WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
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ORGANISATION MONDIALE DE LA SANTÉ
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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО



EUR/ICP/CEH 010(S)
6351B
ORIGINAL: ENGLISH

# SUMMARY REPORT

# Working Group on Human and Environmental Health Impact on Microorganisms in Biotechnology

Dragsholm Castle, Hörve, Denmark
11-12 March 1991



1991

EUR/HFA target 19

# TARGET 19

## MONITORING, ASSESSMENT AND CONTROL OF RISKS IN THE ENVIRONMENT

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# ABSTRACT

The applications of biotechnology are growing continuously, as is work to ensure that they are safe. This work, however, is insufficiently known and coordinated. A WHO Working Group, including representatives of 10 institutes concerned with biosafety, was convened to tackle this problem. The Working Group reviewed work at the national and international levels to assess the risks of biotechnology to the health of workers, the public and the environment, and to develop guidelines and methods to manage these risks. The Group supported a WHO proposal to establish a WHO collaborating centre on the health impact of biotechnology to promote the exchange of information, identify gaps in knowledge, and coordinate research on and the development of safe procedures and operations in biotechnology. The Group also identified an institute - the Netherlands Organization for Applied Scientific Research (TNO) - willing to perform these tasks. The other institutes represented agreed to act as affiliated national focal point centres, and form links between the collaborating centre and other institutes involved in biosafety in their countries.

## Introduction

The Working Group was convened to review work on the assessment and management of health risks posed by biotechnology, to discuss the identification of an institute to act as a WHO collaborating centre on the health impact of biotechnology and to set up a network of affiliated institutions to advise WHO on the workers' health, public health and environmental health aspects of biotechnology. The meeting was organized in cooperation with the Danish Technology Institute, and in close consultation with the Netherlands Organization for Applied Scientific Research (TNO) and the Warren Spring Laboratory in the United Kingdom. Fifteen experts from five countries took part, as well as a representative of the United Nations Industrial Development Organization (UNIDO).

The WHO Regional Office for Europe, which has recognized the need for an institute or organization to be identified as a WHO collaborating centre on the health impact of biotechnology, made some suggestions on the tasks to be undertaken by such a collaborating centre. The funding for the work, however, could be provided, not by WHO, but rather by the centre itself or the government of the country in which it is located. WHO could possibly provide assistance in obtaining some funding for particular projects and programmes from ministries in countries, particularly those responsible for health.

## Discussion

Experts from each of the 10 institutes represented on the Working Group briefly described their biosafety-related interests. These included research on the assessment of the risks of industrial bioprocesses and release into the environment, and the development of codes of practice to comply with national and international laws and guidelines. In addition, the participants were asked to indicate the collaborative links between their institutions and others.

In Denmark, the Danish National Food Agency was studying colonization by *E. coli* in both natural ecosystems and *in vitro* models. The work of the Danish Technology Institute included sampling biological aerosols in the workplace and in deliberate release applications.

In France, the firm Pasteur Mérieux sérum et vaccins investigated the environmental risks of genetically modified microorganisms. Guidelines on biosafety were developed through the French organization ORGANBIO and the French Standards Association (AFNOR).

DECHEMA, an institute supported by the German chemical industry, had tasks in relation to the German law on genetic engineering, including a research project with the German Society for Biotechnology Research (GBF) and a project on education in biosafety. There were plans to build a bioprocessing plant. Other activities focused on the safe handling of mammalian cells and the chemical deactivation of recombinant DNA in wastewater.

In the Netherlands, the TNO biosafety centre coordinated the biosafety work of the various institutes of the Organization.

A number of activities in the United Kingdom were mentioned, including the role of a regulatory body, the Health and Safety Executive, in the application of biotechnology. The Executive's activities were related to the protection of both workers' health and the environment. The Northeast Biotechnology Centre worked on sensors for detecting hazardous airborne biochemicals. The Warren Spring Laboratory was developing safety standards for biological material in the air and for bioprocessing equipment, and was interested in methods for the surveillance of genetically modified microorganisms released into the air. The work of the Centre for Applied Microbiology and Research included studying the airborne stability of genetically modified microorganisms under various environmental conditions.

Topics of research by UNIDO included the genetic modification of plants and animals. Other work included a three-day meeting in Vienna on genetic engineering, the development of a database on the release of microorganisms, the production of codes of good practice and the harmonization of guidelines.

The current biosafety activities of other groups were described by the participants directly involved in them. The Organisation for Economic Co-operation and Development (OECD) was defining and illustrating good large-scale industrial practice for the use of genetically modified microorganisms, and developing principles of occupational and environmental safety for environmental releases. A technical committee of the Commission européenne de normalisation (CEN) was developing standards for biotechnology through four working groups. The biosafety activities of the European Federation of Biotechnology (EFB) and the Commission of the European Communities (CEC) were also described to the Working Group.

Biosafety risk assessment was reviewed. TNO's current approach to quantitative risk assessment in biotechnology was described. The Warren Spring Laboratory developed criteria for the selection and application of appropriate aerobiological monitoring techniques. The biosafety issues of solid, liquid and gaseous waste were considered; some of the technology available to deal with them was being investigated at TNO.

As a prelude to the eventual identification of an institute suitable for designation as a WHO collaborating centre on the health impact of biotechnology, each institute represented was asked to answer the following questions.

1. Do you support the idea of a WHO collaborating centre?

2. Does your institute wish to be the WHO collaborating centre?

3. Would you consider cooperating with the collaborating centre?

4. Do you wish to be part of a support network?

Most of the institutes supported the idea of a WHO collaborating centre, but many had reservations about its function. Two institutes expressed a wish to be the collaborating centre. All the institutes were willing to cooperate and to join a support network.

It was suggested that the institutes represented on the Working Group act as "affiliated national focal point centres". These centres could coordinate relevant biosafety activities, for example, on a national basis and link other

institutes in their countries with the WHO collaborating centre. The Working Group accepted this suggestion, and one of the candidate institutes for the WHO collaborating centre agreed to be one of these affiliated national focal point centres. TNO then remained as a candidate for designation as a WHO collaborating centre.

The Working Group recognized that no organization was responsible for the coordination of biosafety research and development; this could therefore be a key task for the WHO collaborating centre and its network. Other major tasks were discussed, including:

- the inventory of information on the assessment and management of biotechnology risks on existing databases;
- the identification of gaps in knowledge;
- the initiation and coordination of activities to secure funding for joint research on biosafety;
- the dissemination of data and information on biotechnology through, for example, a newsletter, scientific publications, scientific meetings and public information;
- the provision of training courses and the hosting of visiting researchers;
- the provision of information to harmonize and standardize procedures and regulations for use by such organizations as CEC, CEN, EFB, FAO, the US Food and Drug Administration (FDA), the International Organization for Standardization (ISO), and UNIDO; and
- the development of links with national and international bodies concerned with the safety aspects of biotechnology.

In addition, it was suggested that the representatives of the institutes comprising the support network meet twice a year.

## Conclusions

1. Appropriate institutions at the national and international levels in the European and other WHO regions, need to cooperate more fully and exchange more information on their biosafety-related activities.

2. There is a need to review the effects of developments in biotechnology on workers, the public and environmental health.

3. A network needs to be established to review the safety aspects of biotechnology and stimulate research on and technology development for safe procedures and operations in biotechnology.

## Recommendations

1. A WHO collaborating centre should be established to promote the exchange of information, identify gaps in knowledge and coordinate research and

development for safe procedures and operations in biotechnology. TNO has been identified as the most appropriate institution to undertake these tasks.

2. Other institutes with expertise in biosafety and related health issues should act as affiliated national focal point centres to share these tasks and become a vital link between the WHO collaborating centre and additional institutes in Member States.

3. These additional institutes should be incorporated into an overall support network.