



Recommendation of the Council
concerning Safety Considerations
for Applications of Recombinant
DNA Organisms in Industry,
Agriculture and the
Environment

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Background Information

The Recommendation concerning Safety Consideration for Application of Recombinant DNA Organism in Industry, Agriculture and the Environment was adopted by the OECD Council on 16 July 1986 on the proposal of the Committee for Scientific and Technological Policy. The Recommendation is intended to promote a common understanding of the safety issues raised by recombinant DNA techniques in order to provide the basis for taking initial steps toward international consensus, the protection of health and the environment, the promotion of international commerce and the reduction of national barriers to trade in the field of biotechnology.

THE COUNCIL,

HAVING REGARD to Articles 1 c), 3 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the report "Recombinant DNA¹ Safety Considerations - Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms derived by Recombinant DNA Techniques";

CONSIDERING that recombinant DNA techniques have opened up new and promising possibilities in a wide range of applications and can be expected to bring considerable benefits to mankind;

RECOGNISING, in particular, the contribution of these techniques to the improvement of human health and that the extent of this contribution is expected to increase significantly in the near future;

CONSIDERING that a common understanding of the safety issues raised by recombinant DNA techniques will provide the basis for taking initial steps toward international consensus, the protection of health and the environment, the promotion of international commerce and the reduction of national barriers to trade in the field of biotechnology;

CONSIDERING that the vast majority of industrial recombinant DNA large-scale applications will use organisms of intrinsically low risk which warrant only minimal containment consistent with good industrial large-scale practice (GILSP);

CONSIDERING that the technology of physical containment is well known to industry and has successfully been used to contain pathogenic organisms for many years;

RECOGNISING that, when it is necessary to use recombinant DNA organisms of higher risk, additional criteria for risk assessment can be identified and that these organisms can also be handled safely under appropriate physical and/or biological containment;

CONSIDERING that assessment of potential risk of recombinant DNA organisms for environmental or agricultural applications is less developed than the assessment of potential risks for industrial applications;

RECOGNISING that assessment of potential risk to the environment of environmental and agricultural applications of recombinant DNA organisms should be approached with reference to, and in accordance with, information held in the existing data base, gained from the extensive use of traditionally modified organisms in agriculture and the environment generally and that with step-by-step assessment during the research and development process potential risk should be minimised;

CONSIDERING the present state of scientific knowledge;

RECOGNISING that the development of general international guidelines governing agricultural and environmental applications of recombinant DNA organisms is considered premature at this time;

RECOGNISING that there is no scientific basis for specific legislation to regulate the use of recombinant DNA organisms;

On the proposal of the Committee for Scientific and Technological Policy;

I. RECOMMENDS that Member countries:

- a) Share, as freely as possible, information on principles or guidelines for national regulations, on developments in risk analysis and on practical experience in risk management with a view to facilitating harmonization of approaches to recombinant DNA techniques;
- b) Examine their existing oversight and review mechanisms to ensure that adequate review and control of the implementation of recombinant DNA techniques and applications can

be achieved while avoiding any undue burdens that may hamper technological developments in this field;

- c) Recognise, when aiming at international harmonization, that any approach to implementing guidelines should not impede future developments in recombinant DNA techniques;
- d) Examine at both national and international levels further developments such as testing methods, equipment design, and knowledge of microbial taxonomy to facilitate data exchange and minimise trade barriers between countries. Due account should be taken of ongoing work on standards within international organisations, e.g., WHO, CEC, ISO, FAO, MSDN²;
- e) Make special efforts to improve public understanding of the various aspects of recombinant DNA techniques;
- f) Watch the development of recombinant DNA techniques for applications in industry, agriculture and the environment, while recognising that for certain industrial applications, and for environmental and agricultural applications of recombinant DNA organisms, some countries may wish to have a notification scheme;
- g) Ensure that assessment and review procedures protect intellectual property and confidentiality interests in applications of recombinant DNA, recognising the need for innovation while still ensuring that all necessary information is made available to assess safety.

II. RECOMMENDS, with specific reference to industrial applications, that Member countries:

- a) Ensure, in large-scale industrial applications of recombinant DNA techniques, that organisms which are intrinsically of low risk are used wherever possible, and handled under the conditions of Good Industrial Large-Scale Practice (GILSP) described in the report;
- b) Ensure that, when a risk assessment using the criteria defined in the report indicates that a recombinant DNA organism cannot be handled merely by GILSP, appropriate containment measures, in addition to GILSP, and corresponding to the risk assessment are applied;
- c) Encourage, in large-scale industrial applications requiring physical containment, further research to improve techniques for monitoring and controlling non-intentional release of recombinant DNA organisms.

III. RECOMMENDS, with specific reference to agricultural and environmental applications, that Member countries:

- a) Use the existing considerable data on the environmental and human health effects of living organisms to guide risk assessments;
- b) Ensure that recombinant DNA organisms are evaluated for potential risk, prior to applications in agriculture and the environment by means of an independent review of potential risks on a case-by-case basis³;
- c) Conduct the development of recombinant DNA organisms for agricultural or environmental applications in a stepwise fashion, moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited field testing and finally, to large-scale field testing;
- d) Encourage further research to improve the prediction, evaluation, and monitoring of the outcome of applications of recombinant DNA organisms.

IV. INSTRUCTS the Committee for Scientific and Technological Policy to:

- a) Review the experience of Member countries in implementing the principles contained in the report;
- b) Review actions taken by Member countries in pursuance of this Recommendation and to report thereon to the Council;
- c) Consult with other appropriate Committees of the OECD in developing proposals for a co-ordinated future work programme in biotechnology.

¹ DNA: deoxyribonucleic acid.

² World Health Organisation (WHO); Commission of the European Communities (CED); International Standards Organisation (ISO); Food and Agriculture Organisation (FAO); Microbial Strains Data Network (MSDN).

³ Case-by-case means an individual review of a proposal against assessment criteria which are relevant to the particular proposal: this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded.

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