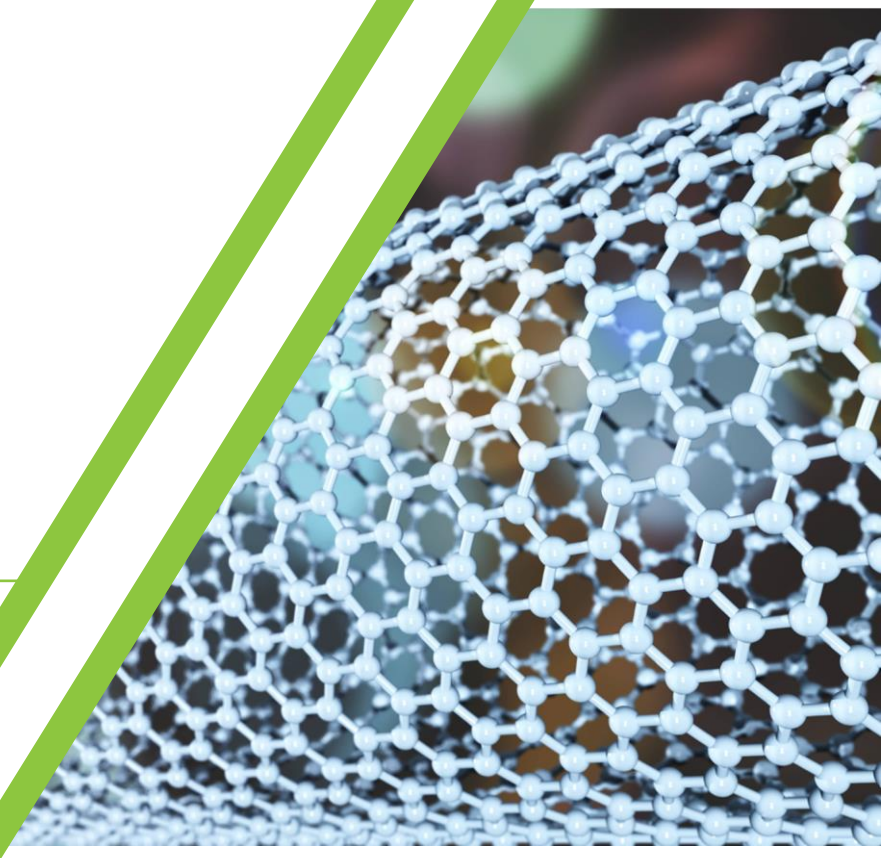
Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials



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Background Information

The Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials was adopted by the OECD Council on 19 September 2013 on the proposal of the Chemicals Committee (now under the responsibility of the Chemicals and Biotechnology Committee, CBC).The Recommendation aims to align the safety testing and assessment of nanomaterials with measures for the safety testing and assessment of chemicals as described in existing OECD Council Acts, notably, those on the Mutual Acceptance of Data in the Assessment of Chemicals (MAD). It recognises that existing regulatory systems can be adapted to cover nanomaterials including the provisions and instruments associated with them to address safety testing and assessment. Hence, the Recommendation calls on Adherents to apply the existing international and national chemical regulatory frameworks and use the tools listed in the Annex for testing and assessment, in conjunction with the OECD Test Guidelines that have been adapted as appropriate to take into account the specific properties of manufactured nanomaterials.

OECD's work on nanomaterials

The Recommendation is an important initiative that helped promote (both within and beyond OECD) the establishment of national programmes that address the safety of manufactured nanomaterials. It was developed as a response to an uncertainty as to how they should be regulated and, especially, how their safety with respect to human health and the environment should be assessed. It was predicted that nanomaterials would increasingly be used in a variety of applications, including paints, food, clothing, cosmetics, medical products, buildings and batteries, to name but a few. Due to their size, nanomaterials may require additional testing beyond the standard suite of tests used for other chemicals. Amongst other things, several subsidiary bodies of the Chemicals and Biotechnology Committee, have been working to align the safety testing and assessment of nanomaterials with methodologies in use for traditional chemicals as described in existing OECD legal instruments, notably, those on the Mutual Acceptance of Data (MAD), i.e. the Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals [OECD/LEGAL/0194] and the Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [OECD/LEGAL/0252]. This work ensures that the tests used to address the safety of nanomaterials are consistent and defensible.

Process for developing the instrument

In the early stages of the work, it was discussed whether or not nanomaterials could be treated as 'traditional' chemical substances or whether they were sufficiently different to require different regulatory regimes including different methods of testing and assessment to ensure an acceptable standard of safety. It was certainly clear that nanomaterials exhibited specific characteristics in contrast to the same material without nanoscale features, which is why they were useful in innovative applications.

Consequently, much of the early work involved an analysis of existing testing and assessment methods for 'traditional' chemical substances to establish whether they were suitable or not for nanomaterials, with a particular emphasis on the OECD Guidelines for the Testing of Chemicals covered by the Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals [OECD/LEGAL/0194] and the Decision-Recommendation on Compliance with Principles of Good Laboratory Practice [OECD/LEGAL/0252]. It was considered that many of the existing OECD Guidelines for the Testing of Chemicals were suitable for nanomaterials and that where a specific test was not suitable, it could be adapted or replaced with a new Test Guideline. This triggered the development of the Recommendation with the aim to ensure nanomaterials where integrated as part of chemicals managements and to avoid unnecessary new regulatory frameworks with divergent strategies.

Next steps

Since nanotechnologies is a rapid developing field, the Recommendation was designed in a flexible way –although the Annex is an integral part of the Recommendation, it can and should be updated as needs arise, to reflect the tools developed by the Working Party on Manufactured Nanomaterials (WPMN) that will facilitate the implementation of the Recommendation. The Council delegated the decision to amend (including through the addition of new documents) the Annex to the CBC. Indeed, the Recommendation provides that the "Annex may be amended by the [CBC], in accordance with Section VII", and in Section VII, the Council "INSTRUCTS the [CBC] to amend the documents listed in the Annex according to Section I and add new documents as appropriate in light of the information provided by Members in accordance with Section IV above"). Accordingly, changes to the existing Annex do not need to be adopted by the Council.

In the context of the Report on the implementation, dissemination and continued relevance of the Recommendation (the "2019 Report ") that was noted and declassified by Council in 2019, Adherents have shown their strong interest in ensuring that the Annex to the Recommendation remains up to date. It was also highlighted that the Annex will require continual updating as the development of relevant tools for implementation continues.

In 2022, the need to update the Annex was discussed, in particular to reflect the latest version of the document Important Issues on Risk Assessment of Manufactured Nanomaterials published in 2022. The WPMN was also invited to review the list of its publications in view of determining whether further amendments to the Annex were needed to reflect recent publications, which was not the case. In October 2023, the CBC approved the amendment transmitted by the WPMN to update the Annex by replacing the cote of the document Important Issues on Risk Assessment of Manufactured Nanomaterials.

For further information please consult: https://www.oecd.org/chemicalsafety/nanosafety & https://www.oecd.org/chemicalsafety/nanomet.
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Implementation

2019 Report to Council

This 2019 Report demonstrated how the Recommendation has been implemented by Adherents thus far. Adherents, individually as well as through the WPMN and the WNT, have taken a wide range of measures to implement the Recommendation. A large part of this work has comprised the development of three new or updated Test Guidelines suitable for nanomaterials, adopted with a guidance document. More specifically, the 2019 Report describes recent developments in the tools for the testing and assessment of nanomaterials, in conjunction with the OECD Guidelines for the Testing of Chemicals that have been adapted to take into account the specific properties of manufactured nanomaterials. The work achieved over the past ten years has brought confidence that existing chemical regulatory frameworks are suitable for managing the risks of nanomaterials. In line with the Recommendation, all Adherents appear to be using existing regulatory frameworks with respect to manufactured nanomaterials. It also shows how Adherents have adapted existing regulatory systems to address nanomaterials.

The 2019 Reports also concluded that the Recommendation has been widely disseminated through a number of avenues including the participation of non-Members (Malaysia, Singapore, South Africa and Thailand) in the work of the WPMN. In addition, the dissemination of the Recommendation is done via official presentations in workshops and other events, as well as through collaboration with the other participating organisations of the Inter-Organisational Programme for the Sound Management of Chemicals (IOMC) including FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, and the World Bank. Further, two non-OECD Members, Argentina and Brazil, have adhered to the Recommendation to date, further evidence of its reach.
Overall, the 2019 Report recognised that while much progress has been made, work still needs to be

done, in particular through the development and updating of Test Guidelines and tools to support implementation. With this in mind and noting that the development of new materials is a fast developing discipline, the next reporting to Council was scheduled five years after.

2025 Report to Council

The 2025 Report reaffirms Adherents' commitment to advancing the Recommendation. Key achievements include:

- Integration of nanosafety into national chemical regulations.
- Use of OECD Test Guidelines (TGs) and Good Laboratory Practice (GLP) under the Mutual Acceptance of Data (MAD) framework.
- Ongoing collaboration to develop and update TGs and guidance documents.

These efforts have strengthened regulatory confidence and supported safe, sustainable innovation. The TGs offer scientifically sound, harmonszed methods for evaluating nanomaterials, enabling informed decision-making across countries. The Recommendation remains a dynamic framework, essential for adapting to emerging challenges in nanomaterials safety. Adherents are committed to its continued implementation, ensuring it supports both innovation and robust safety standards.

While the 2025 Report finds that the Recommendation is generally well-implemented by Adherents and through collective actions, it also underscores that there are some challenges, mainly due to the evolving nature of the field. As scientific knowledge advances, testing methodologies and nanotechnologies continue to evolve. In particular, the 2025 Report identifies areas needing further development, particularly in:

- Exposure assessment;
- New Approach Methodologies (NAMs);
- and, on the evaluation of advanced and complex materials.

Work is ongoing to address these gaps, reflecting the need for regulatory tools to evolve alongside scientific advancements. As a result, regularly updating the TGs, related Guidance Documents, and tools listed in the Annex will remain an ongoing goal to keep pace with these developments. This means that the implementation of many provisions in the Recommendation will always be a moving target for Adherents to work towards.

Accordingly, the CBC will continue to support Adherents in implementing the Recommendation. The next reporting to Council is scheduled for 2035.

THE COUNCIL,

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

HAVING REGARD to the Decision of the Council of 12 May 1981, concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended];

HAVING REGARD to the Recommendation of the Council, concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)] and the Recommendations concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)] and the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)], all dated 26 July 1983;

HAVING REGARD to the Decision-Recommendation of the Council of 2 October 1989 on Compliance with Principles of Good Laboratory Practice [C(89)87(Final), as amended];

HAVING REGARD to the Decision of the Council of 26 November 1997, concerning the Adherence of non-Member Countries to the Council Acts Related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)] [C(97)114/FINAL];

HAVING REGARD to the conclusions of the Chemicals Committee's mid-term evaluation of the programme on the safety of manufactured nanomaterials [ENV/JM/M(2012)2] noting "that the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials";

RECOGNISING that adherence to the OECD Council Acts on Mutual Acceptance of Data in the Assessment of Chemicals does not preclude use or acceptance of test data obtained in accordance with other scientifically valid and specified test methods, as developed for specific chemical product areas;

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

CONSIDERING the SAICM Resolutions II/4 E and III/2 E: Emerging policy issues; Nanotechnology and manufactured nanomaterials;

CONSIDERING that Members and non-Members derive economic, human health and environmental benefits from participation in the OECD Council Acts related to Mutual Acceptance of Data in the Assessment of Chemicals;

CONSIDERING that Members and industry have an interest in harmonised testing and assessment requirements and will benefit from the elimination of costly, duplicative testing and the avoidance of non-tariff barriers to trade, in particular in the field of nanomaterials;

CONSIDERING that expanded international co-operation to reduce duplicative testing would diminish the use of animals for safety testing;

CONSIDERING the increasing use of manufactured nanomaterials in commercial products;

On the proposal of the Chemicals Committee;

I. RECOMMENDS that Members, to manage the risks of manufactured nanomaterials, apply the existing international and national chemical regulatory frameworks or other management systems, adapted to take into account the specific properties of manufactured nanomaterials. For the purpose of such adaptation, Members should use the tools in the documents listed in the Annex to this Recommendation of which it forms an integral part. This Annex may be amended by the Chemicals Committee, in accordance with Section VII below.

II. **RECOMMENDS** that Members, in the testing of manufactured nanomaterials, apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured nanomaterials and using the tools listed in Section I of the Annex to this Recommendation, and the OECD Principles of Good Laboratory Practice, set forth respectively in Annexes I and II to the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended].

III. **RECOMMENDS** that Members update, according to OECD rules and procedures, the OECD Test Guidelines set out in Annex I to the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended] to include new test guidelines specific to, or existing test guidelines amended in the light of experience with, manufactured nanomaterials.

IV. **RECOMMENDS** that Members apprise the Chemicals Committee on a regular basis of any technical issues related to the safety testing and assessment of nanomaterials that need to be addressed, including engagement with other international initiatives, development or update of specific tools for manufactured nanomaterials, and any possible amendment to the documents in the Annex to this Recommendation.

V. **RECOMMENDS** that Members make safety data related to nanomaterials available to the public.

VI. **INVITES:**

i) Non-Members adherents to the Council Acts on Mutual Acceptance of Data [C(81)30(Final), as amended C(89)87(Final), as amended] to adhere to this Recommendation;

ii) Other non-Members to adhere to this Recommendation and collaborate with Members and non-Members adherents to the Council Acts on Mutual Acceptance of Data in its implementation;

iii) Members and adhering non-Members to disseminate this Recommendation to all stakeholders and other international organisations.

VII. **INSTRUCTS** the Chemicals Committee to amend the documents listed in the Annex according to Section I and add new documents as appropriate in light of the information provided by Members in accordance with Section IV above.

VIII. **INSTRUCTS** the Chemicals Committee to promote international awareness of this Recommendation, with a view to informing, advising and encouraging non-Members to participate in the programmes and activities developed by the OECD and its Members in the field of nanomaterials.

IX. **INSTRUCTS** the Chemicals Committee to monitor closely the technical aspects of implementation of this Recommendation and to report to Council within three years of its adoption and thereafter as appropriate.

ANNEX

Tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials include:

I. **Testing**

Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials [ENV/JM/MONO(2009)21]: and

Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials [ENV/JM/MONO(2012)40].

II. Exposure Assessment

Harmonised Tiered Approach to Measure and Assess the Potential Exposure to airborne emissions of engineered nano-objects and their agglomerates at workplaces [ENV/JM/MONO(2015)19].

III. Risk Assessment

Important Issues in Risk Assessment of Manufactured Nanomaterials [ENV/CBC/MONO(2022)3].

About the OECD

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All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions** are adopted by Council and are legally binding on all Members except those which abstain at the time of adoption. They set out specific rights and obligations and may contain monitoring mechanisms.

- **Recommendations** are adopted by Council and are not legally binding. They represent a political commitment to the principles they contain and entail an expectation that Adherents will do their best to implement them.

- **Substantive Outcome Documents** are adopted by the individual listed Adherents rather than by an OECD body, as the outcome of a ministerial, high-level or other meeting within the framework of the Organisation. They usually set general principles or long-term goals and have a solemn character.

- **International Agreements** are negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several other types of substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.