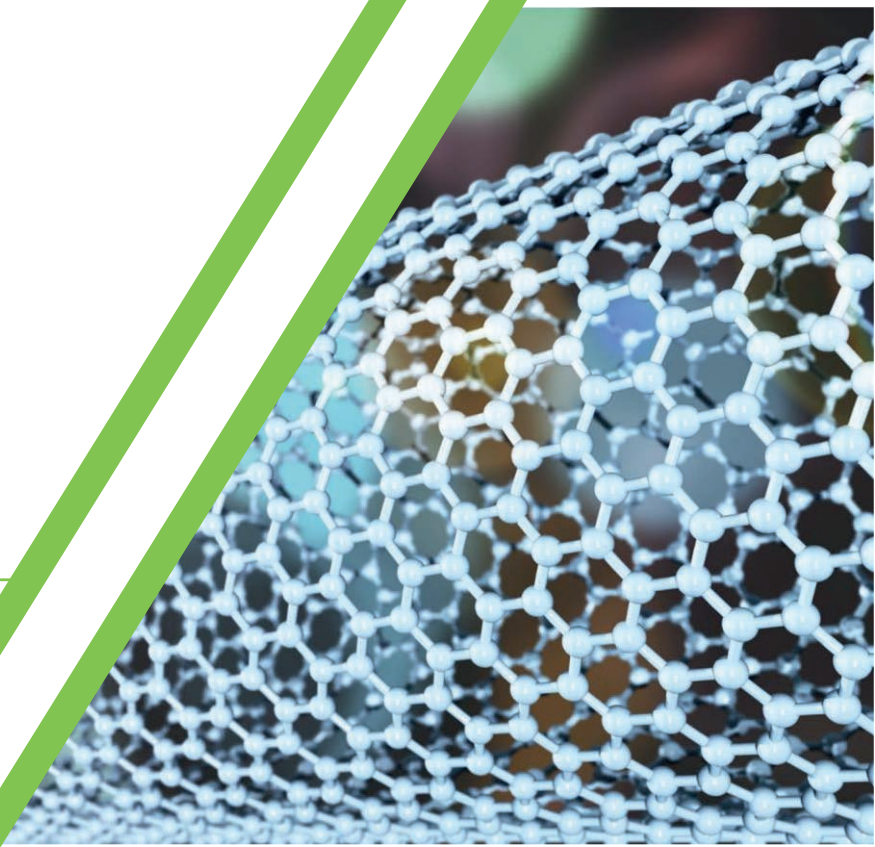




Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials



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Background Information

The Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials was adopted by the OECD Council on the 19 September 2013 on the proposal of the Chemicals Committee. 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.

Implementation

This report demonstrates how the *Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials*, adopted by the OECD Council in 2013, has been implemented by Adherents thus far. Amongst other things, the Recommendation shows how the safety testing and assessment of nanomaterials has been aligned with measures for the safety testing and assessment of 'traditional' chemicals as described in existing OECD Council Acts, including those on the Mutual Acceptance of Data in the Assessment of Chemicals (MAD) (i.e. 1981 Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [[OECD/LEGAL/0194](#)] and 1989 Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice [[OECD/LEGAL/0252](#)]). More specifically, the report describes recent developments in the tools for the testing and assessment of nanomaterials, in conjunction with the OECD Test Guidelines, that have been adapted to take into account the specific properties of manufactured nanomaterials. It also shows how Adherents have adapted existing regulatory systems to address nanomaterials. Overall, the report recognises 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 report recommends that a second implementation report be drafted after five years.

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/JM/MONO(2012)8].

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- **Declarations:** OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.
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