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English - Or. English

COUNCIL

Council

**DRAFT RECOMMENDATION OF THE COUNCIL ON THE SAFETY TESTING AND ASSESSMENT
OF MANUFACTURED NANOMATERIALS**

(Note by the Secretary-General)

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1. This note seeks the adoption by the Council of a draft Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials. The draft 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 Council Acts, notably, those on the Mutual Acceptance of Data in the Assessment of Chemicals (MAD) [C(81)30(Final) and C(89)87(Final)].

Background

2. In 2006, the Chemicals Committee initiated a programme on the safety of manufactured nanomaterials. A subsidiary body was also established, the Working Party on Manufactured Nanomaterials (WPMN). At that time, it was known that an increasing number of nanomaterials were entering commerce in a wide range of products including, for example, sunscreens, sports equipment and paints. There was also uncertainty amongst Members as to how nanomaterials should be tested and assessed for human health and environmental safety. It seemed possible that a new system of safety testing and assessment might be necessary beyond that used for “traditional” chemicals.

3. In the intervening period, a considerable amount of evidence has accumulated through the work of the WPMN and a number of collaborative activities between Members and other stakeholders. In 2011, the WPMN undertook a mid-term evaluation of its nanosafety programme. The findings of this evaluation [[ENV/JM\(2012\)2](#)] were endorsed by the Chemicals Committee at its meeting in February 2012 [[ENV/JM/M\(2012\)1](#), Item 6 i)]. This included the main conclusion 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*”. At the same time, the Chemicals Committee took the view that this conclusion and the consequences arising from it should be recognised in a Council Recommendation. Work on a draft Recommendation was subsequently started, the result of which is set out in the Appendix.

4. Among the main features of the proposed Recommendation, paragraph I recognises a consequence of the above-mentioned conclusion, which is that nanomaterials can be managed within existing international and national chemical regulatory frameworks. Since it is clear that existing regulatory systems can be adapted to cover nanomaterials including the provisions and instruments associated with them to address safety testing and assessment, there is no reason for treating nanomaterials any differently from “traditional” chemicals.

5. It follows, as recognised in paragraph II of the draft Recommendation, that the OECD Test Guidelines for the Safety Testing of Chemicals can be used for the safety assessment of nanomaterials, adapted as appropriate. These Test Guidelines are an important element of the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals (MAD). Consequently, the draft Recommendation provides that these nanomaterials fall within the ambit of the Decision on MAD, thus affording the advantages arising from this instrument to Members as well as adhering partners and other stakeholders.

6. The Annex to this Recommendation forms an integral part of it. It identifies a number of “tools” which will assist countries in applying the OECD Test Guidelines to nanomaterials by adapting them to the specificities of nanomaterials. This list of “tools” will be updated by the Chemicals Committee as further knowledge becomes available.

7. An initial version of this draft Recommendation was agreed by the WPMN at its meeting in February 2013. The text of the draft Recommendation, as set out in the Appendix, was discussed and approved by the Chemicals Committee at the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology on 11 June 2013 [[ENV/JM/M\(2013\)1](#), Item 8].

Proposed Action

8. In the light of the preceding, the Secretary-General invites the Council to adopt the following draft conclusions:

THE COUNCIL

- a) noted document [C\(2013\)107](#);
- b) adopted the draft Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials set out in the Appendix to document [C\(2013\)107](#) and agreed to its declassification;
- c) recalled that the participation of non-Members in OECD bodies is governed by the Resolution of the Council on Partnerships in OECD Bodies [[C\(2012\)100/FINAL](#)].

APPENDIX

DRAFT RECOMMENDATION OF THE COUNCIL ON THE SAFETY TESTING AND ASSESSMENT 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.

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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](#)]

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

II. Exposure Assessment

Identification, Compilation and Analysis of Guidance Information for Exposure Measurement and Exposure Mitigation: Manufactured Nanomaterials [[ENV/JM/MONO\(2009\)15](#)]

III. Risk Assessment

Important Issues in Risk Assessment of Manufactured Nanomaterials [[ENV/JM/MONO\(2012\)8](#)]