

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

OECD Legal Instruments



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Background Information

The Recommendation concerning Safety Considerations for Applications of Recombinant DNA Organisms in Industry, Agriculture and the Environment was adopted by the OECD Council on 16 July 1986 (hereafter the "<u>1986 version of Recommendation</u>" or the "Recommendation") on a proposal of the Committee for Scientific and Technological Policy (CSTP). The Recommendation aims to promote a common understanding of the safety issues raised by applications of recombinant DNA organisms and 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.

In 2019, the responsibility over the Recommendation was transfered from the CSTP to the Chemicals and Biotechnology Committee (CBC) as agreed by the OECD Council. As of this date, the CBC, through the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) and the Working Party for the Safety of Novel Foods and Feeds (WP-SNFF), is in charge of the follow-up actions contained in the Recommendation.

The Recommendation was revised by the OECD Council on 17 September 2024 to take account of biotechnology developments, scientific advances, increased knowledge, current safety practice and regulatory systems developed by Adherents.

The role of the OECD in promoting the safe use of products derived from modern biotechnology

The Recommendation has been a significant OECD legal instrument pertaining to international cooperation in biosafety and food/feed safety regulation. In tight cooperation with other international organisations, the OECD developed a series of basic concepts, tools and key documents that set up the founding principles of the risk/safety assessment of applications of recombinant DNA organisms.

The main output of the WP-HROB and the WP-SNFF consists of 'consensus documents' which are intended to assist authorities in the conduct of risk/safety assessment of recombinant DNA organisms and products derived from them. They are currently used by national Authorities in many jurisdictions worldwide, including non-Members.

2024 revision of the Recommendation

Since 1986, biotechnology has evolved in many applications for the agriculture, food and industry sectors. These include the commercialisation of genetically modified crops, gene drive to control insect-vectors of disease and contained micro-organisms for bio fermentation. In the context of the OECD-wide Standard-Setting Review (2016-2021), the CSTP found that the Recommendation should be reviewed.

Shortly after the transfer of responsibility over the Recommendation to the CBC, the WP-HROB and the WP-SNFF started discussions to evluate the relevance of the Recommendation from their perspective and confirmed that the Recommendation remained relevant but needed to be updated to take account of biotechnology developments, scientific advances, increased knowledge, current safety practice and regulatory systems developed by Adherents.

The WP-HROB and the WP-SNFF circulated a survey in 2020 to their delegates, with three general overarching questions regarding the relevance, purpose and scope of the 1986 version of the Recommendation as well as the extent of the update or revision needed. Between 2022 and 2024, four drafts were developed and discussed by the WP-HROB and the WP-SNFF. In May 2024, the WP-HROB and the WP-SNFF approved the transmission of the draft revised Recommendation to the CBC. In June 2024, the CBC approved the draft revised Recommendation, for transmission to Council for adoption. The Council adopted the revised Recommendation on 17 September 2024.

The revised Recommendation includes the following main revisions:

 Reference to recent OECD work completed under the environmental safety and novel food and feed safety programmes;

- Recognition of the accumulated experience of risk/safety assessment of traditionally bred and recombinant DNA organisms may have relevance to risk/safety assessments of organisms derived by new biotechnology techniques other than recombinant DNA techniques;
- Adjust and clarify references to the work on standards of other relevant international organisations or bodies/entities, update the name of responsible committee, arrange text formatting and align the language and structure with recent OECD Recommendations.

Next steps

The Secretariat will continue to disseminate the Recommendation by sharing it with relevant stakeholders and networks. Adherents are encouraged to organise events to promote the implementation and dissemination of the Recommendation, with the assistance of the OECD Secretariat. The CBC will review the experience of Adherents in implementing this Recommendation and report to the Council on the implementation, dissemination and continued relevance of this Recommendation no later than five years following its revision and at least every ten years thereafter. The on-going programmes implemented by the WP-HROB and WP-SNFF already contribute to this review extensively, including through regular exchange on developments relating to environmental and food and feed safety of biotechnology products, Adherents' participation in elaborating guidance and 'consensus documents' for helping the risk/safety assessment, discussions on emerging issues, update of the BioTrack product database with information provided by delegations on approved recombinant DNA organisms.

For further information please consult: OECD Biosafety, Novel Food and Feed Safety website: <u>https://www.oecd.org/en/topics/biosafety-novel-food-and-feed-safety.html</u>. Contact information: <u>ehs.contact@oecd.org</u>.

Implementation

Report to Council on the implementation, dissemination and continued relevance

In line with current OECD standard-setting practice, a number of follow-up actions are foreseen in the Recommendation, including reporting to the Council on the implementation, dissemination and continued relevance of this Recommendation no later than five years following its revision and at least every ten years thereafter. This report to Council will assess the relevance and impact of Recommendation, with a view to identify follow-up actions to improve implementation and dissemination.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development (OECD) of 14 December 1960;

HAVING REGARD to the report "Recombinant DNA Safety Considerations – Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms derived by Recombinant DNA Techniques" (hereafter 'the report') which was released in 1986 at the same time as the adoption of this Recommendation;

HAVING REGARD to the ongoing OECD work on the programmes for harmonisation of regulatory oversight in biotechnology and the safety of novel foods and feeds, the related publications, database and reports, including: "Safety Considerations for Biotechnology" [DSTI/STP(91)14]; "Safety Considerations for Biotechnology: Scale-Up of Crop Plants" [DSTI/STP/BS(92)2/REV5]; "Safety Evaluation of Foods Derived by Modern Biotechnology – Concepts and Principles" [COM/ENV/DSTI/EPOC/BT(92)83]; Safety Considerations for Biotechnology: Scale-Up of Microorganisms as Biofertilizers" [OECD, 1995];

RECOGNISING that sharing knowledge and experiences on biosafety and novel food and feed safety in OECD has resulted in significant benefits for Members and non-Members;

HAVING REGARD to the standards developed by other international organisations related to the safety of agricultural and environmental applications of recombinant deoxyribonucleic acid (DNA) organisms;

CONSIDERING that recombinant DNA techniques have opened up new and promising possibilities in a wide range of applications;

RECOGNISING the contributions of these techniques to date and that these contributions are expected to continue to increase in the future;

CONSIDERING that a common understanding of the potential safety issues raised by applications of recombinant DNA organisms provides the basis for international consensus, the protection of human and animal 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 large-scale industrial applications of recombinant DNA organisms continues to use organisms which may 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 organisms for decades;

RECOGNISING that, when higher-risk organisms containing recombinant DNA are being researched or evaluated, additional criteria for risk/safety assessment may be identified and that these organisms can also be handled and evaluated safely under appropriate physical and/or biological containment;

RECOGNISING that environmental risk/safety assessment of agricultural and environmental applications of recombinant DNA organisms should be approached with reference to, and in accordance with, the decades of experience gained from the extensive use of traditionally bred organisms and recombinant DNA organisms in agriculture and the environment generally, as well as information held in the existing scientific literature and databases, and risk/safety assessments of recombinant DNA organisms;

RECOGNISING that with step-by-step assessment during the research and development process potential risks should be minimised by appropriate measures;

RECOGNISING that experience now exists from the assessment of potential risk of recombinant DNA organisms in industrial, agricultural and environmental applications informed by the step-by-step and case-by-case approaches proposed in the report;

CONSIDERING the significant accumulation of scientific knowledge of, and ongoing advances in, recombinant DNA techniques and applications of recombinant DNA organisms;

CONSIDERING the development of genomic techniques other than recombinant DNA techniques;

RECOGNISING that the accumulated experience of risk/safety assessment of traditionally bred and recombinant DNA organisms for industrial, agricultural and environmental applications may also have relevance to risk/safety assessments of organisms derived by new biotechnology techniques other than recombinant DNA techniques for the same types of applications.

On the proposal of the Chemicals and Biotechnology Committee, in consultation with the Committee for Scientific and Technological Policy:

I. AGREES that this Recommendation applies to risk/safety considerations related to industrial, agricultural, and environmental applications of organisms derived by recombinant DNA techniques.

II. RECOMMENDS that Members and non-Members having adhered to this Recommendation (hereafter the "Adherents") establish, or update based on experience, and implement domestic regulatory frameworks concerning risk/safety considerations for applications of recombinant DNA organisms. To that effect, Adherents should:

General applications

1. Share, as freely as possible, with a view to facilitating harmonisation in approaches to evaluating and managing applications of recombinant DNA organisms, information on: principles or guidelines for risk/safety assessment under domestic regulations; risk/safety assessments; developments in risk analysis; authorisations and practical experience in risk management;

2. Examine their existing oversight and review mechanisms to ensure that adequate review and control of applications of recombinant DNA organisms can be achieved while avoiding any undue burdens that may hamper innovation and technological developments and their use in this field;

3. Recognise, when working towards international harmonization, that any approach to implementing guidelines should be proportionate to ensure safety while not impeding future developments in recombinant DNA techniques, organisms and their applications;

4. Examine at both national and international levels further developments in science and technology, to facilitate data exchange and minimise trade barriers between countries, taking due account of the ongoing work on standards within the relevant international organisations and bodies/entities;

5. Make special efforts to inform the public about the various aspects of recombinant DNA techniques, organisms and their applications, including domestic regulatory frameworks and risk/safety assessments of industrial, agricultural and environmental applications of recombinant DNA organisms;

6. Monitor the development of recombinant DNA techniques for applications in industry, agriculture and the environment, while recognising that for certain industrial applications, and for agricultural and environmental applications of recombinant DNA organisms, some Adherents have a notification scheme;

7. Ensure that assessment and review procedures protect intellectual property and confidentiality interests, recognising the need for innovation while still ensuring that all necessary information to assess safety is made available.

Industrial applications

8. Ensure, in large-scale industrial applications of recombinant DNA organisms, that organisms which are intrinsically of low risk are used wherever possible and that any appropriate containment measures are applied, including the conditions of Good Industrial Large-Scale Practice (GILSP) described in the report;

9. Encourage, in large-scale industrial applications requiring physical containment, to continue to improve techniques for monitoring and preventing non-intentional release of recombinant DNA organisms.

Agricultural and environmental applications

10. Use the considerable existing scientific data, information and experience on the effects of living organisms (including recombinant DNA organisms) on human and animal health, and the environment to guide future risk/safety assessments;

11. Ensure that, on a case-by-case basis, recombinant DNA organisms are evaluated for potential risks, prior to applications in agriculture and the environment, by means of an independent review. Case-by-case means an individual review of a proposed application of a recombinant DNA organism against assessment criteria which are relevant to the particular proposal, while recognising certain classes of proposals may be excluded from review according to Adherents' domestic regulatory frameworks;

12. Ensure that the development of recombinant DNA organisms for agricultural or environmental applications continues to be conducted in a stepwise fashion, moving, where appropriate, from the laboratory to the confined experimental facility, to limited field testing, to large-scale field testing and finally, general release;

13. Encourage further research to support the risk/safety assessment and monitoring of applications of recombinant DNA organisms.

- **III. INVITES** the Secretary-General and the Adherents to disseminate this Recommendation.
- **IV. INVITES** non-Adherents to take account of and adhere to this Recommendation.
- V. **INSTRUCTS** the Chemicals and Biotechnology Committee to:
 - a) Review the experience of Adherents in implementing this Recommendation;
 - b) Report to the Council on the implementation, dissemination and continued relevance of this Recommendation no later than five years following its revision and at least every ten years thereafter.

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