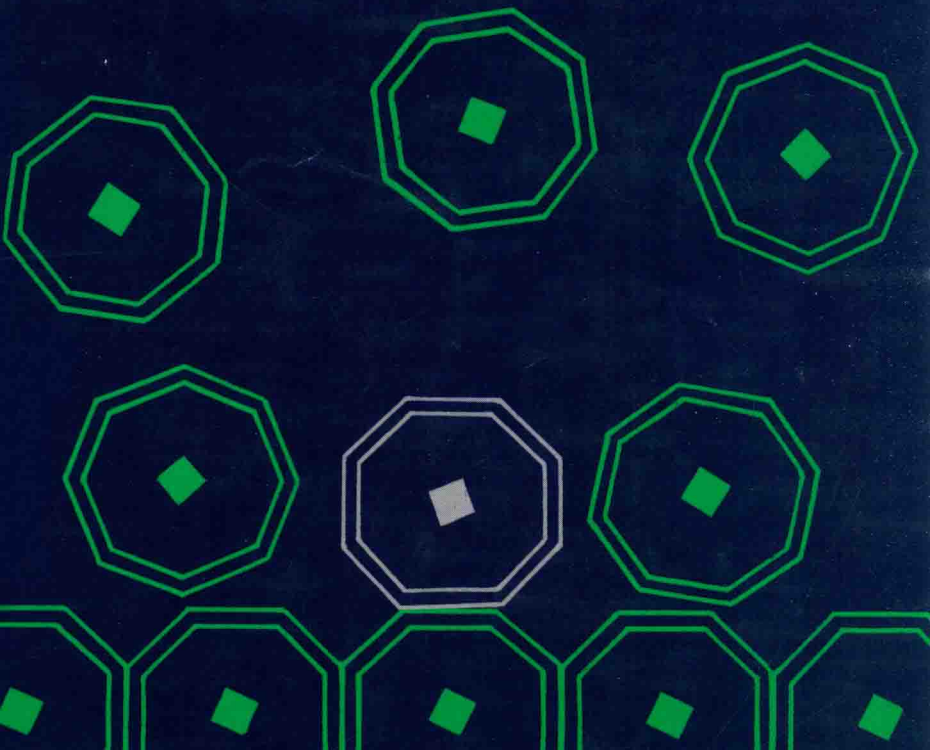
THE ENVIRONMENTAL RISKS FROM BIOTECHNOLOGY

M. CHIARA MANTEGAZZINI



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by M. Chiara Mantegazzini

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1 Introduction

The Third Environmental Action Programme (O.J. C46/1—17 February 1983, Chapter II) outlines the need to develop an environmental policy orientated towards the prevention of pollution. In addition, it establishes a comprehensive framework to prevent and control damage from commercial chemical substances. It is expected that new developments in biotechnology will produce different problems because this technology derives from and relates to natural environmental and ecological systems in many ways. Two aspects are particularly important:

(1) biotechnology, to a great extent, can serve to protect the environment,
(2) due to its very nature, such technology could disturb natural ecosystems and the associated biological and nutrient cycles.

The purpose of this study is to evaluate risk to the environment of products and processes in the field of biotechnology. The study:

- defines biotechnology;
- identifies the possible fields of application and their potential for industrial development;
- examines the potential risks associated with biotechnological processes which may arise at different stages: research, production and processing, marketing of microbial cells or their products;

- reviews relevant laws, regulations and guidelines already established or in preparation at national, Community and international levels;
- indicates suitability of existing legislation, identifies gaps in the legislative coverage of biotechnology and considers the need for changes in Community laws and regulations to protect human health and the environment.

SUMMARY

Commercial products of new techniques in biotechnology will be available in the very near future. Because of the many possible applications, biotechnology may offer significant benefits to society by alleviating problems of disease and pollution and increasing the supply of food, energy and raw materials. However, as with any new process, there are questions about the human health and environmental implications of developing and using organisms for commercial purposes. These arise particularly from:

- large-scale industrial production of commodities through biotechnologies, involving risks from accidental release of living organisms and other specific safety aspects;
- the use of new or novel organisms for various environmental and agricultural purposes.

POTENTIAL RISKS FROM INDUSTRIAL APPLICATIONS

1. Research

Although no major problems have so far arisen, registration of work and appropriate containment levels are generally

required, because there is continued concern about the following:

(1) spontaneous mutations in pure and mixed cultures when growth conditions are changed;
(2) toxins produced in thermophilic systems;
(3) modification of viruses during fermentation and their impact on other organisms;
(4) the cloning of toxic genes and the introduction of antibiotic resistance genes into micro-organisms not known to acquire them naturally.

2. Industrial processing

Hazards associated with the new genetic techniques for industrial processing may be assessed in the same way as those associated with non-engineered organisms, that is, by examining the intrinsic hazardous properties of the components used in the engineering process. Industrial hazards are more likely to be quantitative than qualitative and possible hazards can affect (a) persons who work in industrial production units and/or (b) persons and environment exposed to emissions.

2.1 *The working environment*

Most of the studies on the survival of, and gene transfer by generically engineered bacteria have used mutatant debilitated strains of *Escherichia coli* K-12. Other debilitated genera and species of micro-organisms can be used as hosts for engineered genes, but less information is available about bacteria other than *E.coli*. To avoid the potential danger of transmitting antibiotic resistance traits to pathogenic micro-organisms, whenever the use of antibiotic resistant strains is necessary adequate physical and biological safety precautions should be adopted. Only resistance to antibiotics that are not applied therapeutically should be used for marking strains. Where new micro-organisms are used

of which we have no experience, or which have undergone substantial alteration in structure, rapid ways must be found of establishing their potential as pathogens.

2.2 *Persons and environment outside the industrial installation*

There has been insufficient research to evaluate the mediating influence of environmental factors, both biotic and abiotic, on the survival, establishment and growth of, and genetic transfer by, genetically engineered bacteria. However, the limited data that are available indicate that abiotic factors—such as pH, salinity, aeration, water content—and biotic factors—such as competition between the engineered microbe and the indigenous microbiota of the specific habitat being studied, generation time and plasmid size—exert an influence on the survival and transfer of genetic information by engineered organisms under natural conditions.

Because the growth of dangerous human and animal pathogens must continue on a small scale for diagnostic, research and vaccine production purposes, a list of such organisms should be drawn up and their handling made subject to license in the EEC. (At present, most countries do not list pathogenic organisms and some do not regulate the handling of dangerous pathogens.) However, in general the technology of containment itself appears to offer no special problems once the standards are set.

It is also important to establish that those involved in the work are responsible for safe work practices and for protecting the environment from contamination. Education and training are equally important in minimizing risks. Appropriate education should ensure that managers and industrial workers at all levels are informed about potential hazards and control measures. Training is a prerequisite to ensure that appropriate safeguards associated with industrial processes can be completely carried out.

2.3 *Products*

The appearance of genotypic or phenotypic changes in the various stages of the production process can cause undesirable properties in the product. The prevention of these changes is in the interest of the manufacturer, to maintain maximum profitability. Close process control and quality control of the product should enable the manufacturer to recognize hazards related to changes in the culture media and producing micro-organisms and could be assured by adherence to Current Good Manufacturing Practices as adopted in the United States. Research is needed to develop more convenient and quicker methods to detect microbial contamination within large culture volumes and to discover the potential for phenotypic and genotypic changes in micro-organisms.

3. POTENTIAL RISKS FROM AGRICULTURAL AND ENVIRONMENTAL APPLICATIONS

The changes in established systems brought about by introduction of exotic organisms vary widely. Competition, predation, parasitism or pathogenicity on the part of the invader can result in reduction or exclusion of existing forms. These stresses may also contribute to the establishment of other exotics to cause more ecological imbalance. Over the long term, however, a new organism may finally become integrated into a system. This integration is usually marked by a significant reduction in numbers of individuals. Why this occurs may be obscure as are the reasons for their explosive spread in the first place.

A review of the literature reveals that firstly, the more disturbed, artificial, or simplified an environment is, the less likely it is that a new balance can establish in a reasonable time. Secondly, even if an exotic becomes integrated and is no longer explosive, the system it entered has been modified and is perhaps simpler.

Unfortunately, no quantitative assessment of the risk of ecological damage by genetically manipulated organisms can be made on the basis of existing ecological knowledge. Efforts directed at deriving numerical probability for establishment and disruption based on the number of negative results that have already occurred would not be meaningful or fruitful for a number of reasons. First, what constitutes a negative result is not always clear, and may be a matter of interpretation. Second, very little attention is every paid to exotic organisms unless they become a problem, and we do not really have any idea how many have been introduced and failed to get a foothold. Third, ecologists do not understand enough about the complex interactions in an ecosystem to be able to predict the outcome of an introduction. The many uncontrolled and unknown factors mean that new situations must be considered individually.

3.1 Micro-organisms

Direct or indirect changes may affect the environment when deliberate or accidental release of micro-organisms takes place. Many risks have been foreseen but they cannot, at present, be fully characterized because insufficient information is available. There is an acute need for further research to allow adequate assessment of the risks and the formulation of meaningful guidelines. In addition to producing genetically engineered microbes, the biotechnology industry should assess the survival, establishment and growth of, and the genetic transfer by, these engineered organisms under natural conditions.

3.2 Plants

The introduction of new plants into the environment must always be accompanied by careful evaluation and constant oversight by the agricultural research community. Previously, the continuing development of new crop cultivars

created the need to assess their agricultural stability and also to assure the preservation of the environment. Undesirable properties have usually been detected during experimental trials.

A plant obtained through genetic engineering must be observed under its natural growing conditions to determine whether the genetic trait which was modified is expressed as expected or predicted and to be sure that it does not have any detrimental or debilitating effects.

Applications of biotechnology could be employed in agricultural programmes in less developed countries where, commonly, supplies of fertilizers and lime are scarce, the potential for irrigation is small, and adequate support for technological innovation is limited. In addition, marginal land in northern European countries could be reclaimed for forest products and biomass.

The potential impact of genetic technologies on conservation of natural ecosystems, genetic variability and crop vulnerability is still unknown. Because of the demands of genetic engineering, the need to collect, preserve and study diverse populations is now greater than ever before. Public funds should assist research projects that could entail environmental benefits, because these are of less commercial interest and unlikely to be undertaken by industry.

4. BIOTECHNOLOGY REGULATION IN THE MEMBER STATES OF THE EUROPEAN COMMUNITY

Member countries of the European Community have differing regulatory situations in accordance with their different levels of experience in the new techniques. This means that the level of expertise on evaluation procedures and the attitudes established in respect to environmental risks are correspondingly diverse.

- In the United Kingdom and in Denmark regulations have been set up for observance of notification and safety

guidelines in research work with recombinant DNA (r-DNA).

- In the Federal Republic of Germany notification is compulsory for research work supported by the government while it is voluntary for research funded privately.
- In the Netherlands, France, Greece and Ireland notification applies on a voluntary basis and reviews of protocols take place.
- In Belgium, notification is voluntary for medical research funded by the government but review of protocols is not conducted.
- In Italy and Luxembourg no specific recommendation applies to biotechnology research or its developments.

From the viewpoint of promoting international trade and a common market within the Community, harmonization of biotechnology regulations is necessary, to prevent any temptations for countries to 'under-cut' one another with less stringent regulations. At present, no specific provisions exist for the use in the environment of genetically engineered organisms.

5. THE EXISTING REGULATORY FRAMEWORK FOR PROTECTION OF THE ENVIRONMENT

The adaptability and suitability of existing environmental regulations with respect to biotechnology will probably be a matter of further research. However, environmental regulations, as they stand now, were not designed to control the risks which could arise from accidental or deliberate release into the environment of new living organisms. Further, even if some aspects of these existing measures could be made applicable, there would still be significant areas of concern where various open environment releases would not be subject to these procedures.

In some instances it may be possible to extend present legislation to cover various aspects of environmental

concern. Nevertheless, the number of regulations to be amended is relevant and the inherent complexity and importance of biotechnology applications do not suggest that this piecemeal approach will provide complete, consistent and predictable regulation to ensure environmental protection and productive industrial growth.

2 Definition of biotechnology

In undertaking a study on any aspects of biotechnology the scope of the study must be defined. The definition of biotechnology, in fact, has been a matter of endless debate and many organizations and working parties have worked out definitions which range considerably according to the interest of those involved, but all have recognized the need for a common working definition to assess, for example, the extent of funding or the relevance of publications.

A report of Organization for Economic Cooperation and Development (OECD)[1] has proposed a definition of biotechnology covering a wide range of disciplines while excluding some agro-food activities: 'the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services'. A second relevant definition, from the United States Office of Technology Assessment (OTA) report[2] includes:'any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals or to develop micro-organisms for specific uses'. As stated in a note of the Concertation Unit for Biotechnology in Europe (CUBE—Commission of the European Communities), the OTA definition is better than the OECD's but still far from perfect; it omits the provision of services and by its specificity in fact arbitrarily limits and excludes some possible fields of application (for example, detoxification).

For the purpose of this report, which will focus on the

evaluation of environmental risks of biotechnological products and processes and on the suitability of existing legislation, a sufficiently broad definition will be adopted, which will correspond to the scientific and practical reality of biotechnology as described in the Forecasting and Assessment of Science and Technology (FAST) report (Annex 1)[3] and to the definition proposed by CUBE (a streamlined version of OTA) as follows: 'the use or development of techniques using organisms (or parts of organisms) to provide or improve goods and services'. Other definitions are listed in Annex 2.

It should be stressed that biotechnology, far from being new, represents a developing and expanding technology based on a centuries-old foundation: people have deliberately selected organisms that improved agriculture, animal husbandry and food making since the beginning of civilization. More recently, a better understanding of genetics has led to more effective application of traditional genetics in such areas as antibiotic and chemical production. The rapid development of molecular biology and cellular biology in the last few decades has laid the scientific basis for entirely new technologies. Dynamic and progressive changes, some of which are illustrated in Annex 3, have characterized this sector ever since.