations to constitute an informal UNIDO/WHO/UNEP working group to consider all facets of biotechnology safety pertaining to research institutions, industry and environment, and decided to hold the first meeting at UNIDO headquarters during 27-29 January 1986. The objectives of the meeting were:

(i) To review existing safety practices as they apply to biotechnology R+D and industry.

(ii) To review existing safety rules and regulations that serve to manage biotechnology R+D institutions and bioscience-based industry.

(iii) To review existing practices that attempt to ensure the safety of releasing genetically engineered organisms into the environment.

(iv) As a result of the foregoing, to consider what elements are required for a set of minimal guidelines useful to the managers of the ICGEB and to R+D institutions, especially in the developing countries.

(v) Similar to (iv), 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 if guidelines should be formulated that seek to assure safe practices when genetically engineered organisms are, or will be, released into the environment.

(vii) To indicate further activities for each member of the working group and to prepare for the working group's next session.

3. In the early fall of 1985, UNIDO engaged the services of a consultant to prepare a comprehensive study containing: (1) an overview of existing safety practices and regulations that serve to manage biotechnology R+D and industry; (2) an overview of prevalent practices as to the control over releasing genetically engineered organisms into the environment; and (3) recommendations of activities that the informal working group or the ICGEB could undertake with respect to biotechnology safety. This study, "An International Approach to Biotechnology Safety" (see list of documents) was circulated to members of the working group in early January 1986 and was also available at the first meeting.

II. Meeting Activities

4. The meeting took place as planned in conference room VII of the Vienna International Centre. It was opened at 09:30 on 27 January by a member of the UNIDO Secretariat. In attendance were representatives from UNEP, UNIDO, WHO, as well as observers from the FAO and OECD. The list of participants is in Annex I and the list of documents in Annex II.

5. As the first order of business, the draft agenda was presented and adopted (see Annex III for the Agenda). Each agenda item was taken up in turn.

A. Election of a chairman and rapporteur.

Mr. Wafa Kamel of the UNIDO Secretariat was elected Chairman; it was deemed not necessary to elect a rapporteur since UNIDO staff would undertake to write the report of the meeting.

B. Adoption of the draft agenda.

The draft agenda was adopted with no changes.

C. Presentation of the backgrourd document: An International Approach to Biotechnology Safety.

6. The UNIDO consultant made an in-depth presentation of his study, An International Approach to Biotechnology Safety. He began by explaining the purpose of the study and his methodology in conducting it. He also explained the general organization of the study, which was to break down genetic engineering into three categories: laboratory research; large-scale operations, which included biowastes; and environmental applications of genetically engineered organisms. For each category, the consultant discussed the current views of the experts on the risks and various regulatory mechanisms for addressing those risks. He also identified common principles in the regulatory mechanisms.

7. The consultant stated that, while individual countries were considering the safety issues raised by genetic engineering, it was also appropriate for international organizations to address these issues from an international perspective because the technology will have worldwide impacts. He also noted certain advantages from international bodies addressing the safety issues of genetic engineering. The major advantage would be the harmonization of regulation. In addition, a costly duplication of effort in risk assessment and guideline development could be avoided. This would be especially valuable for countries with limited resources, which would be better off directing those resources toward local genetic engineering efforts.

8. The following activities were proposed for the ICGEB or the Informal Working Group:

(1) Act as a forum for information exchange and debate;

(2) Study potential risks and make findings regarding actual hazards or areas where additional research is needed;

(3) Develop risk assessment methodology;

(4) Conduct risk assessment;

(5) Develop safety guidelines for the various categories of applications of genetically engineered organisms;

(6) Assist other countries, especially less developed countries, in adapting the guidelines to their own special needs; and

(7) Train scientists, technicians, workers, and other support staff to handle genetically engineered organisms safely.

9. The consultant discussed which of the recommended actions were, in his opinion, most appropriate for either the ICGEB or the Informal Working Group. He stated that 1 would be most appropriate for the Informal Working Group and 6 and 7 would be most appropriate for the ICGEB. He stated that both organizations could be involved with 2-5, although 2-4 would probably be more appropriate for the ICGEB, and 5 would be very appropriate for the Informal Working Group, since it could begin this activity immediately.

10. After the report had been discussed by the participants, the UNIDO representatives presented UNIDO's views on biosafety. It was noted that UNIDO has since its inception been involved in several aspects of applied microbiology. However, after 1981 this type of activity has been significantly expanded as the organization initiated a series of measures, the objective of which were, and remain, to make certain that the fruits likely to emanate from advanced biotechnology R+D, including genetic engineering, will be shared by developing countries. The most important initiative being undertaken is to establish and make operational the International Centre for Genetic Engineering and Biotechnology (ICGEB) in two components located in New Delhi, India and Trieste, Italy. As of this writing, 36 countries belong to the ICGEB and several more will undoubtedly join in the near future. Further, operational activities will begin in provisional ICGEB facilities as early as the beginning of 1986.

11. During the preparatory work for the ICGEB, the matter of safe laboratory practices, especially as they pertain to research on genetically engineered microorganisms, became a matter of concern to UNIDO. As several countries offered to host the ICGEB and/or its affiliated centres, it became clear that national rules or guidelines that were aimed at ensuring safe laboratory practices varied from almost no control to control measures akin to the U.S. or U.K. guidelines. As the time grows ever shorter before research begins at both ICGEB components and at its affiliates, the matter of drawing up and applying an adequate and uniform safety rules and practices throughout the ICGEB system takes on an air of urgency. Further, since research at the ICGEB and its affiliates is to be of an applied nature, and since products and processes will ensue as soon as practicable, there is also a need to consider safety rules and practices as they may be applicable to bioscience-based industry (and to industry which will utilize the advanced biotechnology techniques).

D. Presentation of position or concept papers by representatives from WHO and UNEP.

12. The representative from WHO Headquarters presented his Organization's view on biosafety, particularly as they touch on the manufacture of vaccines and biologicals. He noted that recent advances in molecular biology have prompted the WHO to assess them in reference to public health applications. Primary considerations have been infectious diseases. As a result, new or expanded initiatives have been established within WHO's Division of Communicable Diseases. These include:

(a) WHO Programme for Vaccine Development (see list of documents);
(b) New rapid diagnostic techniques;
(c) Transfer of vaccine production technology to developing countries.

13. With these initiatives there is the commitment of the Organization to assure the safety of the product, the safety of the biotechnology industry worker, and the safety of the community from possible hazardous discharges from the industry.

14. WHO is called on by its constitution "...to develop, establish and promote international standards with respect to...biological...products." Accordingly, WHO sets international biological standards and provides relevant information to national health authorities so that national standards, calibrated in international units, can be established. Through this process WHO seeks to assure that vaccines and other biological products developed through its programmes, and others, offered through international trade will be safe for use by the general public.

15. To meet the worker and community safety requirements, WHO's Seventh General Programme of Work calls for the provision of safety guidelines for biotechnology organizations producing vaccines and biological products. Accordingly draft biosafety guidelines are being considered for laboratories and industries engaged in the manufacture or preparation of vaccines and biologicals, where:

1. The process uses organisms or cells that contain foreign DNA inserted by the recombinant DNA technique;

2. The volume of culture, medium or tissue is larger than 10 litres. This definition includes the use of continuous culture where the volume of the culture vessel or of the spent culture is greater than 10 litres; and

3. The work is carried out within contained facilities.

16. While the proposed guidelines are primarily directed towards fermentation technology, the containment specifications and other practices may be used as a basis to derive similar containment standards for other technologies. The guidelines apply only to minimum practices and physical containment.

17. Existing national guidelines for large scale production of vaccines and biological products are serving as the basis of the WHO effort. However, development of the WHO guidelines is currently in abeyance to ascertain if similar guidelines being developed by the OECD or under discussion with UNIDO and UNEP would serve WHO's needs.

18. Next, the WHO representative from the Regional Office for Europe spoke. He explained that the Environmental Health Service of WHO, Regional Office for Europe, includes in its work the impacts of air, food, water, housing waste, and occupational environments on health. Its work covers both chemical and physical safety. Biosafety has been given special consideration, especially as it pertains to food, water waste and housing. Due to the great interests of the member states of the Region on safety aspects and possible adverse impact on human health of new developments in biotechnology, a working group on Health Impact of Biotechnology was organized in Dublin, Ireland during 1982. The recommendations of the group (WHO/EURO Interim Document 16) refers to both occupational and environmental concerns of new developments of biotechnology. Because of the presence of several uncertainties and in view of the rapid development of the field, it was considered necessary to have a follow-up review on the same subject; a review meeting is now scheduled to be held during the second half of 1986.

19. The Regional Office of WHO/EURO is especially concentrating its attention on the possible adverse human health impact of the manipulation of genetic material in the laboratory, the industrial and environmental applications of biotechnology, including those posed by biological waste.

20. The Environmental Health Service of WHO/EURO has also a strong interest in any resear programmes covering health impact assessments of the developments in biotechnology.

21. The Environmental Health Service does not include in its programmes any technological development or assessment of biotechnology systems or products. The latter of these is part of the Regional Programme on Appropriate Technology for Health under its activities on biosafety, which has in the past also been working wih some aspects of safety of biotechnology.

22. Due to their global nature, the ethical issues, being inherent parts of the new developments in biotechnology, are considered as belonging to the mandate of the WHO Headquarters.

23. The view of UNEP was expressed by its representative. He made the following points:

(a) Although biotechnology with its advanced techniques of genetic engineering could generate considerable rewards for humanity, the transfer of genetically manipulated organisms (microorganisms, plants, animals, cell lines and hybridomas) from the carefully controlled laboratory bench and factory where they have been produced to the environment for agricultural, industrial or other benefits is gathering scientific, public and political concerns as man, animal, plant and other ecosystem populations will be exposed to uncommonly large numbers of such organisms. In fact, the critical area in terms of safety issues concerns will be the environment.

(b) The fact that no single health incident has been reported since the commencement of recombinant DNA in the last decade could be attributed to mainly the guidelines developed at that time. They led to strict control on the types of experiments to be conducted and specified containment procedures. In fact, as none of the postulated dangers has materialized, guidelines developed by many agencies are now being relaxed.

(c) Relative to safety considerations associated with laboratory scale and large scale industrial applications little attention was paid to environmental and agricultural applications of genetically manipulated organisms. There is a need for adequate safety measures, guidelines and regulatory actions for the production, field testing and release of genetically manipulated microorganisms in the environment. In fact, as such organisms will be engineered mainly to spread and perform their desired function in the environment (uncontained applications) they will intereact with the ecosystem and potential risks that may be associated with their release will have thus to be evaluated.

(d) A methodology for assessing any potential risk in releasing genetically manipulated organisms (including those produced by conventional methods) in the environment (as compared to laboratory and industrial scales) needs to be developed, so that properly designed uniform guidelines consistent with the level of anticipated risk could be developed.

(e) At present scientific basis for risk assessment involves: (i) hazard identification; (ii) dose - response assessment; (iii) exposure assessment; followed by (iv) risk characterization. Once the risk is characterized alternative regulatory actions could then be evaluated for selecting among them (risk management). In case of environmental applications of genetically manipulated organisms, quantitative risk assessment following the above mentioned approach will be rather difficult for many reasons, including among others:

(i) Lack of reliable sufficient data;

(ii) Lack of data on long term effects;

(iii) Relatively small size of researchers and workers engaged in this field and so assessment would be insignificant;

(iv) Risks likely to be associated with the release of a given organism will differ from one case to the other;

(v) Difficulty in predicting the fate and effects of released organisms;

(vi) Secrecy associated with recombinant DNA technology;

(vii) Absence of monitoring procedures.

(f) Ecological analysis of the likely consequences of releasing genetically manipulated organism in the environment is lacking and is needed on a case by case basis.

(g) The first initial step towards the qualitative (rather than quantitative) assessment of potential risks associated with release of genetically manipulated organisms in the environment would be to conduct a detailed study on successful and unsuccessful introduction of alien organisms in the environment (e.g. bioinsecticides, biofertilizers, new plant varieties, etc.), with the aim of developing conjectural prediction methods. The results of such a survey would provide a data base for follow-up activities, particularly with regard to the development of risk assessment methodology and, hence, safety guidelines.

E. Presentation of Concept Papers by Observers.

24. The observer from OECD made an informal presentation of the OECD study of biotechnology safety issues. The study considers the risks and benefits of industrial and environmental applications of recombinant DNA technology. It sets forth scientific considerations for evaluating the risk of organisms containing recombinant DNA. These are not regulatory standards, but rather guiding principles. She also noted that for industrial applications most organisms would require only minimum containment and that with respect to environmental applications the OECD working group had decided that it was too early to be able to develop guidelines. The OECD working group recommended, among other things, that the OECD continue to watch recombinant DNA technology and that industry use low risk organisms as much as possible. The study was approved by the OECD Committee for Scientific and Technological Policy on 5 February 1986). The observer from FAO stated his organization's interests on the subject. The FAO would like to follow further developments and would probably like to take part in the formulation of safety rules or guidelines.

F. Discussion of Risks and Regulations Pertaining to Laboratory Work.

25. The participants discussed risks and regulations pertaining to laboratory scale applications of genetic engineering. One question was whether actual safety practices could be measured in laboratories. This involved a discussion of the WHO guidelines for good microbiological practices and the extent to which they were being used, particularly in developing countries. The WHO representative stated that he would attempt to do a preliminary survey among his colleagues in the field to assess the extent of use of these guidelines.

G. Discussion of risks and regulations pertaining to large scale biotechnology processes.

26. It was agreed among all present that industrial practices wherein the use of "traditional" techniques and microorganisms has proven to be safe. It was the sense of the meeting that good manufacturing practices properly followed and properly applied to large-scale processes involving genetically engineered organisms, would adequately address any risks presented

by those processes. However, it was noted that there was not yet sufficient experience and data from which definitive conclusions could be drawn about the long-term effects of such processes. Questions also arose about whether wastes from large-scale industrial practices using genetically engineered organisms pose hazards to humans or the environment.

27. The matter whether existing national rules and legislation are adequate to safely manage bioscience-based industry had to be left open. Though it was felt that existing rules and regulations pertaining to good manufacturing practices are probably adequate if properly followed, in the industrialized countries, the situation is much less clear in the developing countries.

28. It was agreed that UNIDO would endeavour to undertake a project in reference to biowastes disposal, while WHO would survey laws directly or indirectly pertaining to biotechnology and its applications (see item J below).

H. Discussion of conjectural risks of environmental applications and the regulations thereof.

29. Whether or not hazards are posed to man and the environment by the deliberate release of genetically engineered organisms is a wide open question. The UNEP representative observed that much information is available about the effects of deliberatively released bioactive substances or agents into the environment, such as biofertilizers, biopesticides, new species of plants, etc. However, this information may not have been appropriately collected and analyzed in a manner to be a useful base for assessing the safety of releasing genetically engineered organisms into the environment.

30. As pointed out by the UNIDO consultant, examples exist where organisms that have been accidentally or otherwise released into a new environment have had deleterious impacts. He pointed out that it would be useful to design a model project to try to determine how organisms establish themselves in a new environment. If such information was available and an information base existed on the lines suggested by UNEP, it could be possible to develop guidelines to guide those who will find it useful to release genetically engineered organisms into the environment. In view of the need for more information, the UNEP representative proposed the undertaking of a project that would have as its objective the study of releasing genetically engineered into the environment (see item J below).

I. Elements to Construct Minimal Guidelines.

31. The Participants considered the issue of what elements were necessary for minimal guidelines for laboratory and industrial scale facilities. It was suggested that guidelines from various countries relating to genetic engineering or microbiology be collected and reviewed to determine their similarities and differences. UNIDO could collect the guidelines by sending written requests to the appropriate governmental body in the countries. The results of the analysis of the guidelines could be used to prepare a first draft of model guidelines, which could then be presented to a group of experts for further work and finalization.

J. Recommendations.

32. The following recommendations were accepted by the Informal Working Group:

(i) A project will be undertaken to develop minimal guidelines for laboratory and industrial scale facilities. In so doing, various national guidelines and guidelines and/or principles proposed by international organizations will be collected and abstracted, with explanations as to why guidelines differ, in order to prepare a first draft of model guidelines. The draft will be discussed and finalized at a workshop of experts in different disciplines and perspectives on the issue of safety, especially in developing countries. UNIDO will be the lead agency in carrying out this project, but with equal input from UNEP and WHO.

(ii) A project will be undertaken to assess whether biowastes from large-scale industrial practices where genetically engineered organisms are used may pose hazards to man or the environment.

This project will require the services of two consultants and will take approximately four man-months, including travel. UNIDO will be the lead agency for this project in close cooperation with UNEP.

(iii) UNEP would act as a leading agency (in co-operation with UNIDO) for the preparation of a study on the successful and unsuccessful release of genetically manipulated organisms (microorganisms, plants, animals, insects, etc. manipulated by conventional or advanced techniques) into the environment (e.g. application of bioinsecticides, biofertilizers, etc.).

This might be achieved through the organization of an expert group meeting where experts will be invited to prepare discussion papers on selected topics followed by the production of a detailed report including recommendations for future actions. Special emphasis will be placed on cases relevant to developing countries.

(iv) UNEP will sponsor a round table discussion on the subject in association with the International Conference on Microbial Ecology to be held in August 1986 in Yugoslavia. Working Group members are invited to participate.

(v) If circumstances allow, UNEP would undertake, in collaboration with its Law Unit, a survey of environmental protection acts already existing in developing and developed countries and the status of their implementation.

(vi) The Working Group agrees that it would be helpful to assess or determine the awareness of biosafety or laboratory safety, particularly in developing countries. The WHO in the past few years has published the WHO Laboratory Biosafety Manual and conducts several biosafety "Train the Trainer" courses. The WHO therefore will survey the impact of these efforts by several means which will include:

(a) Number of manuals distributed;
(b) Programme reviews by its six regional offices;
(c) Assessments by its biosafety collaborating centres, biosafety instructors and participants in the training programmes.

(vii) It was agreed that a review of existing biotechnology legal requirements on a global basis is required. WHO agreed to attempt such a review through information compiled by its Health Legislation Unit. Information regarding national laws, rules or regulations pertaining to biotechnology, including aspects of the technology relating to worker health and safety and environmental protection will be gathered and compiled on a country by country basis.

(viii) WHO has established four biosafety collaborating centres at institutions with expertise in biosafety training, research, and consultation. Their services are made available to member states. These centers are located at the Center for Disease Control CDC, Atlanta, USA; National Institute of Health (NIH), Bethesda, USA; Laboratory Center for Disease Control (LCDC) Ottawa, Canada; and Fairfield Hospital, Melbourne, Australia. The LCDC and NIH have specific expertise in industrial applications of biotechnology. Other institutions with expertise are the National Institute of Virology, Pune, India; NIH, Tokyo, Japan; and the National Bacteriology Laboratory, Stockholm, Sweden. It is suggested that it would be possible to "twin" these institutions with designated affiliated centers of the ICGEB for development of expertise in biotechnology safety programmes for developing countries. A project to do so will be designed.

33. All the foregoing recommendations are to be implemented by the time of the second meeting of the Informal Working Group.

K. Other matters.

(i) The Informal Working Group decided to invite the FAO and the ILO (International Labour Organization) to join it.

(ii) It was decided to hold the second meeting of the Informal Working Group during 3-5 November 1986. The venue will be Geneva, Switzerland.

Annex I

List of Participants

1. Members of the Informal UNIDO/WHO/UNEP Working Group

UNEP — Mr. Hamdallah Zedan
Senior Programme Officer
Environment Management Service
UNEP
P.O. Box 30552
Nairobi, Kenya

WHO — Mr. Vinson R. Oviatt
Coordinator
Safety Measures in Microbiology
World Health Organization
1211 Geneva 27, Switzerland

Mr. Jorma Järvisalo
Regional Officer for Occupational Health
Regional Office for Europe
World Health Organization
8, Scherfigsvej
DK,-2100 Copenhagen, Denmark

UNIDO — Mr. W. Kamel (Chairman of the Meeting)
Officer-in-Charge
Development and Transfer of Technology Branch

2. UNIDO Consultant:

Mr. Geoffrey M. Karny
Finnegan Henderson, et. al.
1775 K Street, N.W.
Washington, D.C. 20006, USA

3. Observers:

FAO — Mr. Björn Sigurbjörnsson
Director
Joint FAO/IAEA Division of Isotope
and Radiation Applications of Atomic Energy
for Food and Agricultural Development

OECD — Ms. Bruna Teso
Biotechnology Unit
Science and Technology Policies Division
Organization for Economic Cooperation and Development
2, Rue André-Pascal
75775 Paris Cedex 16, France

Annex II

List of Documents

	Aide-Memoire
UNIDO/IS.627	An International Approach to Biotechnology Safety
ID/WG.463/1	Safety Guidelines and Procedures for Bioscience-based Industry and other Applied Microbiology
ID/WG.463/2	Biosafety Guidelines for Manufacture of Vaccines and Biologicals
Background Papers:	Health Impact of Biotechnology, WHO Regional Office for Europe, 1984.
	Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques, prepared by the Committee for Scientific and Technological Policy, OECD

Annex III

Agenda

A. Election of a chairman and rapporteur.

B. Adoption of the draft agenda.

C. Presentation of the study "An International Approach to Biotechnology Safety" by UNIDO consultant. Discussion of the study.

D. Presentation of position or concept papers by representatives from WHO and UNEP.

E. Presentation of position or concept papers by other representatives and observers.

F. Discussion of risks and regulations pertaining to laboratory R+D.

G. Discussion of risks and regulations pertaining to large scale biotechnology processes.

H. Discussion of conjectural risks of environmental applications and the regulation thereof.

I. Consider elements required to construct minimal guidelines for biotechnology R+D facilities and for industry using biotechnology.

J. Formulate recommendations for activities to be undertaken by the members of the informal working group before its next session.

K. Other matters.

L. Close of the meeting.