

Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals

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Background Information

The Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Chemicals (hereafter the "Decision-Recommendation") was developed by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (now Chemicals and Biotechnology Committee (CBC)), and was adopted on 25 May 2018 by the OECD Council. It revised and replaced the 1991 Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals (hereafter the "1991 Decision-Recommendation").

Scope of the Decision-Recommendation

In 2016, in line with the CBC Standard-Setting Action Plan, work started to update the 1991 Decision-Recommendation in order to reflect a new emphasis on the development and application of novel methods for assessing the hazards of chemicals, remove outdated language concerning the review of High Production Volume (HPV) chemicals in the legally binding part of the 1991 Decision-Recommendation, as well as to include the re-use of national assessments between Adherents and sharing the burden for data generation. However, a key element of the Decision-Recommendation remains on the 'co-operative' aspects of the investigation and risk reduction of chemicals. While Part B of the 1991 Decision-Recommendation remained relevant, its update was aimed at modernising and strengthening it in order to address both risk prevention and reduction, and a decision was added to implement the Globally Harmonised System on Classification and Labelling of Chemicals (GHS), an internationally agreed system developed by the United Nations for hazard classification and hazard communication for chemicals, and share the results of classifications derived pursuant to the GHS with other Adherents [ENV/JM(2018)9].

As a result, the Council abrogated the 1991 Decision-Recommendation and adopted the current Decision-Recommendation on 25 May 2018. The current Decision-Recommendation has a broader scope than the 1991 one – all references to "chemicals" cover bulk form and nanoforms of chemicals, including manufactured nanomaterials – compared to the 1991 Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Existing Chemicals, which focused on "existing chemicals".

The Decision-Recommendation is composed of two parts: Part A focuses on the development of harmonised hazard and exposure assessment methodologies for chemicals, collaborative assessment, information dissemination and sharing the burden of information generation. Part B focuses on risk prevention and reduction including the establishment and strengthening of national risk reduction programmes, the implementation of the Globally Harmonised System of Classification and Labelling, the undertaking of concerted activities to prevent or reduce the risks of chemicals taking into account a life-cycle perspective and the sharing of best practices regarding risk management approaches including socioeconomic assessment.

Next steps

In the Decision-Recommendation, the Council instructs the CBC to monitor its implementation and to report to the Council five years from the date of its adoption and regularly thereafter. In line with this instruction, the <u>2023 Report</u> on dissemination, implementation, and continued relevance (the "2023 Report to Council") provides an assessment of key activities undertaken to disseminate and implement the Decision-Recommendation, as well as conclusions regarding its continued relevance.

The mandates and work of three subsidiary bodies of the CBC directly support in the implementation of provisions of the Decision-Recommendation, notably in by ensuring the 'co-operative' aspects of the Decision-Recommendation and harmonisation of approaches across Adherents. Since provisions of this Decision-Recommendation are implemented through collaborative activities at the OECD, the dissemination of these implementation activities are also reflected in the context of 'dissemination'.

For further information please consult: our webpage on the assessment of chemicals at http://www.oecd.org/chemicalsafety/risk-assessment/ and on the risk management of chemicals at http://www.oecd.org/chemicalsafety/risk-management/. Additional information on OECD's Chemicals Programme can also be found at: http://ww.oecd.org/chemicalsafety/. Contact information: ehs.contact@oecd.org.

Implementation

2023 Report to Council

The Report on dissemination, implementation, and continued relevance was presented to Council in 2023, assessing key activities undertaken to disseminate and implement the Decision-Recommendation, as well as its continued relevance through a survey to Adherents and the European Union, supplemented by additional information gathered by the Secretariat.

Key findings regarding implementation

The information gathered suggests that Adherents, domestically and in the context of collaborative work at the OECD, have made significant and ongoing efforts to implement the Decision-Recommendation, including progress on the development of novel hazard and exposure assessment methodologies, dissemination of information on hazards and exposure to chemicals including through the GHS (Globally Harmonised System of Classification and Labelling) and increased collaboration regarding risk management approaches.

The implementation of several provisions of the Decision-Recommendation occurs through activities of some of the CBC's subsidiary bodies under its supervision, including more than 65 meetings of OECD bodies, webinars and events related to the topics of the Decision-Recommendation; the publications of more than 95 reports (guidance, case studies, information) related to the provisions of the Decision-Recommendation; and the development or contribution to the the development of, several publicly available electronic tools and portals related to the Decision-Recommendation including examples such as the <u>eChemPortal</u>, the OECD Per- and Polyfluoroalkyl Substances (PFAS) Portal, IUCLID (International Uniform ChemicaL Information Database), the QSAR (Quantitative structure-activity relationship) Toolbox, Substitution and Alternative Assessment (SAAT) Toolbox and the eAOP (Adverse Outcome Pathway) Portal.

Challenges to the implementation

While the Decision-Recommendation is overall well-implemented by Adherents, there are some challenges to its implementation, which mainly pertain to the evolving nature of the field. Given that scientific knowledge is continually advancing, hazard and exposure methodologies as well as risk management approaches are constantly evolving. Therefore, the sharing of best practices and development of novel methodologies will remain a constant goal to keep pace with developments. This means that implementation of many of the provisions of the Decision-Recommendation will always be a moving target for Adherents to work towards (i.e., decision II, recommendations IV, XII, XIV).

One of the constant criticisms in the field of chemical risk assessment and management is the lack of information on chemicals to inform decision-making. While this Report highlights advances in sharing of information on chemicals and risk management decisions, there is a continuing need to improve the implementation of related provisions in the Decision-Recommendation (i.e. decision V, recommendations VII, X, XII).

To continue to promote efficiencies and effectiveness in chemical assessment, it is recommended that Adherents build upon the practices to use the results of investigations of chemicals carried out by other Adherents in preparing assessments of the potential health and environmental impacts of chemicals (recommendation VI). This leverages the results of the development of harmonised approaches and application of best practices.

Continued Relevance and Opportunities to Further Enhance Dissemination and Implementation

Several activities have been undertaken to support the dissemination of the Decision-Recommendation by both the Secretariat and Adherents (e.g. the presentation by the Secretariat of the work implemented under the Decision-Recommendation at over 45 events external to the OECD; briefings and correspondence by Adherents at different levels of their own governements but also to non-Adherents and non-governemental actors; co-operation with other interntional organisations most notably eight United Nations (UN) agencies involved in chemical safety, through the Inter-organization Programme for the Sound Management of Chemicals).

Possible opportunities to further enhance dissemination could include further dissemination of the activities and outputs (reports, electronic tools etc.) in relation to the implementation of the Decision-Recommendation to non-Adherents; or further dissemination of harmonised approaches beyond delegates to the individual Working Parties and the CBC involved in the implementation of the Decision-Recommendation.

The 2023 Report concluded that the Decision-Recommendation remains relevant and proposes actions to further support implementation and dissemination. The next reporting to Council is scheduled to take place in 10 years or earlier if developments in the field warrant it.

Adherents are encouraged to continue disseminating and implementing all aspects of the Decision-Recommendation, and in particular address the challenges identified in the Report including by:

- 1. developing novel hazard and exposure assessment methodologies;
- 2. sharing of risk management approaches and best practices;
- 3. further improving the dissemination of risk assessment outcomes and associated risk management activities including the dissemination of information regarding chemical substances;
- 4. leveraging the investigations of chemicals of other Adherents in their assessment activities.

The Chemicals and Biotechnology Committee (CBC), through its relevant working parties, is invited to continue supporting the implementation of this Decision-Recommendation through collaborative work, in particular to continue to facilitate information exchange, provide fora for implementation of some provisions; and by strengthening its efforts to ensure co-operation with other international organisations, in particular with the other Participating Organisations of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). The CBC is also invited to continue promoting international awareness of this Decision-Recommendation, with a view to informing, advising and encouraging non-Adherents to participate in the OECD's work in the field of cooperative investigation and risk reduction of chemicals.

Implementation toolkit / Good Practice Principles / Practical Guidance

The Report provides links to more than 95 reports (guidance, case studies, information) related to the topics of the Decision-Recommendation as well as information on several publicly available electronic tools and portals related to the Decision-Recommendation. These resources can also be accessed via the OECD website on Chemical Safety <u>www.oecd.org/chemicalsafety</u> and additional webpages outlined in the "Related Documents" section.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Cooperation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and the Environment [C(77)97/FINAL], the Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals [C(87)90(Final)], the Recommendation of the Council on Integrated Pollution Prevention and Control [C(90)164/FINAL], and the Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials [C(2013)107];

HAVING REGARD to the experience gained through the implementation of the Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/FINAL], which this Decision-Recommendation replaces;

HAVING REGARD to the work done by the United Nations in the area of chemical safety, in particular in the development of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), an internationally agreed system for hazard classification and hazard communication for chemicals for improving harmonisation globally;

HAVING REGARD to paragraph 23(c) of the Plan of Implementation of the World Summit on Sustainable Development, which encourages United Nations' members to implement the GHS;

HAVING REGARD to the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy, adopted by the International Conference on Chemicals Management of 4 to 6 February 2006, as part of the Strategic Approach to International Chemicals Management (SAICM);

HAVING REGARD to the Resolution of the Council on the Implementation of the Strategic Approach to International Chemicals Management (SAICM) [C(2008)32];

HAVING REGARD to the United Nations Environment Assembly (UNEA) Resolution 1/5 on chemicals and waste of June 2014 which "[r]ecognizes the continued relevance of the sound management of chemicals and waste beyond 2020" and "[e]mphasizes that the sound management of chemicals and waste is an essential and integral cross-cutting element of sustainable development and is of great relevance to the sustainable development agenda".

HAVING REGARD to the 17 Sustainable Development Goals (SDGs) of the 2030 Agenda for Sustainable Development of September 2015 (A/RES/70/1), in particular SDG 12 and Target 12.4 which refer to the sound management of chemicals and waste, SDG 3 on good health and well-being, and SDG 6 on clean water and sanitation;

HAVING REGARD to the precautionary approach articulated in Principle 15 of the United Nations 1992 Rio Declaration on the Environment and Development (A/CONF.151/26), which provides that lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation;

CONSIDERING that concerted identification, assessment and management of chemicals can produce more efficient use of national and international resources towards prevention or reduction of any risks to the environment or to the health of the general public or workers uncovered in all phases of the life cycle of the chemicals;

CONSIDERING that due consideration should be given to protecting potentially sensitive subpopulations (such as pregnant women, children and the elderly) or ecosystems;

CONSIDERING that decision-making following the assessment of the effects on health and/or the environment for the purpose of preventing or reducing risks should be informed by an understanding of the economic costs and benefits of introducing a control action and an evaluation of the benefits of using the substance and its substitutes;

CONSIDERING that co-operative international efforts constitute an efficient and effective way to apply economic and regulatory approaches for the systematic investigation and prevention or reduction of the risks of hazardous chemicals throughout their life-cycle;

CONSIDERING that strengthened national and co-operative international efforts to investigate, prevent and reduce the risks of hazardous chemicals will substantially alleviate threats of serious or irreversible damage to the environment or human health;

CONSIDERING the efforts to raise awareness of chemicals management within related policy areas such as waste management and resource efficiency in order to increase the sustainability of material cycles;

CONSIDERING that assessments integrate various types of information from predictive models (e.g. animal models, in vitro models, in silico models), epidemiological studies and field studies in order to identify the potential hazards, exposure and risks of a chemical and that the relative level of confidence and uncertainty in the information is weighed in the context of the particular use and regulatory framework;

On the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology:

I. AGREES that all references to "chemicals" in this Decision-Recommendation cover bulk form and nanoforms of chemicals, including manufactured nanomaterials.

Co-operative Investigation and Assessment

II. DECIDES that Members and non-Members having adhered to this Decision-Recommendation (hereafter the "Adherents") shall co-operatively develop harmonised hazard and exposure assessment methodologies for chemicals in order to align approaches for identifying those chemicals which may pose a hazard or risk to the environment or human health. This will also include methodologies to prioritise chemicals for regulatory consideration.

III. DECIDES that Adherents shall co-operatively elaborate and disseminate agreed hazard, exposure or risk assessments on chemicals of mutual interest and, if relevant, classification and labelling designations for these chemicals.

IV. RECOMMENDS that Adherents, when developing harmonised hazard and exposure assessment methodologies, consider:

- i) the risks arising from the combined exposure to multiple chemicals;
- ii) the elaboration of integrated approaches to testing and assessment including harmonised testing strategies; and
- the regulatory applicability of the methods and identify areas of uncertainty which need to be accounted for in their use, especially when assessing hazards of potentially higher concern such as carcinogenicity, mutagenicity or toxicity for reproduction or the combination of persistence, bioaccumulation and toxicity.

V. DECIDES that Adherents shall make information on hazards and exposure to chemicals obtained from their investigations publicly available, respecting the protection of confidential data and proprietary rights.

VI. **RECOMMENDS** that, in order to promote efficiencies and effectiveness in chemical assessment, Adherents use the results of investigations of chemicals carried out by other Adherents in preparing assessments of the potential health and environmental impacts of chemicals.

VII. RECOMMENDS that Adherents co-operate to share the burden for data generation and improve access to information on chemicals throughout their life-cycle, respecting data ownership rights.

Risk Prevention or Reduction

VIII. DECIDES that Adherents shall establish or strengthen national programmes aimed at the prevention or reduction of risks from chemicals to the environment and the health of the general public or workers.

IX. DECIDES that Adherents shall implement the GHS in order to further hazard communication in the supply chain. Such implementation can be done by Adherents applying those elements of the GHS that are appropriate to them and may vary by product category and stage in the lifecycle.

X. RECOMMENDS that Adherents communicate and share classifications derived pursuant to the GHS with other Adherents.

XI. **RECOMMENDS** that, where appropriate, Adherents identify and undertake concerted activities to prevent or reduce the risks of identified chemicals taking into account the entire life-cycle of the chemicals. These activities could encompass both regulatory and non-regulatory measures including: the promotion of new business models such as chemical leasing; the use of cleaner products and technologies; emissions inventories; product labelling; limitations on production or use; economic incentives; substitution with safer alternatives including non-chemical alternatives; and the phase-out or banning of chemicals.

XII. RECOMMENDS that Adherents communicate and share the outcomes of risk assessments, particularly when chemicals are identified as requiring risk management.

XIII. RECOMMENDS that Adherents communicate and share best practices regarding risk management approaches in general and approaches developed for specific chemicals of mutual concern.

XIV. RECOMMENDS that Adherents communicate and share best practices for the socioeconomic assessment of chemicals management.

Dissemination and implementation

XV. INVITES Adherents and the Secretary-General to disseminate this Decision-Recommendation and take the necessary steps to ensure that this work is carried out in co-operation with other international organisations, in particular with the other Participating Organisations of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

XVI. INVITES non-Adherents to take account of and adhere to this Recommendation.

XVII. INSTRUCTS the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, to:

- i) Facilitate the implementation of this Decision-Recommendation, notably through:
 - conducting co-operative work to develop harmonized hazard and exposure assessment methodologies;
 - the development of procedures for the notification and exchange of information on Adherents' activities on assessment of chemicals and on preventing or reducing the risks posed by chemicals;
 - encouraging, where one or more Adherents identify that a chemical may pose a hazard or risk, or implement risk reduction measures in relation to a chemical, other Adherents to report on what similar activities they are engaged in in relation to that identified chemical and associated risk or hazard; and
 - conducting concerted activities to prevent or reduce the risk of specific chemicals or groups of chemicals;

- ii) Promote international awareness of this Decision-Recommendation, with a view to informing, advising and encouraging non-Adherents to participate in the OECD's work in the field of cooperative investigation and risk reduction of chemicals; and
- iii) Monitor the implementation of this Decision-Recommendation and report to the Council no later than five years following its adoption and regularly thereafter.

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