



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

**OECD Legal
Instruments**

This document is published under the responsibility of the Secretary-General of the OECD. It reproduces an OECD Legal Instrument and may contain additional material. The opinions expressed and arguments employed in the additional material do not necessarily reflect the official views of OECD Member countries.

This document, as well as any data and any map included herein, are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

For access to the official and up-to-date texts of OECD Legal Instruments, as well as other related information, please consult the Compendium of OECD Legal Instruments at <http://legalinstruments.oecd.org>.

Please cite this document as:

OECD, *Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials*, OECD/LEGAL/0400

Series: OECD Legal Instruments

© OECD 2018

This document is provided free of charge. It may be reproduced and distributed free of charge without requiring any further permissions, as long as it is not altered in any way. It may not be sold.

This document is available in the two OECD official languages (English and French). It may be translated into other languages, as long as the translation is labelled "unofficial translation" and includes the following disclaimer: *"This translation has been prepared by [NAME OF TRANSLATION AUTHOR] for informational purpose only and its accuracy cannot be guaranteed by the OECD. The only official versions are the English and French texts available on the OECD website <http://legalinstruments.oecd.org>"*

Date(s)

Adopted on 19/09/2013
Amended on 30/05/2017

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.

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].

Adherents*

OECD Members

Australia
Austria
Belgium
Canada
Chile
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Israel
Italy
Japan
Korea
Latvia
Luxembourg
Mexico
Netherlands
New Zealand
Norway
Poland
Portugal
Slovak Republic
Slovenia
Spain
Sweden
Switzerland
Turkey
United Kingdom
United States

Non-Members

Argentina

* Additional information and statements are available in the Compendium of OECD Legal Instruments:
<http://legalinstruments.oecd.org>

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

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:** OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.
- **Recommendations:** OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.
- **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.
- **International Agreements:** OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.
- **Arrangement, Understanding and Others:** several ad hoc 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.